WHO Guidelines on Hand Hygiene in Health Care

World Health Organization

Patient Safety
A World Alliance for Safer Health Care

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First Global Patient Safety Challenge
Clean Care is Safer Care

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CONTENTS

INTRODUCTION

The WHO *Guidelines on Hand Hygiene in Health Care* provide health-care workers (HCWs), hospital administrators and health authorities with a thorough review of evidence on hand hygiene in health care and specific recommendations to improve practices and reduce transmission of pathogenic microorganisms to patients and HCWs. The present *Guidelines* are intended to be implemented in any situation in which health care is delivered either to a patient or to a specific group in a population. Therefore, this concept applies to all settings where health care is permanently or occasionally performed, such as home care by birth attendants. Definitions of health-care settings are proposed in Appendix 1. These *Guidelines* and the associated WHO Multimodal Hand Hygiene Improvement Strategy and an Implementation Toolkit (http://www.who.int/gpsc/en/) are designed to offer health-care facilities in Member States a conceptual framework and practical tools for the application of recommendations in practice at the bedside. While ensuring consistency with the *Guidelines*' recommendations, individual adaptation according to local regulations, settings, needs, and resources is desirable.

The development of the *Guidelines* began in autumn 2004 and the preparation process is thoroughly described in Part I, Section 2. In brief, the present document is the result of the update and finalization of the Advanced Draft, issued in April 2006, according to the literature review and data and lessons learnt from pilot testing. A Core Group of experts coordinated the work of reviewing the available scientific evidence, writing the document, and fostering discussion among authors; more than 100 international experts contributed to preparing the document. Authors, technical contributors, external reviewers, and professionals who actively participated in the work process up to final publication are listed in the Acknowledgements at the end of the document.

The *WHO Guidelines on Hand Hygiene in Health Care* provide a comprehensive review of scientific data on hand hygiene rationale and practices in health care. This extensive review includes in one document sufficient technical information to support training materials and help plan implementation strategies. The document comprises six parts; for convenience, the figures and tables are numbered to correspond to the part and the section in which they are discussed:

- Part I reviews scientific data on hand hygiene practices in health care and in health-care settings in particular.
- Part II reports consensus recommendations of the international panel of experts mandated by WHO together with grading of the evidence and proposes guidelines that could be used worldwide.
- Part III discusses process and outcome measurements.
- Part IV proposes the promotion of hand hygiene on a large scale.
- Part V covers the aspect of patient participation in hand hygiene promotion.
- Part VI reviews existing national and sub-national guidelines for hand hygiene.

An Executive Summary of the Advanced Draft of the Guidelines is available as a separate document, in Chinese, English, French, Russian and Spanish versions (http://www.who.int/gpsc/tools/en/). An Executive Summary of the present Guidelines will be translated into all WHO official languages.

It is anticipated that the recommendations in these Guidelines will remain valid until 2011. The Patient Safety Department (Information, Evidence and Research Cluster) at WHO headquarters is committed to ensuring that the WHO Guidelines on Hand Hygiene in Health Care are updated every two to three years.

1.
Definition of terms

Hand hygiene. A general term referring to any action of hand cleansing (see below "Hand hygiene practices").

Hand hygiene products

Alcohol-based (hand) rub. An alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients with excipients, and humectants.

Antimicrobial (medicated) soap. Soap (detergent) containing an antiseptic agent at a concentration sufficient to inactivate microorganisms and/or temporarily suppress their growth. The detergent activity of such soaps may also dislodge transient microorganisms or other contaminants from the skin to facilitate their subsequent removal by water.

Antiseptic agent. An antimicrobial substance that inactivates microorganisms or inhibits their growth on living tissues. Examples include alcohols, chlorhexidine gluconate (CHG), chlorine derivatives, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan.

Antiseptic hand wipe. A piece of fabric or paper pre-wetted with an antiseptic used for wiping hands to inactivate and/or remove microbial contamination. They may be considered as an alternative to washing hands with non-antimicrobial soap and water but, because they are not as effective at reducing bacterial counts on HCWs' hands as alcohol-based handrubs or washing hands with an antimicrobial soap and water, they are not a substitute for using an alcohol-based handrub or antimicrobial soap.

Detergent (surfactant). Compounds that possess a cleaning action. They are composed of a hydrophilic and a lipophilic part and can be divided into four groups: anionic, cationic, amphoteric, and non-ionic. Although products used for handwashing or antiseptic handwash in health care represent various types of detergents, the term "soap" will be used to refer to such detergents in these guidelines.

Plain soap. Detergents that contain no added antimicrobial agents, or may contain these solely as preservatives.

Waterless antiseptic agent. An antiseptic agent (liquid, gel or foam) that does not require the use of exogenous water. After application, the individual rubs the hands together until the skin feels dry.

Hand hygiene practices

Antiseptic handwashing. Washing hands with soap and water, or other detergents containing an antiseptic agent.

Antiseptic handrubbing (or handrubbing). Applying an antiseptic handrub to reduce or inhibit the growth of microorganisms without the need for an exogenous source of water and requiring no rinsing or drying with towels or other devices.

Hand antisepsis/decontamination/degerming. Reducing or inhibiting the growth of microorganisms by the application of an antiseptic handrub or by performing an antiseptic handwash.

Hand care. Actions to reduce the risk of skin damage or irritation.

Handwashing. Washing hands with plain or antimicrobial soap and water.

Hand cleansing. Action of performing hand hygiene for the purpose of physically or mechanically removing dirt, organic material, and/or microorganisms.

Hand disinfection is extensively used as a term in some parts of the world and can refer to antiseptic handwash, antiseptic handrubbing, hand antisepsis/decontamination/degerming, handwashing with an antimicrobial soap and water, hygienic hand antisepsis, or hygienic handrub. Since disinfection refers normally to the decontamination of inanimate surfaces and objects, this term is not used in these *Guidelines*.

Hygienic hand antisepsis. Treatment of hands with either an antiseptic handrub or antiseptic handwash to reduce the transient microbial flora without necessarily affecting the resident skin flora.

Hygienic handrub. Treatment of hands with an antiseptic handrub to reduce the transient flora without necessarily affecting the resident skin flora. These preparations are broad spectrum and fast-acting, and persistent activity is not necessary.

Hygienic handwash. Treatment of hands with an antiseptic handwash and water to reduce the transient flora without necessarily affecting the resident skin flora. It is broad spectrum, but is usually less efficacious and acts more slowly than the hygienic handrub.

Surgical hand antisepsis/surgical hand preparation/ presurgical hand preparation. Antiseptic handwash or antiseptic handrub performed preoperatively by the surgical team to eliminate transient flora and reduce resident skin flora. Such antiseptics often have persistent antimicrobial activity. **Surgical handscrub(bing)/presurgical scrub** refer to surgical hand preparation with antimicrobial soap and water. **Surgical handrub(bing)** refers to surgical hand preparation with a waterless, alcohol-based handrub.

PART I.

REVIEW OF SCIENTIFIC DATA RELATED TO HAND HYGIENE

Associated terms

Cumulative effect. Increasing antimicrobial effect with repeated applications of a given antiseptic.

Efficacy/efficaceous*.* The (possible) effect of the application of a hand hygiene formulation when tested in laboratory or in vivo situations.

Effectiveness/effective*.* The clinical conditions under which a hand hygiene product has been tested for its potential to reduce the spread of pathogens, e.g. field trials.

Excipient. Inert substance included in a product formulation to serve as a vehicle for the active substance.

Health-care area. Concept related to the "geographical" visualization of key moments for hand hygiene. It contains all surfaces in the health-care setting outside the patient zone of patient X, i.e. other patients and their patient zones and the health-care facility environment.

Humectant. Ingredient(s) added to hand hygiene products to moisturize the skin.

Medical gloves. Disposable gloves used during medical procedures; they include examination (sterile or non-sterile) gloves, surgical gloves, and medical gloves for handling chemotherapy agents (chemotherapy gloves).

Patient zone. Concept related to the "geographical" visualization of key moments for hand hygiene. It contains the patient X and his/her immediate surroundings. This typically includes the intact skin of the patient and all inanimate surfaces that are touched by or in direct physical contact with the patient such as the bed rails, bedside table, bed linen, infusion tubing and other medical equipment. It further contains surfaces frequently touched by HCWs while caring for the patient such as monitors, knobs and buttons, and other "high frequency" touch surfaces.

Persistent activity. The prolonged or extended antimicrobial activity that prevents the growth or survival of microorganisms after application of a given antiseptic; also called "residual", "sustained" or "remnant" activity. Both substantive and non-substantive active ingredients can show a persistent effect significantly inhibiting the growth of microorganisms after application.

Point of care. The place where three elements come together: the patient, the HCW, and care or treatment involving contact with the patient or his/her surroundings (within the patient zone).[1] The concept embraces the need to perform hand hygiene at recommended moments exactly where care delivery takes place. This requires that a hand hygiene product (e.g. alcohol-based handrub, if available) be easily accessible and as close as possible – within arm's reach of where patient care or treatment is taking place. Point-of-care products should be accessible without having to leave the patient zone.

Resident flora (resident microbiota). Microorganisms residing under the superficial cells of the *stratum corneum* and also found on the surface of the skin.

Substantivity. An attribute of some active ingredients that adhere to the *stratum corneum* and provide an inhibitory effect on the growth of bacteria by remaining on the skin after rinsing or drying.

Surrogate microorganism*.* A microorganism used to represent a given type or category of nosocomial pathogen when testing the antimicrobial activity of antiseptics. Surrogates are selected for their safety, ease of handling, and relative resistance to antimicrobials.

Transient flora (transient microbiota). Microorganisms that colonize the superficial layers of the skin and are more amenable to removal by routine handwashing.

Visibly soiled hands*.* Hands on which dirt or body fluids are readily visible.

2. Guidelines' preparation process

The preparation process of the *WHO Guidelines on Hand Hygiene in Health Care* involved the steps that are briefly described in this section.

2.1 Preparation of the Advanced Draft

The present guidelines were developed by the "Clean Care is Safer Care" team (Patient Safety Department, Information, Evidence and Research Cluster).

A Core Group of international experts in the field of infection control, with specific expertise in hand hygiene, participated in the writing and revision of the document. The group was constituted at WHO Headquarters in Geneva in December 2004. During its first meeting, the experts discussed the approach to be emphasized in these guidelines and their content and drew up a plan for their preparation. The objectives identified were to develop a document including a comprehensive overview of essential aspects of hand hygiene in health care and evidence- and consensus-based recommendations for optimal hand hygiene practices and successful hand hygiene promotion. Users were meant to be policy-makers, managers and HCWs in different settings and geographical areas. It was decided to adopt the CDC *Guideline for Hand Hygiene in Health-Care Settings* issued in 2002 as a basis for the present document but to introduce many new topics. A distinctive feature of the present *Guidelines* is the fact that they were conceived with a global perspective; therefore, they are not targeted at only developing or developed countries, but at all countries regardless of the resources available (see also Part VI).

Various task forces were established (Table I.2.1) to examine different controversial topics in depth and reach consensus on the best approach to be included in the document for both implementation and research purposes. According to their expertise, authors were assigned various chapters, the content of which had to be based on the scientific literature and their experience. A systematic review of the literature was performed through PubMed (United States National Library of Medicine), Ovid, MEDLINE, EMBASE, and the Cochrane Library, and secondary papers were identified from reference lists and existing relevant guidelines. International and national infection control guidelines and textbooks were also consulted. Authors provided the list of keywords that they used for use in the next update of the *Guidelines.*

In April 2005 and March 2006, the Core Group reconvened at WHO Headquarters in Geneva for task force meetings, final revision, and consensus on the first draft. Recommendations were formulated on the basis of the evidence described in the various sections; their terminology and consistency were discussed in depth during the expert consultations. In addition to expert consensus, the criteria developed by the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the United States Centers for Disease Control and Prevention (CDC), Atlanta, GA, were used to categorise the consensus recommendations in the *WHO Guidelines for Hand Hygiene in Health Care* (Table I.2.2). In the case of difficulty in reaching consensus, the voting system was adopted. The final draft was submitted to a list of external and internal reviewers whose comments were considered during the March 2006 Core Group consultation. The Advanced Draft of the *WHO Guidelines on Hand Hygiene in Health Care* was published in April 2006.

2.2 Pilot testing the Advanced Draft

According to WHO recommendations for guideline preparation, a testing phase of the guidelines was undertaken. In parallel with the Advanced Draft, an implementation strategy (WHO Multimodal Hand Hygiene Improvement Strategy) was developed, together with a wide a range of tools (Pilot Implementation Pack) to help health-care settings to translate the guidelines into practice (see also Part I, Sections 21.1–4). The aims of this testing were: to provide local data on the resources required to carry out the recommendations; to generate information on feasibility, validity, reliability, and cost–effectiveness of the interventions; and to adapt and refine proposed implementation strategies. Eight pilot sites from seven countries representing the six WHO regions were selected for pilot testing and received technical and, in some cases, financial support from the First Global Patient Safety Challenge team (see also Part I, Section 21.5). Other health-care settings around the world volunteered to participate autonomously in the testing phase, and these were named "complementary test sites". Analysis of data and evaluation of the lessons learnt from pilot and complementary sites were undertaken and are reported in Part I, Section 21.5.

2.3 Finalization of the *WHO Guidelines on Hand Hygiene in Health Care*

In August 2007, the expert Core Group reconvened in Geneva to start the process of guideline finalization. Authors were asked to update their text according to relevant new publications up to October 2007 and to return the work by December 2007; some authors were asked to write new chapters by the same deadline. The First Global Patient Safety Challenge team and the *Guidelines'* editor contributed with the content of several chapters and took the responsibility to revise the updated and new material, to perform technical editing, and to add any further relevant reference published between October 2007 and June 2008. Six new chapters, 11 additional paragraphs, and three new appendices were added in the present final version compared with the Advanced Draft. External and internal reviewers were asked again to comment on the new parts of the guidelines.

In September 2008, the last Core Group consultation took place in Geneva. The final draft of the *Guidelines* was circulated ahead of the meeting, including relevant comments from the reviewers. A specific session of the meeting was dedicated to the evaluation of data and lessons learnt from the testing sites and how to integrate these aspects into the text. Final discussion took place about the content of the final version of the document with a particular focus on the recommendations and the research agenda, and reviewers' comments and queries; approval was obtained by consensus. Following the consultation, the final amendments and insertions were made and, at the latest stage, the document was submitted to a WHO reference editor.

Table I.2.1
Task forces for discussion and expert consensus on critical issues related to hand hygiene in health care

Task forces on hand hygiene in health care
• Behavioural changes
• Education/training/tools
• WHO-recommended hand antisepsis formulations
• Glove use and reuse
• Water quality for handwashing
• Patient involvement
• Religious and cultural aspects of hand hygiene
• Indicators for service implementation and monitoring
• Regulation and accreditation
• Advocacy/communication/campaigning
• National guidelines on hand hygiene
• "Frequently asked questions" development

Table I.2.2
Modified CDC/HICPAC ranking system for evidence

CATEGORY	CRITERIA
IA	Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies.
IB	Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and a strong theoretical rationale.
IC	Required for implementation, as mandated by federal and/or state regulation or standard.
II	Suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale or a consensus by a panel of experts.

3. The burden of health care-associated infection

This section summarizes the epidemiological data and relevant issues related to the global burden of health care-associated infection (HCAI) and emphasizes the importance of preventing HCAI by giving priority to the promotion of hand hygiene best practices in health care. When available, national or multicentre surveys were preferred to single hospital surveys, and only studies or reports published in English were considered. This overview of available data on HCAI is therefore not to be considered exhaustive, but rather as an informative, evidence-based introduction to the topic of hand hygiene in health care.

HCAI is a major problem for patient safety and its surveillance and prevention must be a first priority for settings and institutions committed to making health care safer. The impact of HCAI implies prolonged hospital stay, long-term disability, increased resistance of microorganisms to antimicrobials, massive additional financial burden, high costs for patients and their families, and excess deaths. Although the risk of acquiring HCAI is universal and pervades every health-care facility and system around the world, the global burden is unknown because of the difficulty of gathering reliable diagnostic data. Overall estimates indicate that more than 1.4 million patients worldwide in developed and developing countries are affected at any time.[2] Although data on the burden of diseases worldwide that are published in WHO's *World Health Reports* inform HCWs, policy-makers, and the public of the most important diseases in terms of morbidity and mortality, HCAI does not appear on the list of the 136 diseases evaluated.[3] The most likely reason is that the diagnosis of HCAI is complex, relying on multiple criteria and not on a single laboratory test. In addition, although national surveillance systems exist in many industrialized countries,[4] e.g. the National Nosocomial Infection Surveillance (NNIS) system in the United States of America (USA) (http://www.cdc.gov/ncidod/dhqp/nnis.html), they often use different diagnostic criteria and methods, which render international comparisons difficult due to benchmarking obstacles. In developing countries, such systems are seldom in place. Therefore, in many settings, from hospitals to ambulatory and long-term care, HCAI appears to be a hidden, cross-cutting concern that no institution or country can claim to have solved as yet.

For the purpose of this review on the HCAI burden worldwide, countries are ranked as "developed" and "developing" according to the World Bank classification based on their estimated per capita income (http://siteresources.worldbank.org/DATASTATISTICS/Resources/CLASS.XLS).

3.1 Health care-associated infection in developed countries

In developed countries, HCAI concerns 5–15% of hospitalized patients and can affect 9–37% of those admitted to intensive care units (ICUs).[2,5] Recent studies conducted in Europe reported hospital-wide prevalence rates of patients affected by HCAI ranging from 4.6% to 9.3%.[6-14] According to data provided by the Hospital in Europe Link for Infection Control through Surveillance (HELICS) (http://helics.univ-lyon1.fr/helicshome.htm), approximately 5 million HCAIs are estimated to occur in acute care hospitals in Europe annually, representing around 25 million extra days of hospital stay and a corresponding economic burden of €13–24 billion. In general, attributable mortality due to HCAI in Europe is estimated to be 1% (50 000 deaths per year), but HCAI contributes to death in at least 2.7% of cases (135 000 deaths per year). The estimated HCAI incidence rate in the USA was 4.5% in 2002, corresponding to 9.3 infections per 1000 patient-days and 1.7 million affected patients; approximately 99 000 deaths were attributed to HCAI.[7] The annual economic impact of HCAI in the USA was approximately US$ 6.5 billion in 2004.[15]

In the USA, similar to the position in other industrialized countries, the most frequent type of infection hospitalwide is urinary tract infection (UTI) (36%), followed by surgical site infection (SSI) (20%), bloodstream infection (BSI), and pneumonia (both 11%).[7] It is noteworthy, however, that some infection types such as BSI and ventilator-associated pneumonia have a more severe impact than others in terms of mortality and extra-costs. For instance, the mortality rate directly attributable to BSIs in ICU patients has been estimated to be 16–40% and prolongation of the length of stay 7.5–25 days.[16,17] Furthermore, nosocomial BSI, estimated to account for 250 000 episodes every year in the USA, has shown a trend towards increasing frequency over the last decades, particularly in cases due to antibiotic-resistant organisms.[18]

The HCAI burden is greatly increased in high-risk patients such as those admitted to ICUs. Prevalence rates of infection acquired in ICUs vary from 9.7–31.8% in Europe[19] and 9–37% in the USA, with crude mortality rates ranging from 12% to 80%.[5] In the USA, the national infection rate in ICUs was estimated to be 13 per 1000 patient-days in 2002.[7] In ICU settings particularly, the use of various invasive devices (e.g. central venous catheter, mechanical ventilation or urinary catheter) is one of the most important risk factors for acquiring HCAI. Device-associated infection rates per 1000 device-days detected through the NNIS System in the USA are summarized in Table I.3.1.[20]

In surveillance studies conducted in developed countries, HCAI diagnosis relies mostly on microbiological and/or laboratory criteria. In large-scale studies conducted in the USA, the pathogens most frequently detected in HCAI are reported by infection site both hospitalwide and in ICUs.[21,22]

Furthermore, in high-income countries with modern and sophisticated health-care provision, many factors have been shown to be associated with the risk of acquiring an HCAI. These factors can be related to the infectious agent (e.g. virulence, capacity to survive in the environment, antimicrobial resistance), the host (e.g. advanced age, low birthweight, underlying diseases, state of debilitation, immunosuppression, malnutrition), and the environment (e.g. ICU admission, prolonged hospitalization, invasive devices and procedures, antimicrobial therapy).

3.2 Burden of health care-associated infection in developing countries

While HCAI surveillance is already a challenging task in highly resourced settings, it may often appear an unrealistic goal in everyday care in developing countries. In addition to the usual difficulties to define the diagnosis of HCAI must be added the paucity and unreliability of laboratory data, lack of standardized information from medical records, and scarce access to radiological facilities. Limited data on HCAI from these settings are available from the literature. This is well demonstrated by an electronic search of the period 1995–2008, which allowed the retrieval of around 200 scientific papers published in English and approximately 100 in other languages.[23] Overall, no more than 80 of these papers featured rigorous, high quality, methodological characteristics.

The magnitude of the problem is particularly relevant in settings where basic infection control measures are virtually non-existent. This is the result of the combination of numerous unfavourable factors such as understaffing, poor hygiene and sanitation, lack or shortage of basic equipment, and inadequate structures and overcrowding, almost all of which can be attributed to limited financial resources. In addition to these specific factors, an unfavourable social background and a population largely affected by malnutrition and other types of infection and/or diseases contribute to increase the risk of HCAI in developing countries.[24,25] Under these conditions, thousands of infections – in particular due to hepatitis B and C viruses and human immunodeficiency virus (HIV) transmission – are still acquired from patients, but also from HCWs through unsafe use of injections, medical devices and blood products, inadequate surgical procedures, and deficiencies in biomedical waste management.[24]

When referring to endemic HCAI, many studies conducted in developing countries report hospitalwide rates higher than in developed countries. Nevertheless, it is important to note that most of these studies concern single hospitals and therefore may not be representative of the problem across the whole country.[26-36] For example, in one-day prevalence surveys recently carried out in single hospitals in Albania,[36] Morocco,[35] Tunisia,[34] and the United Republic of Tanzania,[33] HCAI prevalence rates were 19.1%, 17.8%, 17.9%, and 14.8%, respectively. Given the difficulties to comply with the USA Centers for Disease Control and Prevention (CDC) definitions of nosocomial infection,[37] the most frequently surveyed type of infection is SSI, which is the easiest to define according to clinical criteria. The risk for patients to develop SSI in developing countries is significantly higher than in developed countries (e.g. 30.9% in a paediatric hospital in Nigeria,[38] 23% in general surgery in a hospital in the United Republic of Tanzania,[33] and 19% in a maternity unit in Kenya[39]).

The burden of HCAI is also much more severe in high-risk populations such as adults housed in ICUs and neonates, with general infection rates, particularly device-associated infection rates, several-fold higher than in developed countries. As an example, in Table I.3.1, device-associated infection rates reported from multicentre studies conducted in adult and paediatric ICUs are compared with the USA NNIS system rates.[20,40,41] In a systematic review of the literature, neonatal infections were reported to be 3–20 times higher among hospital-born babies in developing than in developed countries.[42]

A very limited number of studies from developing countries assessed HCAI risk factors by multivariate analysis. The most frequently identified were prolonged length of stay, surgery, intravascular and urinary catheters, and sedative medication.[27,30,33-35,43-47]

The magnitude and scope of the HCAI burden worldwide appears to be very important and greatly underestimated. Methods to assess the size and nature of the problem exist and can contribute to correct monitoring and to finding solutions. Nevertheless, these tools need to be simplified and adapted so as to be affordable in settings where resources and data sources are limited. Similarly, preventive measures have been identified and proven effective; they are often simple to implement, such as hand hygiene. However, based on an improved awareness of the problem, infection control must reach a higher position among the first priorities in national health programmes, especially in developing countries.

Table I.3.1

Device-associated infection rates in ICUs in developing countries compared with NNIS rates

Surveillance network, study period, country	Setting	No. of patients	CR-BSI*	VAP*	CR-UTI*
INICC, 2003–2005, 5 developing countries†[41]	PICU	1,529	16.1	10.6	5.3
NNIS, 2002–2004, USA[20]	PICU	—	6.6	2.9	4.0
INICC, 2002–2005, 8 developing countries‡*	Adult ICU	21,069	12.5	24.1	8.9
NNIS, 2002–2004, USA[20]	Adult ICU	—	4.0	5.4	3.9

* Overall (pooled mean) infection rates/1000 device-days.

INICC = International Nosocomial Infection Control Consortium; NNIS = National Nosocomial Infection Surveillance system; PICU = paediatric intensive care unit; CR-BSI = cather-related bloodstream infection; VAP = ventilator-associated pneumonia; CR-UTI = catheter-related urinary tract infection.
†Argentina, Colombia, Mexico, Peru, Turkey
‡Argentina, Brazil, Colombia, India, Mexico, Morocco, Peru, Turkey
Reproduced from Pittet, 2008[25] with permission from Elsevier.

4.

Historical perspective on hand hygiene in health care

Handwashing with soap and water has been considered a measure of personal hygiene for centuries[48,49] and has been generally embedded in religious and cultural habits (see Part I, Section 17). Nevertheless, the link between handwashing and the spread of disease was established only two centuries ago, although this can be considered as relatively early with respect to the discoveries of Pasteur and Lister that occurred decades later.

In the mid-1800s, studies by Ignaz Semmelweis in Vienna, Austria, and Oliver Wendell Holmes in Boston, USA, established that hospital-acquired diseases were transmitted via the hands of HCWs. In 1847, Semmelweiss was appointed as a house officer in one of the two obstetric clinics at the University of Vienna Allgemeine Krankenhaus (General Hospital). He observed that maternal mortality rates, mostly attributable to puerperal fever, were substantially higher in one clinic compared with the other (16% versus 7%).[50] He also noted that doctors and medical students often went directly to the delivery suite after performing autopsies and had a disagreeable odour on their hands despite handwashing with soap and water before entering the clinic. He hypothesized therefore that "cadaverous particles" were transmitted via the hands of doctors and students from the autopsy room to the delivery theatre and caused the puerperal fever. As a consequence, Semmelweis recommended that hands be scrubbed in a chlorinated lime solution before every patient contact and particularly after leaving the autopsy room. Following the implementation of this measure, the mortality rate fell dramatically to 3% in the clinic most affected and remained low thereafter.

Apart from providing the first evidence that cleansing heavily contaminated hands with an antiseptic agent can reduce nosocomial transmission of germs more effectively than handwashing with plain soap and water, this approach includes all the essential elements for a successful infection control intervention: "recognize-explain-act".[51] Unfortunately, both Holmes and Semmelweis failed to observe a sustained change in their colleagues' behaviour. In particular, Semmelweis experienced great difficulties in convincing his colleagues and administrators of the benefits of this procedure. In the light of the principles of social marketing today, his major error was that he imposed a system change (the use of the chlorinated lime solution) without consulting the opinion of his collaborators. Despite these drawbacks, many lessons have been learnt from the Semmelweis intervention; the "recognize-explain-act" approach has driven many investigators and practitioners since then and has also been replicated in different fields and settings. Semmelweis is considered not only the father of hand hygiene, but his intervention is also a model of epidemiologically driven strategies to prevent infection.

A prospective controlled trial conducted in a hospital nursery[52] and many other investigations conducted over the past 40 years have confirmed the important role that contaminated HCWs' hands play in the transmission of health care-associated pathogens (see Part I, Sections 7–9).

The 1980s represented a landmark in the evolution of concepts of hand hygiene in health care. The first national hand hygiene guidelines were published in the 1980s,[53-55] followed by several others in more recent years in different countries. In 1995 and 1996, the CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC) in the USA recommended that either antimicrobial soap or a waterless antiseptic agent be used[56,57] for cleansing hands upon leaving the rooms of patients with multidrug-resistant pathogens. More recently, the HICPAC guidelines issued in 2002[58] defined alcohol-based handrubbing, where available, as the standard of care for hand hygiene practices in health-care settings, whereas handwashing is reserved for particular situations only.[59] The present guidelines are based on this previous document and represent the most extensive review of the evidence related to hand hygiene in the literature. They aim to expand the scope of recommendations to a global perspective, foster discussion and expert consultation on controversial issues related to hand hygiene in health care, and to propose a practical approach for successful implementation (see also Part VI).

As far as the implementation of recommendations on hand hygiene improvement is concerned, very significant progress has been achieved since the introduction and validation of the concept that promotional strategies must be multimodal to achieve any degree of success. In 2000, Pittet et al. reported the experience of the Geneva's University Hospitals with the implementation of a strategy based on several essential components and not only the introduction of an alcohol-based handrub. The study showed remarkable results in terms of an improvement in hand hygiene compliance improvement and HCAI reduction.[60] Taking inspiration from this innovative approach, the results of which were also demonstrated to be long-lasting,[61] many other studies including further original aspects have enriched the scientific literature (see Table I.22.1). Given its very solid evidence base, this model has been adopted by the First Global Patient Safety Challenge to develop the WHO Hand Hygiene Improvement Strategy aimed at translating into practice the recommendations included in the present guidelines. In this final version of the guidelines, evidence generated from the pilot testing of the strategy during 2007–2008 is included (see also Part I, Section 21.5).[62]

5.
Normal bacterial flora on hands

In 1938, Price[63] established that bacteria recovered from the hands could be divided into two categories, namely resident or transient. The resident flora (resident microbiota) consists of microorganisms residing under the superficial cells of the *stratum corneum* and can also be found on the surface of the skin.[64,65] *Staphylococcus epidermidis* is the dominant species,[66] and oxacillin resistance is extraordinarily high, particularly among HCWs.[67] Other resident bacteria include *S. hominis* and other coagulase-negative staphylococci, followed by coryneform bacteria (*propionibacteria*, *corynebacteria*, dermobacteria, and micrococci).[68] Among fungi, the most common genus of the resident skin flora, when present, is *Pityrosporum* (*Malassezia*) spp.[69]. Resident flora has two main protective functions: microbial antagonism and the competition for nutrients in the ecosystem.[70] In general, resident flora is less likely to be associated with infections, but may cause infections in sterile body cavities, the eyes, or on non-intact skin.[71]

Transient flora (transient microbiota), which colonizes the superficial layers of the skin, is more amenable to removal by routine hand hygiene. Transient microorganisms do not usually multiply on the skin, but they survive and sporadically multiply on skin surface.[70] They are often acquired by HCWs during direct contact with patients or contaminated environmental surfaces adjacent to the patient and are the organisms most frequently associated with HCAIs. Some types of contact during routine neonatal care are more frequently associated with higher levels of bacterial contamination of HCWs' hands: respiratory secretions, nappy/diaper change, and direct skin contact.[72,73] The transmissibility of transient flora depends on the species present, the number of microorganisms on the surface, and the skin moisture.[74,75] The hands of some HCWs may become persistently colonized by pathogenic flora such as *S. aureus*, Gram-negative bacilli, or yeast.[76]

Normal human skin is colonized by bacteria, with total aerobic bacterial counts ranging from more than 1 x 10^6 colony forming units (CFU)/cm^2 on the scalp, 5 x 10^5 CFUs/cm^2 in the axilla, and 4 x 10^4 CFU/cm^2 on the abdomen to 1 x 10^4 CFU/cm^2 on the forearm.[77] Total bacterial counts on the hands of HCWs have ranged from 3.9 x 10^4 to 4.6 x 10^6 CFU/cm^2.[63,78-80] Fingertip contamination ranged from 0 to 300 CFU when sampled by agar contact methods.[72] Price and subsequent investigators documented that although the count of transient and resident flora varies considerably among individuals, it is often relatively constant for any given individual.[63,81]

6.
Physiology of normal skin

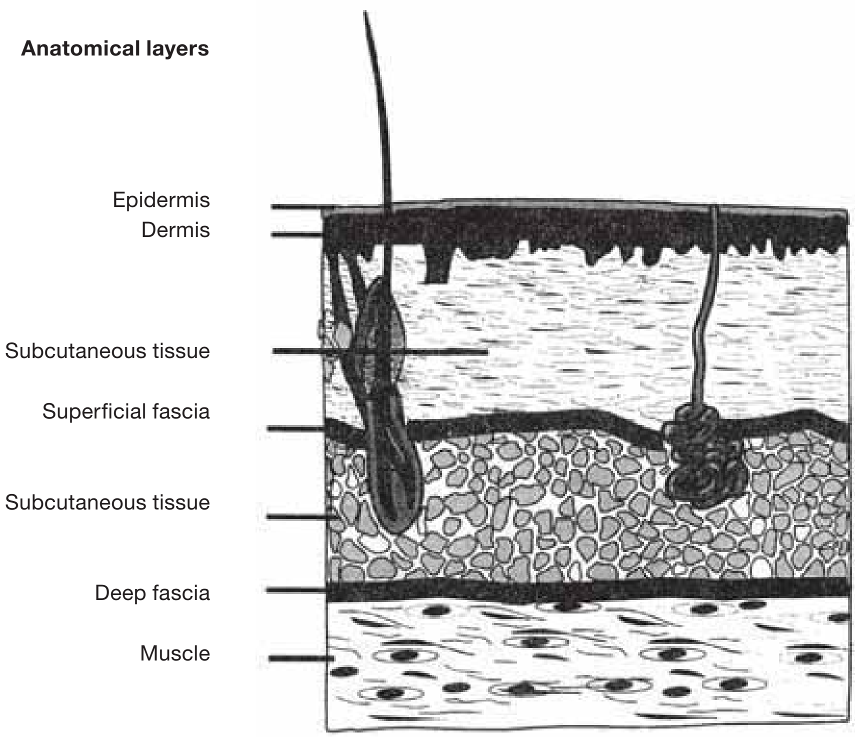
The skin is composed of three layers, the epidermis (50–100 µm), dermis (1–2 mm) and hypodermis (1–2 mm) (Figure I.6.1). The barrier to percutaneous absorption lies within the *stratum corneum*, the most superficial layer of the epidermis. The function of the *stratum corneum* is to reduce water loss, provide protection against abrasive action and microorganisms, and generally act as a permeability barrier to the environment.

The *stratum corneum* is a 10–20 µm thick, multilayer stratum of flat, polyhedral-shaped, 2 to 3 µm thick, non-nucleated cells named *corneocytes. Corneocytes* are composed primarily of insoluble bundled keratins surrounded by a cell envelope stabilized by cross-linked proteins and covalently bound lipids. Corneodesmosomes are membrane junctions interconnecting *corneocytes* and contributing to *stratum corneum* cohesion. The intercellular space between *corneocytes* is composed of lipids primarily generated from the exocytosis of lamellar bodies during the terminal differentiation of the keratinocytes. These lipids are required for a competent skin barrier function.

The epidermis is composed of 10–20 layers of cells. This pluristratified epithelium also contains melanocytes involved in skin pigmentation, and Langerhans' cells, involved in antigen presentation and immune responses. The epidermis, as for any epithelium, obtains its nutrients from the dermal vascular network.

The epidermis is a dynamic structure and the renewal of the *stratum corneum* is controlled by complex regulatory systems of cellular differentiation. Current knowledge of the function of the *stratum corneum* has come from studies of the epidermal responses to perturbation of the skin barrier such as: (i) extraction of skin lipids with apolar solvents; (ii) physical stripping of the *stratum corneum* using adhesive tape; and (iii) chemically-induced irritation. All such experimental manipulations lead to a transient decrease of the skin barrier efficacy as determined by transepidermal water loss. These alterations of the *stratum corneum* generate an increase of keratinocyte proliferation and differentiation in response to this "aggression" in order to restore the skin barrier. This increase in the keratinocyte proliferation rate could directly influence the integrity of the skin barrier by perturbing: (i) the uptake of nutrients, such as essential fatty acids; (ii) the synthesis of proteins and lipids; or (iii) the processing of precursor molecules required for skin barrier function.

Figure I.6.1
The anatomical layers of the cutaneous tissue



7.

Transmission of pathogens by hands

Transmission of health care-associated pathogens from one patient to another via HCWs' hands requires five sequential steps (Figures I.7.1–6): (i) organisms are present on the patient's skin, or have been shed onto inanimate objects immediately surrounding the patient; (ii) organisms must be transferred to the hands of HCWs; (iii) organisms must be capable of surviving for at least several minutes on HCWs' hands; (iv) handwashing or hand antisepsis by the HCW must be inadequate or entirely omitted, or the agent used for hand hygiene inappropriate; and (v) the contaminated hand or hands of the caregiver must come into direct contact with another patient or with an inanimate object that will come into direct contact with the patient. Evidence supporting each of these elements is given below.

7.1 Organisms present on patient skin or in the inanimate environment

Health care-associated pathogens can be recovered not only from infected or draining wounds, but also from frequently colonized areas of normal, intact patient skin.[82-96] The perineal or inguinal areas tend to be most heavily colonized, but the axillae, trunk, and upper extremities (including the hands) are also frequently colonized.[85,86,88,89,91,93,97] The number of organisms such as *S. aureus*, *Proteus mirabilis*, *Klebsiella* spp. and *Acinetobacter* spp. present on intact areas of the skin of some patients can vary from 100 to 10^6 CFU/cm^2.[86,88,92,98] Diabetics, patients undergoing dialysis for chronic renal failure, and those with chronic dermatitis are particularly likely to have skin areas colonized with *S. aureus*.[99-106]. Because nearly 10^6 skin squames containing viable microorganisms are shed daily from normal skin,[107] it is not surprising that patient gowns, bed linen, bedside furniture and other objects in the immediate environment of the patient become contaminated with patient flora.[93-96,108-114] Such contamination is most likely to be due to staphylococci, enterococci or *Clostridium difficile* which are more resistant to desiccation. Contamination of the inanimate environment has also been detected on ward handwash station surfaces and many of the organisms isolated were staphylococci.[115] Tap/faucet handles were more likely to be contaminated and to be in excess of benchmark values than other parts of the station. This study emphasizes the potential importance of environmental contamination on microbial cross contamination and pathogen spread.[115] Certain Gram-negative rods, such as *Acinetobacter baumannii*, can also play an important role in environmental contamination due to their long-time survival capacities.[116-119]

7.2 Organism transfer to health-care workers' hands

Relatively few data are available regarding the types of patient-care activities that result in transmission of patient flora to HCWs' hands.[72,89,110,111,120-123] In the past, attempts have been made to stratify patient-care activities into those most likely to cause hand contamination,[124] but such stratification schemes were never validated by quantifying the level of bacterial contamination that occurred. Casewell & Phillips[121] demonstrated that nurses could contaminate their hands with 100–1000 CFU of *Klebsiella* spp. during "clean" activities such as lifting patients; taking the patient's pulse, blood pressure or oral temperature; or touching the patient's hand, shoulder or groin. Similarly, Ehrenkranz and colleagues[88] cultured the hands of nurses who touched the groin of patients heavily colonized with *P. mirabilis* and found 10–600 CFU/ml in glove juice samples. Pittet and colleagues[72] studied contamination of HCWs' hands before and after direct patient contact, wound care, intravascular catheter care, respiratory tract care or handling patient secretions. Using agar fingertip impression plates, they found that the number of bacteria recovered from fingertips ranged from 0 to 300 CFU. Direct patient contact and respiratory tract care were most likely to contaminate the fingers of caregivers. Gram-negative bacilli accounted for 15% of isolates and *S. aureus* for 11%. Importantly, duration of patient-care activity was strongly associated with the intensity of bacterial contamination of HCWs' hands in this study. A similar study of hand contamination during routine neonatal care defined skin contact, nappy/diaper change, and respiratory care as independent predictors of hand contamination.[73] In the latter study, the use of gloves did not fully protect HCWs' hands from bacterial contamination, and glove contamination was almost as high as ungloved hand contamination

following patient contact. In contrast, the use of gloves during procedures such as nappy/diaper change and respiratory care almost halved the average increase of bacteria CFU/min on HCWs' hands.[73]

Several other studies have documented that HCWs can contaminate their hands or gloves with Gram-negative bacilli, *S. aureus*, enterococci or *C. difficile* by performing "clean procedures" or touching intact areas of skin of hospitalized patients.[89,95,110,111,125,126] A recent study that involved culturing HCWs' hands after various activities showed that hands were contaminated following patient contact and after contact with body fluids or waste.[127] McBryde and colleagues[128] estimated the frequency of HCWs' glove contamination with methicillin-resistant *S. aureus* (MRSA) after contact with a colonized patient. HCWs were intercepted after a patient-care episode and cultures were taken from their gloved hands before handwashing had occurred; 17% (confidence interval (CI) 95% 9–25%) of contacts with patients, a patient's clothing or a patient's bed resulted in transmission of MRSA from a patient to the HCWs' gloves. In another study involving HCWs caring for patients with vancomycin-resistant enterococci (VRE), 70% of HCWs contaminated their hands or gloves by touching the patient and the patient's environment.[114] Furthermore, HCWs caring for infants with respiratory syncytial virus (RSV) infections have acquired infection by performing activities such as feeding infants, nappy/diaper change, and playing with the infant.[122] Caregivers who had contact only with surfaces contaminated with the infants' secretions also acquired RSV.

In the above studies, HCWs contaminated their hands with RSV and inoculated their oral or conjunctival mucosa. Other studies have also documented that the hands (or gloves) of HCWs may be contaminated after touching inanimate objects in patients' rooms.[73,111,112,125-130] Furthermore, a recent two-part study conducted in a non-health-care setting found in the initial phase that patients with natural rhinovirus infections often contaminated multiple environmental sites in their rooms. In the second part of the study, contaminated nasal secretions from the same individuals were used to contaminate surfaces in rooms, and touching contaminated sites 1–178 hours later frequently resulted in the transfer of the virus to the fingertips of the individuals.[131]

Bhalla and colleagues studied patients with skin colonization by *S. aureus* (including MRSA) and found that the organism was frequently transferred to the hands of HCWs who touched both the skin of patients and surrounding environmental surfaces.[96]Hayden and colleagues found that HCWs seldom enter patient rooms without touching the environment, and that 52% of HCWs whose hands were free of VRE upon entering rooms contaminated their hands or gloves with VRE after touching the environment without touching the patient.[114] Laboratory-based studies have shown that touching contaminated surfaces can transfer *S. aureus* or Gram-negative bacilli to the fingers.[132] Unfortunately, none of the studies dealing with HCW hand contamination was designed to determine if the contamination resulted in the transmission of pathogens to susceptible patients.

Many other studies have reported contamination of HCWs' hands with potential pathogens, but did not relate their findings to the specific type of preceding patient contact.[78,79,94,132-142] For example, in studies conducted before glove use was common among HCWs, Ayliffe and colleagues[137] found that 15% of nurses working in an isolation unit carried a median of 1x 10^4 CFU of *S. aureus* on their hands; 29% of nurses working in a general hospital had *S. aureus* on their hands (median count, 3.8 x 10^3 CFU), while 78% of those working in a hospital for dermatology patients had the organism on their hands (median count, 14.3 x 10^6 CFU). The same survey revealed that 17–30% of nurses carried Gram-negative bacilli on their hands (median counts ranged from 3.4 x 10^3 CFU to 38 x 10^3 CFU). Daschner[135] found that *S. aureus* could be recovered from the hands of 21% of ICU caregivers and that 21% of doctors and 5% of nurse carriers had >10^3 CFU of the organism on their hands. Maki[80] found lower levels of colonization on the hands of HCWs working in a neurosurgery unit, with an average of 3 CFU of *S. aureus* and 11 CFU of Gram-negative bacilli. Serial cultures revealed that 100% of HCWs carried Gram-negative bacilli at least once, and 64% carried *S. aureus* at least once. A study conducted in two neonatal ICUs revealed that Gram-negative bacilli were recovered from the hands of 38% of nurses.[138]

7.3 Organism survival on hands

Several studies have shown the ability of microorganisms to survive on hands for differing times. Musa and colleagues demonstrated in a laboratory study that *Acinetobacter calcoaceticus* survived better than strains of *A. lwoffi* at 60 minutes after an inoculum of 10^4 CFU/finger.[143] A similar study by Fryklund and colleagues using epidemic and non-epidemic strains of *Escherichia coli* and *Klebsiella* spp. showed a 50% killing to be achieved at 6 minutes and 2 minutes, respectively.[144] Noskin and colleagues studied the survival of VRE on hands and the environment: both *Enterococcus faecalis* and *E. faecium* survived for at least 60 minutes on gloved and ungloved fingertips.[145] Furthermore, Doring and colleagues showed that *Pseudomonas aeruginosa* and *Burkholderia cepacia* were transmissible by handshaking for up to 30 minutes when the organisms were suspended in saline, and up to 180 minutes when they were suspended in sputum.[146] The study by Islam and colleagues with *Shigella dysenteriae* type 1 showed its capacity to survive on hands for up to 1 hour.[147] HCWs who have hand dermatitis may remain colonized for prolonged time periods. For example, the hands of a HCW with psoriatic dermatitis remained colonized with *Serratia marcescens* for more than three months.[148] Ansari and colleagues[149,150] studied rotavirus, human parainfluenza virus 3, and rhinovirus 14 survival on hands and potential for cross-transfer. Survival percentages for rotavirus at 20 minutes and 60 minutes after inoculation were 16.1% and 1.8%, respectively. Viability at 1 hour for human parainfluenza virus 3 and rhinovirus 14 was <1% and 37.8%, respectively.

The above-mentioned studies clearly demonstrate that contaminated hands could be vehicles for the spread of certain viruses and bacteria. HCWs' hands become progressively colonized with commensal flora as well as with potential pathogens during patient care.[72,73] Bacterial contamination increases linearly over time.[72] In the absence of hand hygiene action, the longer the duration of care, the higher the degree of hand contamination. Whether care is provided to adults or neonates, both the duration and the type of patient care affect HCWs' hand contamination.[72,73] The dynamics of hand contamination are similar on gloved versus ungloved hands; gloves reduce hand contamination, but do not fully protect from acquisition of bacteria during patient care. Therefore, the glove surface is contaminated, making cross-transmission through contaminated gloved hands likely.

7.4 Defective hand cleansing, resulting in hands remaining contaminated

Studies showing the adequacy or inadequacy of hand cleansing by microbiological proof are few. From these few studies, it can be assumed that hands remain contaminated with the risk of transmitting organisms via hands. In a laboratory-based study, Larson and colleagues[151] found that using only 1 ml of liquid soap or alcohol-based handrub yielded lower log reductions (greater number of bacteria remaining on hands) than using 3 ml of product to clean hands. The findings have clinical relevance since some HCWs use as little as 0.4 ml of soap to clean their hands. Kac and colleagues[152] conducted a comparative, cross-over study of microbiological efficacy of handrubbing with an alcohol-based solution and handwashing with an unmedicated soap. The study results were: 15% of HCWs' hands were contaminated with transient pathogens before hand hygiene; no transient pathogens were recovered after handrubbing, while two cases were found after handwashing. Trick and colleagues[153] did a comparative study of three hand hygiene agents (62% ethyl alcohol handrub, medicated handwipe, and handwashing with plain soap and water) in a group of surgical ICUs. They also studied the impact of ring wearing on hand contamination. Their results showed that hand contamination with transient organisms was significantly less likely after the use of an alcohol-based handrub compared with the medicated wipe or soap and water. Ring wearing increased the frequency of hand contamination with potential health care-associated pathogens. Wearing artificial acrylic fingernails can also result in hands remaining contaminated with pathogens after use of either soap or alcohol-based hand gel[154] and has been associated with outbreaks of infection[155] (see also Part I, Section 23.4).

Sala and colleagues[156] investigated an outbreak of food poisoning attributed to norovirus genogroup 1 and traced the index case to a food handler in the hospital cafeteria. Most of the foodstuffs consumed in the outbreak were handmade, thus suggesting inadequate hand hygiene. Noskin and colleagues[145] showed that a 5-second handwash with water alone produced no change in contamination with VRE, and 20% of the initial inoculum was recovered on unwashed hands. In the same study, a 5-second wash with two soaps did not remove the organisms completely with approximately a 1% recovery; a 30-second wash with either soap was necessary to remove the organisms completely from the hands.

Obviously, when HCWs fail to clean their hands between patient contact or during the sequence of patient care – in particular when hands move from a microbiologically contaminated body site to a cleaner site in the same patient – microbial transfer is likely to occur. To avoid prolonged hand contamination, it is not only important to perform hand hygiene when indicated, but also to use the appropriate technique and an adequate quantity of the product to cover all skin surfaces for the recommended length of time.

7.5 Cross-transmission of organisms by contaminated hands

Cross-transmission of organisms occurs through contaminated hands. Factors that influence the transfer of microorganisms from surface to surface and affect cross-contamination rates are type of organism, source and destination surfaces, moisture level, and size of inoculum. Harrison and colleagues[157] showed that contaminated hands could contaminate a clean paper towel dispenser and vice versa. The transfer rates ranged from 0.01% to 0.64% and 12.4% to 13.1%, respectively.

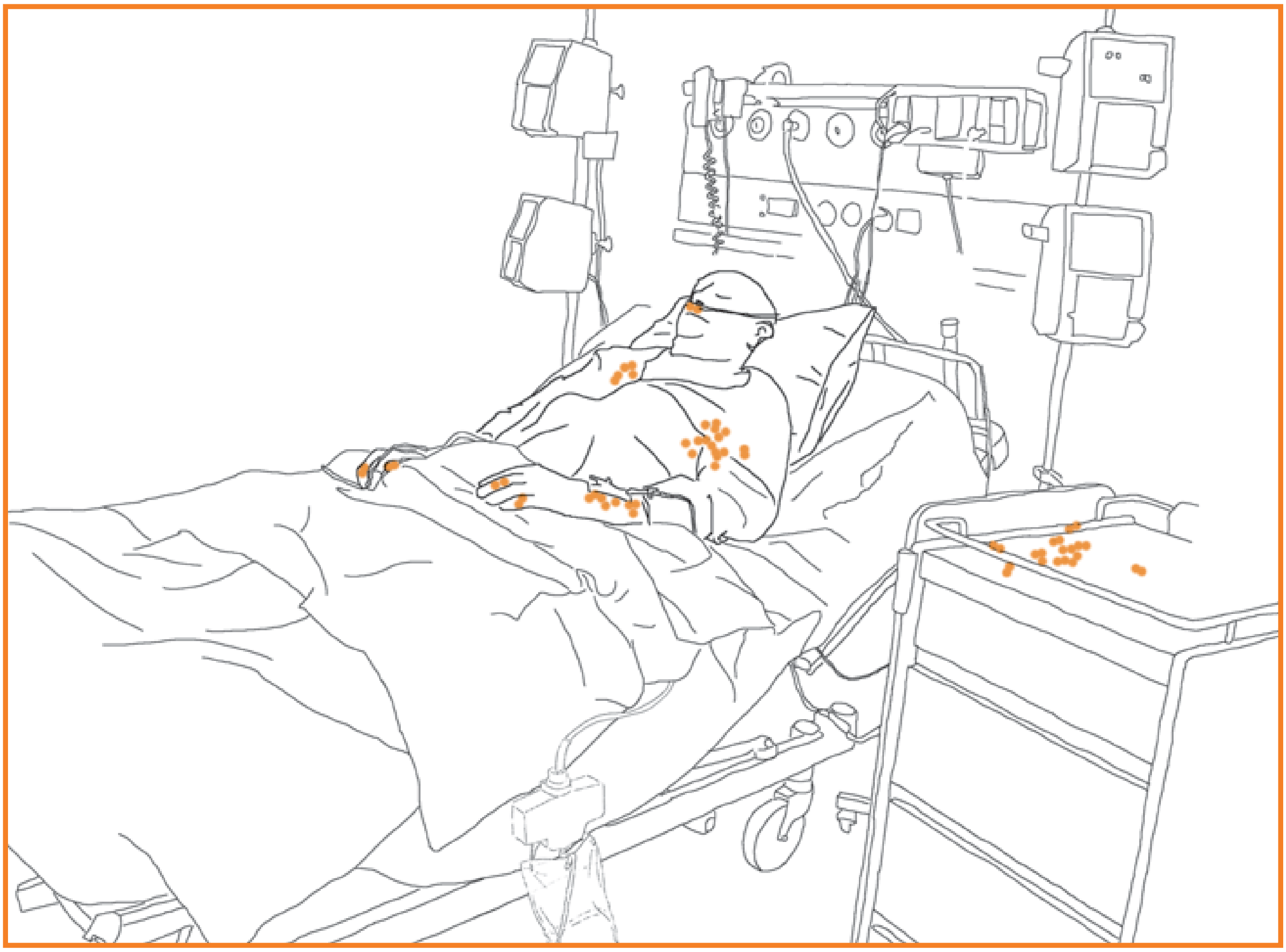
A study by Barker and colleagues[158] showed that fingers contaminated with norovirus could sequentially transfer virus to up to seven clean surfaces, and from contaminated cleaning cloths to clean hands and surfaces. Contaminated HCWs' hands have been associated with endemic HCAIs.[159,160] Sartor and colleagues[160] provided evidence that endemic *S. marcescens* was transmitted from contaminated soap to patients via the hands of HCWs. During an outbreak investigation of *S. liquefaciens*, BSI, and pyrogenic reactions in a haemodialysis centre, pathogens were isolated from extrinsically contaminated vials of medication resulting from multiple dose usage, antibacterial soap, and hand lotion.[161] Duckro and colleagues[126] showed that VRE could be transferred from a contaminated environment or patients' intact skin to clean sites via the hands of HCWs in 10.6% of contacts.

Several HCAI outbreaks have been associated with contaminated HCWs' hands.[162-164] El Shafie and colleagues[164] investigated an outbreak of multidrug-resistant *A. baumannii* and documented identical strains from patients, hands of staff, and the environment. The outbreak was terminated when remedial measures were taken. Contaminated HCWs' hands were clearly related to outbreaks among surgical[148,162] and neonatal[163,165,166] patients.

Finally, several studies have shown that pathogens can be transmitted from out-of-hospital sources to patients via the hands of HCWs. For example, an outbreak of postoperative *S. marcescens* wound infections was traced to a contaminated jar of exfoliant cream in a nurse's home.[167] An investigation suggested that the organism was transmitted to patients via the hands of the nurse, who wore artificial fingernails. In another outbreak, *Malassezia pachydermatis* was probably transmitted from a nurse's pet dogs to infants in an intensive care nursery via the hands of the nurse.[168]

Figure I.7.1

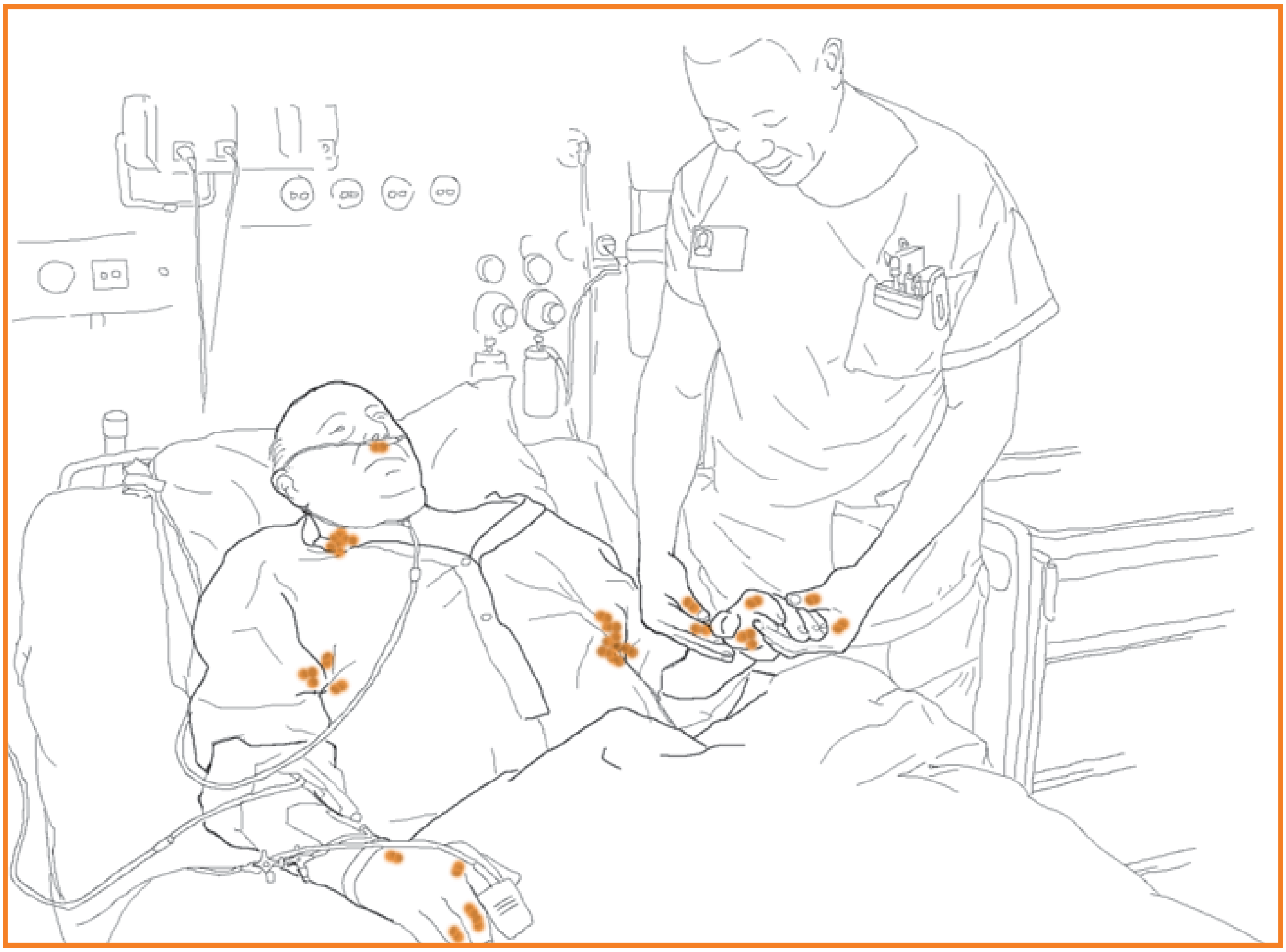
Organisms present on patient skin or the immediate environment



A bedridden patient colonized with Gram-positive cocci, in particular at nasal, perineal, and inguinal areas (not shown), as well as axillae and upper extremities. Some environmental surfaces close to the patient are contaminated with Gram-positive cocci, presumably shed by the patient. Reprinted from Pittet, 2006[885] with permission from Elsevier.

Figure I.7.2

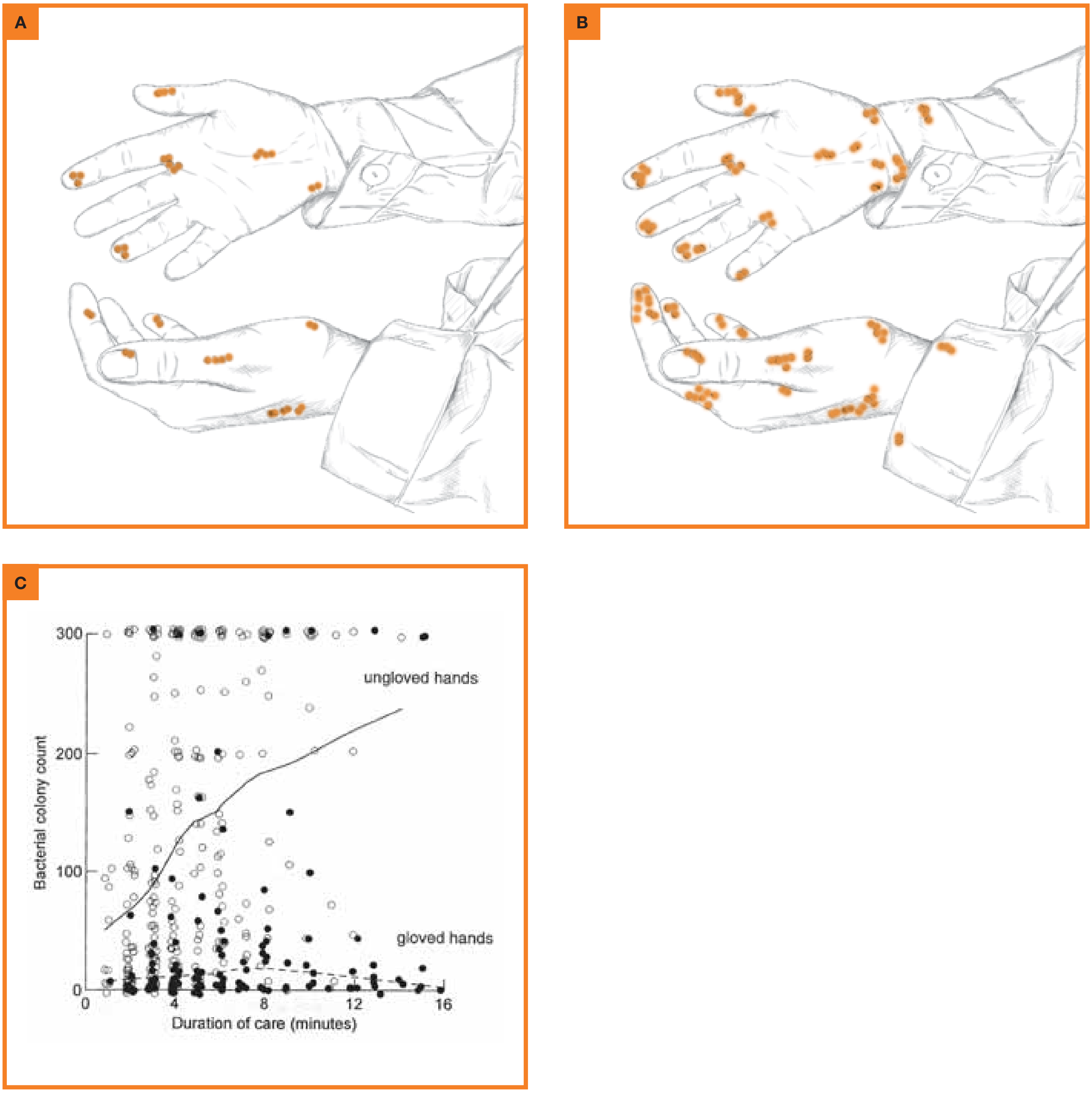
Organism transfer from patient to HCWs' hands



Contact between the HCW and the patient results in cross-transmission of microorganisms. In this case, Gram-positive cocci from the patient's own flora transfer to HCW's hands. Reprinted from Pittet, 2006[885] with permission from Elsevier.

Figure I.7.3

Organism survival on HCWs' hands*



(A) Microorganisms (in this case Gram-positive cocci) survive on hands. Reprinted from Pittet, 2006[885] with permission from Elsevier.

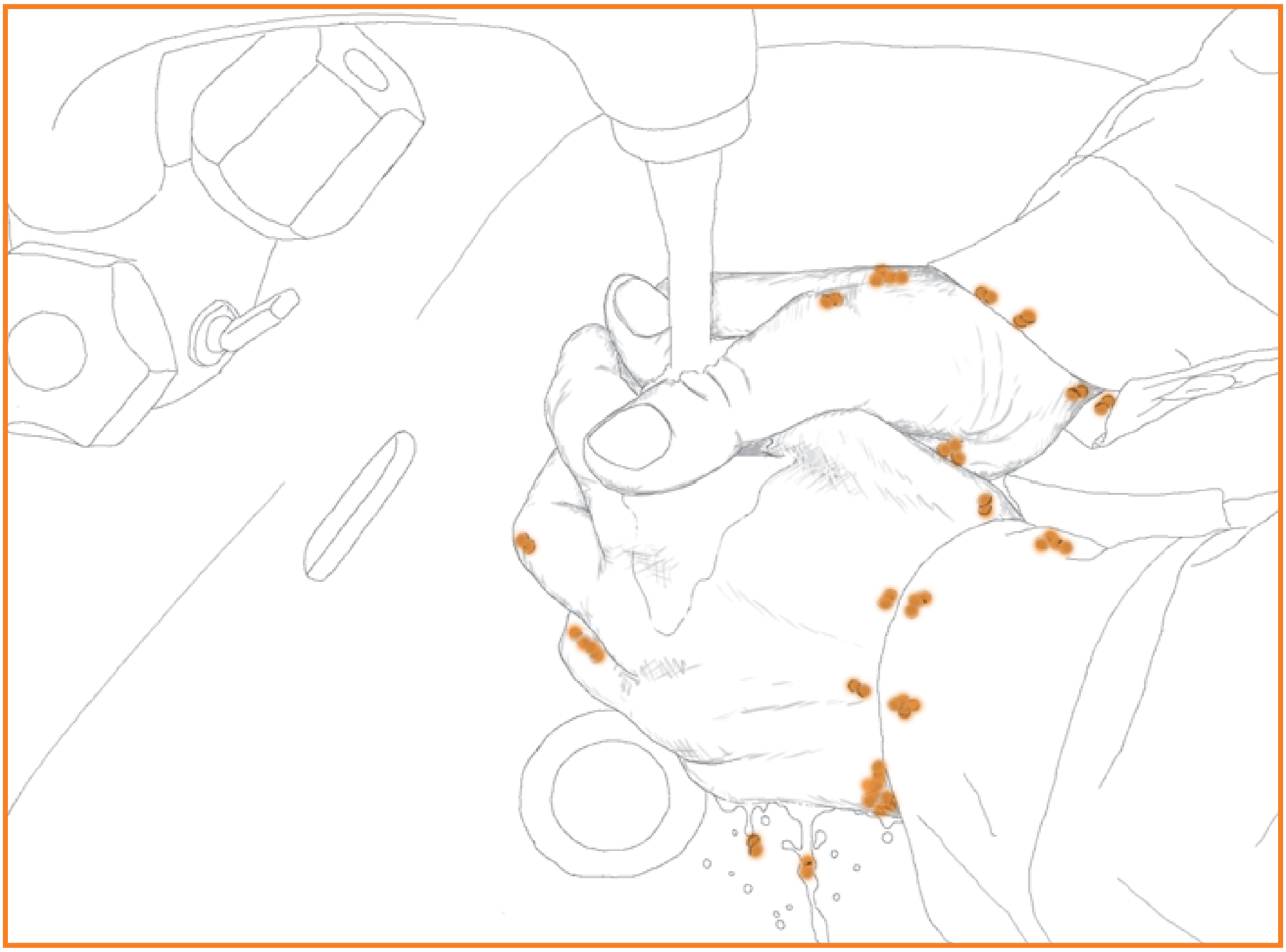
(B) When growing conditions are optimal (temperature, humidity, absence of hand cleansing, or friction), microorganisms can continue to grow. Reprinted from Pittet, 2006[885] with permission from Elsevier.

(C) Bacterial contamination increases linearly over time during patient contact. Adapted with permission from Pittet, 1999.[14]

* The figure intentionally shows that long-sleeved white coats may become contaminated by microorganisms during patient care. Although evidence to formulate it as a recommendation is limited, long sleeves should be avoided.

Figure I.7.4

Incorrect hand cleansing*

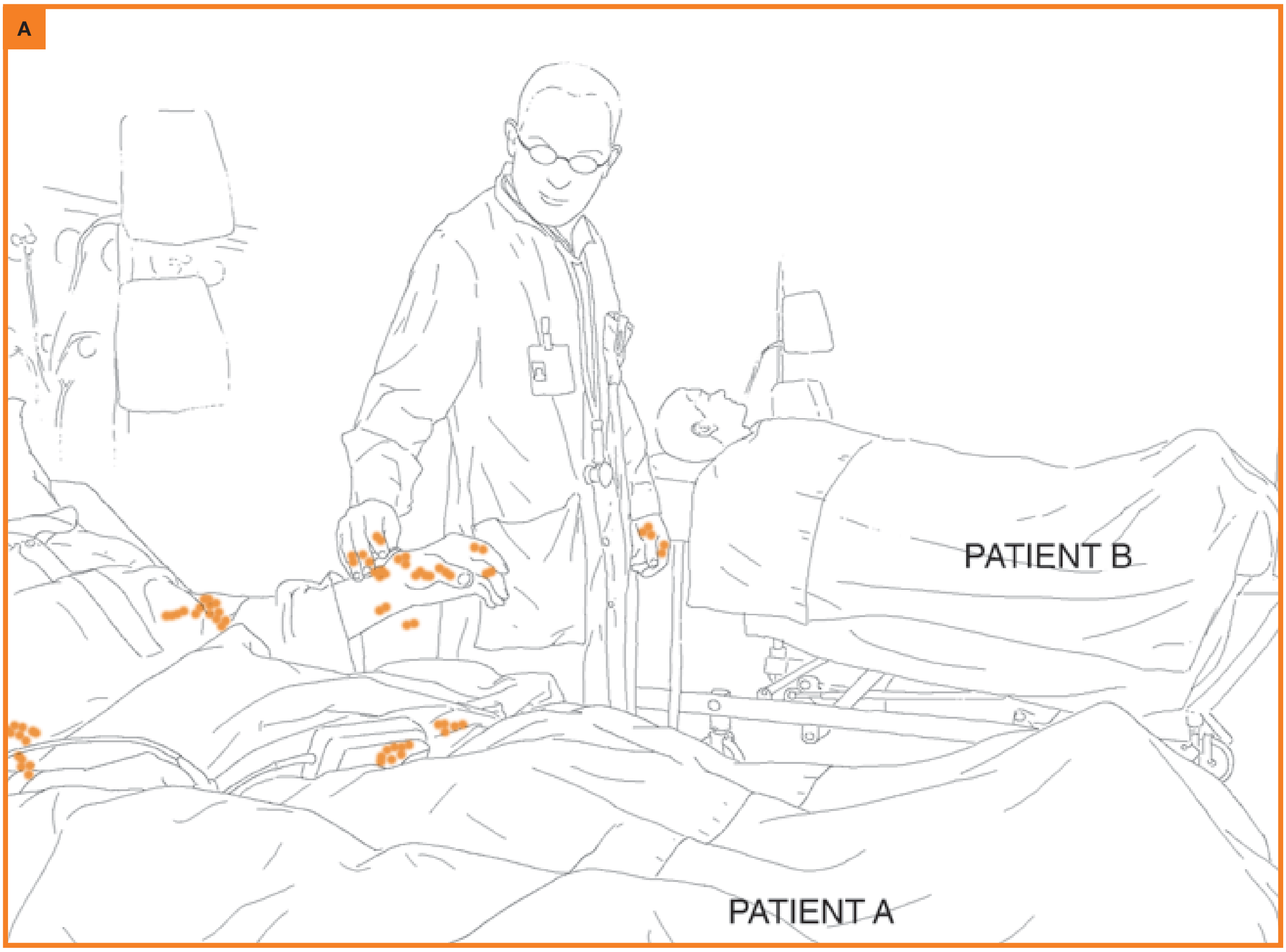


Inappropriate handwashing can result in hands remaining contaminated; in this case, with Gram-positive cocci. Reprinted from Pittet, 2006[885] with permission from Elsevier.

* The figure intentionally shows that long-sleeved white coats may become contaminated by microorganisms during patient care. Although evidence to formulate it as a recommendation is limited, long sleeves should be avoided.

Figure I.7.5a

Failure to cleanse hands results in between-patient cross-transmission*

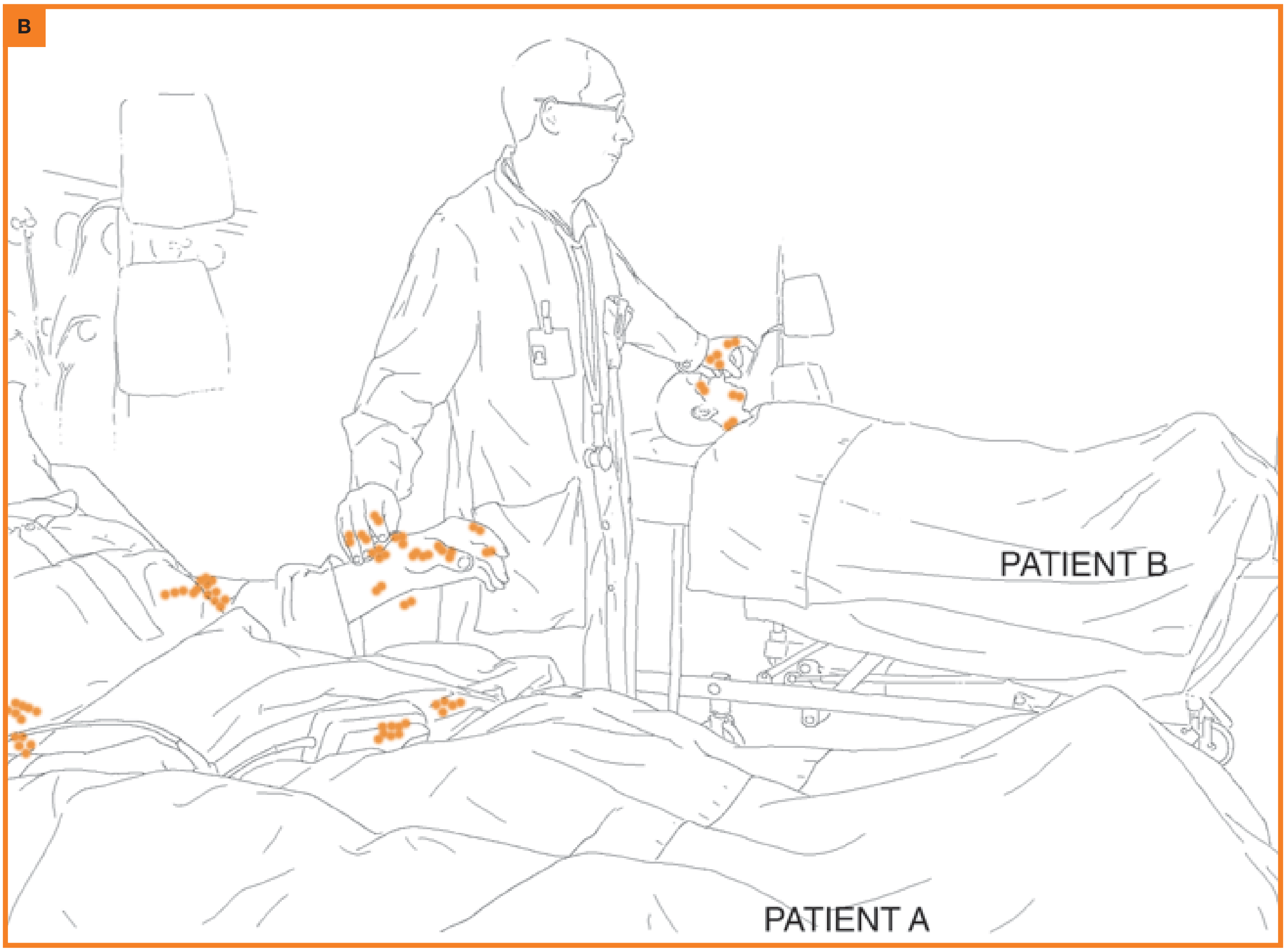


(A) The doctor had a prolonged contact with patient A colonized with Gram-positive cocci and contaminated his hands. Reprinted from Pittet, 2006[885] with permission from Elsevier.

* The figure intentionally shows that long-sleeved white coats may become contaminated by microorganisms during patient care. Although evidence to formulate it as a recommendation is limited, long sleeves should be avoided.

Figure I.7.5b

Failure to cleanse hands results in between-patient cross-transmission*



(B) The doctor is now going to have direct contact with patient B without cleansing his hands in between. Cross-transmission of Gram-positive cocci from patient A to patient B through the HCW's hands is likely to occur. Reprinted from Pittet, 2006[885] with permission from Elsevier.

* The figure intentionally shows that long-sleeved white coats may become contaminated by microorganisms during patient care. Although evidence to formulate it as a recommendation is limited, long sleeves should be avoided.

Figure I.7.6

Failure to cleanse hands during patient care results in within-patient cross-transmission*

The doctor is in close contact with the patient. He touched the urinary catheter bag previously and his hands are contaminated with Gram-negative rods from touching the bag and a lack of subsequent hand cleansing. Direct contact with patients or patients' devices would probably result in cross-transmission. Reprinted from Pittet with permission from Elsevier, 2006.[885]

* The figure intentionally shows that long-sleeved white coats may become contaminated by microorganisms during patient care. Although evidence to formulate it as a recommendation is limited, long sleeves should be avoided.

8.
Models of hand transmission

8.1 Experimental models

Several investigators have studied the transmission of infectious agents using different experimental models. Ehrenkranz and colleagues[88] asked nurses to touch a patient's groin for 15 seconds as though they were taking a femoral pulse. The patient was known to be heavily colonized with Gram-negative bacilli. Nurses then cleansed their hands by washing with plain soap and water or by using an alcohol-based handrub. After cleansing their hands, they touched a piece of urinary catheter material with their fingers and the catheter segment was cultured. The study revealed that touching intact areas of moist skin transferred enough organisms to the nurses' hands to allow subsequent transmission to catheter material despite handwashing with plain soap and water; by contrast, alcohol-based handrubbing was effective and prevented cross-transmission to the device. Marples and colleagues[74] studied the transmission of organisms from artificially contaminated "donor" fabrics to clean "recipient" fabrics via hand contact and found that the number of organisms transmitted was greater if the donor fabric or the hands were wet. Overall, only 0.06% of the organisms obtained from the contaminated donor fabric were transferred to the recipient fabric via hand contact. Using the same experimental model, Mackintosh and colleagues[169] found that *S. saprophyticus*, *P. aeruginosa,* and *Serratia* spp. were transferred in greater numbers than was *E. coli* from a contaminated to a clean fabric following hand contact. Patrick and colleagues[75] found that organisms were transferred to various types of surfaces in much larger numbers (>10^4) from wet hands than from hands that had been dried carefully. Sattar and colleagues[170] demonstrated that the transfer of *S. aureus* from fabrics commonly used for clothing and bed linen to fingerpads occurred more frequently when fingerpads were moist.

8.2 Mathematical models

Mathematical modelling has been used to examine the relationships between the multiple factors that influence pathogen transmission in health-care facilities. These factors include hand hygiene compliance, nurse staffing levels, frequency of introduction of colonized or infected patients onto a ward, whether or not cohorting is practised, characteristics of patients and antibiotic use practices, to name but a few.[171] Most reports describing the mathematical modelling of health care-associated pathogens have attempted to quantify the influence of various factors on a single ward such as an ICU.[172-175] Given that such units tend to house a relatively small number of patients at any time, random variations (stochastic events) such as the number of patients admitted with a particular pathogen during a short time period can have a significant impact on transmission dynamics. As a result, stochastic models appear to be the most appropriate for estimating the impact of various infection control measures, including hand hygiene compliance, on colonization and infection rates.

In a mathematical model of MRSA infection in an ICU, Sebille and colleagues[172] found that the number of patients who became colonized by strains transmitted from HCWs was one of the most important determinants of transmission rates. Of interest, they found that increasing hand hygiene compliance rates had only a modest effect on the prevalence of MRSA colonization. Their model estimated that if the prevalence of MRSA colonization was 30% without any hand hygiene, it would decrease to only 22% if hand hygiene compliance increased to 40% and to 20% if hand hygiene compliance increased to 60%. Antibiotic policies had relatively little impact in this model.

Austin and colleagues[173] used daily surveillance cultures of patients, molecular typing of isolates, and monitoring of compliance with infection control practices to study the transmission dynamics of VRE in an ICU. The study found that hand hygiene and staff cohorting were predicted to be the most effective control measures. The model predicted that for a given level of hand hygiene compliance, adding staff cohorting would lead to the better control of VRE transmission. The rate at which new VRE cases were admitted to the ICU played an important role in the level of transmission of VRE in the unit.

In a study that used a stochastic model of transmission dynamics, Cooper and colleagues[176] predicted that improving hand hygiene compliance from very low levels to 20% or 40% significantly reduced transmission, but that improving compliance to levels above 40% would have relatively little impact on the prevalence of *S. aureus*. Grundmann and colleagues[175] conducted an investigation that included cultures of patients at the time of ICU admission and twice-weekly observations of the frequency of contact between HCWs and patients, cultures of HCWs' hands, and molecular typing of MRSA isolates. A stochastic model predicted that a 12% improvement in adherence to hand hygiene policies or in cohorting levels might have compensated for staff shortages and prevented transmission during periods of overcrowding and high workloads.

A stochastic model by McBryde and colleagues used surveillance cultures, hand hygiene compliance observations, and evaluation of the likelihood of transmission from a colonized patient to a HCW, as well as other factors, to estimate the impact of various interventions on MRSA transmission in an ICU.[177] They found also that improving hand hygiene was predicted to be the most effective intervention. Unlike several earlier studies, their model suggested that increasing levels of hand hygiene compliance above 40% to 60% continued to have a beneficial impact on reducing MRSA transmission. A model using Monte Carlo simulations to study the impact of various control measures on MRSA transmission on a general medical ward also suggested that improving hand hygiene compliance was likely to be the most effective measure for reducing transmission.[178]

While the above-mentioned studies have provided new insights into the relative contribution of various infection control measures, all have been based on assumptions that may not be valid in all situations. For example, most studies assumed that transmission of pathogens occurred only via the hands of HCWs and that contaminated environmental surfaces played no role in transmission. The latter may not be true for some pathogens that can remain viable in the inanimate environment for prolonged periods. Also, most, if not all mathematical models were based on the assumption that when HCWs did clean their hands,100% of the pathogen of interest was eliminated from the hands, which is unlikely to be true in many instances.[176] Importantly, all the mathematical models described above predicted that improvements in hand hygiene compliance could reduce pathogen transmission. However, the models did not agree on the level of hand hygiene compliance that is necessary to halt transmission of health care-associated pathogens. In reality, the level may not be the same for all pathogens and in all clinical situations. Further use of mathematical models of transmission of health care-associated pathogens is warranted. Potential benefits of such studies include evaluating the benefits of various infection control interventions and understanding the impact of random variations in the incidence and prevalence of various pathogens.[171]

9.

Relationship between hand hygiene and the acquisition of health care-associated pathogens

Despite a paucity of appropriate randomized controlled trials, there is substantial evidence that hand antisepsis reduces the transmission of health care-associated pathogens and the incidence of HCAI.[58,179,180] In what would be considered an intervention trial using historical controls, Semmelweis[179] demonstrated in 1847 that the mortality rate among mothers delivering at the First Obstetrics Clinic at the General Hospital of Vienna was significantly lower when hospital staff cleaned their hands with an antiseptic agent than when they washed their hands with plain soap and water.

In the 1960s, a prospective controlled trial sponsored by the USA National Institutes of Health (NIH) and the Office of the Surgeon General compared the impact of no handwashing versus antiseptic handwashing on the acquisition of *S. aureus* among infants in a hospital nursery.[52] The investigators demonstrated that infants cared for by nurses who did not wash their hands after handling an index infant colonized with *S. aureus* acquired the organism significantly more often, and more rapidly, than did infants cared for by nurses who used hexachlorophene to clean their hands between infant contacts. This trial provided compelling evidence that when compared with no handwashing, hand cleansing with an antiseptic agent between patient contacts reduces transmission of health care-associated pathogens.

A number of studies have demonstrated the effect of hand cleansing on HCAI rates or the reduction in cross-transmission of antimicrobial resistant pathogens (see Part I, Section 22 and Table I.22.1). For example, several investigators have found that health care-associated acquisition of MRSA was reduced when the antimicrobial soap used for hygienic hand antisepsis was changed.[181,182] In one of these studies, endemic MRSA in a neonatal ICU was eliminated seven months after introduction of a new hand antiseptic agent (1% triclosan) while continuing all other infection control measures, including weekly active surveillance cultures.[181] Another study reported an MRSA outbreak involving 22 infants in a neonatal unit.[182] Despite intensive efforts, the outbreak could not be controlled until a new antiseptic agent was added (0.3% triclosan) while continuing all previous control measures, which included the use of gloves and gowns, cohorting, and surveillance cultures. Casewell & Phillips[121] reported that increased handwashing frequency among hospital staff was associated with a decrease in transmission of *Klebsiella* spp. among patients, but they did not quantify the level of handwashing among HCWs. It is important to highlight, however, that although the introduction of a new antiseptic product was a key factor to improvement in all these studies, in most cases, system change has been only one of the elements determining the success of multimodal hand hygiene promotion strategies; rather, success results from the overall effect of the campaign.

In addition to these studies, outbreak investigations have suggested an association between infection and understaffing or overcrowding that was consistently linked with poor adherence to hand hygiene. During an outbreak, Fridkin[183] investigated risk factors for central venous catheter-associated BSI. After adjustment for confounding factors, the patient-to-nurse ratio remained an independent risk factor for BSI, suggesting that nursing staff reduction below a critical threshold may have contributed to this outbreak by jeopardizing adequate catheter care. Vicca[184] demonstrated the relationship between understaffing and the spread of MRSA in intensive care. These findings show indirectly that an imbalance between workload and staffing leads to relaxed attention to basic control measures, such as hand hygiene, and spread of microorganisms. Harbarth and colleagues[185] investigated an outbreak of *Enterobacter cloacae* in a neonatal ICU and showed that the daily number of hospitalized children was above the maximal capacity of the unit, resulting in an available space per child well below current recommendations. In parallel, the number of staff on duty was significantly below that required by the workload, and this also resulted in relaxed attention to basic infection control measures. Adherence to hand hygiene practices before device contact was only 25% during the workload peak, but increased to 70% after the end of the understaffing and overcrowding period. Continuous surveillance showed that being hospitalized during this period carried a fourfold increased risk of acquiring an HCAI. This study not only shows the association between workload and infections, but also highlights the intermediate step – poor adherence to hand hygiene practices. Robert and colleagues suggested that suboptimal nurse staffing composition for the three days before BSI (i.e. lower regular-nurse-to-patient and higher pool-nurse-to-patient ratios) was an independent risk factor for infection.[186] In another study in ICU, higher staff level was indeed independently associated with a > 30% infection risk reduction and the estimate was made that, if the nurse-to patient ratio was maintained > 2.2, 26.7% of all infections could be avoided.[187]

Overcrowding and understaffing are commonly observed in health-care settings and have been associated throughout the world, particularly in developing countries where limited personnel and facility resources contribute to the perpetuation of this problem.[183-186,188-190] Overcrowding and understaffing were documented in the largest nosocomial outbreak attributable to *Salmonella* spp. ever reported[191]; in this outbreak in Brazil, there was a clear relationship between understaffing and the quality of health care, including hand hygiene.

10. Methods to evaluate the antimicrobial efficacy of handrub and handwash agents and formulations for surgical hand preparation

With the exception of non-medicated soaps, every new formulation for hand antisepsis should be tested for its antimicrobial efficacy to demonstrate that: (i) it has superior efficacy over normal soap; or (ii) it meets an agreed performance standard. The formulation with all its ingredients should be evaluated to ensure that humectants or rehydrating chemicals added to ensure better skin tolerance do not in any way compromise its antimicrobial action.

Many test methods are currently available for this purpose, but some are more useful and relevant than others. For example, determination of the minimum inhibitory concentration (MIC) of such formulations against bacteria has no direct bearing on the "killing effect" expected of such products in the field. Conditions in suspension and in vitro[192] or ex vivo[193] testing do not reflect those on human skin. Even simulated-use tests with subjects are considered by some as "too controlled", prompting testing under in praxi or field conditions. Such field testing is difficult to control for extraneous influences. In addition, and importantly, the findings of field tests provide scant data on a given formulation's ability to cause a measurable reduction in hand-transmitted nosocomial infections. While the ultimate approach in this context would be clinical trials, they are generally quite cumbersome and expensive. For instance, power analysis reveals that for demonstrating a reduction in hand-transmitted infections from 2% to 1% by changing to a presumably better hand antiseptic agent, almost 2500 subjects would be required in each of two experimental arms at the statistical pre-settings of α (unidirectional) = 0.05 and a power of $1-\beta = 0.9$.[194] For this reason, the number of such trials remains quite limited.[195-197] To achieve a reduction from 7% to 5% would require 3100 subjects per arm. This reinforces the utility of well-controlled, economically affordable, in vivo laboratory-based tests to provide sufficient data to assess a given formulation's potential benefits under field use.

10.1 Current methods

Direct comparisons of the results of in vivo efficacy testing of handwashing, antiseptic handwash, antiseptic handrub, and surgical hand antisepsis are not possible because of wide variations in test protocols. Such variations include: (i) whether hands are purposely contaminated with a test organism before use of the test agent; (ii) the method used to contaminate fingers or hands; (iii) the volume of hand hygiene product applied; (iv) the time the product is in contact with the skin; and (v) the method used to recover the organism from the skin after the test formulation has been used.

Despite the differences noted above, most testing falls into one of two major categories. One category is designed to evaluate handwash or handrub agents to eliminate transient pathogens from HCWs' hands. In most such studies, the subjects' hands are experimentally contaminated with the test organism before applying the test formulation. In the second category, which applies to pre-surgical scrubs, the objective is to evaluate the test formulation for its ability to reduce the release of naturally present resident flora from the hands. The basic experimental design of these methods is summarized below and the procedures are presented in detail in Table 1.10.1.

In Europe, the most commonly used methods to test hand antiseptics are those of the European Committee for Standardization (CEN). In the USA and Canada, such formulations are regulated by the Food and Drug Administration (FDA)[198] and Health Canada, respectively, which refer to the standards of ASTM International (formerly, the American Society for Testing and Materials).

It should be noted that the current group of experts recommends using the term "efficacy" to refer to the (possible) effect of the application of a hand hygiene formulation when tested in laboratory or in vivo situations. By contrast, it would recommend using the term "effectiveness" to refer to the clinical conditions under which hand hygiene products have been tested, such as field trials, where the impact of a hand hygiene formulation is monitored on the rates of cross-transmission of infection or resistance.[199]

10.1.1 Methods to test activity of hygienic handwash and handrub agents

The following in vivo methods use experimental contamination to test the capacity of a formulation to reduce the level of transient microflora on the hands without regard to the resident flora. The formulations to be tested are hand antiseptic agents intended for use by HCWs, except in the surgical area.

CEN standards: EN 1499 and EN 1500

In Europe, the most common methods for testing hygienic hand antiseptic agents are EN 1499[200] and EN 1500.[201] Briefly, the former standard requires 12–15 subjects, and the latter (in the forthcoming amendment) 18–22, and a culture of *E. coli*. Subjects are assigned randomly to two groups where one applies the test formulation and the other a standardized reference solution. In a consecutive run, the two groups reverse roles (cross-over design).

If an antiseptic soap has been tested according to EN 1499,[200] the mean log_{10} reduction by the formulation must be significantly higher than that obtained with the control (soft soap). For handrubs (EN 1500), the mean acceptable reduction with a test formulation shall not be significantly inferior to that with the reference alcohol-based handrub (isopropyl alcohol or isopropanol 60% volume).

ASTM standards

- **ASTM E-1174**[202]
  Currently, handwash or handrub agents are evaluated using this method in North America. The efficacy criteria of the FDA's Tentative Final Monograph (TFM) are a 2-log_{10} reduction of the indicator organism on each hand within 5 minutes after the first use, and a 3-log_{10} reduction of the indicator organism on each hand within 5 minutes after the tenth use.[198]

  The performance criteria in EN 1500 and in the TFM for alcohol-based handrubs are not the same.[48,198,201] Therefore, a formulation may pass the TFM criterion, but may not meet that of EN 1500 or vice versa.[203] It should be emphasized here that the level of reduction in microbial counts needed to produce a meaningful drop in the hand-borne spread of nosocomial pathogens remains unknown.[48,204]

- **ASTM E-1838 (fingerpad method for viruses)**[205]
  The fingerpad method can be applied with equal ease to handwash or handrub agents. When testing handwash agents, it can also measure reductions in the levels of viable virus after exposure to the test formulation alone, after post-treatment water rinsing and post-rinse drying of hands. This method also presents a lower risk to subjects because it entails contamination of smaller and well-defined areas on the skin in contrast to using whole hands (see below). The method can be applied to traditional as well as more recently discovered viruses such as caliciviruses.[206]

- **ASTM E-2276 (fingerpad method for bacteria)**[207]
  This method is for testing handwash or handrub against bacteria. It is similar in design and application to the method E-1838[205] described above for working with viruses.

- **ASTM E-2613 (fingerpad method for fungi)**[208]
  This method is for testing handwash or handrub against fungi. It is similar in design and application to the methods described above for working with viruses (E-1838)[205] and bacteria (E-2276).[207]

- **ASTM E-2011 (whole hand method for viruses)**[209]
  In this method, the entire surface of both hands is contaminated with the test virus, and the test handwash or handrub formulation is rubbed on them. The surface of both hands is eluted and the eluates assayed for viable virus.

10.1.2 Surgical hand preparation

In contrast to hygienic handwash or handrub, surgical hand preparation is directed against the resident hand flora. No experimental contamination of hands is used in any existing methods.

CEN standard: EN 12791 (surgical hand preparation)[210]

This European norm is comparable with that described in EN 1500, except that the bactericidal effect of a product is tested: (i) on clean, not experimentally contaminated hands; (ii) with 18–20 subjects; (iii) using the split-hands model by Michaud, McGrath & Goss[211] to assess the immediate effect on one hand and a 3-hour effect (to detect a possible sustained effect) on the other, meanwhile gloved hand; (iv) in addition, a cross-over design is used but, contrary to hygienic hand antisepsis, the two experimental runs are separated by one week to enable regrowth of the resident flora; (v) the reference antisepsis procedure uses as many 3-ml portions of n-propanol 60% (v/v) as are necessary to keep hands wet for 3 minutes; thus, the total quantity used may vary according to the size and temperature of the hands and other factors; (vi) the product is used according to manufacturer's instructions with a maximum allowed contact time of 5 minutes; (vii) the requirements are that the immediate and 3-hour effects of a product must not be significantly inferior to those of the reference hand antisepsis; and (viii) if there is a claim for sustained activity, the product must demonstrate a significantly lower bacterial count than the reference at 3 hours.

ASTM standard: ASTM E-1115 (surgical hand scrub)[212]

This test method is designed to measure the reduction in bacterial flora on the skin. It is intended for determining immediate and persistent microbial reductions, after single or repetitive treatments, or both. It may also be used to measure cumulative antimicrobial activity after repetitive treatments.

In North America, this method is required to assess the activity of surgical scrubs.[198] The TFM requires that formulations: (i) reduce the number of bacteria 1-log_{10} on each hand within 1 minute of product use and that the bacterial colony count on each hand does not subsequently exceed baseline within 6 hours on day 1; (ii) produce a 2-log_{10} reduction in bacterial counts on each hand within 1 minute of product use by the end of the second day of enumeration; and (iii) accomplish a 3-log_{10} reduction of bacterial counts on each hand within 1 minute of product use by the end of the fifth day when compared to the established baseline.[198]

10.2 Shortcomings of traditional test methods

10.2.1 Hygienic handwash and handrub; HCW handwash and handrub

A major obstacle for testing hand hygiene products to meet regulatory requirements is the cost, which can be prohibitive even for large multinational companies. Cases in point are the extensive and varied evaluations as specified in the TFM[198]; time-kill curves must also be established along with tests on the potential for development of antimicrobial resistance. In vivo, at least 54 subjects are necessary in each arm to test the product and a positive control, hence a minimum of 2 x 54 subjects. The immense expenditure would, however, be much smaller if the same subjects were used to test both formulations concurrently in two runs in a cross-over fashion as described in EN 1499 and EN 1500.[200,201] The results could then be intra-individually compared, thus allowing a considerable reduction in sample size at the same statistical power.

Another shortcoming of existing test methods is the duration of hand treatments that require subjects to treat their hands with the hand hygiene product or a positive control for 30 seconds[198] or 1 minute,[200] despite the fact that the average duration of hand cleansing by HCWs has been observed to be less than 15 seconds in most studies.[124,213-218] A few investigators have used 15-second handwashing or hygienic hand antisepsis protocols.[151,219-222] Therefore, almost no data exist regarding the efficacy of antimicrobial soaps under conditions in which they are actually used. Similarly, some accepted methods for evaluating waterless antiseptic agents for use as antiseptic handrubs, such as the reference hand antisepsis in EN 1500,[201] require that 3 ml of alcohol be rubbed into the hands for 30 seconds, followed by a repeat application of the same type. Again, this type of protocol does not reflect actual usage patterns among HCWs. However, it could be argued that non-inferiority in the efficacy of a test product as compared with the reference is easier to prove with longer skin contact. Or, inversely, to prove a difference between two treatments of very short duration, such as 15 seconds, under valid statistical settings is difficult and requires large sample sizes, i.e. large numbers of subjects. Therefore a reference treatment, which has usually been chosen for its comparatively high efficacy, may include longer skin contact than is usual in real practice. By this, the non-inferiority of a test product can be demonstrated with economically justifiable sample sizes.

The TFM,[198] for instance, requires that a handwash to be used by HCWs demonstrates an in vivo reduction in the number of the indicator organisms on each hand by 2 log within 5 minutes after the first wash and by 3 log after the tenth wash. This requirement is inappropriate to the needs of working in a health-care setting for two reasons. First, to allow a preparation to reduce the bacterial release by only 2 log within a maximum time span of 5 minutes seems an unrealistically low requirement, as even with unmedicated soap and water a reduction of 3 log is achievable within 1 minute.[48,223] Furthermore, 5 minutes is much too long to wait between two patients. Second, the necessity for residual action of a hand antisepsis formulation in the non-surgical area has been challenged.[224-226] The current group of experts does not believe that for the aforementioned purpose a residual antimicrobial activity is necessary in the health-care setting. Rather, a fast and strong immediate effect against a broad spectrum of transient flora is required to render hands safe, not only in a very short time, but also already after the first application of the formulation. Therefore, the requirement that a product must demonstrate a stronger activity after the tenth wash than after the first seems difficult to justify.

An in-use test that is simple to use in the clinical setting to document microbial colonization is the fingerprint imprint method.[72] This method entails taking imprints of the fingerpads and thumb on to a nutritive agar preferably containing neutralizers for the non-alcohol-based antiseptic agent in use. This is done by applying gentle pressure with the fingers and thumb individually on to the agar for 5 seconds. This method provides less accurate bacterial counts than the fingertip rinse method, but it has the advantage of ease of use in the field and provides good results when evaluating transient flora and their inactivation. The problem with such a qualitative method is that it often gives confounding results. Indeed, the bacterial count recovered after the use of the test formulation can be much higher than the one in controls because of the disaggregation of micro-colonies of resident bacteria.

10.2.2 Surgical handwash and handrub; surgical hand scrub; surgical hand preparation

As with hygienic hand antisepsis, a major shortcoming for testing surgical scrubs is the resource expenditure associated with the use of the TFM model. The required in vitro tests are the same as described under Part I, Section 10.2.1, above (see also Table I.10.1) No less than 130 subjects are necessary to test a product, together with an active control in the suggested parallel arm design. For some products, this number will even have to be multiplied for concomitant testing of the vehicle and perhaps of a placebo to demonstrate efficacy.[198] As mentioned with the test model for HCW handwashes and described in EN 12791,[210] this large number of subjects could be much reduced if the tests are not conducted with different populations of subjects for each arm but if the same individuals participate in each arm, being randomly allocated to the various components of a Latin square design, the experiments of which can be carried out at weekly intervals. The results are then treated as related samples with intra-individual comparison. Additionally, it is not clear why the vehicle or a placebo needs to be tested in parallel if a product is shown to be equivalent in its antimicrobial efficacy to an active control scrub. For the patient and for the surgeon, it is of no interest whether the product is sufficiently efficacious because of the active ingredient only or, perhaps, additionally by a synergistic or even antimicrobial effect of the vehicle.

In contrast to the requirement of EN 12791 where a sustained (or persistent) effect of the surgical scrub is optional, the TFM model requires a formulation to possess this feature (see above). However, the continued presence of a microbicidal chemical to produce a sustained effect may be unnecessary in view of the fact that volatile ingredients such as short-chain aliphatic alcohols (e.g. ethanol, iso-propanol, and n-propanol)[48] appear fully capable of producing the same effect.[227] With their strong antibacterial efficacy, the importance of a sustained effect is questionable, as regrowth of the skin flora takes several hours even without the explicitly sustained effect of the alcohols. Furthermore, whether a long-term effect (several days), such as recommended in the TFM model, is necessary or not remains a matter for discussion. It is, however, difficult to understand why the efficacy of a scrub is required to increase from the first to the fifth day of permanent use. Ethical considerations would suggest that the first patient on a Monday, when the required immediate bacterial reduction from baseline is only 1 log, should be treated under the same safety precautions as patients operated on the following Friday when, according to the TFM requirement, the log reduction has to be 3.0.

With regard to the statistical analysis of EN 12791, in which the efficacy of a product is compared with that of a reference (including a handrub with 60% n-propanol for 3 minutes), the currently suggested model of a comparative trial is no longer up to date. It should be exchanged for a non-inferiority trial. Furthermore, the latest CDC/HICPAC guideline for hand hygiene in health-care settings[58] considers it as a shortcoming that in vivo laboratory test models use non-HCWs as surrogates for HCWs, as their hand flora may not reflect that on the hands of caregivers working in health-care settings. This argument is only valid for testing surgical scrubs, however, because protocols for evaluating hygienic handwash or rub preparations include experimental hand contamination. Besides, the antimicrobial spectrum of a product should be known from the results of preceding in vitro tests.

10.3 The need for better methods

Further studies will be needed to identify necessary amendments to the existing test methods and to evaluate amended protocols, to devise standardized protocols for obtaining more realistic views of microbial colonization, and to better estimate the risk of pathogen transfer and cross-transmission.[72]

To summarize, the following amendments to traditional test methods are needed.

- The few existing protocols should be adapted so that they lead to comparable conclusions about the efficacy of hand hygiene products.
- Protocols should be updated so that they can be performed with economically justifiable expenditure.
- To be plausible, results of in vivo test models should show that they are realistic under practical conditions such as the duration of application, the choice of test organism, or the use of subjects.
- Requirements for efficacy should not be formulated with a view to the efficacy of products available on the market, but in consideration of objectively identified needs.
- In vivo studies in the laboratory on surgical hand preparation should be designed as clinical studies, i.e. to determine equivalence (non-inferiority) rather than comparative efficacy.
- Protocols for controlled field trials should help to ensure that hand hygiene products are evaluated under more plausible, if not more realistic, conditions.

In addition, tests on the antimicrobial efficacy of hand hygiene products should be conducted in parallel with studies on the impact (effectiveness) of their use on cross-transmission of infection or resistance. Indeed, there is no doubt that results from well-controlled clinical studies are urgently needed to generate epidemiological data on the benefits of various groups of hand hygiene products on reducing the spread of HCAI, i.e. a more direct proof of clinical effectiveness.

Table I.10.1

Basic experimental design of current methods to test the efficacy of hand hygiene and surgical hand preparation formulations

Method	Test organism(s)	Basic procedure
EN 1499 (hygienic handwash)	*E. coli* (K12)	Hands washed with a soft soap, dried, immersed in broth culture for 5 seconds, excess fluid drained off, and air-dried for 3 minutes. Bacteria recovered for the initial values by kneading the fingertips of each hand separately for 60 seconds in 10 ml of broth without neutralizers. Hands removed from the broth and treated with the product following the manufacturer's instructions (but for no longer than 1 minute) or the reference solution (a 20% solution of soft soap). Recovery of bacteria for final values (see EN 1500).
EN 1500 (hygienic handrub)	*E. coli* (K12)	Basic procedure for hand contamination and initial recovery of test bacteria same as in EN 1499. Hands rubbed for 30 seconds with 3 ml of isopropanol 60% v/v; same operation repeated with a total application time not exceeding 60 seconds. The fingertips of both hands rinsed in water for 5 seconds and excess water drained off. Fingertips of each hand kneaded separately in 10 ml of broth with added neutralizers. These broths are used to obtain the final (post-treatment) values. Log10 dilutions of recovery medium containing neutralizer are prepared and plated out. Within 3 hours, the same subjects tested with the reference formulation or the test product. Colony counts obtained and log reductions calculated.
ASTM E-1174 (efficacy of HCW or consumer handwash formulation)	*S. marcescens* and *E. coli*	To test the efficacy of handwash or handrub agents on the reduction of transient microbial flora. Before baseline bacterial sampling and prior to each wash with the test material, 5 ml of a suspension of test organism are applied to and rubbed over hands. Test material put onto hands and spread over hands and lower third of forearms with lathering. Hands and forearms rinsed with water. Elutions are performed after required number of washes using 75 ml of eluent for each hand in glove. The eluates are tested for viable bacteria.
ASTM E-1838 (fingerpad method for viruses)	Adenovirus, rotavirus, rhinovirus and hepatitis A virus	10 µl of the test virus suspension in soil load placed at the centre of each thumb- and fingerpad, the inoculum dried and exposed for 10–30 seconds to 1 ml of test formulation or control. The fingerpads then eluted and eluates assayed for viable virus. Controls included to assess input titre, loss on drying of inoculum, and mechanical removal of virus. The method applicable to testing both handwash and handrub agents.
ASTM E-2276 (fingerpad method for bacteria)	*E. coli*, *S. marcescens*, *S. aureus*, and *S. epidermidis*	Similar to ASTM E-1838.
ASTM E-2613 (fingerpad method for fungi)	*Candida albicans* and *Aspergillus niger*	Similar to ASTM E-1838.
ASTM E-2011 (whole hand method for viruses)	Rotavirus and rhinovirus	This method is designed to confirm the findings of the fingerpad method (E-1838), if necessary. Both hands are contaminated with the test virus, and test formulation is used to wash or rub on them. The entire surface of both hands eluted and the eluates assayed for infectious virus.
EN 12791 (surgical hand preparation)	Resident skin flora (no artificial contamination)	Same as for EN 1500 with the following exceptions: no artificial contamination; reference hand antisepsis 3-minute rub with n-propanol 60% v/v; longest allowed treatment with product 5 minutes; 1 week between tests with reference and product. Test for persistence (3 hours) with split hands model is optional (product shall be significantly superior to reference).
ASTM E-1115 (test method for evaluation of surgical handscrub formulations)	Resident skin flora (no artificial contamination)	The method is designed to assess immediate or persistent activity against the resident flora. Subjects perform simulated surgical scrub and hands sampled by kneading them in loose-fitting gloves with an eluent. The eluates are assayed for viable bacteria.

11.

Review of preparations used for hand hygiene

11.1 Water

The purpose of routine handwashing in patient care is to remove dirt and organic material as well as microbial contamination acquired by contact with patients or the environment.

While water is often called a "universal solvent", it cannot directly remove hydrophobic substances such as fats and oils often present on soiled hands. Proper handwashing therefore requires the use of soaps or detergents to dissolve fatty materials and facilitate their subsequent flushing with water. To ensure proper hand hygiene, soap or detergent must be rubbed on all surfaces of both hands followed by thorough rinsing and drying. Thus, water alone is not suitable for cleaning soiled hands; soap or detergent must be applied as well as water.

11.1.1 Association of water contamination with infections

Tap water may contain a variety of microorganisms including human pathogens. Tables I.11.1 and I.11.2 list known or suspected waterborne pathogens, together with their health significance, stability in water, and relative infectivity.[228]

11.1.2 Microbially-contaminated tap water in health-care institutions

Tap water in health-care institutions can be a source of nosocomial infections. A Medline search from 1966 to 2001 found 43 such outbreaks, of which 69% (29) could be linked by epidemiological and molecular evidence to biofilms (a community of microorganisms growing as a slimy layer on surfaces immersed in a liquid) in water storage tanks, tap water, and water from showers.[229-232] Pathogens identified in waterborne nosocomial infections include: *Legionella* spp., *P. aeruginosa*,[233,234] *Stenotrophomonas maltophilia*,[235] *Mycobacterium avium*,[236] *M. fortuitum*,[237] *M. chelonae*,[238] *Fusarium* spp.,[239] and *A. fumigatus*.[240] Even if hand hygiene practices are in place, a plausible route for transmitting these organisms from water to patient could be through HCWs' hands if contaminated water is used to wash them. WHO has developed a reference document on *Legionella* spp. and the prevention of legionellosis which provides a comprehensive overview of the sources, ecology, and laboratory detection of this microorganism.[241] It should be noted, however, that *Legionella* spp. are transmitted primarily through inhalation of aerosolized or aspirated water.

A Norwegian study to determine the occurrence, distribution, and significance of mould species in drinking-water found 94 mould species belonging to 30 genera, including *Penicillium*, *Trichoderma,* and *Aspergillus* spp. Of these, *Penicillium* spp. were abundantly distributed and appeared to survive water treatment. Although heating of water reduced the levels of fungal contamination, *A. ustus* appeared to be somewhat resistant to such treatment. Potentially pathogenic species of fungi in tap water may be particularly important in settings where immunocompromised patients are housed.[242]

11.1.3 Tap water quality

Tap water, in addition to being a possible source of microbial contamination, may include substances that may interfere with the microbicidal activities of antiseptics and disinfectants. Examples of common water contaminants and their effects are summarized in Table I.11.1.

The physical, chemical and microbiological characteristics of water to be used for handwashing in health-care institutions must meet local regulations.[228] The institution is responsible for the quality of water once it enters the building. WHO has developed guidelines for essential environmental health standards in health care for developing countries.[243] In Europe, the quality of drinkable water in public buildings is regulated by the European Council's Directive "Water for Human Consumption" (Regulation 1882/2003/EC)[244] (Table I.11.3). In France, national guidelines for health-care settings have recently proposed microbiological standards for water quality (Table I.11.4).

If an institution's water is suspected of being contaminated, it can be made microbiologically safer by filtration and/or disinfection.[228] Disinfectants include chlorine, monochloramine, chlorine dioxide, ozone, and ultraviolet irradiation.[228] Chlorine, in gas or liquid form, remains the most common chemical used for this purpose, but is prone to generating potentially toxic by-products in the treated water. Ozone has high installation costs; monochloramine, while being slower than chlorine in its microbicidal action, does leave a disinfectant residual and is also less likely to generate harmful by-products.

The first step of conventional water treatment is the removal of as much of the organic matter and particulates as possible through coagulation, sedimentation, and filtration. Water is then disinfected before entering the distribution system. It is highly desirable to maintain a disinfectant residual in the treated water while it is in transit, in order to limit the growth of microorganisms in the distribution system and to inactivate any pathogens that may enter the distribution system through cross-connections, leakage, seepage or backflow. However, conventional levels of disinfectant residuals may be ineffective against massive contamination influx.[245]

Ultraviolet radiation is a potential alternative to chemical disinfection of small water systems, as long as such water is free of suspended matter, turbidity, and colour. The main disadvantage is that ultraviolet treatment does not leave a disinfectant residual.[246]

In Japan, the regulation on water supply mandates the use of sterile water instead of tap water for preoperative scrubbing of hands. However, a Japanese study showed that bacterial counts on hands were essentially the same, irrespective of the type of water used, and emphasized the importance of maintaining a free chlorine residual of >0.1 ppm in tap water.[247]

In many developing countries, tap water may be unfit for drinking. While drinkable water may also be ideal for handwashing, available evidence does not support the need for potable water for washing hands. In a resource-limited area of rural Bangladesh,[248] education and promotion of handwashing with plain soap and available water significantly reduced the spread of diarrhoeal diseases across all age groups.[248] A similar study in Pakistan corroborated these findings.[249]

Nevertheless, if the water is considered potentially unsafe for handwashing, the use of antibacterial soap alone may not be adequate. Washed hands may require further decontamination with antiseptic handrubs, especially in areas with high-risk populations,[250] while steps are initiated to improve water quality through better treatment and disinfection.

Health-care institutions in many parts of the developing world may not have piped-in tap water, or it may be available only intermittently. An intermittent water supply system often has higher levels of microbial contamination because of the seepage of contamination occurring while the pipes are supplied with treated water. On-site storage of sufficient water is often the only option in sites without a reliable supply. However, such water is known to be prone to microbial contamination unless stored and used properly and may require point-of-use treatment and/or on-site disinfection.[251]

Containers for on-site storage of water should be emptied and cleaned[252] as frequently as possible and, when possible, inverted to dry. Putting hands and contaminated objects into stored water should be avoided at all times. Storage containers should ideally be narrow-necked to facilitate proper coverage, with a conveniently located tap/faucet for ease of water collection.

CDC has developed guidelines for safe water systems and hand hygiene in health care in developing countries,[253] which were field-tested in Kenya and have been adapted to other countries in Africa and in Asia.[254] According to the recommendations included in this document, drinkable water should be used for handwashing.

11.1.4 Water temperature

Apart from the issue of skin tolerance and level of comfort, water temperature does not appear to be a critical factor for microbial removal from hands being washed. In contrast, in a study comparing water temperatures of 4 °C, 20 °C and 40 °C, warmer temperatures have been shown to be very significantly associated with skin irritation.[255] The use of very hot water for handwashing should therefore be avoided as it increases the likelihood of skin damage.

11.1.5 Hand drying

Because wet hands can more readily acquire and spread microorganisms, the proper drying of hands is an integral part of routine handwashing. Careful hand drying is a critical factor determining the level of bacterial transfer associated with touch-contact after hand cleansing. Care must also be taken to avoid recontamination of washed and dried hands.[75] Recognition of this fact could significantly improve hand hygiene practices in clinical and public health sectors.[75]

Paper towels, cloth towels, and warm air dryers are commonly used to dry washed hands. One study compared four methods of hand drying: cloth towels from a roller; paper towels left on a sink; warm air dryer; and letting hands dry by evaporation;[256] no significant difference in the efficacy of the methods was reported. Reusing or sharing towels should be avoided because of the risk of cross-infection.[257] In a comparison of methods to test the efficiency of hand drying for the removal of bacteria from washed hands, warm air drying performed worse than drying with paper towels.[258] This is in contrast to another study, which found warm air dryers to be the most efficient when compared with paper and cloth towels.[257] However, air dryers may be less practical because of the longer time needed to achieve dry hands,[258] with a possible negative impact on hand hygiene compliance. Furthermore, one study suggested that some air driers may lead to the aerosolization of waterborne pathogens.[259] Further studies are needed to issue recommendations on this aspect. Ideally, hands should be dried using either individual paper towels or hand driers which can dry hands effectively and as quickly as it can be done with paper towels, and have been proven not to be associated with the aerosolization of pathogens.

When clean or disposable towels are used, it is important to pat the skin rather than rub it, to avoid cracking. Skin excoriation may lead to bacteria colonizing the skin and possible spread of bloodborne viruses as well as other microorganisms.[79] Sore hands may also lead to decreased compliance with hand hygiene practices (see also Part I, Section 15).

11.2 Plain (non-antimicrobial) soap

Soaps are detergent-based products that contain esterified fatty acids and sodium or potassium hydroxide. They are available in various forms including bar soap, tissue, leaf, and liquid preparations. Their cleansing activity can be attributed to their detergent properties which result in the removal of lipid and adhering dirt, soil, and various organic substances from the hands. Plain soaps have minimal, if any, antimicrobial activity, though handwashing with plain soap can remove loosely adherent transient flora. For example, handwashing with plain soap and water for 15 seconds reduces bacterial counts on the skin by 0.6–1.1 $\log_{10}$, whereas washing for 30 seconds reduces counts by 1.8–2.8 $\log_{10}$.[48] In several studies, however, handwashing with plain soap failed to remove pathogens from the hands of HCWs.[88,110,260] Handwashing with plain soap can result in a paradoxical increase in bacterial counts on the skin.[220,261-263] Because soaps may be associated with considerable skin irritation and dryness,[220,262,264] adding humectants to soap preparations may reduce their propensity to cause irritation. Occasionally, plain soaps have become contaminated, which may lead to the colonization of HCWs hands with Gram-negative bacilli.[160] Nevertheless, there is some evidence that the actual hazard of transmitting microorganisms through handwashing with previously used soap bars is negligible.[265,266]

11.3 Alcohols

Most alcohol-based hand antiseptics contain either ethanol, isopropanol or n-propanol, or a combination of two of these products. Concentrations are given as either percentage of volume (= ml/100 ml, abbreviated % v/v), percentage of weight (= g/100 g, abbreviated % m/m), or percentage of weight/volume (= g/100 ml, abbreviated % m/v). Studies of alcohols have evaluated either individual alcohols in varying concentrations (most studies), combinations of two alcohols, or alcohol solutions containing small amounts of hexachlorophene, quaternary ammonium compounds (QAC), povidone-iodine, triclosan or CHG.[137,221,267-286]

The antimicrobial activity of alcohols results from their ability to denature proteins.[287] Alcohol solutions containing 60–80% alcohol are most effective, with higher concentrations being less potent.[288,289] This paradox results from the fact that proteins are not denatured easily in the absence of water.[287] The alcohol content of solutions may be expressed as a percentage by weight (m/m), which is not affected by temperature or other variables, or as a percentage by volume (v/v), which may be affected by temperature, specific gravity and reaction concentration.[290] For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15 °C, or 80.5% if prepared at 25 °C.[290] Alcohol concentrations in antiseptic handrubs are often expressed as a percentage by volume.[198]

Alcohols have excellent in vitro germicidal activity against Gram-positive and Gram-negative vegetative bacteria (including multidrug-resistant pathogens such as MRSA and VRE), *M. tuberculosis*, and a variety of fungi.[287-289,291-296] However, they have virtually no activity against bacterial spores or protozoan oocysts, and very poor activity against some non-enveloped (non-lipophilic) viruses. In tropical settings, the lack of activity against parasites is a matter of concern about the opportunity to promote the extensive use of alcohol-based handrubs, instead of handwashing, which may at least guarantee a mechanical removal effect.

Some enveloped (lipophilic) viruses such as herpes simplex virus (HSV), HIV, influenza virus, RSV, and vaccinia virus are susceptible to alcohols when tested in vitro (Table I.11.5).[297] Other enveloped viruses that are somewhat less susceptible, but are killed by 60–70% alcohol, include hepatitis B virus (HBV) and probably hepatitis C virus.[298] In a porcine tissue carrier model used to study antiseptic activity, 70% ethanol and 70% isopropanol were found to reduce titres of an enveloped bacteriophage more effectively than an antimicrobial soap containing 4% CHG.[192]

Numerous studies have documented the in vivo antimicrobial activity of alcohols. Early quantitative studies of the effects of antiseptic handrubs established that alcohols effectively reduce bacterial counts on hands.[63,288,292,299] Typically, log reductions of the release of test bacteria from artificially contaminated hands average 3.5 $\log_{10}$ after a 30-second application, and 4.0–5.0 $\log_{10}$ after a 1-minute application.[48] In 1994, the FDA TFM classified ethanol 60–95% as a generally safe and effective active agent for use in antiseptic hand hygiene or HCW handwash products.[198] Although the TFM considered that there were insufficient data to classify isopropanol 70–91.3% as effective, 60% isopropanol has subsequently been adopted in Europe as the reference standard against which alcohol-based handrub products are compared[201] (see Part I, Section 10.1.1). Although n-propanol is found in some hand sanitizers in Europe,[300] it is not included by the TFM in the list of approved active agents for hand antisepsis and surgical hand preparation in the USA.[58]

Alcohols are rapidly germicidal when applied to the skin, but have no appreciable persistent (residual) activity. However, regrowth of bacteria on the skin occurs slowly after use of alcohol-based hand antiseptics, presumably because of the sub-lethal effect alcohols have on some of the skin bacteria.[301,302] Addition of chlorhexidine, quaternary ammonium compounds, octenidine or triclosan to alcohol-based formulations can result in persistent activity.[48] A synergistic combination of a humectant (octoxyglycerine) and preservatives has resulted in prolonged activity against transient pathogens.[303] Nevertheless, a recent study on bacterial population kinetics on gloved hands following treatment with alcohol-based handrubs with and without supplements (either CHG or mecetronium etilsulfate) concluded that the contribution of supplements to the delay of bacterial regrowth on gloved hands appeared minor.[227]

Alcohols, when used in concentrations present in alcohol-based handrubs, also have in vivo activity against a number of non-enveloped viruses (Table I.11.5). For example, in vivo studies using a fingerpad model have demonstrated that 70% isopropanol and 70% ethanol were more effective than medicated soap or non-medicated soap in reducing rotavirus titres on fingerpads.[257,304] A more recent study using the same test methods evaluated a commercially available product containing 60% ethanol, and found that the product reduced the infectivity titres of three non-enveloped viruses (rotavirus, adenovirus, and rhinovirus) by 3 to 4 logs.[305] Other non-enveloped viruses such as hepatitis A and enteroviruses (e.g. poliovirus) may require 70–80% alcohol to be reliably inactivated.[306,307] It is worth noting that both 70% ethanol and a 62% ethanol foam product with humectants reduced hepatitis A virus titres on whole hands or fingertips to a greater degree than non-medicated soap, and both reduced viral counts on hands to about the same extent as antimicrobial soap containing 4% CHG.[308] The same study found that both 70% ethanol and the 62% ethanol foam product demonstrated greater virucidal activity against poliovirus than either non-antimicrobial soap or a 4% CHG-containing soap.[308] However, depending on the alcohol concentration, time, and viral variant, alcohol may not be effective against hepatitis A and other non-lipophilic viruses. Schurmann concluded that the inactivation of naked (non-enveloped) viruses is influenced by temperature, the ratio of disinfectant to virus volume, and protein load.[309] Various 70% alcohol solutions (ethanol, n-propanol, isopropanol) were tested against a surrogate of norovirus and ethanol with 30-second exposure demonstrated virucidal activity superior to the others.[310] In a recent experimental study, ethyl alcohol-based products showed significant reductions of the tested surrogate for a non-enveloped human virus; however, activity was not superior to non-antimicrobial or tap/faucet water controls[311]. In general, ethanol has greater activity against viruses than isopropanol[70]. Further *in vitro* and *in vivo* studies of both alcohol-based formulations and antimicrobial soaps are warranted to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings.

Alcohols are not good cleansing agents and their use is not recommended when hands are dirty or visibly contaminated with proteinaceous materials. When relatively small amounts of proteinaceous material (e.g. blood) are present, however, ethanol and isopropanol may reduce viable bacterial counts on hands,[312] but do not obviate the need for handwashing with water and soap whenever such contamination occurs.[179] A few studies have examined the ability of alcohols to prevent the transfer of health care-associated pathogens by using experimental models of pathogen transmission.[74,88,169] Ehrenkranz and colleagues[88] found that Gram-negative bacilli were transferred from a colonized patient's skin to a piece of catheter material via the hands of nurses in only 17% of experiments following antiseptic handrub with an alcohol-based hand rinse. In contrast, transfer of the organisms occurred in 92% of experiments following handwashing with plain soap and water. This experimental model suggests that when HCWs hands are heavily contaminated, alcohol-based handrubbing can prevent pathogen transmission more effectively than handwashing with plain soap and water.

Table I.11.6 summarizes a number of studies that have compared alcohol-based products with plain or antimicrobial soaps to determine which was more effective for standard handwashing or hand antisepsis by HCWs (for details see Part I, Section 11.13).[88,125,137,221,223,273-279,286,313-321]

The efficacy of alcohol-based hand hygiene products is affected by a number of factors including the type of alcohol used, concentration of alcohol, contact time, volume of alcohol used, and whether the hands are wet when the alcohol is applied. Small volumes (0.2–0.5 ml) of alcohol applied to the hands are no more effective than washing hands with plain soap and water.[74,169] Larson and colleagues[151] documented that 1 ml of alcohol was significantly less effective than 3 ml. The ideal volume of product to apply to the hands is not known and may vary for different formulations. In general, however, if hands feel dry after being rubbed together for less than 10–15 seconds, it is likely that an insufficient volume of product was applied. Alcohol-impregnated towelettes contain only a small amount of alcohol and are not much more effective than washing with soap and water.[74,322,323]

Alcohol-based handrubs intended for use in hospitals are available as solutions (with low viscosity), gels, and foams. Few data are available regarding the relative efficacy of various formulations. One small field trial found that an ethanol gel was somewhat less effective than a comparable ethanol solution at reducing bacterial counts on the hands of HCWs.[324] Recent studies found similar results demonstrating that solutions reduced bacterial counts on the hands to a significantly greater extent than the tested gels.[203,325] Most gels showed results closer to a 1-minute simple handwash than to a 1-minute reference antisepsis.[296] New generations of gel formulations with higher antibacterial efficacy than previous products have since been proposed.[70] Further studies are warranted to determine the relative efficacy of alcohol-based solutions and gels in reducing transmission of health care-associated pathogens. Furthermore, it is worth considering that compliance is probably of higher importance, thus if a gel with lower in vitro activity is more frequently used, the overall outcome is still expected to be better.

Frequent use of alcohol-based formulations for hand antsepsis tends to cause drying of the skin unless humectants or other skin conditioning agents are added to the formulations. For example, the drying effect of alcohol can be reduced or eliminated by adding 1–3% glycerol or other skin conditioning agents.[219,221,267,268,273,301,313,326,327]

Moreover, in prospective trials, alcohol-based solutions or gels containing humectants caused significantly less skin irritation and dryness than the soaps or antimicrobial detergents tested.[262,264,328,329] These studies, which were conducted in clinical settings, used a variety of subjective and objective methods for assessing skin irritation and dryness. Further studies of this type are warranted to establish if products with different formulations yield similar results.

Even well-tolerated alcohol-based handrubs containing humectants may cause a transient stinging sensation at the site of any broken skin (cuts, abrasions). Alcohol-based handrub preparations with strong fragrances may be poorly tolerated by a few HCWs with respiratory allergies. Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol, or to various additives present in some alcohol-based handrubs, occurs rarely (see also Part I, Section 14).[330-332]

A systematic review of publications between 1992 and 2002 on the effectiveness of alcohol-based solutions for hand hygiene showed that alcohol-based handrubs remove organisms more effectively, require less time, and irritate skin less often than handwashing with soap or other antiseptic agents and water.[333] The availability of bedside alcohol-based solutions increased compliance with hand hygiene among HCWs.[60,333-335] Regarding surgical hand preparation, an alcohol-based waterless surgical scrub was shown to have the same efficacy and demonstrated greater acceptability and fewest adverse effects on skin compared with an alcohol-based water-aided solution and a brush-based iodine solution.[336]

Alcohols are flammable, and HCWs handling alcohol-based preparations should respect safety standards (see Part I, Section 23.6). Because alcohols are volatile, containers should be designed so that evaporation is minimized and initial concentration is preserved. Contamination of alcohol-based solutions has seldom been reported. One report documented a pseudo-epidemic of infections resulting from contamination of ethyl alcohol by *Bacillus cereus* spores[337] and in-use contamination by *Bacillus* spp. has been reported.[338]

11.4 Chlorhexidine

CHG, a cationic bisbiguanide, was developed in the United Kingdom in the early 1950s and introduced into the USA in the 1970s.[204,339] Chlorhexidine base is barely soluble in water, but the digluconate form is water-soluble. The antimicrobial activity of chlorhexidine appears to be attributable to the attachment to, and subsequent disruption of cytoplasmic membranes, resulting in precipitation of cellular contents.[48,204] Chlorhexidine's immediate antimicrobial activity is slower than that of alcohols. It has good activity against Gram-positive bacteria, somewhat less activity against Gram-negative bacteria and fungi, and minimal activity against mycobacteria.[48,204,339] Chlorhexidine is not sporicidal.[48,339]. It has in vitro activity against enveloped viruses such as herpes simplex virus, HIV, cytomegalovirus, influenza, and RSV, but significantly less activity against non-enveloped viruses such as rotavirus, adenovirus, and enteroviruses.[297,340,341] The antimicrobial activity of chlorhexidine is not seriously affected by the presence of organic material, including blood. Because chlorhexidine is a cationic molecule, its activity can be reduced by natural soaps, various inorganic anions, non-ionic surfactants, and hand creams containing anionic emulsifying agents.[204,339,342] CHGhas been incorporated into a number of hand hygiene preparations. Aqueous or detergent formulations containing 0.5%, 0.75% , or 1% chlorhexidine are more effective than plain soap, but are less effective than antiseptic detergent preparations containing 4%CHG.[301,343] Preparations with 2% CHGare slightly less effective than those containing 4% chlorhexidine.[344] A scrub agent based on CHG(4%) was shown to be significantly more effective to reduce bacterial count than a povidone iodine (7.5%) scrub agent.[247]

Chlorhexidine has significant residual activity.[273,281-283,285,301,315,343] Addition of low concentrations (0.5–1%) of chlorhexidine to alcohol-based preparations results in significantly greater residual activity than alcohol alone.[283,301] When used as recommended, chlorhexidine has a good safety record.[339] Little, if any, absorption of the compound occurs through the skin. Care must be taken to avoid contact with the eyes when using preparations with 1% chlorhexidine or greater as the agent can cause conjunctivitis or serious corneal damage. Ototoxicity precludes its use in surgery involving the inner or middle ear. Direct contact with brain tissue and the meninges should be avoided. The frequency of skin irritation is concentration-dependent, with products containing 4% most likely to cause dermatitis when used frequently for antiseptic handwashing.[345] True allergic reactions to CHGare very uncommon (see also Part I, Section 14).[285,339] Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of chlorhexidine.[346-349] Resistance to chlorhexidine has also been reported.[350]

11.5 Chloroxylenol

Chloroxylenol, also known as para-chloro-meta-xylenol (PCMX), is a halogen-substituted phenolic compound that has been used widely as a preservative in cosmetics and other products and as an active agent in antimicrobial soaps. It was developed in Europe in the late 1920s and has been used in the USA since the 1950s.[351]

The antimicrobial activity of chloroxylenol is apparently attributable to the inactivation of bacterial enzymes and alteration of cell walls.[48] It has good in vitro activity against Gram-positive organisms and fair activity against Gram-negative bacteria, mycobacteria and some viruses.[48,351,352] Chloroxylenol is less active against *P. aeruginosa*, but the addition of ethylene-diaminetetraacetic acid (EDTA) increases its activity against *Pseudomonas* spp. and other pathogens.

Relatively few articles dealing with the efficacy of chloroxylenol-containing preparations intended for use by HCWs have been published in the last 25 years, and the results of studies have sometimes been contradictory. For example, in experiments where antiseptics were applied to abdominal skin, Davies and colleagues found that chloroxylenol had the weakest immediate and residual activity of any of the agents studied.[353]. When 30-second handwashes were performed, however, using 0.6% chloroxylenol, 2% CHG or 0.3% triclosan, the immediate effect of chloroxylenol was similar to that of the other agents. When used 18 times/day for five days, chloroxylenol had less cumulative activity than didCHG.[354] When chloroxylenol was used as a surgical scrub, Soulsby and colleagues[355] reported that 3% chloroxylenol had immediate and residual activity comparable to 4%CHG, while two other studies found that the immediate and residual activity of chloroxylenol was inferior to both CHG and povidone-iodine.[344,356] The disparity between published studies may result in part from the various concentrations of chloroxylenol included in the preparations evaluated and to other aspects of the formulations tested, including the presence or absence of EDTA.[351,352] Larson concluded that chloroxylenol is not as rapidly active as CHG or iodophors, and that its residual activity is less pronounced than that observed withCHG.[351,352] In 1994, the FDA TFM tentatively classified chloroxylenol as a Category IIISE active agent (insufficient data to classify as safe and effective).[198] Further evaluation of this agent by the FDA is ongoing.

The antimicrobial activity of chloroxylenol is minimally affected by the presence of organic matter, but is neutralized by non-ionic surfactants. Chloroxylenol is absorbed through the skin.[351,352] Chloroxylenol is generally well tolerated; some cases of allergic reactions have been reported,[357] but they are relatively uncommon.

Chloroxylenol is available in concentrations ranging from 0.3% to 3.75%. In-use contamination of a chloroxylenol-containing preparation has been reported.[358]

11.6 Hexachlorophene

Hexachlorophene is a bisphenol composed of two phenolic groups and three chlorine moieties. In the 1950s and early 1960s, emulsions containing 3% hexachlorophene were widely used for hygienic handwashing as surgical scrubs and for routine bathing of infants in hospital nurseries. The antimicrobial activity of hexachlorophene is related to its ability to inactivate essential enzyme systems in microorganisms. Hexachlorophene is bacteriostatic, with good activity against *S. aureus* and relatively weak activity against Gram-negative bacteria, fungi, and mycobacteria.[352]

Studies of hexachlorophene as a hygienic handwash or surgical scrub demonstrated only modest efficacy after a single handwash.[125,313,359] Hexachlorophene has residual activity for several hours after use and gradually reduces bacterial counts on hands after multiple uses (cumulative effect).[48,268,359,360] In fact, with repeated use of 3% hexachlorophene preparations, the drug is absorbed through the skin. Infants bathed with hexachlorophene and caregivers regularly using a 3% hexachlorophene preparation for handwashing have blood levels of 0.1–0.6 parts per million (ppm) hexachlorophene.[361] In the early 1970s, infants bathed with hexachlorophene sometimes developed neurotoxicity (vacuolar degeneration).[362] As a result, in 1972, the FDA warned that hexachlorophene should no longer be used routinely for bathing infants. After routine use of hexachlorophene for bathing infants in nurseries was discontinued, a number of investigators noted that the incidence of *S. aureus* infections associated with health care in hospital nurseries increased substantially.[363,364] In several instances, the frequency of infections decreased when hexachlorophene bathing of infants was reinstituted. However, current guidelines recommend against routine bathing of neonates with hexachlorophene because of its potential neurotoxic effects.[365] The agent is classified by the FDA TFM as not generally recognized as safe and effective for use as an antiseptic handwash.[198] Hexachlorophene should not be used to bathe patients with burns or extensive areas of abnormal, sensitive skin. Soaps containing 3% hexachlorophene are available by prescription only.[352] Due to its high rate of dermal absorption and subsequent toxic effects,[70,366] hexachlorophene-containing products should be avoided and hexachlorophene has been banned worldwide.

11.7 Iodine and iodophors

Iodine has been recognized as an effective antiseptic since the 1800s, though iodophors have largely replaced iodine as the active ingredient in antiseptics because iodine often causes irritation and discolouring of skin.

Iodine molecules rapidly penetrate the cell wall of microorganisms and inactivate cells by forming complexes with amino acids and unsaturated fatty acids, resulting in impaired protein synthesis and alteration of cell membranes.[367] Iodophors are composed of elemental iodine, iodide or triiodide, and a polymer carrier (complexing agent) of high molecular weight. The amount of molecular iodine present (so-called "free" iodine) determines the level of antimicrobial activity of iodophors. "Available" iodine refers to the total amount of iodine that can be titrated with sodium thiosulfate.[368] Typical 10% povidone-iodine formulations contain 1% available iodine and yield free iodine concentrations of 1 ppm.[368] Combining iodine with various polymers increases the solubility of iodine, promotes sustained-release of iodine, and reduces skin irritation. The most common polymers incorporated into iodophors are polyvinyl pyrrolidone (povidone) and ethoxylated nonionic detergents (poloxamers).[367,368] The antimicrobial activity of iodophors can also be affected by pH, temperature, exposure time, concentration of total available iodine, and the amount and type of organic and inorganic compounds present (e.g. alcohols and detergents).

Iodine and iodophors have bactericidal activity against Gram-positive, Gram-negative and some spore-forming bacteria (clostridia, *Bacillus* spp.) and are active against mycobacteria, viruses, and fungi.[204,367,369-372] However, in concentrations used in antiseptics, iodophors are not usually sporicidal.[373] In vivo studies have demonstrated that iodophors reduce the number of viable organisms that may be recovered from HCWs' hands.[280,314,317,320,374] Povidone-iodine 5–10% has been tentatively classified by the FDA TFM as a safe and effective (Category I) active agent for use as an antiseptic handwash and HCW handwash.[198] The extent to which iodophors exhibit persistent antimicrobial activity once they have been washed off the skin is a matter of some controversy. In a study by Paulson,[344] persistent activity was noted for six hours, but several other studies demonstrated persistent activity for 30–60 minutes after washing hands with an iodophor.[137,284,375] In studies where bacterial counts were obtained after individuals wore gloves for 1–4 hours after washing, however, iodophors demonstrated poor persistent activity.[48,271,282,360,376-381] The in vivo antimicrobial activity of iodophors is significantly reduced in the presence of organic substances such as blood or sputum.[204] Povidone iodine has been found to be less effective than alcohol 60% (v/v) and hydrogen peroxide 3% and 5% on *S. epidermidis* biofilms.[382]

Most iodophor preparations used for hand hygiene contain 7.5–10% povidone-iodine. Formulations with lower concentrations also have good antimicrobial activity, because dilution tends to increase free iodine concentrations.[383] As the amount of free iodine increases, however, the degree of skin irritation also may increase.[383] Iodophors cause less skin irritation and fewer allergic reactions than iodine, but more irritant contact dermatitis than other antiseptics commonly used for hand hygiene.[220] Occasionally, iodophor antiseptics have become contaminated with Gram-negative bacilli as a result of poor manufacturing processes and have caused outbreaks or pseudo-outbreaks of infection.[368,384] An outbreak of *P. cepacia* pseudobacteremia involving 52 patients in four hospitals in New York over six months was attributed to the contamination of a 10% povidone-iodine solution used as an antiseptic and disinfectant solution.[384]

11.8 Quaternary ammonium compounds

Quaternary ammonium compounds (QACs) are composed of a nitrogen atom linked directly to four alkyl groups, which may vary considerably in their structure and complexity.[385] Among this large group of compounds, alkyl benzalkonium chlorides are the most widely used as antiseptics. Other compounds that have been used as antiseptics include benzethonium chloride, cetrimide, and cetylpyridium chloride.[48] The antimicrobial activity of these compounds was first studied in the early 1900s, and a QAC for preoperative cleaning of surgeons' hands was used as early as 1935.[385] The antimicrobial activity of this group of compounds appears to be attributable to adsorption to the cytoplasmic membrane, with subsequent leakage of low molecular weight cytoplasmic constituents.[385]

QACs are primarily bacteriostatic and fungistatic, although they are microbicidal against some organisms at high concentrations.[48] They are more active against Gram-positive bacteria than against Gram-negative bacilli. QACs have relatively weak activity against mycobacteria and fungi and have greater activity against lipophilic viruses (Table I.11.7). Their antimicrobial activity is adversely affected by the presence of organic material, and they are not compatible with anionic detergents.[48,385]

A QAC is present as a supplement in some commercially available alcohol-based handrubs. A study on the population kinetics of skin flora on gloved hands indicated that the effect of an alcohol-based handrub containing mecetronium etilsulfate (isopropanol 45% wt/wt plus n-propanol 30% wt/wt plus mecetronium etilsulfate 0.2% wt/wt) was not significantly different from n-propanol 60% v/v.[227]

Depending on the QAC type and formulation, the antimicrobial efficacy can be severely affected in the presence of hard water (if it is a diluted product) and fatty materials. Later generations of QACs, e.g. didecyldimethyl ammonium chloride (DDAC), have stronger antimicrobial activity and good performance in the presence of hard water and organic soiling, but their activity has been studied on inanimate surfaces only.

In 1994, the FDA TFM tentatively classified benzalkonium chloride and benzethonium chloride as Category IIISE active agents (insufficient data to classify as safe and effective for use as an antiseptic handwash).[198] Further evaluation of these agents by the FDA is in progress.

In general, QACs are relatively well tolerated. Unfortunately, because of weak activity against Gram-negative bacteria, benzalkonium chloride is prone to contamination by these organisms and a number of outbreaks of infection or pseudo-infection have been traced to QACs contaminated with Gram-negative bacilli.[386-388] For this reason, these compounds have seldom been used for hand antisepsis during the last 15–20 years in the USA. More recently, newer hand hygiene products containing benzalkonium chloride or benzethonium chloride have been introduced for use by HCWs. A recent clinical study performed among surgical ICU HCWs found that cleaning hands with antimicrobial wipes containing a QAC was almost as effective as handwashing with plain soap and water, and that both were significantly less effective than decontaminating hands with an alcohol-based handrub.[389] One laboratory-based study reported that an alcohol-free handrub product containing a QAC was efficacious in reducing microbial counts on the hands of volunteers.[390] Further studies of such products are needed to determine if newer formulations are effective in health-care settings.

QACs have been used as antiseptics to reduce the bioburden on skin (e.g. for wound cleansing and on mucous membrane as mouthwashes for the control of dental plaque). They are also extensively used as disinfectants ("spray & wipe") for household, industrial, and health-care surfaces, as well as for food surface disinfection, as most formulations do not require to be rinsed off with water after application.[391] The presence of low-level residues may allow the selective development of bacterial strains with greater tolerance of QACs over time; intrinsic and acquired resistance mechanisms have been described.[392,393]

In general, QACs are relatively well tolerated and have low allergenic potential. In higher concentrations, though, they can cause severe irritation to skin and mucous membranes.

11.9 Triclosan

Triclosan (chemical name 2,4,4'–trichloro-2'-hydroxydiphenyl ether) is known commercially as Irgasan DP-300. It is a nonionic, colourless substance developed in the 1960s; it is poorly soluble in water, but dissolves well in alcohols. Concentrations ranging from 0.2% to 2% have antimicrobial activity. Triclosan has been incorporated in detergents (0.4% to 1%) and in alcohols (0.2% to 0.5%) used for hygienic and surgical hand antisepsis or preoperative skin disinfection; it is also used for antiseptic body baths to control MRSA. This agent is incorporated into some soaps (at a 1% w/v concentration) and a variety of other consumer products (deodorants, shampoos, lotions, etc.), as well as being integrated also into various dressings and bandages for release over time onto the skin.

Triclosan enters bacterial cells and affects the cytoplasmic membrane and synthesis of RNA, fatty acids, and proteins.[394] Recent studies suggest that this agent's antibacterial activity is attributable in large part to binding to the active site of enoyl-acyl carrier protein reductase.[395,396]

Triclosan has a fairly broad range of antimicrobial activity (Table I.11.7), but tends to be bacteriostatic.[48] Minimum inhibitory concentrations (MICs) range from 0.1 to 10 μg/ml, while minimum bactericidal concentrations are 25–500 μg/ml. Triclosan's activity against Gram-positive organisms (including MRSA) is greater than against Gram-negative bacilli, particularly *P. aeruginosa*.[48,394] The agent possesses reasonable activity against mycobacteria and *Candida* spp., but has little activity against filamentous fungi and most viruses of nosocomial significance. Triclosan (0.1%) reduces bacterial counts on hands by 2.8 $\log_{10}$ after a 1-minute hygienic handwash.[48] In a number of studies, log reductions achieved have been lower than with chlorhexidine, iodophors or alcohol-based products.[48,137,223,354,397]/ In 1994, the FDA TFM tentatively classified triclosan up to 1% as a Category IIISE active agent (insufficient data to classify as safe and effective for use as an antiseptic handwash).[198] Further evaluation of this agent by the FDA is under way. Similar to chlorhexidine, triclosan has persistent activity on the skin. Its activity in hand-care products is affected by pH, the presence of surfactants or humectants, and the ionic nature of the particular formulation.[48,394] Triclosan's activity is not substantially affected by organic matter, but may be inhibited by sequestration of the agent in micelle structures formed by surfactants present in some formulations. Most formulations containing less than 2% triclosan are well tolerated and seldom cause allergic reactions. A few reports suggest that providing HCWs with a triclosan-containing preparation for hand antisepsis has led to decreased infections caused by MRSA.[181,182] Triclosan's lack of potent activity against Gram-negative bacilli has resulted in occasional reports of contaminated triclosan.[398]

A recent study compared an antibacterial soap containing triclosan with a non-antibacterial soap and concluded that the former did not provide any additional benefit.[399] Concerns have been raised about the use of triclosan, because of the development of bacterial resistance to low concentrations of biocide and cross-resistance to some antibiotics. For example, *Mycobacterium smegmatis* mutations in inhA gene leading to triclosan resistance are known to carry resistance also to isoniazid.[400] Increased tolerance (i.e increased MICs) to triclosan due to mutations in efflux pumps has been reported in *E. coli* and *P. aerugninosa*.[401] Laboratory studies involving exposure of some microorganisms to subinhibitory concentrations of triclosan have resulted in increased triclosan MICs. However, the clinical relevance of increased triclosan MICs generated in the laboratory is unclear, since affected strains remain susceptible to in-use concentrations of triclosan.[401,402] Further research dealing with the relationship between triclosan use and antimicrobial resistance mechanisms is warranted, and surveillance for triclosan-resistant pathogens in clinical and environmental settings is needed.

11.10 Other agents

More than 100 years after Semmelweis demonstrated the impact of rinsing hands with a solution of chlorinated lime on maternal mortality related to puerperal fever, Lowbury and colleagues[403] studied the efficacy of rubbing hands for 30 seconds with an aqueous hypochlorite solution. They found that the solution was no more effective than rinsing with distilled water. Rotter[404] subsequently studied the regimen used by Semmelweis, which called for rubbing hands with a 4% hypochlorite solution[405] until the hands were slippery (approximately 5 minutes). He found that the regimen was 30 times more effective than a 1-minute rub using 60% isopropanol. However, because hypochlorite solutions tend to be very irritating to the skin when used repeatedly and have a strong odour, they are seldom used for hand hygiene today. A number of other agents are being evaluated by the FDA for use in antiseptics related to health care.[198] However, the efficacy of these agents has not been evaluated adequately for use in hand hygiene preparations intended for use by HCWs. Further evaluation of some of these agents may be warranted. Products that utilize different concentrations of traditional antiseptics (e.g. low concentrations of iodophor) or contain novel compounds with antiseptic properties are likely to be introduced for use by HCWs. For example, preliminary studies have demonstrated that adding silver-containing polymers to an ethanol carrier (Surfacine) results in a preparation that has persistent antimicrobial activity on animal and human skin.[406] A unique chlorhexidine-loaded, nanocapsule-based gel showed immediate bactericidal effect, comparable to isopropanolol 60% v/v against aerobic bacteria; surviving anaerobic bacteria were significantly lower compared with ethanol-based gel 62% v/v. Persistant bactericidal effect was observed throughout the 3-hour test period. The immediate and sustained antibacterial effect was explained by an efficient chlorhexidine carrier system which improved the drug targeting to bacteria.[407] The clinical significance of these findings deserves further research. New compounds with good in vitro activity must be tested in vivo to determine their abilities to reduce transient and resident skin flora on the hands of caregivers.

11.11 Activity of antiseptic agents against spore-forming bacteria

The increasing incidence of *C. difficile*-associated diarrhoea in health-care facilities in several countries, and the occurrence in the USA of human *Bacillus anthracis* infections related to contaminated items sent through the postal system, have raised concerns about the activity of antiseptic agents against spores. The increasing morbidity and mortality of *C. difficile*-associated disease in the USA, Canada, and some European countries since 2001 has been especially attributed to more frequent outbreaks and the emergence of a new, more virulent strain (ribotype 027).[408] Epidemic strains differ among countries: for instance, while in Canada and the Netherlands ribotype 027 is predominant, the United Kingdom detected three different strains (ribotype 001, 027 and 106) responsible for 70% of *C. difficile*-associated diarrhoea.[409-417]

Apart from iodophors, but at a concentration remarkably higher than the one used in antiseptics,[373] none of the agents (including alcohols, chlorhexidine, hexachlorophene, chloroxylenol, and triclosan) used in antiseptic handwash or antiseptic handrub preparations is reliably sporicidal against *Clostridium* spp. or *Bacillus* spp.[287,339,418,419] Mechanical friction while washing hands with soap and water may help physically remove spores from the surface of contaminated hands.[110,420,421] This effect is not enhanced when using medicated soap.[420] Contact precautions are highly recommended during *C. difficile*-associated outbreaks, in particular, glove use (as part of contact precautions) and handwashing with a non-antimicrobial or antimicrobial soap and water following glove removal after caring for patients with diarrhoea.[422,423] Alcohol-based handrubs can then be exceptionally used after handwashing in these instances, after making sure that hands are perfectly dry. Moreover, alcohol-based handrubs, now considered the gold standard to protect patients from the multitude of harmful resistant and non-resistant organisms transmitted by HCWs' hands, should be continued to be used in all other instances at the same facility. Discouraging their widespread use, just because of the response to diarrhoeal infections attributable to *C. difficile*, will only jeopardize overall patient safety in the long term.

The widespread use of alcohol-based handrubs was repeatedly given the major blame for the increase of *C. difficile*-associated disease rates because alcohol preserves spores and is used in the laboratory to select *C. difficile* spores from stools.[424,425] Although alcohol-based handrubs may not be effective against *C. difficile,* it has not been shown that they trigger the rise of *C. difficile*-associated disease.[426-429] *C. difficile*-associated disease rates began to rise in the USA long before the wide use of alcohol-based handrubs.[430,431] One outbreak with the epidemic strain REA-group B1 (≃ribotype 027) was successfully managed while introducing alcohol-based handrub for all patients other than those with *C. difficile*-associated disease.[427] Furthermore, abandoning alcohol-based handrub for patients other than those with *C. difficile*-associated disease would do more harm than good, considering the dramatic impact on overall infection rates observed through the recourse to handrubs at the point of care.[320]

A guide on how to deal with *C. difficile* outbreaks, including frequently asked questions on hand hygiene practices, is provided in Appendix 2.

A recent study demonstrated that washing hands with either non-antimicrobial soap or antimicrobial soap and water reduced the amount of *B. atrophaeus* (a surrogate for *B. anthracis*) on hands, whereas an alcohol-based handrub was not effective.[432] Accordingly, HCWs with suspected or documented exposure to *B. anthracis*-contaminated items should wash their hands with a non-antimicrobial or antimicrobial soap and water.

11.12 Reduced susceptibility of microorganisms to antiseptics

Reduced susceptibility of bacteria to antiseptic agents can be an intrinsic characteristic of a species, or can be an acquired trait.[433] A number of reports have described strains of bacteria that appear to have acquired reduced susceptibility to antiseptics such as chlorhexidine, QAC, or triclosan when defined by MICs established in vitro.[433-436] However, since "in-use" concentrations of antiseptics are often substantially higher than the MICs of strains with reduced antiseptic susceptibility, the clinical relevance of the in vitro findings may be inaccurate. For example, some strains of MRSA have chlorhexidine and QAC MICs that are several-fold higher than methicillin-susceptible strains, and some strains of *S. aureus* have elevated MICs to triclosan.[433,434,437] However, such strains were readily inhibited by in-use concentrations of these antiseptics.[433,434] Very high MICS for triclosan were reported by Sasatsu and colleagues,[438] and the description of a triclosan-resistant bacterial enzyme has raised the question of whether resistance may develop more readily to this agent than to other antiseptic agents.[396] Under laboratory conditions, bacteria with reduced susceptibility to triclosan carry cross-resistance to antibiotics.[439,440] Reduced triclosan susceptibility or resistance was detected in clinical isolates of methicillin-resistant *S. epidermidis* and in MRSA, respectively.[441,442] Of additional concern, exposing *Pseudomonas* strains containing the MexAB-OprM efflux system to triclosan may select for mutants that are resistant to multiple antibiotics, including fluoroquinolones.[436,439,440] Nevertheless, a recent study failed to demonstrate a statistically significant association between elevated triclosan MICs and reduced antibiotic susceptibility among staphylococci and several species of Gram-negative bacteria.[443] Clearly, further studies are necessary to determine if reduced susceptibility to antiseptic agents is of epidemiological importance, and whether or not resistance to antiseptics may influence the prevalence of antibiotic-resistant strains.[433] Periodic surveillance may be needed to ensure that this situation has not changed.[444]

11.13 Relative efficacy of plain soap, antiseptic soaps and detergents, and alcohols

Comparing the results of laboratory studies dealing with the in vivo efficacy of plain soap, antimicrobial soaps, and alcohol-based handrubs may be problematic for various reasons. First, different test methods produce different results,[445] especially if the bacteriostatic effect of a formulation is not (or not sufficiently) abolished – either by dilution or chemical neutralizers – prior to quantitative cultivation of post-treatment samples. This leads to results that might overstate the efficacy of the formulation,[446] Second, the antimicrobial efficacy of a hand antiseptic agent is significantly different among a given population of individuals.[315] Therefore, the average reductions of bacterial release by the same formulation will be different in different laboratories or in one laboratory with different test populations.[447] Inter-laboratory results will be comparable only if they are linked up with those of a reference procedure performed in parallel by the same individuals in a cross-over designed test and compared intra-individually. Summarizing the relative efficacy of agents in each study can provide a useful overview of the in vivo activity of various formulations (Tables I.11.6 and I.11.8). From there, it can be seen that antiseptic detergents are usually more efficacious than plain soap and that alcohol-based rubs are more efficacious than antiseptic detergents. A few studies show that chlorhexidine may be as effective as plain soap against MRSA, but not as effective as alcohol and povidone iodine.[448] Studies conducted in the community setting bring additional findings on the topic of the relative efficacy of different hand hygiene products. Some indicate that medicated and plain soaps are roughly equal in preventing the spread of childhood gastrointestinal and upper respiratory tract infections or impetigo[249,449,450] . This suggests that the health benefits from clean hands probably result from the simple removal of potential pathogens by handwashing rather than their in situ inactivation by medicated soaps. Other studies clearly demonstrated the effectiveness of alcohol-based handrubs used for hand hygiene in schools in reducing the incidence of gastrointestinal and/or respiratory diseases and absenteeism attributable to these causes.[451-454]

In most studies on hygienic hand antisepsis that included plain soap, alcohols were more effective than soap (Tables I.11.6 and I.11.8). In several trials comparing alcohol-based solutions with antimicrobial detergents, alcohol reduced bacterial counts on hands to a greater extent than washing hands with soaps or detergents containing hexachlorophene, povidone-iodine, CHG(CHG) or triclosan. In a cross-over study comparing plain soap with one containing 4% CHG, unexpectedly, the latter showed higher final CFU counts after use of CHG-soap compared with plain soap, but the comparative CFU log reduction was not provided to permit conclusions concerning relative efficacy.[455] In another clinical study in two neonatal intensive care units comparing an alcohol rub with 2% CHG-soap, no difference was found either in infection rates or in microbial counts from nurses' hands.[456] Of note, the ethanol concentration (61%) of the sanitizer was low and the chemicals to neutralize CHG washed from the hands into the sampling fluids might not have been appropriate. However, a randomized clinical trial comparing the efficacy of handrubbing versus conventional handwashing with antiseptic soap showed that the median percentage reduction in bacterial contamination was significantly higher with handrubbing than with hand antisepsis with 4% CHG-soap.[457] In another trial to compare the microbiological efficacy of handrubbing with an alcohol-based solution and handwashing with water and unmedicated soap in HCWs from different wards, with particular emphasis on transient flora, handrubbing was more efficacious than handwashing for the decontamination of HCWs' hands.[152] In studies dealing with antimicrobial-resistant organisms, alcohol-based products reduced the number of multidrug-resistant pathogens recovered from the hands of HCWs more effectively than handwashing with soap and water.[225,374,458] An observational study was conducted to assess the effect of an alcohol-based gel handrub on infection rates attributable to the three most common multidrug-resistant bacteria (*S. aureus, K. pneumoniae,* and *P. aeruginosa*) in Argentina.[459] Two periods were compared, 12 months before (handwashing with soap and water) and 12 months after starting alcohol gel use. The second period (alcohol gel use) showed a significant reduction in the overall incidence rates of *K. pneumoniae* with extended-spectrum beta-lactamase (ESBL) infections, in particular bacteraemias. Nevertheless, on the basis of this study, the authors could not conclude whether this was a result of alcohol gel itself or an increase in hand hygiene compliance.

The efficacy of alcohols for surgical hand antisepsis has been reviewed in numerous studies.[48,268,271,280-286,301,313,316,460-463] In many of these studies, bacterial counts on the hands were determined immediately after using the product and again 1–3 hours later. The delayed testing is performed to determine if regrowth of bacteria on the hands is inhibited during operative procedures; this has been shown to be questionable by in vivo experiments only if a suitable neutralizer is used to stop any prolonged activity in the sampling fluids and on the counting plates.[227] The relative efficacy of plain soap, antimicrobial soaps, and alcohol-based solutions to reduce the number of bacteria recovered from hands immediately after use of products for surgical hand preparation is shown in Table I.11.9. A comparison of five surgical hand antisepsis products – two alcohol-based handrubs and three handwashes (active ingredient triclosan, CHG or povidone-iodine) – by EN 12791, an in vivo laboratory test, showed that preparations containing povidone-iodine and triclosan failed the test, although all products passed the in vitro suspension test of prEN 12054. Better results were achieved with the alcohol-based handrubs.[464] Alcohol-based solutions were more effective than washing hands with plain soap in all studies, and reduced bacterial counts on hands to a greater extent than antimicrobial soaps or detergents in most experiments.[268,271,280-286,301,313,316,461-463] Table I.11.10 shows the log_{10} reductions in the release of resident skin flora from clean hands immediately and 3 hours after use of surgical handrub products. Alcohol-based preparations proved more efficacious than plain soap and water, and most formulations were superior to povidone-iodine- or CHG-containing detergents. Among the alcohols, a clear positive correlation with their concentration is noticeable and, when tested at the same concentration, the range of order in terms of efficacy is: ethanol is less efficacious than isopropanol, and the latter is less active than n-propanol.

Table I.11.1

Examples of common water contaminants and their effects

Contaminant	Examples	Concerns
Inorganic salts	• Hardness (dissolved compounds of calcium and magnesium) • Heavy metals (metallic elements with high atomic weights, e.g. iron, chromium, copper, and lead)	• Inhibit activities of cleaning and biocidal products; can also cause the build-up of scale over time or "spotting" on a surface • Can inhibit the activities of cleaners and biocidal products; cause damage to some surfaces (e.g. corrosion); in some cases, are toxic and bioaccumulative
Organic matter	• Trihalomethanes • Proteins, lipids, polysaccharides	• Toxic chlorine disinfection by-products • Can leave harmful residues, including protein toxins and endotoxins (lipopolysaccharide); can also reduce the effectiveness of biocides
Biocides	• Chlorine, bromine	• Can cause corrosion and rusting on surfaces (in particular, when carried in steam)
Microorganisms	• Pseudomonas, Salmonella, and oocysts of Cryptosporidium (see Table I.11.2)	• Biofilm formation and biofouling; deposition onto surfaces or products and cross-contamination
Dissolved gases	• CO_2, Cl_2 and O_2	• Can cause corrosion and rusting (in particular, when carried in steam); non-condensable gases, such as CO_2 and O_2, can inhibit the penetration of steam in sterilization processes

Source: reproduced with permission from McDonnell, 2007.[465]

Table I.11.2
Waterborne pathogens and their significance in water supplies

Pathogen	Health significance	Persistence in water supplies	Relative infectivity
Bacteria			
Campylobacter jejuni, C. coli	High	Moderate	Moderate
Pathogenic *Escherichia coli*	High	Moderate	Low
Enterohaemorrhagic *E. coli*	High	Moderate	High
Legionella spp.	High	Multiply	Moderate
Non-tuberculosis mycobacteria	Low	Multiply	Low
Pseudomonas aeruginosa	Moderate	May multiply	Low
Salmonella typhi	High	Moderate	Low
Other salmonellae	High	Short	Low
Shigella spp.	High	Short	Moderate
Vibrio cholerae	High	Short	Low
Burkholderia pseudomallei	Low	May multiply	Low
Yersinia enterocolitica	High	Long	Low
Viruses			
Adenoviruses	High	Long	High
Enteroviruses	High	Long	High
Hepatitis A	High	Long	High
Hepatitis E	High	Long	High
Noroviruses and sapoviruses	High	Long	High
Rotaviruses	High	Long	High
Protozoa			
Acanthamoeba spp.	High	Long	High
Cryptosporidium parvum	High	Long	High
Cyclospora cayetanensis	High	Long	High
Entamoeba histolytica	High	Moderate	High
Giardia lamblia	High	Moderate	High
Naegleria fowleri	High	May multiply	High
Toxoplasma gondii	High	Long	High
Helminths			
Dracunculus medinensis	High	Moderate	High
Schistosoma spp.	High	Short	High

Source: *WHO Guidelines for drinking-water quality, 2006.*[228]

Table I.11.3

Microbiological indicators for drinking-water quality according to 1882/2003/EC

Indicator	1882/2003/EC	Comment
Escherichia coli	0 CFU/100 ml 0 CFU/250 ml (for bottled water)	
Pseudomonas aeruginosa	0 CFU/250 ml	Specified only for bottled water
Enterococci	0 CFU/250 ml	
Total bacteria 22 °C 36/37 °C	 100 CFU/ml 20 CFU/ml	Specified only for bottled water

CFU: colony-forming unit

Table I.11.4

Microbiological indicators for water quality in health-care settings in France

Indicator	Level	Frequency
Aerobic flora at 22 °C and 36 °C	No variation above a 10-fold compared to the usual value at the entry point	1 control/100 beds/year with a minimum of 4 controls per year
Pseudomonas aeruginosa	< 1 CFU/100 ml	Quarterly
Total coliforms	< 1 CFU/100 ml	Quarterly

CFU: colony-forming unit

Source: adapted with permission from: *L'eau dans les établissements de santé. Guide technique (Water in health-care facilities. A technical guide)*, 2005.[466]

Table I.11.5
Virucidal activity of antiseptic agents

Reference	Test method	Viruses	Agent	Results
		Enveloped viruses		
Spire et al., 1984[467]	Suspension	HIV	19% EA	LR=2.0 in 5 min
Martin, McDougal & Loskoski, 1985 [468]	Suspension	HIV	50% EA 35% IPA	LR>3.5 LR>3.7
Resnick et al., 1986[469]	Suspension	HIV	70% EA	LR=7.0 in 1 min
van Bueren, Larkin & Simpson, 1994[470]	Suspension	HIV	70% EA	LR= 3.2–5.5 in 30 s
Montefiori et al., 1990[471]	Suspension	HIV	70% IPA + 0.5% CHG 4% CHG	LR= 6.0 in 15 s LR= 6.0 in 15 s
Wood & Payne 1998[472]	Suspension	HIV	Chloroxylenol Benzalkonium chloride	Inactivated in 1 min Inactivated in 1 min
Harbison & Hammer, 1989[473]	Suspension	HIV	Povidone-iodine CHG	Inactivated Inactivated
Lavelle et al., 1989[474]	Suspension	HIV	Detergent + 0.5% chloroxylenol	Inactivated in 30 s
Bond et al., 1983[475]	Suspension/dried plasma Chimpanzee challenge	HBV	70% IPA	LR= 6.0 in 10 min
Kobayashi et al., 1984[476]	Suspension/plasma Chimpanzee challenge	HBV	80% EA	LR= 7.0 in 2 min
Kurtz, 1979[477]	Suspension	HSV	95% EA 75% EA 95% IPA 70% EA + 0.5% CHG	LR>5.0 in 1 min LR>5.0 LR>5.0 LR>5.0
Platt & Bucknall, 1985[297]	Suspension	RSV	35% IPA 4% CHG	LR>4.3 in 1 min LR>3.3
Schurmann & Eggers, 1983[309]	Suspension	Influenza Vaccinia	95% EA 95% EA	Undetectable in 30 s Undetectable in 30 s
Schurmann & Eggers, 1983[309]	Hand test	Influenza Vaccinia	95% EA 95% EA	LR> 2.5 LR> 2.5

Table I.11.5
Virucidal activity of antiseptic agents (Cont.)

Reference	Test method	Viruses	Agent	Results
		Non-enveloped viruses		
Sattar et al., 1983[478]	Suspension	Rotavirus	4% CHG 10% Povidone-iodine 70% IPA/0.1% HCP	LR<3.0 in 1 min LR>3.0 LR>3.0
Schurmann & Eggers, 1983[309]	Hand test	Adenovirus Poliovirus Coxsackie	95% EA 95% EA 95% EA	LR>1.4 LR=0.2–1.0 LR=1.1–1.3
	Finger test	Adenovirus Poliovirus Coxsackie	95% EA 95% EA 95% EA	LR>2.3 LR=0.7–2.5 LR=2.9
Kurtz, 1979[477]	Suspension	ECHO virus	95% EA 75% EA 95% IPA 70% IPA+0.5%CHG	LR≥3.0 in 1 min LR≤1.0 LR=0 LR=0
Mbithi, Springthorpe & Sattar, 2000[308]	Fingerpad	HAV	70% EA 62% EA foam Plain soap 4% CHG 0.3% Triclosan	87.4% reduction 89.3% reduction 78.0% reduction 89.6% reduction 92.0% reduction
Bellamy et al., 1993[272]	Fingertips	Bovine rotavirus	n-propanol+IPA 70% IPA 70% EA 2% Triclosan Water (control) 7.5% povidone-iodine Plain soap 4% CHG	LR=3.8 in 30 s LR=3.1 LR=2.9 LR=2.1 LR=1.3 LR=1.3 LR=1.2 LR=0.5
Ansari et al., 1991[257]	Fingerpad	Human rotavirus	70% IPA Plain soap	98.9% reduction in 10 s 77.1%
Ansari et al., 1989[304]	Fingerpad	Human rotavirus	70% IPA Plain soap	80.3% 72.5%
Sattar et al., 2000[305]	Fingerpad	Rotavirus Rhinovirus Adenovirus	60% EA gel 60% EA gel 60% EA gel	LR>3.0 in 10 s LR>3.0 LR>3.0
Steinmann et al., 1995[307]	Fingerpad	Poliovirus	70% EA 70% IPA	LR=1.6 in 10 s LR=0.8
Davies, Babb & Bradley, 1993[372]	Fingertips	Poliovirus	Plain soap 80% EA	LR=2.1 LR=0.4

HIV = human immunodeficiency virus; EA = ethanol; LR = Log_{10} Reduction; IPA = isopropanol; CHG = chlorhexidine gluconate; HBV = hepatitis B virus; RSV = respiratory syncytial virus; HSV = herpes simplex virus; HAV = hepatitis A virus.

Table I.11.6

Studies comparing the relative efficacy (based on $\log_{10}$ reductions achieved) of plain soap or antimicrobial soaps versus alcohol-based antiseptics in reducing counts of viable bacteria on hands

Reference	Skin contamination	Assay method	Time (s)	Relative efficacy
Dineen & Hildick-Smith, 1965[313]	Existing hand flora	Fingertip agar culture	60	Plain soap < HCP < 50% EA foam
Ayliffe et al., 1975[286]	Existing hand flora	Handrub broth culture	—	Plain soap < 95% EA
Ayliffe, Babb & Quoraishi, 1978[273]	Artificial contamination	Fingertip broth culture	30	Plain soap < 4% CHG < P-I < 70% EA = alc. CHG
Lilly & Lowbury 1978[321]	Artificial contamination	Fingertip broth culture	30	Plain soap < 4% CHG < 70% EA
Lilly, Lowbury & Wilkins, 1979[274]	Existing hand flora	Handrub broth culture	120	Plain soap < 0.5% aq. CHG < 70% EA < 4% CHG < alc.CHG
Rotter, Koller & Wewalka, 1980[314]	Artificial contamination	Fingertip broth culture	60-120	4% CHG < P-I < 60% IPA
Ojajarvi, 1980[125]	Artificial contamination	Fingertip broth culture	15	Plain soap < 3% HCP < P-I < 4% CHG < 70% EA
Ulrich, 1982[275]	Artificial contamination	Glove juice test	15	P-I < alc. CHG
Bartzokas et al., 1983[276]	Artificial contamination	Fingertip broth culture	120	0.3-2% triclosan = 60% IPA = alc. CHG < alc. Triclosan
Rotter, 1984[315]	Artificial contamination	Fingertip agar culture	60	Phenolic < 4% CHG < P-I < EA < IPA < n-P
Blech, Hartemann & Paquin, 1985[316]	Existing hand flora	Fingertip agar culture	60	Plain soap < 70% EA < 95% EA
Rotter et al., 1986[277]	Artificial contamination	Fingertip broth culture	60	Phenolic = P-I < alc. CHG < n-P
Larson, Eke & Laughon, 1986[221]	Existing hand flora	Sterile broth bag technique	15	Plain soap < IPA < 4% CHG = IPA-H = alc. CHG
Ayliffe et al., 1988[137]	Artificial contamination	Fingertip broth culture	30	Plain soap < triclosan < P-I < IPA < alc. CHG < n-P
Ehrenkranz & Alfonso, 1991[88]	Patient contact	Glove juice test	15	Plain soap < IPA-H
Leyden et al., 1991[317]	Existing hand flora	Agar plate/image analysis	30	Plain soap < 1% triclosan < P-I < 4% CHG < IPA
Kjolen & Andersen, 1992[278]	Artificial contamination	Fingertip agar culture	60	Plain soap < IPA < EA < alc. CHG
Rotter & Koller, 1992[223]	Artificial contamination	Fingertip broth culture	60	Plain soap < 60% n-P
Namura, Nishijima & Asada, 1994[279]	Existing hand flora	Agar plate/image analysis	30	Plain soap < alc. CHG
Zaragoza et al., 1999[318]	Existing hand flora	Agar plate culture	N.S.	Plain soap < commercial alcohol mixture
Paulson et al., 1999[319]	Artificial contamination	Glove juice test	20	Plain soap < 0.6% PCMX < 65% EA
Cardoso et al., 1999[320]	Artificial contamination	Fingertip broth culture	30	4% CHG < plain soap < P-I < 70% EA

Existing hand flora = without artificially contaminating hands with bacteria; alc. CHG = alcohol-based chlorhexidine gluconate; aq. CHG = aqueous chlorhexidine gluconate; 4% CHG = chlorhexidine gluconate detergent; EA = ethanol;
HCP = hexachlorophene soap/detergent; IPA = isopropanol; IPA-H = isopropanol + humectants; n-P = n-propanol;
PCMX = para-chloro-meta-xylenol detergent; P-I = povidone-iodine detergent; NS = not stated.
Note: Hexachlorophene has been banned worldwide because of its high rate of dermal absorption and subsequent toxic effects[70,366].

Table I.11.7

Antimicrobial activity and summary of properties of antiseptics used in hand hygiene

Antiseptics	Gram-positive bacteria	Gram-negative bacteria	Viruses enveloped	Viruses non-enveloped	Myco-bacteria	Fungi	Spores
Alcohols	+++	+++	+++	++	+++	+++	-
Chloroxylenol	+++	+	+	±	+	+	-
Chlorhexidine	+++	++	++	+	+	+	-
Hexachlorophene[a]	+++	+	?	?	+	+	-
Iodophors	+++	+++	++	++	++	++	±[b]
Triclosan[d]	+++	++	?	?	±	±[e]	-
Quaternary ammonium compounds[c]	++	+	+	?	±	±	-

Antiseptics	Typical conc. in %	Speed of action	Residual activity	Use
Alcohols	60-70 %	Fast	No	HR
Chloroxylenol	0.5-4 %	Slow	Contradictory	HW
Chlorhexidine	0.5-4%	Intermediate	Yes	HR,HW
Hexachlorophene[a]	3%	Slow	Yes	HW, but not recommended
Iodophors	0.5-10 %)	Intermediate	Contradictory	HW
Triclosan[d]	(0.1-2%)	Intermediate	Yes	HW; seldom
Quaternary ammonium compounds[c]		Slow	No	HR,HW; Seldom; +alcohols

Good = +++, moderate = ++, poor = +, variable = ±, none = –
HR: handrubbing; HW: handwashing
*Activity varies with concentration.
[a] Bacteriostatic.
[b] In concentrations used in antiseptics, iodophors are not sporicidal.
[c] Bacteriostatic, fungistatic, microbicidal at high concentrations.
[d] Mostly bacteriostatic.
[e] Activity against *Candida* spp., but little activity against filementous fungi.
Source: adapted with permission from Pittet, Allegranzi & Sax, 2007.[479]

Table I.11.8

Hygienic handrub efficacy of various agents in reducing the release of test bacteria from artificially-contaminated hands

Agent	Concentration[a] (%)	Test bacterium	Mean log reduction exposure time (min)		
			0.5	1.0	2.0
n-Propanol	100	*E. coli*		5.8	
	60			5.5	
	50			5.0	
			3.7	4.7	4.9
	40			4.3	
Isopropanol	70	*E. coli*		4.9	
				4.8	
			3.5		
	60			4.4	
				4.3	
				4.2	
				4.0	
		S. marcescens		4.1	
		E. coli			
	50		3.4	3.9	4.4
Ethanol	80	*E. coli*		4.5	
	70			4.3	5.1
				4.3	4.9
				4.0	
			3.6	3.8	4.5
			3.4	4.1	
		S. aureus	3.7		
			2.6		
Tosylchloramide (aq. sol.)	60	*S. saprophyticus*	3.5	3.8	
Povidone-iodine (aq. sol.)	2.0[b]	*E. coli*		4.2	
Chlorhexidine diacetate (aq. sol.)	1.0[b]	*E. coli*		4.0–4.3	
	0.5[b]	*E. coli*		3.1	
Chloro-cresol (aq. sol.)	1.0[b]	*E. coli*		3.6	
Hydrogen peroxide	7.5	*E. coli*		3.6	

[a] If not stated otherwise, v/v.

[b] m/v.

Sources: reprinted with permission from Rotter, 2004.[480,481]

Table I.11.9

Studies comparing the relative efficacy of plain soap or antimicrobial soap versus alcohol-containing products in reducing counts of bacteria recovered from hands immediately after use of products for preoperative surgical hand preparation

Reference	Assay method	Relative efficacy
Dineen & Hildick-Smith, 1965[313]	Fingertip agar culture	HCP < 50% EA foam + QAC
Berman & Knight, 1969[461]	Fingertip agar culture	HCP < P-I < 50% EA foam + QAC
Gravens, 1973[268]	Fingertip agar culture	HCP soap < EA foam + 0.23% HCP
Lowbury, Lilly & Ayliffe, 1974[301]	Broth culture	Plain soap < 0.5% CHG det. < 4% CHG det. < alc. CHG
Ayliffe et al., 1975[286]	Hand broth test	Plain soap < 0.5% CHG det. < 4% CHG det. < alc. CHG
Rosenberg, Alatary & Peterson, 1976[285]	Glove juice test	0.5% CHG det. < 4% CHG det. < alc. CHG
Pereira, Lee & Wade, 1997[281]	Glove juice test	P-I < CHG det. < alc. CHG
Galle, Homesley & Rhyne, 1978[284]	Fingertip agar culture	P-I = 46% EA + 0.23% HCP
Jarvis et al., 1979[280]	Broth culture of hands	Plain soap < P-I < alc. CHG < alc. P-I
Aly & Maibach, 1979[283]	Glove juice test	70% IPA = alc. CHG
Zaragoza et al., 1999[316]	Fingertip agar culture	Plain soap < 70% - 90% EA
Larson et al., 1990[282]	Glove juice test, modified	Plain soap < triclosan < CHG det. < P-I < alc. CHG
Babb, Davies & Ayliffe, 1991[271]	Glove juice test	Plain soap < 2% triclosan < P-I < 70% IPA
Rotter, Simpson & Koller, 1998[462]	Fingertip broth culture	70% IPA < 90% IPA = 60% n-P
Hobson et al., 1998[463]	Glove juice test	P-I < CHG det. < 70% EA
Mulberry et al., 2001[482]	Glove juice test	4% CHG det. < CHG det./61% EA
Furukawa et al., 2004[483]	Glove juice test	P-I < CHG det. < 70% EA

QAC = quaternary ammonium compound; alc. CHG = alcoholic chlorhexidine gluconate;
CHG det. = chlorhexidine gluconate detergent; EA = ethanol; HCP = hexachlorophene detergent; IPA = isopropanol;
P-I = povidone-iodine detergent.

Table I.11.10

Efficacy of surgical handrub solutions in reducing the release of resident skin flora from clean hands

Rub	Concentration[a] (%)	Time (min)	Mean log reduction	
			Immediate	Persistent (3h)
n-Propanol	60	5	2.9[b]	1.6[b]
		5	2.7[b]	NA
		5	2.5[b]	1.8[b]
		5	2.3[b]	1.6[b]
		3	2.9[c]	NA
		3	2.0[b]	1.0[b]
		1	1.1[b]	0.5[b]
Isopropanol	90	3	2.4[c]	1.4[c]
	80	3	2.3[c]	1.2[c]
	70	5	2.4[b]	2.1[b]
		5	2.1[b]	1.0[b]
		3	2.0[c]	0.7[c]
		3	1.7[c]	NA
		3	1.5[b]	0.8[b]
		2	1.2	0.8
		1	0.7[b]	0.2
		1	0.8	NA
	60	5	1.7	1.0
Isopropanol + chlorhexidine gluc. (m/v)	70 + 0.5	5	2.5[b]	2.7[b]
		2	1.0	1.5
Ethanol	95	2	2.1	NA
	85	3	2.4[c]	NA
	80	2	1.5	NA
	70	2	1.0	0.6
Ethanol + chlorhexidine gluc. (m/v)	95 + 0.5	2	1.7	NA
	77 + 0.5	5	2.0	1.5[d]
	70 + 0.5	2	0.7	1.4
Chlorhexidine gluc. (aq. Sol., m/v)	0.5	2	0.4	1.2
Povidone-iodine (aq. Sol., m/v)	1.0	5	1.9[b]	0.8[b]
Peracetic acid (m/v)	0.5	5	1.9	NA

NA = not available.

[a] v/v unless otherwise stated.

[b] Tested according to the Deutsche Gesellschaft fur Hygiene and Mikrobiologic (German Society of Hygiene and Microbiology).

[c] Tested according to European Standard EN 12791.

[d] After 4 hours.

Source: reprinted with permission from Rotter, 1999.[48]

12.
WHO-recommended handrub formulations

12.1 General remarks

To help countries and health-care facilities to achieve system change and adopt alcohol-based handrubs as the gold standard for hand hygiene in health care, WHO has identified formulations for their local preparation. Logistic, economic, safety, and cultural and religious factors have all been carefully considered by WHO before recommending such formulations for use worldwide (see also Part I, Section 14).

At present, alcohol-based handrubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.[60,221,329,484-487]

WHO recommends alcohol-based handrubs based on the following factors:

1. evidence-based, intrinsic advantages of fast-acting and broad-spectrum microbicidal activity with a minimal risk of generating resistance to antimicrobial agents;
2. suitability for use in resource-limited or remote areas with lack of accessibility to sinks or other facilities for hand hygiene (including clean water, towels, etc.);
3. capacity to promote improved compliance with hand hygiene by making the process faster and more convenient;
4. economic benefit by reducing annual costs for hand hygiene, representing approximately 1% of extra-costs generated by HCAI (see also Part III, Section 3);[488-490]
5. minimization of risks from adverse events because of increased safety associated with better acceptability and tolerance than other products (see also Part I, Section 14).[491-498]

For optimal compliance with hand hygiene , handrubs should be readily available, either through dispensers close to the point of care or in small bottles for on-person carriage.[335,485]

Health-care settings currently using commercially-available handrubs should continue to use them, provided that they meet recognized standards for microbicidal efficacy (ASTM or EN standards) and are well accepted/tolerated by HCWs (see also Implementation Toolkit available at http://www.who.int/gpsc/en/). It is obvious that these products should be regarded as acceptable, even if their contents differ from those of the WHO-recommended formulations described below. WHO recommends the local production of the following formulations as an alternative when suitable commercial products are either unavailable or too costly.

12.1.1 Suggested composition of alcohol-based handrub formulations for local production

The choice of components for the WHO-recommended handrub formulations takes into account cost constraints and microbicidal activity. The following two formulations are recommended for local production with a maximum of 50 litres per lot to ensure safety in production and storage.

Formulation I

To produce final concentrations of ethanol 80% *v/v*, glycerol 1.45% *v/v*, hydrogen peroxide (H_2O_2) 0.125% *v/v*.

Pour into a 1000 ml graduated flask:

a) ethanol 96% *v/v,* 833.3 ml
b) H_2O_2 3%, 41.7 ml
c) glycerol 98% ,14.5 ml

Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Formulation II

To produce final concentrations of isopropyl alcohol 75% *v/v*, glycerol 1.45% *v/v*, hydrogen peroxide 0.125% *v/v*:

Pour into a 1000 ml graduated flask:

a) isopropyl alcohol (with a purity of 99.8%), 751.5 ml
b) H_2O_2 3%, 41.7 ml
c) glycerol 98%, 14.5 ml

Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Only pharmacopoeial quality reagents should be used (e.g. *The International Pharmacopoeia*) and not technical grade products.

12.1.2 Method for local production

12.1.2.1 Volume of production, containers

- **10-litre** preparations: glass or plastic bottles with screw-threaded stoppers can be used.
- **50-litre** preparations: large plastic (preferably polypropylene, translucent enough to see the liquid level) or stainless steel tanks with an 80 to100 litre capacity should be used to allow for mixing without overflowing.

The tanks should be calibrated for the ethanol/isopropyl alcohol volumes and for the final volumes of either 10 or 50 litres. It is best to mark plastic tanks on the outside and stainless steel ones on the inside.

12.1.2.2 Preparation

1) The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark.

2) H_2O_2 is added using the measuring cylinder.
3) Glycerol is added using a measuring cylinder. As the glycerol is very viscous and sticks to the walls of the measuring cylinder, it can be rinsed with some sterile distilled or cold boiled water to be added and then emptied into the bottle/ tank.
4) The bottle/tank is then topped up to the corresponding mark of the volume (10-litre or 50-litre) to be prepared with the remainder of the distilled or cold, boiled water.
5) The lid or the screw cap is placed on the bottle/tank immediately after mixing to prevent evaporation.
6) The solution is mixed by gently shaking the recipient where appropriate (small quantities),or by using a wooden, plastic or metallic paddle. Electric mixers should not be used unless "EX" protected because of the danger of explosion.
7) After mixing, the solution is immediately divided into smaller containers (e.g. 1000, 500 or 100 ml plastic bottles). The bottles should be kept in quarantine for 72 hours. This allows time for any spores present in the alcohol or the new or re-used-bottles to be eliminated by H_2O_2.

12.1.2.3 *Quality control*

If concentrated alcohol is obtained from local production, verify the alcohol concentration and make the necessary adjustments in volume to obtain the final recommended concentration. An alcoholmeter can be used to control the alcohol concentration of the final use solution; H_2O_2 concentration can be measured by titrimetry (oxydo-reduction reaction by iodine in acidic conditions). A higher level quality control can be performed using gas chromatography[499] and the titrimetric method to control the alcohol and the hydrogen peroxide content, respectively. Moreover, the absence of microbial contamination (including spores) can be checked by filtration, according to the European Pharmacopeia specifications.[500]

For more detailed guidance on production and quality control of both formulations, see the "WHO-recommended hand antisepsis formulation - guide to local production" (Implementation Toolkit available at http://www.who.int/gpsc/en/).

12.1.2.4 *Labelling of the bottles*

The bottles should be labelled in accordance with national guidelines. Labels should include the following:

- Name of institution
- Date of production and batch number
- Composition: ethanol or isopropanol, glycerol and hydrogen peroxide (% *v/v* can also be indicated) and the following statements:
- WHO-recommended handrub formulation
- For external use only
- Avoid contact with eyes
- Keep out of reach of children
- Use: apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry. Flammable: keep away from flame and heat.

12.1.2.5 *H_2O_2*

While alcohol is the active component in the formulations, certain aspects of other components should be respected. All raw materials used should be preferably free of viable bacterial spores. The low concentration of H_2O_2 is incorporated in the formulations to help eliminate contaminating spores in the bulk solutions and excipients[501,502] and is *not* an active substance for hand antisepsis. While the use of H_2O_2 adds an important safety aspect, the use of 3–6% of H_2O_2 for the production might be complicated by its corrosive nature and by difficult procurement in some countries. Further investigation is needed to assess H_2O_2 availability in different countries as well as the possibility of using a stock solution with a lower concentration.

12.1.2.6 *Glycerol*

Glycerol is added to the formulation as a humectant to increase the acceptability of the product. Other humectants or emollients may be used for skin care, provided that they are affordable, available locally, miscible (mixable) in water and alcohol, non-toxic, and hypoallergenic. Glycerol has been chosen because it is safe and relatively inexpensive. Lowering the percentage of glycerol may be considered to further reduce stickiness of the handrub.

12.1.2.7 *Other additives to the formulations*

It is strongly recommended that no ingredients other than those specified here be added to the formulations. In the case of any additions, full justification must be provided together with documented safety of the additive, its compatibility with the other ingredients, and all relevant details should be given on the product label.

In general, it is not recommended to add any bittering agents to reduce the risk of ingestion of the handrubs. Nevertheless, in exceptional cases where the risk of ingestion might be very high (paediatric or confused patients), substances such as methylethylketone and denatonium benzoate[503]) may be added to some household products to make them less palatable and thus reduce the risk of accidental or deliberate ingestion. However, there is no published information on the compatibility and deterrent potential of such chemicals when used in alcohol-based handrubs to discourage their abuse. It is important to note that such additives may make the products toxic and add to production costs. In addition, the bitter taste may be transferred from hands to food being handled by individuals using handrubs containing such agents. Therefore, compatibility and suitability, as well as cost, must be carefully considered before deciding on the use of such bittering agents.

A colorant may be incorporated to differentiate the handrub from other fluids as long as such an additive is safe and compatible with the essential components of the handrubs (see also Part I, Section 11.3). However, the H_2O_2 in the handrubs may tend to fade any colouring agent used and prior testing is recommended.

No data are available to assess the suitability of adding gelling agents to the WHO-recommended liquid formulations, but this could increase potentially both production difficulties and costs, and may compromise antimicrobial efficacy.[203,325]

The addition of fragrances is not recommended because of the risk of allergic reactions.

All handrub containers must be labelled in accordance with national/international guidelines.

To further reduce the risk of abuse and to respect cultural and religious sensitivities, product containers may be labelled simply as "antimicrobial handrubs" (see Part I, Section 17.4).

12.1.2.8 Use of proper water for the preparation of the formulations

While sterile distilled water is preferred for making the formulations, boiled and cooled tap water may also be used as long as it is free of visible particules.

12.1.3 Production and storage

Manufacture of the WHO-recommended handrub formulations is feasible in central pharmacies or dispensaries. Whenever possible and according to local policies, governments should encourage local production, support the quality assessment process, and keep production costs as low as possible. Special requirements apply for the production and stock piling of the formulations, as well as for the storage of the raw materials.

Because undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities should directly dilute it to the above-mentioned concentration (Section 12.1.1). The flash points of ethanol 80% (*v/v*) and isopropyl alcohol 75% (*v/v*) are 17.5˚C and 19˚C, respectively,(Rotter M, personal communication) and special attention should be given to proper storage in tropical climates (see also Part I, Section 23.6.1). Production and storage facilities should be ideally air-conditioned or cool rooms. Open flames and smoking must be strictly prohibited in production and storage areas. Pharmacies and small-scale production centres supplying the WHO-recommended handrub formulations are advised not to manufacture locally batches of more than 50 litres at a time. For safety reasons, it is advisable to produce smaller volumes and to adhere to local and/or national guidelines and regulations. The production should not be undertaken in central pharmacies lacking specialized air conditioning and ventilation. National safety guidelines and local legal requirements must be adhered to for the storage of ingredients and the final product.

12.1.4 Efficacy

It is the consensus opinion of the WHO expert group that the WHO-recommended handrub formulations can be used both for hygienic hand antisepsis and for presurgical hand preparation.

12.1.4.1 Hygienic handrub

The microbicidal activity of the two WHO-recommended formulations was tested by a WHO reference laboratory according to EN standards (EN 1500) (see also Part I, section 10.1.1). Their activity was found to be equivalent to the reference substance (isopropanol 60 % *v/v*) for hygienic hand antisepsis.

12.1.4.2 Presurgical hand preparation

Both WHO-recommended handrub formulations were tested by two independent reference laboratories in different European countries to assess their suitability for use for pre-surgical hand preparation, according to the European Standard EN 12791. The results are reported in Part I, Section 13.5.

12.1.5 Safety standards

With regard to skin reactions, handrubbing with alcohol-based products is better tolerated than handwashing with soap and water (see also Part I, Section 14).

In a recent study conducted among ICU HWs, the short-term skin tolerability and acceptability of the WHO-recommended handrub formulations were significantly higher than those of a reference product[504]. Lessons learnt about acceptability and tolerability of the WHO-recommended formulations in some sites where local production has taken place are summarized below (Section 12.2).

12.1.6 Distribution

To avoid contamination with spore-forming organisms,[338] disposable bottles should preferably be used although reusable sterilizable bottles may reduce production costs and waste management. To prevent evaporation, containers should have a maximum capacity of 500 ml on ward and 1 litre in operating theatres, and possibly fit into a wall dispenser. Leakage-free pocket bottles with a capacity of no more than 100 ml should also be available and distributed individually to HCWs, but it should be emphasized that the use of these products should be confined to health care only. The production or re-filling unit should follow norms on how to clean and disinfect the bottles (e.g. autoclaving, boiling, or chemical disinfection with chlorine). Autoclaving is considered the most suitable procedure. Reusable bottles should never be refilled until they have been completely emptied and then cleansed and disinfected.

Cleansing and disinfection process for reusable handrub bottles: empty bottles should be brought to a central point to be reprocessed using standard operating procedures. Bottles should be thoroughly washed with detergent and tap water to eliminate any residual liquid. If they are heat-resistant, bottles should be thermally disinfected by boiling in water. Whenever possible, thermal disinfection should be chosen in preference to chemical disinfection, since chemical disinfection might not only increase costs but also needs an extra step to flush out the remains of the disinfectant. Chemical disinfection should include soaking the bottles in a solution containing 1000 ppm of chlorine for a minimum of 15 minutes and then rinsing with sterile/cooled boiled water.[505] After thermal or chemical disinfection, bottles should be left to dry completely upside-down, in a bottle rack. Dry bottles should be closed with a lid and stored, protected from dust, until use.

12.2 Lessons learnt from local production of the WHO-recommended handrub formulations in different settings worldwide

Since the Guide to Local Production has been disseminated through the WHO complementary sites platform and pilot sites, many settings around the world have undertaken local production of the two WHO-recommended formulations.

A web-based survey (http://www.surveymonkey.com) was carried out to gather information on the feasibility, quality control and cost of local production, and the acceptability and tolerability of the formulations by HCWs in different countries. Questions were designed to collect information on issues such as training and numbers of personnel involved in production, the source and cost of each component, quality control of each component and the final product, equipment used for production, adequacy of facility for preparation and storage, and finally distribution and end use. There were also open-ended questions on lessons learnt related to each item. Responses were obtained from eleven sites located in Bangladesh, Costa Rica, Egypt, Hong Kong SAR, Kenya, Mali, Mongolia, Pakistan (two sites), Saudi Arabia, and Spain.

12.2.1 Production facilities and personnel

Production of a WHO-recommended handrub formulation took place at the pharmacy of the health-care facility itself in Egypt, Kenya, Mali, Mongolia, the two sites in Pakistan, and Spain. In Bangladesh, Costa Rica, Hong Kong SAR, and Saudi Arabia, either private commercial or government companies were asked to manufacture the product; in these countries, it is intended that the production will supply numerous health-care settings.

The quantity of handrub produced ranged from 10 litres to 600,000 litres per month. Qualified pharmacists were involved in the production at all sites. However, in the case of local production at the hospital level and also in some large-scale production facilities (e.g. in Bangladesh), this task was added to the regular workload as economic constraints did not permit to dedicate a staff member only for this reason. Other categories of workers were also required for the production, but varied in numbers and qualifications. The facilities for preparation and storage were considered adequate by all but two sites (in Mali and one in Pakistan). Adequate ventilation and temperature control and fire safety signs were also available at most sites.

12.2.2 Procurement of components

All sites, except for the one in Bangladesh and the two located in Pakistan, produced the WHO-recommended formulation I, based on ethanol, mostly because of easier procurement (from local suppliers in most cases) and lower cost. In some cases, ethanol was derived from sugar cane or wheat. In Pakistan, isopropyl alcohol was used because, although cheaper, ethanol is subject to licensing restrictions and to strict record-keeping. Glycerol was procured by local suppliers in most cases while hydrogen peroxide had to be imported in five sites.

12.2.3 Equipment

Procurement of the equipment for production was relatively easy and not particularly expensive in most sites. Either plastic or stainless steel containers were used for mixing except in Egypt where glass containers were used. In contrast, finding adequate dispensers for the final product use was more problematic. In Kenya and Mali, it was not possible to purchase suitable dispensers in the country and they were donated by Swiss institutions. For HCWs, 100 ml pocket bottles are in use in Hong Kong SAR, Mali, Mongolia and Pakistan; 500 ml wall-mounted dispensers are also available in Egypt, Hong Kong SAR, Kenya, Mongolia, Pakistan and Spain. Bangladesh has been using 100 ml glass bottles and 500 ml plastic bottles, Costa Rica 385 ml bottles and Saudi Arabia 1 litre bottles or bags. For long-term sustainability, container moulds of both bottles and caps, for final use may have to be made locally which may represent a very high initial cost. Pakistan was successful in enlisting the support of a private sector company in making bottles using new moulds. Bangladesh too identified local suppliers who are able to make the desired plastic dispensers.

The cleaning and recycling process proposed by WHO has been put in place and is working well in six sites. Methods used for disinfection varied and included treatment with chlorine or alcohol.

12.2.4 Quality control

The quality control of alcohol concentrations in the final product was regularly performed by alcoholmeter in all sites but one. Hydrogen peroxide was quality checked at six sites (Bangladesh, Costa Rica, Mali, Mongolia, Pakistan, and Saudi Arabia).

Multiple samples from seven sites (Costa Rica, Egypt, Hong Kong SAR, Mali, Mongolia, Pakistan,and Saudi Arabia) were sent to the University of Geneva Hospitals, Geneva, Switzerland, for more sophisticated quality checks by gas chromatography[499] and the titrimetric method to control the alcohol and the hydrogen peroxide content. Initial results from four sites showed either higher or lower alcohol and/or H_2O_2 concentrations, but the product was eventually declared to conform to acceptable ranges in all sites. Quality was shown to be optimal also for three types of formulations made in Saudi Arabia in which either a fragrance or special humectants were added to the WHO formulation I. Interestingly, samples from Mali, which were kept in a tropical climate without air conditioning or special ventilation, were in accordance with the optimal quality parameters in all samples even 19 months after production. The site located in Bangladesh was able to perform gas chromatography and titrimetry for quality control locally and reported optimal results for all tests.

12.2.5 Costs

Cost calculation of the local production of the WHO-recommended handrub formulations at the different sites has been quite complex in the attempt to consider several aspects such as the cost of raw materials and dispensers, the recycling process (when applicable), and production staff salaries. The cost of imported items was linked to the US$ and fluctuated markedly. Cost also varied according to the supplier and the pack sizes. The cost of equipment (if any) to enable the facility to start production was not considered in the cost calculations of the examples below because it varied considerably based on local needs and sources.

The production cost (including salaries but not the dispenser) per 100 ml was US$ 0.37 and US$ 0.30 for formulation I in Kenya and Mali respectively and US$ 0.30 for formulation II in Bangladesh. In Hong Kong SAR and Pakistan, the cost including the pocket bottle was US$ 0.44 per 100 ml of formulation II, and US$ 0.50 per 100 ml of formulation I, respectively. Prices of some commercially-available handrubs may be much higher and vary greatly: US$ 2.50-5.40 for a 100 ml pocket bottle; prices of gels can be as high as US$ 8 for a 100 ml pocket bottle. Effective actions to facilitate local procurement of some raw ingredients for the production of the WHO-recommended handrub formulations would lead very likely to a further reduction of the overall cost of the end product.

Studies are necessary to evaluate the cost-effectiveness of the local production of the WHO-recommended handrub formulation in the course of a hand hygiene promotion campaign. As an example, in 2005 the cost of an alcohol-based hand rinse originally developed by the pharmacy of the University of Geneva Hospitals and currently commercially marketed, was € 0.57 for a 100 ml pocket bottle, € 1.74 for a 500 ml bottle, and € 3.01 for a 1000 ml bottle. A study performed in this institution on the cost implications of a successful hand hygiene campaign showed that the total cost of hand hygiene promotion, including the provision of the alcohol-based handrub, corresponded to less than 1% of the costs associated with HCAI.[490]

12.2.6 Issues raised by the survey

Several issues related to the expertise and time availability of personnel involved in production were identified by the survey participants. These included the request for additional training in production aspects for pharmacists, the need for existing staff to take on responsibilities in addition to their primary roles, decisions to include production as part of the job description of hospital pharmacists, and the question of remuneration for these additional responsibilities.

Some participants emphasized that more attention needs to be paid to the requirements for preparation and storage facilities, especially if production has to be scaled up to peripheral hospitals. A purpose-built production area with proper humidity and temperature control according to the recommendations for good manufacturing practices is a prerequisite for production. Several items of equipment were inadequate in some facilities, particularly for scaling up. Clearer guidance on large-scale production would be beneficial and WHO is exploring practical solutions to resolve this issue.

There were also lessons learnt related to the procurement of raw ingredients. Sub-standard materials are available on the market and it is important to select local sources with care. It would be important to have specific recommendations on the chemical grade of the component and acceptable manufacturers. However, actual requirements need to be considered when taking decisions on quantities to be purchased and specific attention should be paid to the risk of shortages of supplies, especially in remote areas.

In some cases, the possibility of theft and accidental ingestion of the alcohol-based handrub made it difficult to obtain support from hospital administrators.

The survey showed that in many hospitals the facilities and the equipment for quality control are inadequate, especially as far as testing for hydrogen peroxide is concerned. However the centralization of high-level quality control at the University Hospitals of Geneva overcame these obstacles and provided timely and very helpful support. Nevertheless, the availability of this service may be reduced with the expansion of local production to more sites around the world. Indeed, the fact that some samples failed to meet the standard required concentrations indicated the importance of the quality check, and it would be very important to identify other reference laboratories able to perform it.

Tolerability and acceptability information were available from four sites (Bangladesh, Hong Kong SAR, Pakistan and Saudi Arabia) where, in general, the WHO-recommended formulations were well appreciated by HCWs. In Hong Kong SAR and Pakistan, the WHO-recommended formulations were preferred to the product previously in use because of better tolerability. Hair bleaching and one case of dermatitis were the rare adverse effects reported. Issues related to the unpleasant smell of the final product were raised by HCWs from all four sites, but were not a major obstacle to adoption. No religious issues related to the alcohol content were identified in the survey.

13.

Surgical hand preparation: state-of-the-art

13.1 Evidence for surgical hand preparation

Historically, Joseph Lister (1827–1912) demonstrated the effect of disinfection on the reduction of surgical site infections (SSIs).[506] At that time, surgical gloves were not yet available, thereby making appropriate disinfection of the surgical site of the patient and hand antisepsis by the surgeon even more imperative.[507] During the 19th century, surgical hand preparation consisted of washing the hands with antimicrobial soap and warm water, frequently with the use of a brush.[508] In 1894, three steps were suggested: 1) wash hands with hot water, medicated soap, and a brush for 5 minutes; 2) apply 90% ethanol for 3–5 minutes with a brush; and 3) rinse the hands with an "aseptic liquid".[508] In 1939, Price suggested a 7-minute handwash with soap, water, and a brush, followed by 70% ethanol for 3 minutes after drying the hands with a towel.[63] In the second half of the 20th century, the recommended time for surgical hand preparation decreased from >10 minutes to 5 minutes.[509-512] Even today, 5-minute protocols are common.[197] A comparison of different countries showed almost as many protocols as listed countries.[513]

The introduction of sterile gloves does not render surgical hand preparation unnecessary. Sterile gloves contribute to preventing surgical site contamination[514] and reduce the risk of bloodborne pathogen transmission from patients to the surgical team.[515] However, 18% (range: 5–82%) of gloves have tiny punctures after surgery, and more than 80% of cases go unnoticed by the surgeon. After two hours of surgery, 35% of all gloves demonstrate puncture, thus allowing water (hence also body fluids) to penetrate the gloves without using pressure[516] (see Part I, Section 23.1). A recent trial demonstrated that punctured gloves double the risk of SSIs.[517] Double gloving decreases the risk of puncture during surgery, but punctures are still observed in 4% of cases after the procedure.[518,519] In addition, even unused gloves do not fully prevent bacterial contamination of hands.[520] Several reported outbreaks have been traced to contaminated hands from the surgical team despite wearing sterile gloves.[71,154,162,521-523]

Koiwai and colleagues detected the same strain of coagulase-negative staphylococci (CoNS) from the bare fingers of a cardiac surgeon and from a patient with postoperative endocarditis with a matching strain.[522] A similar, more recent outbreak with CoNS and endocarditis was observed by Boyce and colleagues, strain identity being confirmed by molecular methods.[162] A cardiac surgeon with onychomycosis became the source of an outbreak of SSIs due to *P. aeruginosa*, possibly facilitated by not routinely practising double gloving.[523] One outbreak of SSIs even occurred when surgeons who normally used an antiseptic surgical scrub preparation switched to a non-antimicrobial product.[524]

Despite a large body of indirect evidence for the need of surgical hand antisepsis, its requirement before surgical interventions has never been proven by a randomized, controlled clinical trial.[525] Most likely, such a study will never be performed again nor be acceptable to an ethics committee. A randomized clinical trial comparing an alcohol-based handrub versus a chlorhexidine hand scrub failed to demonstrate a reduction of SSIs, despite considerably better in vitro activity of the alcohol-based formulation.[197] Therefore, even considerable improvements in antimicrobial activity in surgical hand hygiene formulations are unlikely to lead to significant reductions of SSIs. These infections are the result of multiple risk factors related to the patient, the surgeon, and the health-care environment, and the reduction of only one single risk factor will have a limited influence on the overall outcome.

In addition to protecting the patients, gloves reduce the risk for the HCW to be exposed to bloodborne pathogens. In orthopaedic surgery, double gloving has been a common practice that significantly reduces, but does not eliminate, the risk of cross-transmission after glove punctures during surgery.[526]

13.2 Objective of surgical hand preparation

Surgical hand preparation should reduce the release of skin bacteria from the hands of the surgical team for the duration of the procedure in case of an unnoticed puncture of the surgical glove releasing bacteria to the open wound.[527] In contrast to the hygienic handwash or handrub, surgical hand preparation must eliminate the transient and reduce the resident flora.[484,528,529] It should also inhibit growth of bacteria under the gloved hand. Rapid multiplication of skin bacteria occurs under surgical gloves if hands are washed with a non-antimicrobial soap, whereas it occurs more slowly following preoperative scrubbing with a medicated soap. The skin flora, mainly coagulase-negative staphylococci, *Propionibacterium* spp., and *Corynebacteria* spp., are rarely responsible for SSI, but in the presence of a foreign body or necrotic tissue even inocula as low as 100 CFU can trigger such infection.[530] The virulence of the microorganisms, extent of microbial exposure, and host defence mechanisms are key factors in the pathogenesis of postoperative infection, risk factors that are largely beyond the influence of the surgical team. Therefore, products for surgical hand preparation must eliminate the transient and significantly reduce the resident flora at the beginning of an operation and maintain the microbial release from the hands below baseline until the end of the procedure.

The spectrum of antimicrobial activity for surgical hand preparation should be as broad as possible against bacteria and fungi.[529,531] Viruses are rarely involved in SSI and are not part of test procedures for licensing in any country. Similarly, activity against spore-producing bacteria is not part of international testing procedures.

13.3 Selection of products for surgical hand preparation

The lack of appropriate, conclusive clinical trials precludes uniformly acceptable criteria. In vitro and in vivo trials with healthy volunteers outside the operating theatre are the best evidence currently available. In the USA, antiseptic preparations intended for use as surgical hand preparation (based on the FDA TFM of 17 June 1994)[198] are evaluated for their ability to reduce the number of bacteria released from hands: a) immediately after scrubbing; b) after wearing surgical gloves for 6 hours (persistent activity); and c) after multiple applications over 5 days (cumulative activity). Immediate and persistent activities are considered the most important. Guidelines in the USA recommend that agents used for surgical hand preparation should significantly reduce microorganisms on intact skin, contain a non-irritating antimicrobial preparation, have broad-spectrum activity, and be fast-acting and persistent (see Part I, Section 10).[532] In Europe, all products must be at least as efficacious as a reference surgical rub with n-propanol, as outlined in the European Norm EN 12791. In contrast to the USA' guidelines, only the immediate effect after the hand hygiene procedure and the level of regrowth after 3 hours under gloved hands are measured. The cumulative effect over 5 days is not a requirement of EN 12791.

Most guidelines prohibit any jewellery or watches on the hands of the surgical team (Table I.13.1).[58,529,533] Artificial fingernails are an important risk factor, as they are associated with changes of the normal flora and impede proper hand hygiene.[154,529] Therefore, they should be prohibited for the surgical team or in the operating theatre.[154,529,534]

13.4 Surgical hand antisepsis using medicated soap

The different active compounds included in commercially available handrub formulations are described in Part I, Section 11. The most commonly used products for surgical hand antisepsis are chlorhexidine or povidone-iodine-containing soaps. The most active agents (in order of decreasing activity) are chlorhexidine gluconate, iodophors, triclosan, and plain soap.[282,356,378,529,535-537] Triclosan-containing products have also been tested for surgical hand antisepsis, but triclosan is mainly bacteriostatic, inactive against *P. aeruginosa,* and has been associated with water pollution in lakes.[538,539] Hexachlorophene has been banned worldwide because of its high rate of dermal absorption and subsequent toxic effects.[70,366] Application of chlorhexidine or povidone-iodine result in similar initial reductions of bacterial counts (70–80%), reductions that achieves 99% after repeated application**.** Rapid regrowth occurs after application of povidone-iodine, but not after use of chlorhexidine.[540] Hexachlorophene and triclosan detergents show a lower immediate reduction, but a good residual effect. These agents are no longer commonly used in operating rooms because other products such as chlorhexidine or povidone-iodine provide similar efficacy at lower levels of toxicity, faster mode of action, or broader spectrum of activity. Despite both in vitro and in vivo studies demonstrating that it is less efficacious than chlorhexidine, povidone-iodine remains one of the widely-used products for surgical hand antisepsis, induces more allergic reactions, and does not show similar residual effects.[271,463] At the end of a surgical intervention, iodophor-treated hands can have even more microorganisms than before surgical scrubbing. Warm water makes antiseptics and soap work more effectively, while very hot water removes more of the protective fatty acids from the skin. Therefore, washing with hot water should be avoided. The application technique is probably less prone to errors compared with handrubbing (Table I.13.2) as all parts of the hands and forearms get wet under the tap/faucet. In contrast, all parts of the hands and forearms must actively be put in contact with the alcohol-based compound during handrubbing (see below).

13.4.1 Required time for the procedure

Hingst and colleagues compared hand bacterial counts after 3-minute and 5-minute scrubs with seven different formulations.[378] Results showed that the 3-minute scrub could be as effective as the 5-minute scrub, depending on the formula of the scrub agent. Immediate and postoperative hand bacterial counts after 5-minute and 10-minute scrubs with 4% chlorhexidine gluconate were compared by O'Farrell and colleagues before total hip arthroplasty procedures.[512] The 10-minute scrub reduced the immediate colony count more than the 5-minute scrub. The postoperative mean log CFU count was slightly higher for the 5-minute scrub than for the 10-minute scrub; however, the difference between post-scrub and postoperative mean CFU counts was higher for the 10-minute scrub than the 5-minute scrub in longer (>90 minutes) procedures. The study recommended a 5-minute scrub before total hip arthroplasty.

A study by O'Shaughnessy and colleagues used 4% chlorhexidine gluconate in scrubs of 2, 4, and 6-minutes duration. A reduction in post-scrub bacterial counts was found in all three groups. Scrubbing for longer than 2 minutes did not confer any advantage. This study recommended a 4-minute scrub for the surgical team's first procedure and a 2-minute scrub for subsequent procedures.[541] Bacterial counts on hands after 2-minute and 3-minute scrubs with 4% chlorhexidine gluconate were compared.[542] A statistically significant difference in mean CFU counts was found between groups with the higher mean log reduction in the 2-minute group. The investigators recommended a 2-minute procedure. Poon and colleagues applied different scrub techniques with a 10% povidone-iodine formulation.[543] Investigators found that a 30-second handwash can be as effective as a 20-minute contact with an antiseptic in reducing bacterial flora and that vigorous friction scrub is not necessarily advantageous.

13.4.2 Use of brushes

Almost all studies discourage the use of brushes. Early in the 1980s, Mitchell and colleagues suggested a brushless surgical hand scrub.[544] Scrubbing with a disposable sponge or combination sponge-brush has been shown to reduce bacterial counts on the hands as effectively as scrubbing with a brush.[511,545,546] Recently, even a randomized, controlled clinical trial failed to demonstrate an additional antimicrobial effect by using a brush.[547] It is conceivable that a brush may be beneficial on visibly dirty hands before entering the operating room. Members of the surgical team who have contaminated their hands before entering the hospital may wish to use a sponge or brush to render their hands visibly clean before entering the operating room area.

13.4.3 Drying of hands

Sterile cloth towels are most frequently used in operating theatres to dry wet hands after surgical hand antisepsis. Several methods of drying have been tested without significant differences between techniques.[256]

13.4.4 Side-effects of surgical hand scrub

Skin irritation and dermatitis are more frequently observed after surgical hand scrub with chlorhexidine than after use of surgical hand antisepsis with an alcohol-based hand rinse.[197] Overall, skin dermatitis is more frequently associated with hand antisepsis using a medicated soap than with an alcohol-based handrub.[548] Boyce and colleagues quantified the epidermal water content of the dorsal surface of nurses' hands by measuring electrical capacitance of the skin. The water content decreased significantly during the washing phase compared with the alcohol-based handrub-in phase.[264] Most data have been generated outside the operating room, but it is conceivable that these results apply for surgical hand antisepsis as well.[549]

13.4.5 Potential for recontamination

Surgical hand antisepsis with medicated soap requires clean water to rinse the hands after application of the medicated soap. However, *Pseudomonas* spp., specifically *P. aeruginosa*, are frequently isolated from taps/faucets in hospitals.[550]. Taps are common sources of *P. aeruginosa* and other Gram-negative bacteria and have even been linked to infections in multiple settings, including ICUs.[551] It is therefore prudent to remove tap aerators from sinks designated for surgical hand antisepsis.[551-553] Even automated sensor-operated taps were linked to *P. aeruginosa* contamination.[554] Outbreaks or cases clearly linked to contaminated hands of surgeons after proper surgical hand scrub have not yet been documented. However, outbreaks with *P.aeruginosa* were reported as traced to members of the surgical team suffering from onychomycosis,[154,523] but a link to contaminated tap water has never been established. In countries lacking continuous monitoring of drinking-water and improper tap maintenance, recontamination may be a real risk even after correct surgical hand scrub. Of note, one surgical hand preparation episode with traditional agents uses approximately 20 litres of warm water, or 60 litres and more for the entire surgical team.[555] This is an important issue worldwide, particularly in countries with a limited safe water supply.

13.5 Surgical hand preparation with alcohol-based handrubs

Several alcohol-based handrubs have been licensed for the commercial market,[531,556,557] frequently with additional, long-acting compounds (e.g. chlorhexidine gluconate or quaternary ammonium compounds) limiting regrowth of bacteria on the gloved hand,[377,529,558-561] The antimicrobial efficacy of alcohol-based formulations is superior to that of all other currently available methods of preoperative surgical hand preparation. Numerous studies have demonstrated that formulations containing 60–95% alcohol alone, or 50–95% when combined with small amounts of a QAC, hexachlorophene or chlorhexidine gluconate, reduce bacterial counts on the skin immediately post-scrub more effectively than do other agents.

The WHO-recommended handrub formulations were tested by two independent reference laboratories in different European countries to assess their suitability for use for surgical hand preparation. Although formulation I did not pass the test in both laboratories and formulation II in only one of them, the expert group is, nevertheless, of the opinion that the microbicidal activity of surgical antisepsis is still an ongoing issue for research as due to the lack of epidemiological data there is no indication that the efficacy of n-propanol (propan-1-ol) 60 % v/v as a reference in EN 12791 finds a clinical correlate. It is the consensus opinion of the WHO expert group that the choice of n-propanol is inappropriate as the reference alcohol for the validation process because of its safety profile and the lack of evidence-based studies related to its potential harmfulness for humans. Indeed, only a few formulations worldwide have incorporated n-propanol for hand antisepsis.

Considering that other properties of the WHO recommended formulations, such as their excellent tolerability, good acceptance by HCWs and low cost are of high importance for a sustained clinical effect, the above results are considered acceptable and it is the consensus opinion of the WHO expert group that the two formulations can be used for surgical hand preparation. Institutions opting to use the WHO-recommended formulations for surgical hand preparation should ensure that a minimum of three applications are used, if not more, for a period of 3 to 5 minutes. For surgical procedures of more than a two hours' duration, ideally surgeons should practise a second handrub of approximately 1 minute, even though more research is needed on this aspect.

Hand-care products should not decrease the antimicrobial activity of the handrub. A study by Heeg[562] failed to demonstrate such an interaction, but manufacturers of a handrub should provide good evidence for the absence of interaction.[563]

It is not necessary to wash hands before handrub unless hands are visibly soiled or dirty.[562,564] The hands of the surgical team should be clean upon entering the operating theatre by washing with a non-medicated soap (Table I.13.1). While this handwash may eliminate any risk of contamination with bacterial spores, experimental and epidemiological data failed to demonstrate an additional effect of washing hands before applying handrub in the overall reduction of the resident skin flora.[531] The activity of the handrub formulation may even be impaired if hands are not completely dried before applying the handrub or by the washing phase itself.[562,564,565] A simple handwash with soap and water before entering the operating theatre area is highly recommended to eliminate any risk of colonization with bacterial spores.[420] Non-medicated soaps are sufficient,[566] and the procedure is necessary only upon entering the operating theatre: repeating handrubbing without prior handwash or scrub is recommended before switching to the next procedure.

13.5.1 Technique for the application of surgical hand preparation using alcohol-based handrub

The application technique has not been standardized throughout the world. The WHO approach for surgical hand preparation requires the six basic steps for the hands as for hygienic hand antisepsis, but requires additional steps for rubbing the forearms (Figure I.13.1). This simple procedure appears not to require training, though two studies provide evidence that training significantly improves bacterial killing.[531,567] The hands should be wet from the alcohol-based rub during the whole procedure, which requires approximately 15 ml depending on the size of the hands. One study demonstrated that keeping the hands wet with the rub is more important than the volume used.[568] The size of the hands and forearms ultimately determines the volume required to keep the skin area wet during the entire time of the handrub. Once the forearms and hands have been treated with an emphasis on the forearms – usually for approximately 1 minute – the second part of the surgical handrub should focus on the hands, following the identical technique as outlined for the hygienic handrub. The hands should be kept above the elbows during this step.

13.5.2 Required time for the procedure

For many years, surgical staff frequently scrubbed their hands for 10 minutes preoperatively, which frequently led to skin damage. Several studies have demonstrated that scrubbing for 5 minutes reduces bacterial counts as effectively as a 10-minute scrub.[284,511,512] In other studies, scrubbing for 2 or 3 minutes reduced bacterial counts to acceptable levels.[378,380,460,529,541,542] Surgical hand antisepsis using an alcohol-based handrub required 3 minutes, following the reference method outlined in EN 12791. Very recently, even 90 seconds of rub have been shown to be equivalent to a 3-minute rub with a product containing a mixture of iso- and n-propanol and mecetronium etilsulfate[557] when tested with healthy volunteers in an in vivo experiment. These results were corroborated in a similar study performed under clinical conditions with 32 surgeons.[569]

Alcohol-based hand gels should not be used unless they pass the test EN 12791 or an equivalent standard, e.g. FDA TFM 1994, required for handrub formulations.[533] Many of the currently available gels for hygienic handrub do not meet the European standard EN 1500.[203] The technique to apply the alcohol-based handrub defined by EN 1500 matches the one defined by EN 12791. The latter requires an additional rub of the forearms that is not required for the hygienic handrub (Figure I.13.1). At least one gel on the market has been tested and introduced in a hospital for hygienic hand antisepsis and surgical hand preparation that meets EN 12791,[570] and several gels meet the FDA TFM standard.[482] As mentioned above, the minimal killing is not defined and, therefore, the interpretation of the effectiveness remains elusive.

In summary, the time required for surgical alcohol-based handrubbing depends on the compound used. Most commercially available products recommend a 3-minute exposure, although the application time may be longer for some formulations, but can be shortened to 1.5 minutes for a few of them. The manufacturer of the product must provide recommendations as to how long the product must be applied. Manufacturer's recommendations should be based on in vivo evidence at least, considering that clinical effectiveness testing is unrealistic.

13.6 Surgical handscrub with medicated soap or surgical hand preparation with alcohol-based formulations

Both methods are suitable for the prevention of SSIs. However, although medicated soaps have been and are still used by many surgical teams worldwide for presurgical hand preparation, it is important to note that the antibacterial efficacy of products containing high concentrations of alcohol by far surpasses that of any medicated soap presently available (see Part I, section 13.5). In addition, the initial reduction of the resident skin flora is so rapid and effective that bacterial regrowth to baseline on the gloved hand takes more than six hours. [227] This makes the demand for a sustained effect of a product superfluous. For this reason, preference should be given to alcohol-based products. Furthermore, several factors including rapid action, time savings, less side-effects, and no risk of recontamination by rinsing hands with water, clearly favour the use of presurgical handrubbing. Nevertheless, some surgeons consider the time taken for surgical handscrub as a ritual for the preparation of the intervention[571] and a switch from handscrub to handrub must be prepared with caution. In countries with limited resources, particularly when the availability, quantity or quality of water is doubtful, the current panel of experts clearly favours the use of alcohol-based handrub for presurgical hand preparation also for this reason.

Table I.13.1
Steps before starting surgical hand preparation

Key steps
• Keep nails short and pay attention to them when washing your hands – most microbes on hands come from beneath the fingernails.
• Do not wear artificial nails or nail polish.
• Remove all jewellery (rings, watches, bracelets) before entering the operating theatre.
• Wash hands and arms with a non-medicated soap before entering the operating theatre area or if hands are visibly soiled.
• Clean subungual areas with a nail file. Nailbrushes should not be used as they may damage the skin and encourage shedding of cells. If used, nailbrushes must be sterile, once only (single use). Reusable autoclavable nail brushes are on the market.

Table I.13.2
Protocol for surgical scrub with a medicated soap

Procedural steps
• Start timing. Scrub each side of each finger, between the fingers, and the back and front of the hand for 2 minutes.
• Proceed to scrub the arms, keeping the hand higher than the arm at all times. This helps to avoid recontamination of the hands by water from the elbows and prevents bacteria-laden soap and water from contaminating the hands.
• Wash each side of the arm from wrist to the elbow for 1 minute.
• Repeat the process on the other hand and arm, keeping hands above elbows at all times. If the hand touches anything at any time, the scrub must be lengthened by 1 minute for the area that has been contaminated.
• Rinse hands and arms by passing them through the water in one direction only, from fingertips to elbow. Do not move the arm back and forth through the water.
• Proceed to the operating theatre holding hands above elbows.
• At all times during the scrub procedure, care should be taken not to splash water onto surgical attire.
• Once in the operating theatre, hands and arms should be dried using a sterile towel and aseptic technique before donning gown and gloves.

Figure I.13.1

Surgical hand preparation technique with an alcohol-based handrub formulation

The handrubbing technique for surgical hand preparation must be performed on perfectly clean, dry hands.
On arrival in the operating theatre and after having donned theatre clothing (cap/hat/bonnet and mask), hands must be washed with soap and water.
After the operation when removing gloves, hands must be rubbed with an alcohol-based formulation or washed with soap and water if any residual talc or biological fluids are present (e.g. the glove is punctured).

Surgical procedures may be carried out one after the other without the need for handwashing, provided that the handrubbing technique for surgical hand preparation is followed (Images 1 to 17).

1

Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your left hand, using the elbow of your other arm to operate the dispenser

2

Dip the fingertips of your right hand in the handrub to decontaminate under the nails (5 seconds)

3

Images 3–7: Smear the handrub on the right forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10-15 seconds)

4

See legend for Image 3

5

See legend for Image 3

6

See legend for Image 3

7

See legend for Image 3

8

Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your right hand, using the elbow of your other arm to operate the dispenser

9

Dip the fingertips of your left hand in the handrub to decontaminate under the nails (5 seconds)

Figure I.13.1

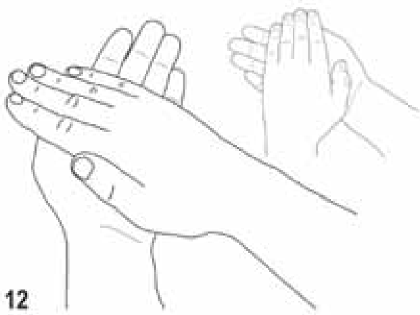
Surgical hand preparation technique with an alcohol-based handrub formulation (Cont.)

10

Smear the handrub on the left forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10-15 seconds)

11

Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your left hand, using the elbow of your other arm to operate the distributor. Rub both hands at the same time up to the wrists, and ensure that all the steps represented in Images 12-17 are followed (20-30 seconds)



12

Cover the whole surface of the hands up to the wrist with alcohol-based handrub, rubbing palm against palm with a rotating movement

13

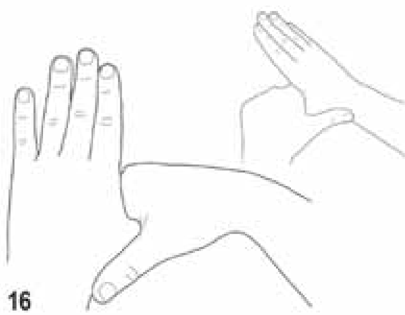
Rub the back of the left hand, including the wrist, moving the right palm back and forth, and vice-versa

14

Rub palm against palm back and forth with fingers interlinked

15

Rub the back of the fingers by holding them in the palm of the other hand with a sideways back and forth movement



16

Rub the thumb of the left hand by rotating it in the clasped palm of the right hand and vice versa

17

When the hands are dry, sterile surgical clothing and gloves can be donned

Repeat the above-illustrated sequence (average duration, 60 sec) according to the number of times corresponding to the total duration recommended by the manufacturer for surgical hand preparation with an alcohol-based handrub.

14.

Skin reactions related to hand hygiene

There are two major types of skin reactions associated with hand hygiene. The first and most common type includes symptoms that can vary from quite mild to debilitating, including dryness, irritation, itching, and even cracking and bleeding. This array of symptoms is referred to as irritant contact dermatitis. The second type of skin reaction, allergic contact dermatitis, is rare and represents an allergy to some ingredient in a hand hygiene product. Symptoms of allergic contact dermatitis can also range from mild and localized to severe and generalized. In its most serious form, allergic contact dermatitis may be associated with respiratory distress and other symptoms of anaphylaxis. Therefore it is sometimes difficult to differentiate between the two conditions. HCWs with skin reactions or complaints related to hand hygiene should have access to an appropriate referral service.

14.1 Frequency and pathophysiology of irritant contact dermatitis

Irritant contact dermatitis is extremely common among nurses, ranging in prevalence surveys from 25% to 55%, and as many as 85% relate a history of having skin problems.[572,573] Frequent and repeated use of hand hygiene products, particularly soaps and other detergents, is an important cause of chronic irritant contact dermatitis among HCWs.[574] Cutaneous adverse reaction was infrequent among HCWs (13/2750 exposed HCWs) exposed to an alcohol-based preparation containing chlorhexidine gluconate and skin emollient during a hand hygiene culture change, multimodal programme;[548] it represented one cutaneous adverse event per 72 years of HCW exposure. The potential of detergents to cause skin irritation varies considerably and can be reduced by the addition of humectants. Irritation associated with antimicrobial soaps may be attributable to the antimicrobial agent or to other ingredients of the formulation. Affected HCWs often complain of a feeling of dryness or burning, skin that feels “rough”, and erythema, scaling or fissures. An example of a hand skin self-assessment tool is given in Appendix 3. In addition, two similar protocols to assess skin tolerance and product acceptability by HCWs after use of an alcohol-based handrub are included in the Implementation Toolkit of the WHO Multimodal Hand Hygiene Improvement Strategy.[575] The method is based on: 1) objective evaluation of dermal tolerance by an investigator using a validated scale; 2) subjective evaluation by the HCW of his/her own skin conditions and of the product characteristics. The simpler protocol is meant to be used to assess a single product in the short term (3–5 days after use) and in the longer term (1 month after use); it is easy to implement under ordinary conditions. A more investigational protocol has been designed to make a fast-track comparison of two or more products using a double-blind, randomized, cross-over methodology.[504]

Hand hygiene products damage the skin by causing denaturation of *stratum corneum* proteins, changes in intercellular lipids (either depletion or reorganization of lipid moieties), decreased corneocyte cohesion and decreased *stratum corneum* water-binding capacity.[574,576] Among these, the main concern is the depletion of the lipid barrier that may be consequent to contact with lipid-emulsifying detergents and lipid-dissolving alcohols.[577] Frequent handwashing leads to progressive depletion of surface lipids with resulting deeper action of detergents into the superficial skin layers. During dry seasons and in individuals with dry skin, this lipid depletion occurs more quickly.[577] Damage to the skin also changes skin flora, resulting in more frequent colonization by staphylococci and Gram-negative bacilli.[79,219]

Although alcohols are safer than detergents,[262] they can cause dryness and skin irritation.[48,578] The lipid-dissolving effect of alcohols is inversely related to their concentration,[577] and ethanol tends to be less irritating than n-propanol or isopropanol.[578] Numerous reports confirm that alcohol-based formulations are well tolerated and often associated with better acceptability and tolerance than other hand hygiene products.[504,548,579-584]

In general, irritant contact dermatitis is more commonly reported with iodophors[220] Other antiseptic agents that may cause irritant contact dermatitis, in order of decreasing frequency, include chlorhexidine, chloroxylenol, triclosan, and alcohol-based products. Skin that is damaged by repeated exposure to detergents may be more susceptible to irritation by all types of hand antisepsis formulations, including alcohol-based preparations.[585] Graham and colleagues reported low rates of cutaneous adverse reactions to an alcohol-based handrub (isopropyl alcohol 70%) formulation containing chlorhexidine (0.5%) with emollient.[548]

Information regarding the irritancy potential of commercially prepared hand hygiene products, which is often determined by measuring the transepidermal water loss of persons using the preparation, may be available from the manufacturer. Other factors that may contribute to dermatitis associated with frequent hand cleansing include using hot water for handwashing, low relative humidity (most common in winter months in the northern hemisphere), failure to use supplementary hand lotion or cream, and perhaps the quality of paper towels.[586,587] Shear forces associated with wearing or removing gloves and allergy to latex proteins may also contribute to dermatitis of the hands of HCWs.[577]

In a recent study conducted among ICU HCWs, the short-term skin tolerability and acceptability of the WHO-recommended alcohol-based formulations (see Section 12) were significantly higher than those of a reference product.[504] Risk factors identified for skin alteration following handrub use were male sex, fair and very fair skin, and skin alteration before use.

14.2 Allergic contact dermatitis related to hand hygiene products

Allergic reactions to products applied to the skin (contact allergy) may present as delayed type reactions (allergic contact dermatitis) or less commonly as immediate reactions (contact urticaria). The most common causes of contact allergies are fragrances and preservatives, with emulsifiers being less common.[588-591] Liquid soaps, hand lotion, ointments or creams used by HCWs may contain ingredients that cause contact allergies.[589,590]

Allergic reactions to antiseptic agents including QAC, iodine or iodophors, chlorhexidine, triclosan, chloroxylenol and alcohols[285,330,332,339,588,592-597] have been reported, as well as possible toxicity in relation to dermal absorption of products.[598,599] Allergic contact dermatitis attributable to alcohol-based handrubs is very uncommon. Surveillance at a large hospital in Switzerland where a commercial alcohol-based handrub has been used for more than 10 years failed to identify a single case of documented allergy to the product.[484] In late 2001, a Freedom of Information Request for data in the FDA's Adverse Event Reporting System regarding adverse reactions to popular alcohol-based handrubs in the USA yielded only one reported case of an erythematous rash reaction attributed to such a product (J. M. Boyce, personal communication). However, with the increasing use of such products by HCWs, it is likely that true allergic reactions to such products will occasionally be encountered. There are a few reports of allergic dermatitis resulting from contact with ethyl alcohol[600-602] and one report of ethanol-related contact urticaria syndrome.[331] More recently, Cimiotti and colleagues reported adverse reactions associated with an alcohol-based handrub preparation. In most cases, nurses who had symptoms were able to resume use of the product after a brief hiatus.[332] This study raises the alert for possible skin reactions to alcohol-based handrub preparations. In contrast, in a double-blind trial by Kampf and colleagues[582] of 27 persons with atopic dermatitis, there were no significant differences in the tolerability of alcohol-based handrubs when compared with normal controls.

Allergic reactions to alcohol-based formulations may represent true allergy to the alcohol, or allergy to an impurity or aldehyde metabolite, or allergy to another product constituent.[330] Allergic contact dermatitis or immediate contact urticarial reactions may be caused by ethanol or isopropanol.[330] Allergic reactions may be caused by compounds that may be present as inactive ingredients in alcohol-based handrubs, including fragrances, benzyl alcohol, stearyl or isostearyl alcohol, phenoxyethanol, myristyl alcohol, propylene glycol, parabens, or benzalkonium chloride.[330,491,588,603-606]

14.3 Methods to reduce adverse effects of agents

There are three primary strategies for minimizing hand hygiene-related irritant contact dermatitis among HCWs: selecting less irritating hand hygiene products; avoiding certain practices that increase the risk of skin irritation; and using moisturizing skin care products following hand cleansing.[607]

14.3.1 Selecting less irritating products

Because HCWs must clean hands frequently, it is important for health-care facilities to provide products that are both efficacious and as safe as possible for the skin. The tendency of products to cause skin irritation and dryness is a major factor influencing their acceptance and ultimate use by HCWs.[137,264,608-611] For example, concern about the drying effects of alcohol was a major cause of poor acceptance of alcohol-based handrubs in hospitals.[313,612] Although many hospitals have provided HCWs with plain soaps in the hope of minimizing dermatitis, frequent use of such products has been associated with even greater skin damage, dryness and irritation than some antiseptic preparations.[220,262,264] One strategy for reducing exposure of HCWs to irritating soaps and detergents is to promote the use of alcohol-based handrubs containing humectants. Several studies have demonstrated that such products are tolerated better by HCWs and are associated with a better skin condition when compared with either plain or antimicrobial soap.[60,262,264,326,329,486,577,613,614] With rubs, the shorter time required for hand antisepsis may increase acceptability and compliance.[615] In settings where the water supply is unsafe, waterless hand antisepsis presents additional advantages over soap and water.[616]

14.3.2 Reducing skin irritation

Certain hand hygiene practices can increase the risk of skin irritation and should be avoided. For example, washing hands regularly with soap and water immediately before or after using an alcohol-based product is not only unnecessary, but may lead to dermatitis.[617] Additionally, donning gloves while hands are still wet from either washing or applying alcohol increases the risk of skin irritation. For these reasons, HCWs should be reminded not to wash their hands before or after applying alcohol and to allow their hands to dry completely before donning gloves. A recent study demonstrated that HCW education regarding proper skin care management was effective in preventing occupational skin disorders.[618] No product, however, is free of potential risk. Hence, it is usually necessary to provide an alternative for use by individuals with sensitivity or reactions to the hand hygiene product available in the institution.

14.3.3 Use of moisturizing skin care products

The effects of hand hygiene products on skin vary considerably, depending upon factors such as the weather and environmental conditions. For example, in tropical countries and during the summer months in temperate climates, the skin remains more moisturized than in cold, dry environments. The effects of products also vary by skin type. In one recent study, nurses with darker skin were rated as having significantly healthier skin and less skin irritation than nurses with light skin, both by their own self-assessment as well as by observer rating.[619] Results of a prevalence survey of 282 Chinese hospital nurses suggested that hand dermatitis was less common among this group when compared with those in other parts of the world.[620] In contrast, the reported prevalence of dermatitis was 53.3% in a survey of 860 Japanese nurses, and the use of hand cream was associated with a 50% reduction.[621] The need for moisturizing products will thus vary across health-care settings, geographical locations and respective climate conditions, and individuals.

For HCWs at risk of irritant contact dermatitis or other adverse reactions to hand hygiene products, additional skin moisturizing may be needed. Hand lotions and creams often contain humectants, fats, and oils that increase skin hydration and replace altered or depleted skin lipids that contribute to the barrier function of the skin.[576,622] Several controlled trials have shown that regular use of such products can help prevent and treat irritant contact dermatitis caused by hand hygiene products.[623-627]

Importantly, in a trial by McCormick and colleagues,[624] improved skin condition resulting from the frequent and scheduled use of an oil-containing lotion led to a 50% increase in hand cleansing frequency among HCWs. These investigators emphasized the need to educate HCWs regarding the value of regular, frequent use of hand-care products. However, most hand moisturizing agents are not sterile and thus may easily become contaminated; they have been associated also with outbreaks in the neonatal ICU setting.[628] In particular, if the lotion is poured from a large bottle into smaller bottles, the smaller containers should be washed and disinfected between uses and not topped up.

Recently, barrier creams have been marketed for the prevention of hand hygiene-related irritant contact dermatitis. Such products are absorbed into the superficial layers of the epidermis and are designed to form a protective layer that is not removed by standard hand cleansing. Evidence of the efficacy of such products, however, is equivocal.[623,624,629] Furthermore, such products are expensive, so their use in health-care settings, particularly when resources are limited, cannot be recommended at present. Whether the use of basic, oil-containing products, not specifically manufactured for hand skin protection, would have similar efficacy as currently available manufactured agents remains to be determined.

Frequent wearing of gloves can increase the risk of skin problems. In a study among healthy volunteers, when a moisturizer was applied prior to wearing occlusive gloves, there was a statistically significant improvement in skin hydration.[630] More recently, an examination glove coated with aloe vera resulted in improved skin integrity and decreased erythema in 30 women with occupational dry skin.[631] Nevertheless, such products cannot yet be recommended as field trials, larger sample sizes, and cost analyses are needed.

In addition to evaluating the efficacy and acceptability of hand-care products, product selection committees should inquire about potential deleterious effects that oil-containing products may have on the integrity of rubber gloves and on the efficacy of antiseptic agents used in the facility,[204,632] as well as the fact that, as previously mentioned, most of these products are not sterile and can easily become contaminated.

15.

Factors to consider when selecting hand hygiene products

To achieve a high rate of hand hygiene adherence, HCWs need education, clear guidelines, some understanding of infectious disease risk, and acceptable hand hygiene products.[60,197,492,608,609,613,633,634] The selection of hand hygiene products is a key component of hand hygiene promotion, and at the same time a difficult task. The selection strategy requires the presence of a multidisciplinary team (e.g. infection control and prevention professionals, occupational disease professionals, administrative staff, pharmacists, and behavioural scientists) and efforts to evaluate factors related to hand hygiene products and to conduct clinical pilot projects to test these factors.[48,58,351,607,610,635,636] The major determinants for product selection are antimicrobial profile, user acceptance, and cost. A decision-making tool for the selection of an appropriate product is available within the Implementation Toolkit (http://www.who.int/gpsc/en/). The antimicrobial efficacy of hand hygiene agents is provided by in vitro and in vivo studies (see Part I, Section 10) which are reproducible and can be generalized. Pilot studies aiming to help select products at the local level should mainly concentrate on tolerance and user acceptability issues. Other aspects such as continuous availability, storage, and costs should also be taken into account on a local basis, so as to guarantee feasibility and sustainability.

15.1 Pilot testing

Pilot testing to assess acceptability is strongly recommended before final selection, aiming at fostering a system change and involving the users in the selection of the product they like most and therefore are most likely to use. Characteristics that can affect HCWs' acceptance of a hand hygiene product include dermal tolerance and skin reactions to the product, and its characteristics such as fragrance, consistency, and colour,[220,493,504,598,610] Structured, self-administered questionnaires may be useful tools to assess HCWs' acceptability of hand hygiene products. A standardized and validated survey to evaluate acceptability and tolerability among HCWs is available within the Implementation Toolkit (http://www.who.int/gpsc/en/). Such tools should be adapted to the local setting because of differences in sociocultural backgrounds, climate and environmental conditions, and clinical practices among users. Skin reactions to hand hygiene products may be increased by low relative humidity. For example, dry weather during winter months in the northern hemisphere should be taken into account during pilot testing, and the introduction of new products during dry and cold periods with low relative humidity should be avoided. For an efficient test, more than one product should be compared, if possible with products already in use. Each product should be tested by several users for at least 2–3 weeks. A fast track method comparing different products (including the WHO formulations) was tested and validated in high intensity users, such as nurses in intensive care, emergency rooms or postoperative rooms, by the First Global Patient Safety Challenge team.[504] The detailed protocol can be obtained from WHO upon request. If comparison is not possible, at least the pre-selected product should be tested for tolerance and acceptance with the above-mentioned tool. Dryness and irritation should be assessed with sufficient numbers of HCWs to ensure that the results can be generalized. If more than one new product is to be tested, either a period with the routine product or, preferably, a minimum of a 2-day washout period should be observed between test periods.[504,579] When considering the replacement of a product, the new product should be at least as good as the previous one. An inferior product could be responsible for a decrease in hand hygiene compliance. After careful evaluation of suitable hand hygiene agents, HCWs should be given the option to choose themselves the product for use at their institution. Freedom of choice at an institutional level was rated the second most important feature reported by HCWs to improve hand hygiene compliance in the audit of a successful promotion programme in Victoria, Australia.[494] Prior to product pilot testing, the appropriate administrative decision-makers in the institution should determine which products have demonstrated efficacy and which ones can be purchased at the best cost. Only products that have already been identified as efficacious and affordable should be tested by HCWs.

15.2 Selection factors

Factors to be taken into consideration for product selection include:

- relative efficacy of antiseptic agents (see Part I, Section 10) and consideration for selection of products for hygienic hand antisepsis and surgical hand preparation;
- dermal tolerance and skin reactions;
- cost issues;
- aesthetic preferences of HCWs and patients such as fragrance, colour, texture, "stickiness", and ease of use;
- practical considerations such as availability, convenience and functioning of dispenser, and ability to prevent contamination;
- time for drying (consider that different products are associated with different drying times; products that require longer drying times may affect hand hygiene best practice);
- freedom of choice by HCWs at an institutional level after consideration of the above-mentioned factors.

15.2.1 Dermal tolerance and skin reactions

Several studies have published methods to evaluate dermal tolerance such as dryness or irritation[220,577], either by self-assessment or by expert clinical evaluation[197,221,264,326,327,329,405,495,504,608,610,613,636] (see Part I, Section 14). Some studies have confirmed that these assessment techniques correlate well with other physiological measures such as transepidermal water loss or desquamation, tests which are not practical to use in clinical settings.[264,326,405,495,549,577,613,636] An example of a tolerability assessment framework for use in the clinical setting is included in Appendix 3[220,504,572] and is part of the WHO alcohol-based handrub tolerability and acceptability survey (Implementation Toolkit available at http://www.who.int/gpsc/en/) (see also Part I, Section 14). Dermal tolerance is one of the main parameters leading to the product acceptability by HCWs that influences directly the compliance with hand hygiene. It is demonstrated that dermal tolerance of alcohol-based handrubs is related to the addition and the quality of emollient in the product;[504,580,627] even alcohols, frequently used in alcohol-based handrubs, are known to generate a minor skin irritant effect compared with handwashing with soap and water.[548,583]

15.2.2 Aesthetic preferences

Fragrance.
Products with a strong fragrance may lead to discomfort and respiratory symptoms in some HCWs allergic to perfume or fragrances. Many patients complain about perfumed products, especially in oncology. Therefore, consideration should be given to selecting a product with mild or no added fragrances.

Consistency (texture).
Handrubs are available as gels, solutions or foams. Dermal tolerance and efficacy were not considered as they are not affected by consistency.[203,495] Although more expensive than solutions, gels have recently become the most popular type of alcohol-based handrub preparation in many countries. Due to their formulations, some gels may produce a feeling of humectant “build-up”, or the hands may feel slippery or oily with repeated use. This difference in consistency has not been associated with better objective tolerance or higher compliance with hand cleansing in a controlled study.[579] A prospective intervention study and a comparison study have shown that the use of a gel formulation was associated with better skin condition, superior acceptance, and a trend towards improved compliance.[493,496] Nevertheless, it is worth recalling that first generations of gel formulations have reduced antimicrobial efficacy compared with solutions.[205,218] A recent study suggests that the antibacterial efficacy of alcohol-based gels may depend mainly on concentration and type of alcohol in the formulation.[496]

Solutions generally have a consistency similar to water while some are slightly viscous. They often dry more quickly than gels or foams (a potential advantage) and may be less likely to produce a feeling of humectant “build-up”. They are more likely to drip from the hands onto to the floor during use, and it has been reported that these drips have created spots on the floor under the dispensers in some hospitals. Solutions often have a stronger smell of alcohol than do gels.[495,636]

Foams are used less frequently and are more expensive. Similar to gels, they are less likely to drip from the hands onto the floor during application, but may produce stronger “build-up” feeling with repeated use and may take longer to dry. Some manufacturers of foams recommend the use of a relatively large amount of product for each application, and HCWs should be reminded to follow the manufacturer’s recommendation.

15.2.3 Practical considerations

Product accessibility.
Several studies suggest that the frequency of hand cleansing is determined by the accessibility of hand hygiene facilities.[335,486,492,493,497,498,637-639] A reliable supplier (industrial or local at the health-care facility) is essential to ensure a continuous supply of products. If industrial products are not available or are too expensive, products may be produced within the local setting (see also Part I, Section 12). WHO identified and validated two different alcohol-based formulations, and a Guide to Local Production (Implementation Toolkit, available at http://www.who.int/gpsc/en/). However, even if a simple method is proposed, it is difficult to regulate the quality control of locally made products, and more sophisticated but feasible methods to monitor quality are needed.

Issues related to infrastructure necessary to ensure continuous access to hand hygiene products and equipment are specifically dealt with in Part I, Section 23.5.

Risk of contamination.
Alcohol-based rubs have a low risk of contamination,[338] but soap contamination is more common.[160,640-644] Multiple-use bar soap should be avoided because it is difficult to store bar soap dry at a sink, with a subsequent increase in the risk of contamination.[640-642] Although liquid soaps are generally preferred over bar soaps for handwash, the risk for either intrinsic[643] or extrinsic[160,644] microbial contamination still exists.

15.2.4 Cost

The promotion of hand hygiene is highly cost effective (see Part III, Section 3), and the introduction of a waterless system for hand hygiene is a cost-effective measure.[329,645,646] While the cost of hand hygiene products will continue to be an important issue for departments responsible for purchasing such products, the level of acceptance of products by HCWs is even more important. An inexpensive product with undesirable characteristics may discourage hand hygiene among HCWs and the resulting poor compliance will not be cost effective.

Financial strategies to support programmes designed to improve hand hygiene across a nation may benefit from a centralized design and production of supporting materials. This strategy may be more cost effective to the overall health economy (see also Part III, Section 3).

16.

Hand hygiene practices among health-care workers and adherence to recommendations

16.1 Hand hygiene practices among health-care workers

Understanding hand hygiene practices among HCWs is essential in planning interventions in health care. In observational studies conducted in hospitals, HCWs cleaned their hands on average from 5 to as many as 42 times per shift and 1.7–15.2 times per hour (Table I.16.1).[79,137,217-219,262,264,611,613,623,624,647-655] The average frequency of hand hygiene episodes fluctuates with the method used for monitoring (see Part III, Section 1.1) and the setting where the observations were conducted; it ranges from 0.7 to 30 episodes per hour (Table I.16.1). On the other hand, the average number of opportunities for hand hygiene per HCW varies markedly between hospital wards; nurses in paediatric wards, for example, had an average of eight opportunities for hand hygiene per hour of patient care, compared with an average of 30 for nurses in ICUs.[334,656] In some acute clinical situations, the patient is cared for by several HCWs at the same time and, on average, as many as 82 hand hygiene opportunities per patient per hour of care have been observed at post-anaesthesia care unit admission.[652] The number of opportunities for hand hygiene depends largely on the process of care provided: revision of protocols for patient care may reduce unnecessary contacts and, consequently, hand hygiene opportunities.[657]

In 11 observational studies, the duration of hand cleansing episodes by HCWs ranged on average from as short as 6.6 seconds to 30 seconds. In 10 of these studies, the hand hygiene technique monitored was handwashing,[79,124,135,213-216,218,572,611] while handrubbing was monitored in one study.[457].In addition to washing their hands for very short time periods, HCWs often failed to cover all surfaces of their hands and fingers.[611,658] In summary, the number of hand hygiene opportunities per hour of care may be very high and, even if the hand hygiene compliance is high too, the applied technique may be inadequate.

16.2 Observed adherence to hand cleansing

Adherence of HCWs to recommended hand hygiene procedures has been reported with very variable figures, in some cases unacceptably poor, with mean baseline rates ranging from 5% to 89%, representing an overall average of 38.7% (Table I.16.2).[60,140,215,216,334,335,485,486,492,493,496,497,613,633,637,648-651,654,655,657,659-711] It should be pointed out that the methods for defining adherence (or non-adherence) and the methods for conducting observations varied considerably in the reported studies, and many articles did not include detailed information about the methods and criteria used. Some studies assessed compliance with hand hygiene concerning the same patient,[60,334,648,652,666,667,683,685-687] and an increasing number have recently evaluated hand hygiene compliance after contact with the patient environment.[60,334,648,652,654,657,670,682,683,686,687,691,698,700-702,704,707-709,711 ,712]

A number of investigators reported improved adherence after implementing various interventions, but most studies had short follow-up periods and did not establish if improvements were of long duration. Few studies reported sustained improvement as a consequence of the long-running implementation of programmes aimed at promoting optimal adherence to hand hygiene policies.[60,494,657,713-719]

16.3 Factors affecting adherence

Factors that may influence hand hygiene include risk factors for non-adherence identified in epidemiological studies and reasons reported by HCWs for lack of adherence to hand hygiene recommendations.

Risk factors for poor adherence to hand hygiene have been determined objectively in several observational studies or interventions to improve adherence.[608,656,663,666,720-725] Among these, being a doctor or a nursing assistant, rather than a nurse, was consistently associated with reduced adherence. In addition, compliance with hand cleansing may vary among doctors from different specialities.[335] Table I.16.3 lists the major factors identified in observational studies of hand hygiene behaviour in health care.

In a landmark study,[656] the investigators identified hospitalwide predictors of poor adherence to recommended hand hygiene measures during routine patient care. Predicting variables included professional category, hospital ward, time of day/week, and type and intensity of patient care, defined as the number of opportunities for hand hygiene per hour of patient care. In 2834 observed opportunities for hand hygiene, average adherence was 48%. In multivariate analysis, non-adherence was the lowest among nurses compared with other HCWs and during weekends. Non-adherence was higher in ICUs compared with internal medicine, during procedures that carried a high risk of bacterial contamination, and when intensity of patient care was high. In other words, the higher the demand for hand hygiene, the lower the adherence. The lowest adherence rate (36%) was found in ICUs, where indications for hand hygiene were typically more frequent (on average, 22 opportunities per patient-hour). The highest adherence rate (59%) was observed in paediatrics, where the average intensity of patient care was lower than elsewhere (on average, eight opportunities per patient-hour). The results of this study suggested that full adherence to previous guidelines was unrealistic and that easy access to hand hygiene at the point of patient care, i.e. in particular through alcohol-based handrubbing, could help improve adherence,[615,656,720] Three recent publications evaluating the implementation of the CDC hand hygiene guidelines[58] in the USA tend to concur with these results and considerations.[726-728] Various other studies have confirmed an inverse relation between intensity of patient care and adherence to hand hygiene.[60,334,335,493,649,652,653,656,689,729,730]

Perceived barriers to adherence with hand hygiene practice recommendations include skin irritation caused by hand hygiene agents, inaccessible hand hygiene supplies, interference with HCW–patient relationships, patient needs perceived as a priority over hand hygiene, wearing of gloves, forgetfulness, lack of knowledge of guidelines, insufficient time for hand hygiene, high workload and understaffing, and the lack of scientific information showing a definitive impact of improved hand hygiene on HCAI rates.[608,656,663,666,722-725,729,731,732] Some of the perceived barriers to adherence with hand hygiene guidelines have been assessed or quantified in observational studies.[608,663,666,720,722-724] Table I.16.3 lists the most frequently reported reasons that are possibly, or effectively, associated with poor adherence. Some of these barriers are discussed in Part I, Section 14 (i.e. skin irritation, no easy access to hand hygiene supplies), and in Part I, Section 23.1 (i.e. impact of use of gloves on hand hygiene practices).

Lack of knowledge of guidelines for hand hygiene, lack of recognition of hand hygiene opportunities during patient care, and lack of awareness of the risk of cross-transmission of pathogens are barriers to good hand hygiene practices. Furthermore, some HCWs believed that they washed their hands when necessary even when observations indicated that they did not.[218,220,666,667,676,733]

Additional perceived barriers to hand hygiene behaviour are listed in Table I.16.3. These are relevant not only on the institutional level, but also to particular HCWs or HCW groups.

Table I.16.1
Frequency of hand hygiene actions among health-care workers

Reference	Year of publication	Average no. of hand hygiene actions
Ayliffe et al.[137]	1988	5 per 8 hours
Broughall[218]	1984	5–10 per shift
Winnefeld et al.[262]	2000	10 per shift
McCormick, Buchman & Maki[624]	2000	13.1–15.9 per day*
Boyce, Kelliher & Vallande[264]	2000	1.7 per hour*
Boyce, Kelliher & Vallande[264]	2000	1.8 per hour**
Ojajarvi, Makela & Rantasalo[219]	1977	20–42 per 8-hour shift*
Larson et al.[647]	2000	1.8 per hour*
Larson et al.[647]	2000	2.0 per hour
Berndt et al.[623]	2000	22 per day
Larson et al.[217]	1991	1.7–2.1 per hour
Larson et al.[79]	1998	2.1 per hour*
Lam, Lee & Lau[648]	2004	2.2 per hour*
Taylor[611]	1978	3 per hour
Gould[649]	1994	3.3 per hour
Girard, Amazian & Fabry[613]	2001	3.5 per hour
Noritomi et al.[650]	2007	6.3 per hour
Rosenthal et al.[651]	2003	9.9 per hour*
Pittet et al.[652]	2003	4.4 per hour
Harbarth et al.[653]	2001	12 per hour
Larson, Albrecht & O'Keefe[654]	2005	7.0 per hour
Girou et al.[655]	2006	15.2 per hour

* Handwashing only reported in the study.
** Handrubbing only reported in the study.

Table I.16.2

Hand hygiene adherence by health-care workers (1981–June 2008)

Reference	Year	Setting	Before/ after contact	Adherence baseline (%)	Adherence after intervention (%)	Intervention
Preston, Larson & Stamm[492]	1981	ICU	A	16	30	More convenient sink locations
Albert & Condie[660]	1981	ICU	A	41	—	—
Preston, Larson & Stamm[492]	1981	ICU	A	28	—	—
Larson[661]	1983	All wards	A	45	—	—
Kaplan & McGuckin[497]	1986	SICU	A	51	—	—
Mayer et al.[633]	1986	ICU	A	63	92	Performance feedback
Donowitz[662]	1987	PICU	A	31	30	Wearing overgown
Conly et al.[663]	1989	MICU	B/A	14/28 *	73/81	Feedback, policy reviews, memo, posters
DeCarvalho et al.[734]	1989	NICU	A/B	75/50	—	—
Graham[665]	1990	ICU	A	32	45	Alcohol-based handrub introduced
Dubbert et al.[666]	1990	ICU	A**	81	92	In-service first, then group feedback
Simmons et al.[667]	1990	ICU	B/A**	22	30	—
Pettinger & Nettleman[668]	1991	SICU	A	51	—	—
Lohr et al.[669]	1991	Pedi OPDs	B	49	49	Signs, feedback, verbal reminders to doctors
Raju & Kobler[670]	1991	Nursery & NICU	B/A ***	28	63	Feedback, dissemination of literature, results of environmental cultures
Larson et al.[671]	1992	NICU/ others	A	29	—	—
Doebbeling et al.[659]	1992	ICU	NS	40	—	—
Zimakoff et al.[672]	1993	ICUs	A	40	—	—
Meengs et al.[216]	1994	Emerg Room	A	32	—	—
Lund et al.[215]	1994	All wards	A	32	—	—
Wurtz, Moye & Jovanovic[637]	1994	SICU	A	22	38	Automated handwashing machines available
Pelke et al.[673]	1994	NICU	A	62	60	No gowning required
Gould[649]	1994	ICUs Wards	A A	30 29	—	—
Shay et al.[674]	1995	ICU Oncol Ward	A	56	—	—
Berg, Hershow & Ramirez[675]	1995	ICU	NS	5	63	Lectures, feedback, demonstrations
Tibballs[676]	1996	PICU	B/A	12/11	13/65	Overt observation, followed by feedback
Slaughter et al.[677]	1996	MICU	A	41	58	Routine wearing of gowns and gloves

Table I.16.2
Hand hygiene adherence by health-care workers (1981–June 2008) (Cont.)

Reference	Year	Setting	Before/after contact	Adherence baseline (%)	Adherence after intervention (%)	Intervention
Dorsey, Cydulka Emerman[678]	1996	Emerg Dept	A	54	64	Signs/distributed review paper
Larson et al.[684]	1997	ICU	B/A**	56	83	Lectures based on previous questionnaire on HCWs' beliefs, feedback, administrative support, Automated handwashing machines available
Watanakunakorn, Wang & Hazy[679]	1998	All wards	A	30	—	—
Avila-Aguero et al.[680]	1998	Paediat-ric wards	B/A	52/49	74/69	Feedback, films, posters, brochures
Kirkland, Weinstein[681]	1999	MICU	B/A	12/55	—	—
Pittet et al.[60]	2000	All wards	B/A** and ***	48	67	Posters, feedback, administrative support, alcohol rub
Maury et al.[485]	2000	MICU	A	42	61	Alcohol handrub made available
Bischoff et al.[486]	2000	MICU CTICU	B/A B/A	10 / 22 4 / 13	23 / 48 7 / 14	Education, feedback, alcohol gel made available
Muto, Sistrom & Farr[682]	2000	Medical wards	A***	60	52	Education, reminders, alcohol gel made available
Girard, Amazian & Fabry[613]	2001	All wards	B/A	62	67	Education, alcohol gel made available
Karabey et al[685]	2002	ICU	B/A**	15	—	—
Hugonnet, Perneger & Pittet[334]	2002	MICU/ SICU NICU	B/A** and ***	38	55	Posters, feedback, administrative support, alcohol rub
Harbarth et al.[686]	2002	PICU / NICU	B/A** and ***	33	37	Posters, feedback, alcohol rub
Rosenthal et al.[651]	2003	All wards 3 hospi-tals	B/A	17	58	Education, reminders, more sinks made available
Brown et al.[687]	2003	NICU	B/A** and ***	44	48	Education, feedback, alcohol gel made available
Pittet et al.[652]	2003	PACU	B/A** and ***	19.6	—	—
Ng et al.[735]	2004	NICU	B/A***	40	53	Education, reminders
Pittet et al.[335]	2004	Doctors in all wards	B/A** and ***	57	—	—
Kuzu et al.[683]	2005	All wards	B/A** and ***	39	—	—
Arenas et al.[689]	2005	Haemo-dialysis units	B/A and ***	B 13.8 Ar 35.6	—	—
Saba et al.[690]	2005	Haemo-dialysis units*	B/A	26	—	—

Table I.16.2

Hand hygiene adherence by health-care workers (1981–June 2008) (Cont.)

Reference	Year	Setting	Before/ after contact	Adherence baseline (%)	Adherence after intervention (%)	Intervention
Larson, Albrecht & O'Keefe[654]	2005	Pediatric ER and PICU	B/A	38.4	—	—
Jenner et al.[691]	2006	Medical, surgical wards	B/A		—	—
Maury et al.[692]	2006	MICU	NS	47.1	55.2	Announcement of observations (compared to covert observation at baseline)
Furtado et al.[693]	2006	2 MSI-CUs	B/A	22.2 / 42.6	—	—
das Neves et al.[694]	2006	NICU	B/A	62.2	61.2	Posters, musical parodies on radio, slogans
Hayden et al.[140]	2006	MICU	B/A	29	43	Wall dispensers, education, brouchures, buttons, posters
Sacar et al.[695]	2006	Hospital-wide	B/A	45.1	—	—
Berhe, Edmond & Bearman[696]	2006	MICU, SICU	B/A	31.8 / 50	39 / 50.3	Performance feedback
Girou et al.[655]	2006	Rehab institu-tion-wide	B/A	60.8	—	—
Eckmanns et al.[736]	2006	ICU	B/A	29	45	Announcement of observations (compared to covert observation at baseline)
Santana et al.[698]	2007	MSICU	B/A	18.3	20.8	Introduction of alcohol-based handrub dispensers, posters, stickers, education
Swoboda et al.[699]	2007	IMCU	A	19.1	25.6	Voice prompts if failure to handrub
Novoa et al.[700]	2007	Hospital-wide	B/A	20	—	—
Barbut et a.[496]	2007	MICU	B/A	53 / 63 / 68	—	3 different handrub products
Trick et al.[701]	2007	3 study hospi-tals, one control, hospital-wide	A	23 / 30 / 35 / 32	46 / 50 / 43 / 31	Increase in handrub availability, education, poster
Dedrick et al.[702]	2007	ICU	A	45.1	—	—
Noritomi et al.[650]	2007	Multidis-ciplinary ICU	B/A	27.9	—	—
Pan et al.[703]	2007	Hospital-wide	B/A	19.6	—	—

Table I.16.2

Hand hygiene adherence by health-care workers (1981–June 2008) (Cont.)

Reference	Year	Setting	Before/ after contact	Adherence baseline (%)	Adherence after intervention (%)	Intervention
Hofer et al.[704]	2007	Hospital-wide, paediatric hospital	B/A	34	—	—
Raskind et al.[705]	2007	NICU	B	89	100	Education
Traore et al.[493]	2007	MICU	B/A	32.1	41.2	Gel versus liquid handrub formulation
Pessoa-Silva et al.[657]	2007	NICU	B/A	42	55	Posters, focus groups, education, questionnaires, review of care protocols
Khan & Siddiqui[706]	2008	Anaesthesia	A	62	—	—
Rupp et al.[707]	2008	ICU	B/A	38 / 37	69 / 68	Introduction of alcohol-based handrub gel
Ebnother et al.[708]	2008	All wards	B/A	59	79	Multimodal intervention
Haas & Larson[709]	2008	Emerg department	B/A	43	62	Introduction of wearable personal handrub dispeners
Venkatesh et al.[710]	2008	Hematology unit	B/A	36.3	70.1	Voice prompts if failure to handrub
Duggan et al.[711]	2008	Hospital-wide	B/A	84.5	89.4	Announced visit by auditor

ICU = intensive care unit; SICU = surgical ICU; MICU = medical ICU; MSICU = medical/surgical ICU;
PICU = paediatric ICU; NICU = neonatal ICU; Emerg = emergency; Oncol = oncology; CTICU = cardiothoracic ICU; PACU = post-anaesthesia care unit: OPD = outpatient department; NS = not stated.

* Percentage compliance before/after patient contact.

** Hand hygiene opportunities within the same patient also counted.

*** After contact with inanimate objects.

**** Use of gloves almost universal (93%) in all activities.

Table I.16.3

Factors influencing adherence to hand hygiene practices

	Factors for poor adherence / low compliance	References
A.	**Observed risk factors for poor adherence to recommended hand hygiene practices**	
	Doctor status (rather than a nurse)	Pittet & Perneger, 1999[737] Pittet, 2000[738] Pittet et al., 2000[60] Lipsett & Swoboda, 2001[730] Hugonnet, Perneger & Pittet, 2002[334] Rosenthal et al., 2003[651] Zerr et al., 2005[715] Pan et al., 2007[703]
	Nursing assistant status (rather than a nurse)	Pittet & Perneger, 1999[737] Pittet, 2000[738] Lipsett & Swoboda, 2001[730] Hugonnet, Perneger & Pittet, 2002[334] Rosenthal et al., 2003[651] Arenas et al., 2005[689] Novoa et al., 2007[700] Pan et al., 2007[703]
	Physiotherapist	Pan et al., 2007[703]
	Technician	Pittet et al., 2000[60]
	Male sex	Pittet, 2000[738] Rosenthal et al., 2003[651]
	Working in intensive care	Pittet & Perneger, 1999[737] Pittet, 2000[738] O'Boyle, Henly & Larson, 2001[729] Hugonnet, Perneger & Pittet, 2002[334] Rosenthal et al., 2003[651] Pittet et al., 2004[335]
	Working in surgical care unit	Lipsett & Swoboda, 2001[730] Pittet et al., 2004[335] Zerr et al., 2005[715]
	Working in emergency care	Pittet et al., 2004[335]
	Working in anaesthiology	Pittet et al., 2004*(Pittet, 2004 #261}*
	Working during the week (vs. weekend)	Pittet & Perneger, 1999[737] Pittet, 2000[738]
	Wearing gowns/ gloves	Thompson et al., 1997[739] Khatib et al., 1999[740] Pittet, 2000[738] Pessoa-Silva et al., 2007[657]
	Before contact with patient environment	Zerr, 2005[715]
	After contact with patient environment e.g. equipment	Zerr, 2005[715] Pessoa-Silva et al., 2007[657]
	Caring of patients aged less than 65 years old	Pittet et al., 2003[652]
	Caring of patients recovering from clean/clean-contaminated surgery in postanaesthesia care unit	Pittet et al., 2003[652]
	Patient care in non-isolation room	Arenas et al., 2005[689]
	Duration of contact with patient (< or equal to 2 minutes)	Dedrick et al., 2007[702]
	Interruption in patient-care activities	Harbarth et al., 2001[653]
	Automated sink	Larson et al., 1991[217] Pittet, 2000[738]

Table I.16.3

Factors influencing adherence to hand hygiene practices (Cont.)

	Factors for poor adherence / low compliance	References
	Activities with high risk of cross-transmission	Pittet & Perneger, 1999[737] Pittet, 2000[738] Pittet et al., 2000[60] Hugonnet, Perneger & Pittet, 2002[334] Pan et al., 2007[703]
	Understaffing or overcrowding	Haley & Bregman, 1982[741] Pittet & Perneger, 1999[737] Harbarth et al., 1999[185] Pittet, 2000[738] Pittet et al., 2000[60] O'Boyle, Henly & Larson, 2001[729] Kuzu et al., 2005[683]
	High patient-to-nurse ratio and more shifts per day (for haemodialysis unit)	Arenas et al., 2005[689]
	High number of opportunities for hand hygiene per hour of patient care	Pittet & Perneger, 1999[737] Pittet, 2000[738] Pittet et al., 2000[60] O'Boyle, Henly & Larson, 2001[729] H Hugonnet, Perneger & Pittet, 2002[334] Pittet et al., 2003[652] Kuzu et al., 2005[683] Pan et al., 2007[703] Pessoa-Silva et al., 2007[657]
B.	**Self-reported factors for poor adherence to hand hygiene**	
	Handwashing agents cause irritations and dryness	Larson & Killien, 1982[608] Larson, 1985[742] Pettinger & Nettleman, 1991[668] Heenan, 1992[743] Zimakoff et al., 1992[609] Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Huskins et al., 1999[744] Pittet, 2000[738] Pittet et al., 2000[60] Patarakul et al., 2005[745]
	Sinks are inconveniently located or shortage of sinks	Larson & Killien, 1982[608] Kaplan & McGuckin, 1986[497] Pettinger & Nettleman, 1991[668] Heenan, 1992[743] Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Huskins et al., 1999[744] Pittet, 2000[738] Pittet et al., 2000[60]
	Lack of soap, paper towel, handwashing agents	Heenan, 1992[743] Huskins et al., 1999[744] Pittet, 2000[738] Pittet et al., 2000[60] Suchitra & Lakshmi Devi, 2007[746]

Table I.16.3

Factors influencing adherence to hand hygiene practices (Cont.)

Factors for poor adherence / low compliance	References
Often too busy or insufficient time	Larson & Killien, 1982[608] Pettinger & Nettleman, 1991[668] Heenan, 1992[743] Williams et al., 1994[747] Larson & Kretzer, 1995[722] Voss & Widmer, 1997[615] Kretzer & Larson, 1998[724] Boyce, 1999[720] Pittet & Perneger, 1999[737] Weeks, 1999[748] Bischoff et al., 2000[486] Pittet, 2000[738] Pittet et al., 2000[60] Dedrick et al., 2007[702] Suchitra & Lakshmi Devi, 2007[746]
Patient needs take priority	Kretzer & Larson, 1998[724] Pittet, 2000[738] Patarakul et al., 2005[745]
Hand hygiene interferes with HCW-patient relationship	Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Pittet, 2000[738]
Low risk of acquiring infection from patients	Pittet, 2000[738]
Wearing of gloves or belief that glove use obviates the need for hand hygiene	Pittet & Perneger, 1999[737] Pittet, 2000[738] Pittet et al., 2000[60]
Lack of institutional guidelines/ lack of knowledge of guidelines and protocols	Larson & Killien, 1982[608] Pettinger & Nettleman, 1991[668] Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Boyce & Pittet, 2002[58] Rosenthal, Guzman & Safdar, 2005[716] Suchitra & Lakshmi Devi, 2007[746]
Lack of knowledge, experience and education	Larson & Killien, 1982[608] Pettinger & Nettleman, 1991[668] Suchitra & Lakshmi Devi, 2007[746]
Lack of rewards/ encouragement	Larson & Killien, 1982[608] Pettinger & Nettleman, 1991[668] Suchitra & Lakshmi Devi, 2007[746]
Lack of role model from colleagues or superiors	Larson & Killien, 1982[608] Pettinger & Nettleman, 1991[668] Muto, Sistrom & Farr, 2000[682] Pittet, 2000[738] Pittet et al., 2000[60] Suchitra & Lakshmi Devi, 2007[746]
Not thinking about it, forgetfulness	Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Pittet, 2000[738] Pittet et al., 2000[60] Patarakul et al., 2005[745]
Scepticism about the value of hand hygiene	Pittet, 2000[738] Pittet et al., 2000[60] Boyce & Pittet, 2002[58]
Disagreement with recommendations	Pittet, 2000[738]
Lack of scientific information of definitive impact of improved hand hygiene on HCAI rates	Weeks, 1999[748] Pittet, 2000[738] Pittet et al., 2000[60]

Table I.16.3

Factors influencing adherence to hand hygiene practices (Cont.)

	Factors for poor adherence / low compliance	References
C.	**Additional perceived barriers to appropriate hand hygiene**	
	Lack of active participation in hand hygiene promotion at individual or institutional level	Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Larson et al., 2000[713] Pittet, 2000[738] Pittet et al., 2000[60] Pittet & Boyce, 2001[749] Pittet, 2001[750]
	Lack of institutional priority for hand hygiene	Pittet, 2000[738] Pittet et al., 2000[60] Pittet, 2001[750]
	Lack of administrative sanction of non-compliers or rewarding of compliers	Kelen et al., 1991[751] Jarvis, 1994[721] Kretzer & Larson, 1998[724] Boyce, Kelliher & Vallande, 2000[264] Pittet, 2000[738] Pittet & Boyce, 2001[749] Pittet, 2001[750]
	Lack of institutional safety climate/ culture of personal accountability of HCWs to perform hand hygiene	Larson & Kretzer, 1995[722] Kretzer & Larson, 1998[724] Larson et al., 2000[713] Pittet, 2000[738] Pittet et al., 2000[60] Pittet & Boyce, 2001[749] Pittet, 2001[750] Goldmann, 2006[752]
	Factors for good adherence/ improved compliance	**References**
A.	**Observed factors for improved compliance**	
	Introduction of widely accessible alcohol-based handrub (e.g. bedside handrub, small bottles/pocket-sized handrub); or combined with a multimodal multidisciplinary approach targeted at individual and institution levels.	Pittet & Perneger, 1999[737] Bischoff et al., 2000[486] Maury, 2000[485] Pittet et al., 2000[60] Earl, 2001[753] Girard, Amazian & Fabry, 2001[613] Harbarth et al., 2002[686] Hugonnet, Perneger & Pittet, 2002[334] Mody et al., 2003[754] Brown et al., 2003[687] Lam, Lee & Lau, 2004 [648] Pittet et al., 2004[335] Johnson et al., 2005[494] Zerr et al., 2005[715] Hussein, Khakoo & Hobbs, 2007[755] Pessoa-Silva et al., 2007[657] Trick et al., 2007[701] Rupp et al., 2008[707]
	Multifaceted approach to improve hand hygiene (e.g. education, training, observation, feedback, easy access to hand hygiene supplies (sinks/ soap/ medicated detergents), sink automation, financial incentives, praises by superior, admonishment of suboptimal performance, administrative support, prioritization to infection control needs, active participation at institutional level)	Conly et al., 1989[663] Dubbert et al., 1990[666] Larson et al., 1997[684] Rosenthal et al., 2003[651] Won et al., 2004[756] Rosenthal, Guzman & Safdar, 2005[716]
B.	**Predictive factors for hand hygiene compliance (by observational study / interventional study*)**	
	(i) Status of HCW Non-doctor HCW status (with attending doctors as reference group)	 Duggan et al., 2008[711]

Table I.16.3
Factors influencing adherence to hand hygiene practices (Cont.)

	Factors for good adherence/ improved compliance	References
	Respiratory therapist (with nurses as reference group)	Harbarth et al., 2001[653] Harbarth et al., 2002[686]
	(ii) Type of patient care Under precaution care (perceived as greater risk of transmission to HCWs themselves) • care of patient under contact precautions • care of patient in isolation room	Dedrick et al., 2007[702] Swoboda et al., 2007[699]
	Completing care/ between patients	Pessoa-Silva et al., 2007[657]
	(iii) Activities perceived as having a high risk of cross-contamination or cross-infection to HCWs (e.g. after direct patient contact; before wound care; before/after contact with invasive devices or aseptic techniques; before/after contact with body fluid secretions; contact with nappies/diapers; or assessed by level of dirtiness of tasks)	Lipsett & Swoboda, 2001[730] Harbarth et al., 2001[653] Harbarth et al., 2002[686] Kuzu et al., 2005[683] Jenner et al., 2006[700] Pessoa-Silva et al., 2007[657] Trick et al., 2007[701] Haas & Larson, 2008[709]
	(iv) Type of unit • Intensive care unit • Neonatal ICU • Acute haemiodialysis unit	Novoa et al., 2007[700] Harbarth et al., 2001[653] Arenas et al., 2005[689]
	(v) During the 3-month period after an announced accreditation visit	Duggan et al., 2008[711]
	(vi) Strong administrative support	Rosenthal et al., 2003[651]
C.	**Determinants/ predictors/ self-reported factors for good adherence to hand hygiene (by questionnaire or focus group study)**	
	Normative beliefs	
	Peer behaviour (role model)/ perceived expectation from colleagues (peer pressure)	Wong & Tam, 2005[757] Whitby, McLaws & Ross, 2006[725] Sax et al., 2007[732]
	Being perceived as role model (for doctors)/ with good adherence by colleagues	Pittet et al., 2004[335]
	Perceived positive opinion / pressure from superior or important referent others e.g. senior doctors, administrators	Seto et al., 1991[758] Pittet et al., 2004[335] Pessoa-Silva et al., 2005[731] Whitby, McLaws & Ross, 2006[725] Sax et al., 2007[732]
	Control beliefs	
	Perception that hand hygiene is easy to perform/ easy access to alcohol-based handrub	Pittet et al., 2004[335] Sax et al., 2007[732]
	Perceived control over hand hygiene behaviour	Pessoa-Silva et al., 2005[731]
	Attitudes	
	Awareness of being observed	Pittet et al., 2004[335]
	Positive attitude towards hand hygiene after patient contact	Pittet et al., 2004[335]
	Perceived risk of infection (level of dirtiness) during patient contact/ perceived high public health threat	Parker et al., 2006[254] Whitby, McLaws & Ross, 2006[725]
	Beliefs in benefits of performing hand hygiene/ protection of HCWs from infection	Shimokura et al., 2006[759] Whitby, McLaws & Ross, 2006[725]
	Translation of community hand washing behaviour (behaviour developed in early childhood) into healthcare settings (for nurses in handwashing)	Whitby, McLaws & Ross, 2006[725]

Table I.16.3
Factors influencing adherence to hand hygiene practices (Cont.)

	Factors for good adherence/ improved compliance	References
	Others	
	Female sex	Sax et al., 2007[732]
	HCW status – technician	Shimokura et al., 2006[759]
	Previous training	Sax et al., 2007[732]
	Participation in previous hand hygiene campaign	Sax et al., 2007[732]
	Patient expectation (for doctors)	Sax et al., 2007[732]
D.	**Factors for preferential recourse to handrubbing vs handwashing**	
	Doctors e.g. critical care (with nurses as reference group)	Pittet et al., 2000[60] Hugonnet, Perneger & Pittet, 2002[334] Dedrick et al., 2007[702] Trick et al., 2007[701]
	Activities with high risk of cross-transmission/ level of dirtiness	Hugonnet, Perneger & Pittet, 2002[334] Kuzu et al., 2005[683]
	High activity index (>60 opportunities per hour)	Hugonnet, Perneger & Pittet, 2002[334]

17.

Religious and cultural aspects of hand hygiene

There are several reasons why religious and cultural issues should be considered when dealing with the topic of hand hygiene and planning a strategy to promote it in health-care settings. The most important is that these *Guidelines*, issued as a WHO document, are intended to be disseminated all over the world and in settings where very different cultural and religious beliefs may strongly influence their implementation. Furthermore, the guidelines consider new aspects of hand hygiene promotion, including behavioural and transcultural issues. Within this framework, a WHO Task Force on Religious and Cultural Aspects of Hand Hygiene was created to explore the potential influence of transcultural and religious factors on attitudes towards hand hygiene practices among HCWs and to identify some possible solutions for integrating these factors into the hand hygiene improvement strategy. This section reflects the findings of the Task Force.

In view of the vast number of religious faiths worldwide, only the most widely represented have been taken into consideration (Figure I.17.1).[760] For this reason, this section is by no means exhaustive. Some ethno-religious aspects such as the followers of local, tribal, animistic or shamanistic religions were also considered.

Philanthropy, generally inherent in any faith, has often been the motivation for establishing a relationship between the mystery of life and death, medicine, and health care. This predisposition has often led to the establishment of health-care institutions under religious affiliations. Faith and medicine have always been integrated into the healing process as many priests, monks, theologians and others inspired by religious motivations studied, researched, and practised medicine. In general, religious faith has often represented an outstanding contribution to highlighting the ethical implications of health care and to focusing the attention of health-care providers on both the physical and spiritual natures of human beings.

Well-known examples already exist, however, of health interventions where the religious point of view had a critical impact on implementation or even interfered with it.[761,762] Research has already been conducted into religious and cultural factors influencing health-care delivery, but mostly in the field of mental health or in countries with a high influx of immigrants where unicultural care is no longer appropriate.[49,763] In a recent world conference on tobacco use, the role of religion in determining health beliefs and behaviours was raised; it was considered to be a potentially strong motivating factor to promote tobacco control interventions.[764] A recent review enumerates various potential positive effects of religion on health, as demonstrated by studies showing its impact on disease morbidity and mortality, behaviour, and lifestyles as well as on the capacity to cope with medical problems.[765] Beyond these particular examples, the complex association between religion, culture, and health, in particular hand hygiene practices among HCWs, still remains an essentially unexplored, speculative area.

In the increasingly multicultural, globalized community that is health-care provision today, cultural awareness has never been more crucial for implementing good clinical practice in keeping with scientific developments. Immigration and travel are more common and extensive than ever before as a result of the geopolitically active forces of migration, asylum-seeking and, in Europe, the existence of a broad, borderless multi-state Union. With the increasingly diverse populations accompanying these changes, very diverse cultural beliefs are also more prevalent than ever. This evolving cultural topography demands new, rapidly acquired knowledge and highly sensitive, informed insights of these differences, not only among patients but also among HCWs who are subject to the same global forces.

It is clear that cultural – and to some extent, religious – factors strongly influence attitudes to inherent community handwashing which, according to behavioural theories (see Part I, Section 18), are likely to have an impact on compliance with hand cleansing during health care.

In general, the degree of HCWs' compliance with hand hygiene as a fundamental infection control measure in a public health perspective may depend on their belonging to a community-oriented, rather than an individual-oriented society. The existence of a wide awareness of everyone's contribution to the common good, such as health of the community, may certainly foster HCWs' propensity to adopt good hand hygiene habits. For instance, hand cleansing as a measure of preventing the spread of disease is clearly in harmony with the fundamental Hindu value of non-injury to others *(ahimsa)* and care for their well-being *(daya).*

Another interesting aspect may be to evaluate optional methods of hand cleansing which exist in some cultures according to deep-seated beliefs or available resources. As an example, in the Hindu culture, hands are rubbed vigorously with ash or mud and then rinsed with water. The belief behind this practice is that soap should not be used as it contains animal fat. If water is not available, other substances such as sand are used to rub the hands. In a scientific study performed in Bangladesh to assess faecal coliform counts from post-cleansing hand samples, hand cleansing with mud and ash was demonstrated to be as efficient as with soap.[766]

In addition to these general considerations, some specific issues to be investigated in a transcultural and transreligious context are discussed.

Based on a review of the literature and the consultation of religious authorities, the most important topics identified were the importance of hand hygiene in different religions, hand gestures in different religions and cultures, the interpretation of the concept of "visibly dirty hands", and the use of alcohol-based handrubs and alcohol prohibition by some religions.

17.1 Importance of hand hygiene in different religions

Personal hygiene is a key component of human well-being regardless of religion, culture or place of origin. Human health-related behaviour, however, results from the influence of multiple factors affected by the environment, education, and culture.

According to behavioural theories[725,767] (see Part I, Section 18), hand cleansing patterns are most likely to be established in the first 10 years of life. This imprinting subsequently affects the attitude to hand cleansing throughout life, in particular, regarding the practice called "inherent hand hygiene,[725,767] which reflects the instinctive need to remove dirt from the skin. The attitude to handwashing in more specific opportunities is called "elective handwashing practice"[725] and may much more frequently correspond to some of the indications for hand hygiene during health-care delivery.

In some populations, both inherent and elective hand hygiene practices are deeply influenced by cultural and religious factors. Even though it is very difficult to establish whether a strong inherent attitude towards hand hygiene directly determines an increased elective behaviour, the potential impact of some religious habits is worth considering.
Hand hygiene can be practised for hygienic reasons, ritual reasons during religious ceremonies, and symbolic reasons in specific everyday life situations (seeTable I.17.1). Judaism, Islam and Sikhism, for example, have precise rules for handwashing included in the holy texts and this practice punctuates several crucial moments of the day. Therefore, a serious, practising believer is a careful observer of these indications, though it is well known that in some cases, such as with Judaism, religion underlies the very culture of the population in such a way that the two concepts become almost indistinguishable. As a consequence of this, even those who do not consider themselves strong believers behave according to religious principles in everyday life. However, it is very difficult to establish if inherent[725] and elective[725] behaviour in hand hygiene, deep-seated in some communities, may influence HCWs' attitude towards hand cleansing during health-care delivery. It is likely that those who are used to caring about hand hygiene in their personal lives are more likely to be careful in their professional lives as well, and to consider hand hygiene as a duty to guarantee patient safety. For instance, in the Sikh culture, hand hygiene is not only a holy act, but an essential element of daily life. Sikhs will always wash their hands properly with soap and water before dressing a cut or a wound. This behaviour is obviously expected to be adopted by HCWs during patient care. A natural expectation, such as this one, could also facilitate patients' ability to remind the HCW to clean their hands without creating the risk of compromising their mutual relationship.

Of the five basic tenets of Islam, observing regular prayer five times daily is one of the most important. Personal cleanliness is paramount to worship in Islam.[763] Muslims must perform methodical ablutions before praying, and clear instructions are given in the Qur'an as to precisely how these should be carried out.[768] The Prophet Mohammed always urged Muslims to wash hands frequently and especially after some clearly defined tasks (Table I.17.1).[769] Ablutions must be made in freely running (not stagnant) water and involve washing the hands, face, forearms, ears, nose, mouth and feet, three times each. Additionally, hair must be dampened with water. Thus, every observant Muslim is required to maintain scrupulous personal hygiene at five intervals throughout the day, aside from his/her usual routine of bathing as specified in the Qur'an. These habits transcend Muslims of all races, cultures and ages, emphasizing the importance ascribed to correct ablutions.[770]

With the exception of the ritual sprinkling of holy water on hands before the consecration of bread and wine, and of the washing of hands after touching the holy oil (the latter only in the Catholic Church), the Christian faith seems to belong to the third category of the above classification (Table I.17.1) regarding hand hygiene behaviour. In general, the indications given by Christ's example refer more to spiritual behaviour, but the emphasis on this specific point of view does not imply that personal hygiene and body care are not important in the Christian way of life. Similarly, there are no specific indications regarding hand hygiene in daily life in the Buddhist faith, nor during ritual occasions, apart from the hygienic act of washing hands after each meal.

Similarly, specific indications regarding hand hygiene are nonexistent in the Buddhist faith. No mention is made of hand cleansing in everyday life, nor during ritual occasions. According to Buddhist habits, only two examples of pouring water over hands can be given, both with symbolic meaning. The first is the act of pouring water on the hands of the dead before cremation in order to demonstrate forgiveness to each other, between the dead and the living. The second, on the occasion of the New Year, is the young person's gesture of pouring some water over the hands of elders to wish them good health and a long life.

Culture might also be an influential factor whatever the religious background. In certain African countries (e.g. Ghana and some other West African countries) hand hygiene is commonly practised in specific situations of daily life according to some ancient traditions. For instance, hands must always be washed before raising anything to one's lips. In this regard, there is a local proverb: "when a young person washes well his hands, he eats with the elders". Furthermore, it is customary to provide facilities for hand aspersion (a bowl of water with special leaves) outside the house door to welcome visitors and to allow them to wash their face and hands before even enquiring the purpose of their visit.

Unfortunately, the above-mentioned hypothesis that community behaviour influences HCWs' professional behaviour has been corroborated by scanty scientific evidence until now (see also Part I, Section 18). In particular, no data are available on the impact of religious norms on hand hygiene compliance in health-care settings where religion is very deep-seated. This is a very interesting area for research in a global perspective, because this kind of information could be very useful to identify the best components of a programme for hand hygiene promotion. It could be established that, in some contexts, emphasizing the link between religious and health issues may be very advantageous. Moreover, an assessment survey may also show that in populations with a high religious observance of hand hygiene, compliance with hand hygiene in health care will be higher than in other settings and, therefore, does not need to be further strengthened or, at least, education strategies should be oriented towards different aspects of hand hygiene and patient care.

17.2 Hand gestures in different religions and cultures

Hand use and specific gestures take on considerable significance in certain cultures.[771] The most common popular belief about hands, for instance in Hindu, Islam, and some African cultures, is to consider the left hand as "unclean" and reserved solely for "hygienic" reasons, while it is thought culturally imperative to use the right hand for offering, receiving, eating, for pointing at something or when gesticulating.

In the Sikh and Hindu cultures, a specific cultural meaning is given to the habit of folding hands together either as a form of greeting, as well as in prayer.

There are many hand gestures in Mahayana and Tibetan Buddhism. In Theravada Buddhist countries, putting two hands together shaped like a lotus flower is representative of the flower offered to pay respect to the Buddha, *Dhamma* (teaching) and *Sangha* (monk). Walking clockwise around the relic of the Buddha or stupa is also considered to be a proper and positive form of respect towards the Buddha. Washing hands in a clockwise movement is suggested and goes well with the positive manner of cheerful and auspicious occasions. Studies have shown the importance of the role of gesture in teaching and learning and there is certainly a potential advantage to considering this for the teaching of hand hygiene, in particular, its representation in pictorial images for different cultures.[772,773] In multimodal strategies to promote hand hygiene, posters placed in key points in health-care settings have been shown to be very effective tools to remind HCWs to cleanse their hands.[58,60] Efforts to consider specific hand uses and gestures according to local customs in visual posters, including educational and promotional material, may help to convey the intended message more effectively and merits further research.

17.3 The concept of "visibly dirty" hands

Both the CDC guidelines[58] and the present WHO guidelines recommend that HCWs wash their hands with soap and water when visibly soiled. Otherwise, handrubbing with an alcohol-based rub is recommended for all other opportunities for hand hygiene during patient care as it is faster, more effective, and better tolerated by the skin.

Infection control practitioners find it difficult to define precisely the meaning of "visibly dirty" and to give practical examples while schooling HCWs in hand hygiene practices. In a transcultural perspective, it could be increasingly difficult to find a common understanding of this term. In fact, actually seeing dirt on hands can be impeded by the colour of the skin: it is, for example, more difficult to see a spot of blood or other proteinaceous material on very dark skin. Furthermore, in some very hot and humid climates, the need to wash hands with fresh water may also be driven by the feeling of having sticky or humid skin.

According to some religions, the concept of dirt is not strictly visual, but reflects a wider meaning which refers to interior and exterior purity.[774,775] In some cultures, it may be difficult to train HCWs to limit handwashing with soap and water to some rare situations only. For instance, external and internal cleanliness is a scripturally enjoined value in Hinduism, consistently listed among the cardinal virtues in authoritative Hindu texts *(Bhagavadgita, Yoga Shastra of Patanjali)*. Furthermore, in the Jewish religion, the norm of washing hands immediately after waking in the morning refers to the fact that during the night, which is considered one sixtieth of death, hands may have touched an impure site and therefore implies that dirt can be invisible to the naked eye. Therefore, the concept of dirt does not refer only to situations in which it is visible. This understanding among some HCWs may lead to a further need to wash hands when they feel themselves to be impure and this may be an obstacle to the use of alcohol-based handrubs.

The cultural issue of feeling cleaner after handwashing rather than after handrubbing was recently raised within the context of a widespread hand hygiene campaign in Hong Kong and might be at the basis of the lack of long-term sustainability of the excellent results of optimal hand hygiene compliance achieved during the Severe Acute Respiratory Syndrome pandemic (W H Seto, personal communication).

From a global perspective, the above considerations highlight the importance of making every possible effort to consider the concept of "visibly dirty" in accordance with racial, cultural and environmental factors, and to adapt it to local situations with an appropriate strategy when promoting hand hygiene.

17.4 Use of alcohol-based handrubs and alcohol prohibition by some religions

According to scientific evidence arising from efficacy and cost–effectiveness, alcohol-based handrubs are currently considered the gold standard approach. For this purpose, WHO recommends specific alcohol-based formulations taking into account antimicrobial efficacy, local production, distribution, and cost issues at country level worldwide (see also Part I, Section 12).

In some religions, alcohol use is prohibited or considered an offence requiring a penance (Sikhism) because it is considered to cause mental impairment (Hinduism, Islam) (Table I.17.1). As a result, the adoption of alcohol-based formulations as the gold standard for hand hygiene may be unsuitable or inappropriate for some HCWs, either because of their reluctance to have contact with alcohol, or because of their concern about alcohol ingestion or absorption via the skin. Even the simple denomination of the product as an "alcohol-based formulation" could become a real obstacle in the implementation of WHO recommendations.

In some religions, and even within the same religious affiliation, various degrees of interpretation exist concerning alcohol prohibition. According to some other faiths, on the contrary, the problem does not exist (Table I.17.1). In general, in theory, those religions with an alcohol prohibition in everyday life demonstrate a pragmatic vision which is followed by the acceptance of the most valuable approach in the perspective of optimal patient-care delivery. Consequently, no objection is raised against the use of alcohol-based products for environmental cleaning, disinfection, or hand hygiene. This is the most common approach in the case of faiths such as Sikhism and Hinduism. For example, in a fundamental Hindu textbook, the

Shantiparvan, it is explicitly stated that it is not sinful to drink alcohol for medicinal purposes.

In Buddhism, obstacles to the use of alcohol in health care are certainly present, but from a completely different perspective. According to the law of *kamma*, the act or the intention to kill living creatures is considered a sinful act. As microorganisms are living beings, killing them with an alcohol-based handrub may lead to demerit. According to Expositor (1:128), the five conditions for the act of killing are: a living being; knowledge that it is a being; intention of killing; effort; and consequent death. Nevertheless, considering that HCWs for the most part have good intentions in their work, namely, to protect patients from pathogen transmission, the result of this sinful action does not bear heavy consequences. Therefore, when comparing a human patient's life with a bacterium's life, most people adhering to the Buddhist *kamma* agree that a patient's life is more valuable. Furthermore, according to Phra Depvethee, a Thai Buddhist monk and scholar, the consequences of killing depends on the size and good contribution of that being.[776]

The Islamic tradition poses the toughest challenge to alcohol use. Fortunately, this is also the only context where reflection on alcohol use in health care has begun. Alcohol is clearly designated as *haram* (forbidden) in Islam because it is a substance leading to *sukur*, or intoxication leading to an altered state of mind. For Muslims, any substance or process leading to a disconnection from a state of awareness or consciousness (to a state in which she or he may forget her or his Creator) is called *sukur*, and this is *haram*. For this reason, an enormous taboo has become associated with alcohol for all Muslims. Some Muslim HCWs may feel ambivalent about using alcohol-based handrub formulations. However, any substance that man can manufacture or develop in order to alleviate illness or contribute to better health is permitted by the Qur'an and this includes alcohol used as a medical agent. Similarly, cocaine is permitted as a local anaesthetic (*halal*, allowed) but is inadmissible as a recreational drug (*haram*, forbidden).

To understand Muslim HCWs' attitudes to alcohol-based hand cleansers in an Islamic country, the experience reported by Ahmed and colleagues at the King Abdul Aziz Medical City (KAAMC) in Riyadh, Kingdom of Saudi Arabia, is very instructive.[770] At the KAAMC, the policy of using alcohol handrub is not only permitted, but has been actively encouraged in the interest of infection control since 2003. No difficulties or reluctance were encountered in the adoption of alcohol-containing hand hygiene substances. Though Saudi Arabia is considered to be the historic epicentre of Islam, no state policy or permission or *fatwa* (Islamic religious edict) were sought for approval of the use of alcohol-containing handrubs, given that alcohol has long been a component present in household cleaning agents and other materials for public use, including perfume, without legislated restriction within the Kingdom. In all these instances, the alcohol content is permitted because it is not for ingestion. In 2005, the Saudi Ministry of Health pledged its commitment to the WHO Global Patient Safety Challenge, and most hospitals across the country have joined in a national campaign implementing the WHO multimodal Hand Hygiene Improvement Strategy centred on the use of alcohol-based handrub at the point of care. Given this high level commitment, WHO selected hospitals in Saudi Arabia in 2007 for the testing of the present *Guidelines*. Preliminary results indicate a very strong adoption of the strategy, including a preference for handrubbing instead of handwashing, which has led to a significant increase of hand hygiene compliance among HCWs and a reduction of HCAI rates in ICUs.[777] This example shows that positive attitudes to the medicinal benefits of alcohol, coupled with a compassionate interpretation of Qur'anic teachings, have resulted in a readiness to adopt new hand hygiene policies, even within an Islamic Kingdom which is legislated by *Sharia* (Islamic law).

The risk of accidental or intentional ingestion of alcohol-based preparations is one of the arguments presented by sceptics concerning the introduction of these products because of cultural or religious reasons. Even if this is a potential problem, it is important to highlight that only a few cases have been reported in the literature.[599,778-781] In specific situations, however, this unusual complication of hand hygiene should be considered and security measures planned to be implemented (see Part I, Section 23.6.2). Another concern regarding the use of handrub formulations by HCWs is the potential systemic diffusion of alcohol or its metabolites following skin absorption or airborne inhalation. Only a few anecdotal and unproven cases of alcohol skin absorption leading to clinical symptoms are reported in the literature.[779,780] In contrast, reliable studies on human volunteers clearly demonstrate that the quantity of alcohol absorbed following application is minimal and well below toxic levels for humans.[599,782-784] In a study mimicking use in large quantities and at a high frequency,[783] the cutaneous absorption of two alcohol-based handrubs with different alcohol components (ethanol and isopropanol) was carefully monitored. Whereas insignificant levels of ethanol were measured in the breath and serum of a minority of participants, isopropanol was not detected (see Part I, Section 23.6.2). Finally, alcohol smell on skin may be an additional barrier to handrubbing, and further research should be conducted to eliminate this smell from handrub preparations.

17.5 Possible solutions

In addition to targeting areas for further research, possible solutions may be identified (Table I.17.2). For example, from childhood, the inherent nature of hand hygiene which is strongly influenced by religious habits and norms in some populations could be shaped in favour of an optimal elective behaviour towards hand hygiene. Indeed, some studies have demonstrated that it is possible to successfully educate children of school age to practise optimal hand hygiene for the prevention of common paediatric community-acquired infections.[449,454,785]

When preparing guidelines, international and local religious authorities should be consulted and their advice clearly reported. An example is the statement issued by the Muslim Scholars' Board of the Muslim World League during the Islamic Fiqh Council's 16th meeting held in Mecca, Saudi Arabia, in January 2002: "It is allowed to use medicines that contain alcohol in any percentage that may be necessary for manufacturing if it cannot be substituted. Alcohol may be used as an external wound cleanser, to kill germs and in external creams and ointments.[786]

In hand hygiene promotion campaigns in health-care settings where religious affiliations prohibiting the use of alcohol are represented, educational strategies should include focus groups on this topic to allow HCWs to raise their concerns openly regarding the use of alcohol-based handrubs, help them to understand the scientific evidence underlying this recommendation, and identify possible solutions to overcome obstacles (Table I.17.2). Results of these discussions could be summarized in an information leaflet to be produced and distributed locally. It has been suggested to avoid the use of the term “alcohol” in settings where the observance of related religious norms is very strict and rather use the term “antiseptic” handrubs. However, concealing the true nature of the product behind the use of a non-specific term could be construed as deceptive and considered unethical; further research is thus needed before any final recommendation can be made.

Medical practices different from Western medicine, such as traditional medicines, should be explored for further opportunities to promote hand hygiene in different cultural contexts. For instance, traditional Chinese medicine practitioners are very open to the concept of hand hygiene. During a usual traditional Chinese medicine consultation, both inpatient and outpatient, there can be a vast array of direct contacts with the patient. These include various kinds of physical examination such as the routine taking of the pulse and blood pressure for almost all patients, but may also involve various kinds of massages and examination of the oral cavities or other orifices, and contact can be often more intense than in Western medicine. In this context, the potential for using an alcohol-based handrub is tremendous for the practitioner, given the high frequency of hand hygiene actions, and there is a definite avenue for further research in this setting.

Finally, the opportunity to involve patients in a multimodal strategy to promote hand hygiene in health care should be carefully evaluated (see Part V). Despite its potential value, this intervention through the use of alcohol-based handrubs may be premature in settings where religious norms are taken literally; rather, it could be a subsequent step, following the achievement of awareness and compliance among HCWs.

Table I.17.1

Hand hygiene indications and alcohol prohibition in different religions

Religion	Specific indications for hand hygiene	Type of cleansing[a]	Alcohol prohibition		
			Existence	Reason	Potentially affecting use of alcohol-based handrub
Buddhism	After each meal	H	Yes	It kills living organisms (bacteria)	Yes, but surmountable
	To wash the hands of the deceased	S			
	At New Year, young people pour water over elders' hands	S			
Christianity	Before the consecration of bread and wine	R	No	—	No
	After handling Holy Oil (Catholics)	H			
Hinduism	During a worship ceremony *(puja)* (water)	R	Yes	It causes mental impairment	No
	End of prayer (water)	R			
	After any unclean act (toilet)	H			
	Before and after any meal	H			
Islam	Repeating ablutions at least three times with running water before prayers (5 times a day)	R	Yes	It causes disconnection from a state of spitritual awareness or consciousness	Yes, but surmountable. Very advanced and close scrutiny of the problem
	Before and after any meal	H			
	After going to the toilet	H			
	After touching a dog, shoes or a cadaver	H			
	After handling anything soiled	H			
Judaism	Immediately after waking in the morning	H	No	—	No
	Before and after each meal	H			
	Before praying	R			
	Before the beginning of Shabbat	R			
	After going to the toilet	H			
Orthodox Christianity	After putting on liturgical vestments before beginning the ceremony	R	No	—	No
	Before the consecration of bread and wine	R			
Sikhism	Early in the morning	H	Yes	Unacceptable behaviour as disrespectful of the faith Considered as an intoxicant	Yes, but probably surmountable
	Before every religious activity	R			
	Before cooking and entering the community food hall	H			
	After each meal	H			
	After taking off or putting on shoes	H			

[a] H = hygienic; R = ritual; S = symbolic.

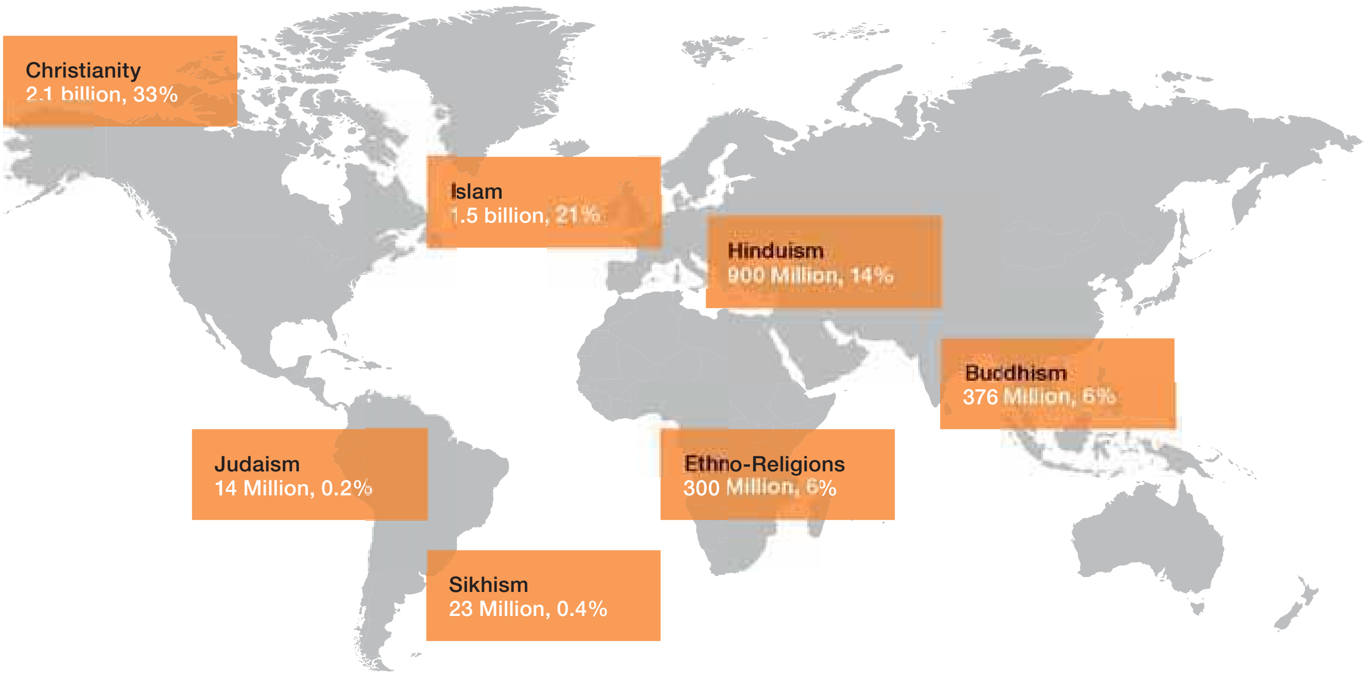
Table I.17.2

Religious and cultural aspects of hand hygiene in health care and potential impact and/or solutions

Topic	Potential impact and/or solutions
Hand hygiene practices	Both inherent and elective hand hygiene practices are deeply influenced by cultural and religious factors Area for research: potential impact of some religious habits on hand hygiene compliance in health care
Hand gestures	Consider specific gestures in different cultures to be represented in posters and other promotional material for educational purposes in multimodal hand hygiene campaigns
The concept of "visibly dirty" hands	Consider different skin colour, different perceptions of dirtiness and climiate variations when educating HCWs on hand hygiene indications
Prohibition of alcohol use	Consultation of local clergy and wise interpretation of holy texts Focus groups on this topic within education strategies Use of the most appropriate term for alcohol-based handrubs Careful evaluation of patient involvement Area for research: quantitative studies on potential toxicity of accidental ingestion and inhalation or skin absorption of alcohol related to alcohol-based handrubs; elimination of alcohol smell

Figure I.17.1

Most widely represented religions worldwide, 2005[760]



Source: http://www.adherents.com/Religions_By_Adherents.html, accessed 26 February 2009

18.
Behavioural considerations

18.1 Social sciences and health behaviour

Hand hygiene behaviour varies significantly among HCWs within the same unit, institution[494,656,688] or country,[787] thus suggesting that individual features could play a role in determining behaviour. Social psychology attempts to understand these features, and individual factors such as social cognitive determinants may provide additional insight into hand hygiene behaviour.[724,767,788,789]

18.1.1 Social cognitive variables

Over the last quarter of the 20th century, it was stated that social behaviour could be best understood as a function of people's perceptions rather than as a function of real life (objective facts, etc.).[790] This assumption gave birth to several models which were based on social cognitive variables and tried to better understand human behaviour. The determinants that shape behaviour are acquired through the socialization process and, more importantly, are susceptible to change – for which reason they are the focus of behavioural models. In other areas of health-care promotion, the application of social cognitive models in intervention strategies has regularly resulted in a change towards positive behaviour.[790] Some of the so-called "social cognitive models" applied to evaluate predictors of health behaviour include: Health Belief Model (HBM); Health Locus of Control (HLC); Protection Motivation Theory (PMT); Theory of Planned Behaviour (TPB); and Self-efficacy Model (SEM). The cognitive variables used in these models are:

- knowledge;
- motivation;
- intention: a person's readiness to behave in a given way, which is considered to be the immediate antecedent of behaviour;
- outcome expectancy: an individual's expectation that a given behaviour can counteract or increase a threat and how one perceives the threat;
- perception of threat: based on the perceived risk/ susceptibility and the perceived severity of the consequences;
- perceived behavioural control (self-efficacy): the perception that performance of a given behaviour is within one's control;
- subjective norm: beliefs about the expectations of an important referent towards a given behaviour;[790,791]
- behavioural norm: an individual's perception of the behaviour of others;[792] subjective and behavioural norms represent the perceived social pressure towards a certain behaviour.

18.1.2 Modelling human behaviour

Current models and theories that help to explain human behaviour, particularly as they relate to health education, can be classified on the basis of being directed at the individual (intrapersonal), interpersonal, or community levels. The social cognitive models mentioned above deal with intrapersonal and interpersonal determinants of behaviour. Among the community-level models, the Theory of Ecological Perspective (also referred to as the Ecological Model of Behavioural Change) can successfully result in behavioural change. This theory is based on two key ideas: (i) behaviour is viewed as being affected by and affecting multiple levels of influence; and (ii) behaviour both influences and is influenced by the social environment. Levels of influence for health-related behaviour and conditions include intrapersonal (individual), interpersonal, institutional and community factors.[758]

Intrapersonal factors are individual characteristics that influence behaviour such as knowledge, attitudes, beliefs and personality traits.These factors are contained in social cognitive determinants.[790]

Interpersonal factors include interpersonal processes and primary groups, i.e. family, friends and peers, who provide social identity, support and role definition. HCWs, like others in the wider community, can be influenced by or are influential in their social environments. Behaviour is often influenced by peer group pressure,[688,732] which indicates that responsibilities for each HCW's individual group should be clearly recognized and defined.

Community factors are social networks and norms that exist either formally or informally between individuals, groups and organizations. For example, in the hospital, the community level would be the ward.[758] Community-level models are frameworks for understanding how social systems function and change, and how communities and organizations can be activated. The conceptual framework of community organization models is based on social networks and support, focusing on the active participation and development of communities that can help evaluate and solve health problems. Lower hand hygiene rates in non-nursing staff during ward-specific observations may, in part, be the result of inconsistent influences from the immediate social or community environment for those doctors, student HCWs, and agency nursing staff who move in and out or between subspecialities. Public policy factors include local policies that regulate or support practices for disease prevention, control and management. The role of local community-based communication through ward-based liaison or link infection control nurses should be considered when attempting to have HCWs adopt a core infection control policy.

18.1.3 Application of social sciences to the infection control field

Few studies have applied social sciences to assess HCWs' behaviour related to infection control practices. Seto identified three fields of study in the behavioural sciences with some degree of relevance to the field of infection control: social psychology, organizational behaviour and consumer behaviour.[788] By applying a basic concept from each field, Seto and colleagues demonstrated the potential value of these theories to achieve staff compliance with different infection control policies in the hospital.[758,788,793]

Social cognitive models have been applied to evaluate HCWs' cognitive determinants towards hand hygiene behaviour[335,729,731,732,794,795] and are discussed in the next section (Part I, Section 18.2).

Curry & Cole[796] applied the Theory of Ecological Perspective and reported their experience in the medical and surgical ICUs in a large teaching hospital experiencing an increased patient colonization rate with VRE. Their intervention consisted of a multifaceted approach to the problem, considering the five levels of influence (individual, interpersonal, institutional, community, and administrative factors). They implemented in-service education and developed references, policies, and programmes directed at each of the five levels of influence. The Health Belief Model was employed for assessment of beliefs and intervention design. The authors observed a significant decrease in the number of patients with active surveillance cultures or clinical isolates positive for VRE within six months in both ICUs, and the benefit seemed to persist even two years later.

18.2 Behavioural aspects of hand hygiene

The inability over two decades to motivate HCW compliance with hand cleansing[722,738] suggests that modifying hand hygiene behaviour is a complex task. Human health-related behaviour is the consequence of multiple influences from our biology, environment, education, and culture. While these influences are usually interdependent, some have more effect than others; when the actions are unwise, they are usually the result of trade-offs with acknowledged or denied consequences. Thus, this complexity of individual, institutional and community factors must be considered and investigated when designing behavioural interventions.[720,724,732,789]

Research into hand hygiene using behavioural theory has primarily focused on the individual, although this may be insufficient to effect sustained change. O'Boyle and colleagues[729] investigated the possible association of cognitive factors and nursing unit workload with hand hygiene compliance, the first-ever attempt using a well-established behavioural model. The three major motivating factors were predictive of intention, and while intention related to self-reported estimates of compliance, the relationship was not strong (r=0.38). Intention to wash hands did not predict observed handwashing behaviour. However, the intensity of activity of the nursing unit was significantly and negatively associated with observed adherence to hand hygiene recommentations (r=-33). In a neonatal ICU, a perceived positive opinion of a senior staff member towards hand hygiene and the perception of control over hand hygiene behaviour were independently associated with the intention to perform hand hygiene among HCWs.[731] Perceived behavioural control and intention were significant predictors of hand hygiene behaviour in another study.[794]

Focus group data[725] suggested that hand hygiene patterns are likely to be firmly established before the age of 9 or 10 years, probably beginning at the time of toilet training. They are patterns of a ritualized behaviour carried out to be, in the main, self-protective from infection. However, the drivers to practise hand cleansing both in the community and in the health-care setting are not overtly microbiologically based and appear seriously influenced by the emotional concepts of "dirtiness" and "cleanliness".[725,797] This same behaviour pattern has previously been recognized in developing countries,[798] and Curtis & Biran have postulated that the emotion of disgust in humans is an evolutionary protective response to environmental factors that are perceived to pose a risk of infection.[799] Yet in most communities, this motivation results in levels of hand hygiene that are, in microbiological terms, suboptimal for ideal protection.[800,801]

An individual's hand hygiene behaviour is not homogenous and can be classified into at least two types of practice.[725] Inherent hand hygiene practice, which drives the majority of community and HCW hand hygiene behaviour, occurs when hands are visibly soiled, sticky or gritty. Among nurses, this also includes occasions when they have touched a patient who is regarded as "unhygienic" either through appearance, age or demeanour, or after touching an "emotionally dirty" area such as the axillae, groin or genitals.[725] This inherent practice appears to require subsequent handwashing with water or with soap and water. The other element to hand hygiene behaviour, elective hand hygiene practice, represents those opportunities for hand cleansing not encompassed in the inherent category. In HCWs, this component of hand hygiene behaviour would include touching a patient such as taking a pulse or blood pressure, or having contact with an inanimate object around a patient's environment. This type of contact is similar to many common social interactions such as shaking hands, touching for empathy, etc. As such, it does not trigger an intrinsic need to cleanse hands, although it may lead to hand contamination in the health-care environment with the risk of cross-transmission of organisms. It therefore follows that it is this component of hand hygiene which is likely to be omitted by busy HCWs.

Compliance with hand cleansing protocols is most frequently investigated in nurses, as this group represents the majority of HCWs in hospitals and the category of HCWs with the highest number of opportunities for hand hygiene.[59,60,656] However, it is also well documented that doctors are usually less compliant with practices recommended for hand hygiene than are other HCWs.[60,608,656] Yet these clinicians are possibly the peer facilitators of hand hygiene compliance for nurses,[725] with different groups acting as peer facilitators for other HCWs.[335,732] Behavioural modelling[725] suggests that the major influence on nurses' handwashing practices in hospitals is the translation of their community attitudes into the health-care setting. Thus, activities that would lead to inherent community handwashing similarly induce inherent handwashing in the health-care setting. The perceived protective nature of this component of hand hygiene behaviour means that it will be carried out whenever nurses believe that hands are physically or emotionally soiled, regardless of barriers, and will require washing with water. This model indicates that other factors including perceived behaviour of peers and other influential social groups, together with a nurse's own attitude towards hand hygiene, have much less effect on inherent hand hygiene behavioural intent.[725]

Elective community behaviour has been shown to have a major impact on nurses with regard to their intention to undertake elective in-hospital hand cleansing. Other important facilitators of nurses electing to practise hand hygiene are attitude and an expectation of compliance not by their nursing peers, but by doctors and administrators.[725] Nurses and doctors were more likely to report high levels of compliance if they believed that their own peer group also complied.[732] Reduction in effort required to undertake hand hygiene has no influence on inherent hand hygiene behaviour and only minimal impact on elective hand hygiene intent.[725] Yet, the strongest predictor of self-reported compliance by nurses and doctors who had previously been exposed to hand hygiene campaigns was the belief that the practice was relatively easy to perform.[732] Hand hygiene behaviour considered as being relatively easy to perform is likely to be elective hand hygiene opportunities. Whether the hand hygiene opportunity the HCW is presented with is elective or inherent, the primary motivator to undertake it is self-protection.[725] Therefore, future cognitive programmess aiming to modify HCWs' hand hygiene behaviour should consider adjusting the benefits to include self-protection and patient protection.

The nursing behaviour model predicts a positive influence by senior administrators and doctors on the hand hygiene compliance of nurses but, surprisingly, there was no influence by senior nurses on junior nurses. Lankford and colleagues[802] found that poor hand hygiene practices in senior medical and nursing staff could provide a negative influence on others, while Pittet and colleagues[335] reported that doctors' perception of being role models to other colleagues had a positive influence on their compliance, independent of system constraints and hand hygiene knowledge.

All influences in the model for nursing hand hygiene behaviour[725] act independently of behavioural intent. This suggests that the effective component of the Geneva programme,[60] which has demonstrated significantly improved and sustained hand hygiene compliance over a period of several years.[60,490] was not only the introduction of an alcohol-based handrub per se, but were those components of the programme that directly promoted the desired behaviour: peer support from high-level hospital administrators and clinicians[789] and the perception that one's colleagues' adherence behaviour was good.[732]

Results of a behaviour modification at an organizational level further support these conclusions. Larson and colleagues[713] described a significant increase in handwashing compliance in a teaching hospital sustained over a 14-month period. The focus of this behaviour-based programme was directed to induce an organizational cultural change towards optimal handwashing with senior clinical and administrative staff overtly supporting and promoting the intervention.

The dynamic of behavioural change is complex and multifaceted.[60,713,725,789] It involves a combination of education, motivation, and system change.[789] Wide dissemination of hand hygiene guidelines alone is not sufficient motivation for a change in hand hygiene behaviour.[728] With our current knowledge, it can be suggested that programmes to improve hand hygiene compliance in HCWs cannot rely solely on awareness, but must take into account the major barriers to altering an individual's pre-existing hand hygiene behaviour.

18.2.1 Factors influencing behaviour

Patterns of hand hygiene behaviour are developed and established in early life. As most HCWs do not begin their careers until their early twenties, improving compliance means modifying a behaviour pattern that has already been practised for decades and continues to be reinforced in community situations.

Self-protection: this is not invoked on a true microbiological basis, but on emotive sensations including feelings of unpleasantness, discomfort, and disgust. These sensations are not normally associated with the majority of patient contacts within the health-care setting. Thus, intrinsic motivation to cleanse hands does not occur on these occasions.

18.2.2 Potential target areas for improved compliance

Education. While HCWs must be schooled in how, when and why to clean hands, emphasis on the derivation of their community and occupational hand hygiene behaviour patterns may assist in altering attitudes.

Motivation. Influenced by role modelling and perceived peer pressure by senior medical, nursing, and administrative staff, motivation requires overt and continuing support of hand hygiene as an institutional priority by the hospital administration.[789] This will, in due course, act positively at both the individual and organizational levels. Such support must be embedded in an overall safety climate directed by a top-level management committee, with visible safety programmes, an acceptable level of work stress, a tolerant and supportive attitude towards reported problems, and a belief in the efficacy of preventive strategies.

Reinforcement of appropriate hand hygiene behaviour

Cues to action such as cartoons and even alcohol-based rub itself appropriately located at the point of care should continue to be employed.

Patient empowerment. While involvement of patients in hand hygiene programmes for HCWs has been demonstrated to be effective[803-806] and also incorporated in a national programme,[807] one campaign found less than a third of patients and public wanted to be involved.[808] Further study of the approach of engaging the public is required before its widespread application will result in acceptance. Possible obstacles to be addressed include cultural constraints, the barrier of patient dependency on caregivers, and the lack of applicability of this tactic to ventilated, unconscious and/or seriously ill patients who are often at most risk of cross-infection.[656] Furthermore, whether patients reminding HCWs that they have to clean their hands before care would interfere with the patient–caregiver relationship remains to be properly assessed in different sociocultural and care situations.

System change

Structural. As successful behavioural hand hygiene promotion programmes induce increased compliance, the convenience and time-saving effects of cosmetically acceptable alcohol-based handrubs will prove of further benefit. However, inherent hand hygiene behaviour will always persist and will continue to require handwashing with water and soap; hence, the accessibility of sinks must still be carefully considered.

Philosophical*.* Heightened institutional priority for hand hygiene will require that a decision be made, at least at the organizational level as for many social behaviours, as to whether these other promotional facets of hand hygiene are then supported by law or marketing. Rewards and/or sanctions for acceptable or unacceptable behaviour may prove necessary and effective in both the short and long term, given both the duration of pre-existing hand hygiene behaviour inappropriate to the health-care setting and its continued reinforcement in the community. This approach has been successfully applied in many countries to other public health issues such as smoking and driving under the influence of alcohol, but further studies are necessary to assess its application to hand hygiene promotion. Alternatively, the philosophy of marketing may be considered; such an approach takes particular consideration of self-interest, which may be extremely pertinent given that self-protection continues to be the primary motivational force behind all hand hygiene practice. The value of active participation at the institutional level and its impact on HCWs' compliance with hand hygiene have been demonstrated in several studies.[60,651,713]

Patterns of hand hygiene both in the community and in health care represent a complex, socially entrenched and ritualistic behaviour. It is thus not surprising that single interventions have failed to induce a sustained improvement in HCW behaviour. Multi-level, multimodal and multidisciplinary strategies, responding to these behavioural determinants, would seem to hold most promise.[59,60,684,789]

18.2.3 Research implementation

Confirmation of behavioural determinants of hand hygiene in all other health-care occupational groups and in varying ethnic and professional groups is essential to ensure that these findings are constant and the implications that flow from them are universally relevant.

The impact in practice of each behavioural factor influencing hand hygiene must be carefully measured and considered, so as to design cost-effective motivational programmes suitable for both high- and low-resource health-care settings.

19. Organizing an educational programme to promote hand hygiene

Education of HCWs is an inherent component of the work of the infection control team. Through education, the infection control team can influence inappropriate patient-care practices and induce improved ones. Traditionally, a formal education programme is relied on to introduce new infection control policies successfully in health care. It is now recognized that for hand hygiene, however, education alone may not be sufficient. There are also reports that a unique teaching session is unlikely to be successful and, even after positive change is noted, it might not be maintained.[705,809] HCWs' attitudes and compliance with hand hygiene are extremely complex and multifactorial,[738,750,789,810,811] and studies indicate that a successful programme would have to be multidisciplinary and multifaceted.[684,701,750,767]

Education is important and critical for success and represents one of the cornerstones for improvement of hand hygiene practices.[812] It is therefore an essential component of the WHO multimodal Hand Hygiene Improvement Strategy together with other elements, in particular, the building of a strong and genuine institutional safety culture which is inherently linked to education. The reasons why education is important can be summarized as follows.

Successful hand hygiene programmes reported in the literature inevitably have an educational component.[60,651,676,684,813,814] They are not all consistently successful and their impact is not always sustainable. Some[811] appear to have only a short-term influence, particularly the one-time educational interventions.[666,705,740,809] It is important to emphasize that educational programmes alone are inadequate for long-lasting improvement, and other behaviour-modifying strategies must be included in a multifaceted approach in order to achieve change.[657,684,701,750,767,809,815,816] There is also clear evidence that adequate physical facilities for hand cleansing could affect the success of the programme itself and must certainly be in place.[335,810,817] However, these considerations do not negate the critical role of the formal education programme for achieving better adherence to hand hygiene.

Surveys and studies on HCWs have shown that valid information and knowledge about hand hygiene do influence good practices.[335,814,818-820] This is consistent with the finding that informational power is the most influential social power in infection control.[821] An educational programme providing accurate and pertinent facts is therefore indispensable for success.

Educational programmes have been reported as an essential ingredient for success in other infection control strategies, including the control of ventilator-associated pneumonia[822-825] reducing needlestick injuries,[826] and the implementation of isolation precautions.[423,827] There are also reports on the effective use of education for hand hygiene promotion strategies outside the acute hospital care setting.[449,828-830] It is important, therefore, to continue to use the formal education programme as one feature of the implementation strategy for hand hygiene improvement in health care.

It is noteworthy that robust hand hygiene guidelines are now available for infection control teams around the world.[58,831] This offers a distinct advantage because studies have shown that guidelines are in themselves an effective means of influencing behaviour regarding infection control.[832] However, the wide dissemination of guidelines alone is insufficient to change clinical practice.[728] It is important to realize that HCWs' compliance can be extremely low when guidelines are simply circulated down the hospital hierarchy: research indicates that the compliance rate can be as low as 20%.[793] When monitored, compliance with MRSA precautions was only 28% in a teaching hospital[833]; compliance was as low as 8% during the evening shift and 3% during the night shift. The success of the implementation process depends on the effectiveness of the education programme, and careful planning is essential.

If a formal education programme is organized to introduce the guidelines, the effects would be more assured, especially when there is firm administrative support.[728] The programme must be well designed[701] and the use of a prepackaged educational toolkit will aid uptake.[1,834,835] The WHO Implementation Toolkit (available at http://www.who.int/gpsc/en/) offers a blueprint for practitioners interested in hand hygiene improvement.[836] In this section, guidance is given on the planning process of the education programme, together with a guideline review scheme that could help in developing an effective strategy for implementation.

19.1 Process for developing an educational programme when implementing guidelines

It is important that all audiences are considered when developing and implementing educational programmes. Inclusion of the elements suggested in this section should be promoted in all settings, including in undergraduate programmes.

Prerequisite conditions: submitting a customized guideline according to updated knowledge; local resources and goals for endorsement; and instructions for implementation.

1. Customize the recommendations to meet the requirements of the health-care facility. The central part of this scheme is a method for reviewing guidelines before implementation.[837,838] Following this review, the infection control team will obtain essential information for the formulation of the education programme (Figure I.19.1). An infection control guideline consists generally of a list of recommendations on appropriate patient-care practices. In the education programme, instead of covering all the recommendations in a similar fashion for all categories of HCWs, a better strategy is to focus on patient-care practices that require adaptations, particularly those that would meet resistance from HCWs. The review scheme seeks to anticipate the educational needs so that the infection control team can plan accordingly. This might highlight some of the recommendations that are deemed to be critically important for success or, on the other hand, choose to exclude recommendations that are not relevant for the institution. The document should provide specific information such as the actual person to contact for queries and the precise location of the supply of hand antisepsis products. A final draft of the guideline will often require endorsement for implementation from the management of the institution or from the infection control committee. Importantly, institutional experts need to be knowledgeable about evidence-based information regarding hand hygiene.

2. Categorize all recommendations into the four types of practice described below in Section 19.1.1. This task should be performed with the help of a panel of experienced HCWs in the institution. It is recommended that a senior infection control professional in the hospital conducts the initial review.[837] Other senior nurses in the institution should also be coopted for this exercise. Using this scheme, studies have shown that front-line senior nurses in the hospital are accurate in predicting actual practices on the wards. A survey comparing their predictions with practices reported on the wards showed a significant correlation.[837]

(a) *work with the institution to provide the necessary resources for non-established practices detailed in the recommendations (lack of resources)*. The infection control team must ensure that these resources are actually available for the wards when the guideline is introduced.

(b) *identify reasons for HCW resistance to non-established practice (HCW resistance)*. The easiest method will be to convene a focus group consisting of HCWs from the relevant wards. Discussions can be followed, if necessary, by a simple survey of the key issues identified by the focus group. It is also worth while to gather information on the determinants of good adherence to hand hygiene so that these points can be emphasized in the educational programme. A good example of such research is reported by Sax and colleagues.[732]

3. Measure baseline rates before the introduction of the new guideline. The infection rate may be included, but by itself it may be difficult to document improvement because large numbers are usually needed. Other structural, process or outcome indicators may be measured, and it is also pragmatic to obtain the compliance rate or evidence of behavioural change. This involves assessing the level of several key practices before introduction of the guideline, e.g. observations for hand hygiene compliance rates before and after patient contact, or the amount of antisepsis product used in the institution.

4. Formulate and execute an educational programme focusing on the resistance factors of non-established practice (HCW resistance). Presenting a standardized technique for hand hygiene such as the "five moments" will be an advantage.[1] Many techniques[788,839] for persuasion, such as the use of opinion leaders[758] and participatory decision-making have been described, and successful application in the health-care facility context has been reported.[788,839] The use of these persuasion interventions could be time-consuming and should be reserved only for programmes requiring attitude change, i.e. the non-established practice (HCW resistance) recommendations.

19.1.1 Categorization of recommendations in the guidelines in order to identify educational needs

(i) *Established practice.* A policy for the practice is already present in the institution or is already standard practice. An example is the washing of hands that are visibly dirty or contaminated with proteinaceous material, or are visibly soiled with blood or other body fluids. Even without an official guideline for hand hygiene, many health-care facilities will usually already have such a practice in place.

(ii) *Non-established practice (easy implementation).* It is expected that HCWs would agree with the rationale of the recommendation and also that resources for implementation, if needed, are already in place. Therefore, the practice should be easily implemented by the usual educational programme of in-service lectures or posters. An example is hand antisepsis before inserting peripheral vascular catheters or other invasive devices, as most HCWs will not object to such a reasonable practice. Azjen & Fishbein have shown that, under such circumstances, the desired behaviour will often follow the intent.[840] Studies have shown that where there is agreement for a patient-care practice, a standard educational programme of lectures or posters will be effective.[793]

(iii) *Non-established practice (difficult implementation: lack of resources).* For this category, it is anticipated that implementation would be difficult mainly because of the lack of resources. An example is the need to provide a sufficient supply of alcohol-based handrub for use in areas of high workload and high-intensity patient care so that it is available at the entrance to the patient's room or at the bedside and other convenient locations. A list of such resources should be compiled for the new guideline, and the infection control team must ensure that these materials are in place before launching the implementation programme.

(iv) *Non-established practice (difficult implementation: HCW resistance)*. Implementation is difficult in this category because HCW resistance is expected to be high. An example is the recommendation for hand antisepsis after glove removal as many HCWs may consider their hands to be clean, having been protected by the wearing of gloves. The successful implementation of the new guideline usually hinges on this category of non-established practices (HCW resistance). Disagreement from HCWs is anticipated, and a programme of persuasion is needed to institute the required change. It will be worth while for the infection control team to understand the reasons for resistance, and both quantitative and qualitative studies may be required to elicit these factors. Special studies or surveys may be carried out on the various barriers to hand hygiene that have been identified in the literature. After understanding the reasons for resistance, a special behavioural change strategy might also be adopted to implement these practices[788,839] (see Part I, Sections 18 and 20).

19.2 Organization of a training programme

An educational programme is intended to raise awareness, build knowledge, and help to remind about critical issues and ways of focusing on them. A promotional programme should include a specific training programme if the aim is the development of core competencies (i.e. a system of conceptual and procedural knowledge allowing the identification and the efficient resolution of a problem).[841] Although HCWs are expected to perform hand hygiene, theoretically a very simple act, the contextual sequence of care is often complex, and hand hygiene does not always fall naturally within the care flow. Ideally, hand hygiene should be an automated behaviour that the HCW is able to analyse and adjust according to each specific care situation.

An optimal training programme must be tailored to the target audience, its skills, and requisite capacities. It should focus on different objectives covering the three learning "domains" known as Bloom's taxonomy[842] – affective, psychomotor, cognitive – which are designed to facilitate learning, training, and evaluation. As part of a promotional project, training should include not only educational content (Table I.19.1), but also strategies for promoting, teaching, practising, and assessing practice performance. Teaching and training strategies should aim at progressive educational objectives and preferably facilitate different ways of learning; lessons learnt should be used to strengthen and sustain awareness and practice improvement. The training programme should reach out to each individual in the target audience and include refresher sessions to update knowledge. A variety of educational methods should be used. Among these, the proven instructional effectiveness of five pedagogic methods can be identified: 1) *presentation* of the topic by a traditional lecture accompanied by one or several other methods (e.g. interactive whiteboards, mind mapping, video); 2) *demonstration*: the trainer shows how to perform a certain procedure, assists the trainee in its performance, and asks the trainee to explain the procedure; 3) *interaction*: based on his/her expected background (knowledge, acquired mastery of a given topic), the trainee establishes links and builds knowledge starting from a specific question; 4) *discovery*: a problem-solving approach where the trainee is asked to find the information needed to solve the problem, but without any previous lecture on the topic; and 5) *experiment:* the trainee is stimulated to evaluate his/her personal experience in practical situations and learn from these. The more the methods are integrated into the training programme, the more the programme will relate to each trainee, respond to various needs, and help to build the competence required.

Although training sessions usually require the systematic presence of both the trainer and the trainee, some new perspectives are offered by e-learning, i.e. learning where the medium of instruction is computer technology. E-learning offers considerable flexibility in time, space, and selection of curricula and content which may be particularly useful if a large HCW population has to be trained.[843] Basic computer skills and easy access to a personal computer and the Internet are required, which may preclude the use of e-learning in resource-poor facilities.[843,844] To conceive and construct an e-learning module is a very time-consuming task requiring specific competences by the trainer.[845] However, this form of distance learning ultimately reduces the time and energy investment by the teacher and is very advantageous for easily monitoring the learning process[844]. Successful e-learning programmes in medical and care domains have recently been described,[845,846] with one used in association with traditional training (blended-learning). In building a curriculum, it is recommended to consider e-learning as a pedagogic approach including instruction, social construction, and cognitive, emotional and behavioural perspectives, also encompassing the contextual perspective by facilitating interaction with other people. E-learning should be a strategy that complements the classic teaching methods and remains associated to them.

The focus group technique is well adapted to the subject of hand hygiene. It considers the complexity of an expected behaviour, depending on several multi-influenced aspects (such as perception, attitude, beliefs) independent of the existing knowledge before developing a training intervention. The qualitative research of focus groups may help in tailoring the training aimed at improving hand hygiene.[684,731,847]

Visual demonstration of the effectiveness of hand hygiene with the fingerprint imprint method[72] or the use of a fluorescent dye[814] during practical sessions seems to have a strong impact on persuading HCWs of the importance of hand hygiene.

In many studies, promoting hand hygiene through a multimodal strategy including feedback of local data on HCAI and hand hygiene practices was an essential element of educational sessions and constituted the basis for motivating staff to improve their performance.[60,494,657,663,714,716]

To facilitate the process of starting the project and its following implementation activities.[705,820,834], it is very important to ensure that training sessions are accompanied and supported by educational material such as a guideline summary, leaflets, brochures, information sheets, and flipcharts.

The present WHO guidelines are accompanied by educational material to convey the key recommendations and support training activities. The WHO Implementation Toolkit includes an extensive range of tools for education, including a slide presentation; a brochure summarizing why, when, and how to perform hand hygiene; a leaflet containing the core recommendations of the guidelines; a practical pocket leaflet; and a training film. All these educational tools are centred on the concepts of the "Five moments for hand hygiene" and the correct technique to perform hand hygiene; they are intended to be used as a basis for training the trainers, observers and HCWs, following local adaptation if required. Figure I.19.1 shows the different educational methods that can be used for each category of recommendations.

19.3 The infection control link health-care worker

Research has indicated that the effect of a formal education programme for infection control would be significantly improved when front-line ward HCWs have been recruited to participate in the education programme for the guideline.[758,848] The "infection control link HCW" programme is an attempt to apply this principle in practice and has been widely used to assist in the implementation of guidelines in health-care facilities.[849]

In the infection control link HCW programme, a senior member of staff is appointed from each hospital ward from the pool of HCW staff presently working in that clinical area. She or he becomes the ward or department representative assisting the infection control team in implementing new policies in the institution. The position of the infection control link HCW is generally a voluntary assignment without monetary remuneration, and the HCW is under no obligation to accept the appointment. Special training must be provided for the infection control link HCW so that she or he can be the person on the spot to enhance compliance with guidelines.

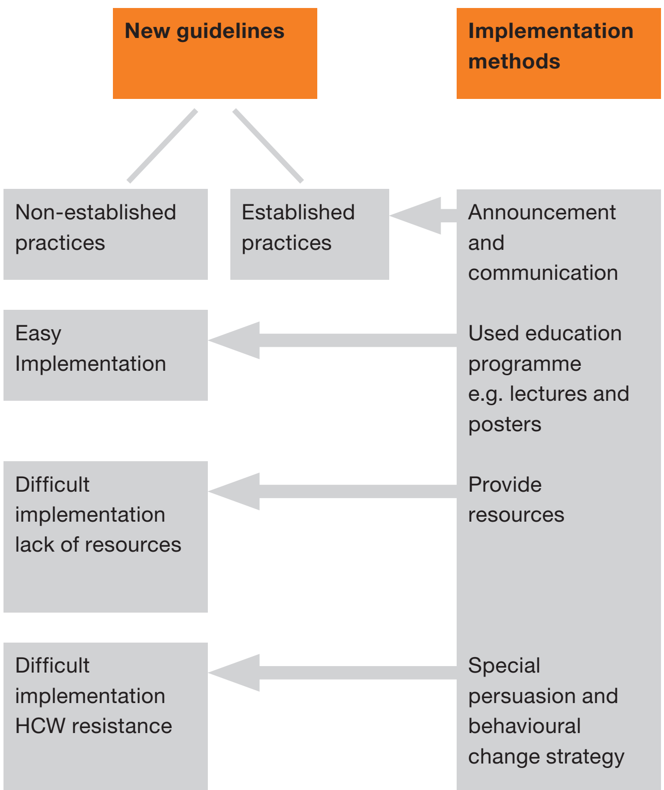
The infection control link HCW could be enlisted to participate in the educational programme of the hand hygiene guideline, and could help to identify the reasons for resistance to the non-established practice (HCW resistance) recommendations. An initial educational session should be organized for the infection control link HCWs before the launch of the formal programme for the entire institution. They could then begin preparing their wards for better acceptance of the guideline. Subsequently, in the institutionwide, formal educational programme, they could also be present to assist in providing comments and answering questions, especially for HCWs who are from their clinical areas.

Other innovative methods should also be explored. For instance, a recent paper reported that the use of an electronic voice prompt is effective in enhancing practice.[699] Social marketing has also been proposed as a possible new approach to enhance compliance in infection control, and perhaps it may be applicable for the implementation of the hand hygiene programme[850] (see Part I, Section 20.3). Indeed, adherence to guidelines is critical for the success of the entire field of infection prevention and control, and not only for hand hygiene. Therefore, organizing an effective formal educational programme requires considerable time and effort, but it remains essential to effect changes in staff behaviour.

Table I.19.1
Contents of educational and training programme for health-care workers

Global burden of health care-associated infections
• Global Patient Safety Challenge
• Morbidity, mortality, and costs associated with HCAIs
Transmission of pathogens
• Routes of transmission
• Consequences for the patient and the HCW (colonization and infections)
Strategy to prevent the transmission of pathogens
• Standard precautions
• Hand hygiene
• Care-associated precautions
Indications for hand hygiene
• Concept of health-care area and patient zone
• "My five moments for hand hygiene"
• Hand hygiene agents and procedures: Care of hands Glove use

Figure I.19.1
Scheme for effective education approaches and implementation of a new guideline



20.

Formulating strategies for hand hygiene promotion

20.1 Elements of promotion strategies

Targets for the promotion of hand hygiene are derived from studies assessing risk factors for non-adherence, reported reasons for the lack of adherence to recommendations, and additional factors perceived as important to facilitate appropriate HCW behaviour (see also Part I, Section 16.3). Although some factors cannot be modified (Table I.20.1), others are definitely amenable to change. Based on the studies and successful experiences in some institutions described below, it appears that strategies to improve adherence to hand hygiene practices should be multimodal and multidisciplinary.

The last 20 years have shown an increasing interest in the subject and many intervention studies aimed at identifying effective strategies to promote hand hygiene have been connducted.[60,217,334,429,485,486,613,648,651,663,666,667,670,680,682,684,686,687,713,714,803,804,851,852] Recent studies have further enriched the scientific literature.[140,428,493,494,655,657,694,698,699,701,705,707-710,715-718,728,853] In general, most studies differed greatly in their duration and intervention approach. Moreover, the outcome measure of hand hygiene compliance varied in terms of the definition of a hand hygiene opportunity and assessment of hand hygiene by means of direct observation[60,217,334,485,486,494,572,613,645,651,657,663,666,667,670,680,682,686,687,701,716] or consumption of hand hygiene products, [60,334,429,486,494,713,717,718,803,804,851] making comparison difficult, if not impossible. Despite different methodologies, most interventions have been associated with an increase in hand hygiene compliance, but a sustainable improvement demonstrated by a follow-up evaluation of two years or more after implementation has rarely been documented.[60,490,494,657,714,715,717,718] Most studies used multiple strategies, which included: HCWs' education,[60,140,334,429,485,486,613,651,663,666,667,670,676,682,684,686,687,698,705,707,708,713,716,717,813,814,819,834,851] performance feedback,[60,334,485,486,651,657,663,666,667,670,676,680,682,684,686,687,713,715,716] reminders,[60,140,334,429,485,494,651,663,666,667,680,682,686,687,694,698,701,717,847] use of automated sinks, and/or introduction of an alcohol-based handrub.[429,485,486,494,645,651,682,686,687,694,698,701,707,717,718,851,854-856] Similarly, these elements are the most frequently represented in the national campaigns recently initiated in many countries worldwide.[857]

Lack of knowledge of guidelines for hand hygiene – combined with an unawareness of hand hygiene indications during daily patient care and the potential risks of transmission of microorganisms to patients – constitute barriers to hand hygiene compliance. Lack of awareness of the very low average adherence rate to hand hygiene of most HCWs and lack of knowledge about the appropriateness, efficacy and use of hand hygiene and skin care protection agents determine poor hand hygiene performance.[738] To overcome these barriers, education is one of the cornerstones of improvement in hand hygiene practices.[58,60,140,334,429,485,486,613,648,651,663,666,667,670,676,682,684,686,687,698,705,707,708,713-717,750,813,814,819,834,851] However, lack of knowledge of infection control measures has been repeatedly shown after training.[789]

Audits of hand hygiene practices (see also Part III, Section 1.1) and performance feedback have comprised several multifaceted promotion campaigns and are valued as one of the most effective strategies.[60,334,651,657,665,676,684,686,687,715,716,738,858] Two studies have reported a very positive impact on hand hygiene attributable to feedback performance.[666,676] Conversely, these results should be viewed with caution. In one study,[666] no statistical evaluation is provided and the very low number of observed opportunities during the three surveys precludes further conclusions. Tibballs and colleagues[676] showed an extraordinary improvement after feedback of hand hygiene practices. One of the caveats in this study is that baseline compliance was obtained by covert observation and the subsequent survey was overtly performed, which might have favoured better results.[335]

The change in system from the time-consuming handwashing practice to handrub with an alcohol-based preparation has revolutionized hand hygiene practices, and is now considered the standard of care.[58] Several studies show a significant increase in hand hygiene compliance after the introduction of handrub solutions.[60,140,334,428,429,485,486,494,613,645,682,686,687,698,701,707,717,718,855]

Of note, handrub promotion with an alcohol-based preparation only started to be tested in intervention studies during the late 1990s. In most of these studies, baseline hand hygiene compliance was below 50%, and the introduction of handrubs was associated with a significant improvement in hand hygiene compliance. In contrast, in the two studies with baseline compliance equal to or higher than 60%,[613,682] no significant increase was observed. These findings may suggest that high profile settings may require more specifically targeted strategies to achieve further improvement.

Most studies conducted to test the effectiveness of hand hygiene promotion strategies were multimodal and used a quasi-experimental design, and all but one[713] used internal comparison. Consequently, the relative efficacy of each of these components remains to be evaluated.

HCWs necessarily evolve within a group, which functions within an institution. It appears that possible targets for improvement in hand hygiene behaviour not only include factors linked to the individual, but also those related to the group and the institution as a whole.[494,715,724,738,789] Examples of possible targets for hand hygiene promotion at the group level include education and performance feedback on hand hygiene adherence, efforts to prevent high workloads (i.e. downsizing and understaffing), and encouragement and role modelling from key HCWs in the unit. At the institutional level, targets for improvement are the lack of written guidelines, available or suitable hand hygiene agents, skin care promotion/agents or hand hygiene facilities, lack of culture or tradition of adherence, and the lack of administrative leadership, sanctions, rewards or support. Enhancing individual and institutional attitudes regarding the feasibility of making changes (self-efficacy), obtaining active participation at both levels, and promoting an institutional safety climate all represent major challenges that go well beyond the current perception of the infection control professional's usual role.

Table I.20.1 reviews published strategies for the promotion of hand hygiene in hospitals and indicates whether these require education, motivation or system change. Some of the strategies may be unnecessary in certain circumstances, but may be helpful in others. In particular, changing the hand hygiene agent could be beneficial in institutions or hospital wards with a high workload and a high demand for hand hygiene when alcohol-based handrub is not available.[182,185,656,859] A change in the recommended hand hygiene agent could be deleterious, however, if introduced during winter in the northern hemisphere at a time of higher hand skin irritability and, in particular, if not accompanied by skin care promotion and availability of protective cream or lotion.

More research is needed on whether increased education, individual reinforcement technique, appropriate rewarding, administrative sanction, enhanced self-participation, active involvement of a larger number of organizational leaders, enhanced perception of health threat, self-efficacy, and perceived social pressure,[720,724,751,789,860] or combinations of these factors would improve HCWs' adherence to hand hygiene. Ultimately, adherence to recommended hand hygiene practices should become part of a culture of patient safety where a set of interdependent elements of quality interact to achieve the shared objective.[861,862]

It is important to note, however, that the strategies proposed in Table I.20.1 reflect studies conducted mainly in developed countries. Whether their results can be generalized to different backgrounds for implementation purposes still needs further research.

20.2 Developing a strategy for guideline implementation

Most guidelines, including the present document, contain a relatively large number of recommendations that vary in their degree of supporting evidence and importance in preventing infection. Moreover, some recommendations focus on interrupting the transmission of pathogens from patient to patient, while others focus on preventing contamination of intravenous catheters and other devices with the patient's own microbial flora. Because of the complexity and scope of these recommendations, prioritization is critical to achieve rapid improvement. These strategic priorities should guide education and guideline implementation.

The first step is to choose the specific recommendations that are most likely to result in fundamental change if practised reliably (in other words, performed correctly almost all the time). Consideration should be given to the specific site and complexity of local health-care delivery, as well as the cultural norms that are in play. These guidelines provide recommendations on a package (so-called "bundle") of interventions that are most likely to have the largest impact on preventing infection in a wide variety of health-care delivery settings. These recommendations balance formal evidence with consensus regarding each specific intervention.

The second step is to perform an assessment (see also Part III, Section 1) to determine whether these practices are indeed being performed. This assessment need not be exhaustive. Sampling strategies should be employed. For example, was hand hygiene practised after the next 10 patient contacts in the dispensary or ward when monitored one day a week over a one-month period? What percentage of bedsides had a filled, operative alcohol dispenser present at 07:00 on one day, 12:00 on another day, and 18:00 on a third? For each recommended high-priority intervention, determine whether:

- the practice is being performed rarely, or not at all;
- the practice is being performed, but not reliably (for example, hand hygiene is performed on leaving a patient's bedside less than 90% of the time);
- the practice is well established and is performed reliably (for example, at least 90% of the time).

Clearly, if a practice is being performed reliably, it is not necessary to have a major education campaign or quality improvement intervention. Simple continuing education and reinforcement together with monitoring to ensure that performance has not deteriorated should suffice. For practices that are not being performed at all, or should be performed more reliably, consider answers to the following questions in deciding how to prioritize and focus education and improvement work:

- Do we agree, and can we convince others, that the practice really is important and is supported by sufficient evidence or consensus?
- Is implementation likely to be easy and timely (e.g. will HCWs resist, are there key opinion leaders who will object, will a long period of culture change be required)?
- Do we have the resources to implement the practice now, and if not, are we likely to obtain the resources (e.g. a reliable supply of alcohol at a price we can afford)?
- Is change within our own power, and if not, what would be required to be successful (e.g. will success require a change in policy by the government, or the development of a reliable, high-quality source for required materials)?

If possible, try to implement the high priority practices as a bundle, emphasizing that the greatest impact can be expected if all of the practices are performed reliably. Experience has demonstrated that this bundled approach catalyses breakthrough levels of improvement and fundamental change in attitude and practice in infection control (see, for example, the "5 Million Lives" campaign at www.ihi.org).[863] Educational programmes are easier to design and digest if they have a coherent theme and emphasize a limited number of critical points. In addition, competency checks and compliance monitoring are simplified.

The Registered Nurses Association of Ontario (RNAO) has produced a series of recommendations for successful implementation based on four published systematic reviews;[864-867] a summary is presented in Table I.20.2. The RNAO goes on to suggest that consideration of the different needs and state of readiness of each target group should be assessed early in the planning stages, citing for example, that implementation approaches for doctors and nurses may require different methods. Acknowledging the context and culture into which a guideline will be implemented is important in attaining "stickiness" (i.e. capacity to "stick" in the minds of the target public and influence its future behaviour) and assuring successful implementation,[868,869] Curran and colleagues[870] reinforce this, by suggesting that local participation and contextualization of implementation interventions is key to adoption and sustainability.

The WHO Multimodal Hand Hygiene Improvement Strategy and tools for implementation are detailed in Part I, Section 21.

20.3 Marketing technology for hand hygiene promotion

In the commercial world, marketing appears to be an efficient and essential technology, judging by the amount of expenditure dedicated to it. Even if a strange idea at first, looking at hand hygiene promotion through a marketer's eyes could help to overcome the dead end of a more traditional, moralistic approach. It would be an error to reduce marketing to simply advertising. Marketing governs all activities that link the product to the consumer and includes components such as market research, product design, packaging, vendor channels, product placing and long-term relationships with customers. Marketing strategies are based on knowledge from psychology, sociology, engineering and economics. Applying marketing to the non-commercial field is not an entirely new concept. Since Philip Kotler introduced the idea of social marketing[871] in the 1970s, the concept has been applied successfully in preventive medicine, and there are increasing numbers of reported examples within the field of infection control[850] and, more recently, in hand hygiene promotion.[1,872]

When applying marketing strategies to infection control, definitions (Table I.20.3) have to be adapted to the health-care setting. Here, HCWs take on the role of customers. Marketing is fiercely "consumer obsessed": it is not about objective truth, but all about what customers believe and feel. Therefore, every product launch starts with "market research" to understand what customers – or HCWs in this case – want, need or demand. The ultimate goal is to ensure that HCWs perceive hand hygiene as an innovative, intuitive-to-use, and appealing object that they associate with professionalism, security, and efficiency. To achieve this goal might involve actions across all levels of marketing as it is understood today.

As a tangible product, a redesigned handrub bottle would constitute a promising object to be used in a marketing strategy. The bottle design will be particularly important. It should not only be practical but attractive to look at and appealing to touch. The cap could open with a discreet but readily recognizable click. The click could then become a stickiness factor to be used in promotional material ("Patient safety – just a click away") and become a slogan among HCWs. The handrub solution should ideally improve skin condition. Market research could single out the best model among various prototypes or identify several different models that each fits a particular segment of the market among all HCWs.

A "marketing strategy" can be developed by making use of the renowned marketing mix known as the "4 Ps" (product, price, promotion, and place).[873] These are considered as the basic building blocks of the marketing mix because they are deduced from four generic conditions for any commercial exchange to come about:

- existence of a tangible or intangible exchange goods (product);
- at least two parties willing to exchange goods of reciprocal value (price);
- communication about the existence and quality of the exchange goods (promotion);
- an interaction in the physical world to deliver the goods (place).

Along with the traditional 4 Ps, we propose a fifth, persistence, to stress the need for specific actions that lead to sustainability in hand hygiene promotion. Explanation of these "5 Ps" and examples of their application in social marketing with regard to hand hygiene promotion are shown in Table I.20.4. The 5 Ps constitute a very powerful and actionable checklist when engaging in a promotional endeavour.

The evolution of marketing science goes in the direction of "societal marketing", "relationship marketing", and "viral marketing" to gain greater effect and sustainability. The Internet brought a new edge to this movement with intercustomer networks and individualized two-way relationships between customers and the industry. Why should hand hygiene advocacy not also profit from this evolution and continue to assimilate new concepts of marketing as they are developed by the industry?

Table I.20.1

Strategies for successful promotion of hand hygiene in health-care settings

Strategy	Action	Selected references[a]
1. System change	Make hand hygiene possible, easy, convenient	60,429,469,493,648,651,684,705,709,851,852,858
	Make alcohol-based handrub available	60,140,429,485,486,494,645,686,687,698,701,707,714,717,718,855,856
	Make water and soap continuously available	633,659
	Install voice prompts	699,710,852,853
2. Hand hygiene education		60,140,334,429,648,651,666,676,684,686,687,698,705,707,708,714-717,813,814,819,851,858
3. Promote/facilitate skin care for HCWs' hands		60,180,608,609
4. Routine observation and feedback		60,334,651,657,665,676,684,686,687,715,716,858
5. Reminders in the workplace		60,140,429,485,489,494,648,651,663,667,680,686,694,698,701,714,717,740,847
6. Improve institutional safety climate	General	60,429,494,651,713,724
	Promote active participation at individual and institutional level	60,429,494,651,713,715,724,847
	Avoid overcrowding, understaffing, excessive workload	60,185,656,668,708,741
	Institute administrative sanction/rewarding	714,720,724
	Ensure patient empowerment	486,803-805,874,875
7. Combination of several of the above strategies		60,140,429,651,657,666,676,684,686,687,701,713,716,717,724

[a]Readers should refer to more extensive reviews for exhaustive reference lists.[48,204,724,738,749,809]

Table I.20.2

Evidence on implementation strategies: data from the Registered Nurses Association of Ontario

Evidence on implementation strategies		
Generally effective	**Sometimes effective**	**Little or no effect**
• Educational outreach visits • Reminders • Interactive education visits • Multifaceted intervention including two or more of the following: – Audit and feedback – Reminders – Local consensus process – Marketing	• Audit and feedback • Local opinion leaders • Local consensus processes • Patient-mediated interventions	• Educational materials • Didactic educational meetings

Table I.20.3
Key marketing concepts and their application to the field of hand hygiene

Concept	Marketing	Hand hygiene
Product	The exchange good can be a tangible object or an intangible service	Hand hygiene: a handrub solution, a moment of its use
Customer	An individual or institution interested in acquiring a product; can be a party that does not actually consume the product but delivers it to a further party.	HCW Health-care institution
Consumer	Customer who actually consumes the product	Could be the patient who profits from hand hygiene use
Need	Basic requirements to live	HCWs have no need for hand hygiene, but they have a need for recognition and for self-protection that can be associated with optimal hand hygiene performance
Want	A desire for a product that can or cannot be met by an exchange value to meet its price	HCWs do not usually 'want' hand hygiene
Demand	A desire for a product that is met by the necessary exchange value	Ideally, hand hygiene becomes a demand for HCWs; this would be achieved when they perceive enough benefit against the 'costs'
Market	Customers who are targeted by a given product	All HCWs: eventually including patients as consumers
Market research	Research to understand customers and their needs, wants, and demands	Understanding the values and perceptions of HCWs (and eventually patients) towards hand hygiene
Market segmentation	Grouping of customers into groups with similar behaviour vis-à-vis a product; the market mix	Groups of HCWs and/or patients with unique common values and interests in hand hygiene
Exchange	Act of exchanging a product against an exchange value that corresponds to the price between the firm and their customers	Making HCWs perform hand hygiene in exchange of a perceived added value (i.e. appreciation by patients)
Branding	To give a firm or a product a unique set of attributes with a high value of recognition	Giving hand hygiene a positive image optimally linked to a correct use
Market mix	Building a marketing strategy from basic building blocks called the 4 Ps (Product, Price, Place, Promotion), optimized according to the findings of market research	Optimal design of promotional activity to increase hand hygiene compliance according to the 4 Ps after investigation of the HCWs' demands, groups with similar views, and the position of hand hygiene in the institution

Table I.20.4
The "5 Ps" of the market mix and their translation into hand hygiene promotion

5 Ps	Description	Commercial marketing example	Hand hygiene marketing example
Product	An object or a service designed to fulfil the needs, wants or demands of customers	Soda brand, computer operating system, adventure holidays, counselling	• New hand hygiene formula • One hand-operated personal handrub dispenser • "My five moments for hand hygiene" • Clear and uniform language in hand hygiene matters • Building a local hand hygiene "brand"
Price (cost)	The price is the amount a customer pays for a product. It is determined by a number of factors including market share, competition, material costs, product identity and the customer's perceived value of the product. The price relates to what can be gained by buying the product, its exchange value	Introduction price, overpricing, sales	• Costs to buy the handrub for the institution's management; • Non-monetary cost for good compliance for the HCWs such as negative image with colleagues • Price as time consumption, hand hygiene going against the rhythm of work flow • Negative impact on skin condition • Negative perception
Place	Place represents the location where a product can be bought. It is often referred to as the distribution channel. In a second, wider sense, the "place" refers to the *emotional* context in which the product appears	Web site, convenient proximity to other products, motor race atmosphere, adventure, admired film star, success	• Use-centred placement of handrub dispensers • Distribution channels of handrub, training location • Perceived emotional environment of hand hygiene
Promotion	Promotion embraces all communication about a product with the intention to sell it. Four channels are usually distinguished: 1) advertising that promotes the product or service through paid for channels; 2) public relations, free of charge press releases, sponsorship deals, exhibitions, conferences, etc.; 3) word of mouth, where customers are taking over the communication; and 4) point of sale	TV spot for a shower gel, contest to introduce a new telephone service, sponsorship for a solar car race, "non-smokers are cool" TV spot	• Promotion of alcohol-based handrub for hand hygiene on posters • By word of mouth • Through subtle 'product placing' in scientific meetings or coffee breaks
Persistence	Marketing approach to increase sustainability, 'relationship marketing', investing in long-term relations between the firm or a brand on one side and customers on the other; investment in social consumer networks	VIP customer card with cash-back function, investment in brand value, creation of a consumer community network	Integration in the institutional culture and system: • integration in all training courses and material on any other topic • frequent and natural integration in printed and spoken information on any topic • abundant and ergonomically placed handrub dispensers; • institutional and by-sector re-engineering of hand hygiene as a 'brand' with the participation of local staff • ongoing staff feedback mechanisms on usability and preferences

21.

The WHO Multimodal Hand Hygiene Improvement Strategy

21.1 Key elements for a successful strategy

The successful implementation of guidelines into practice continues to elude health improvement efforts globally.[876] The Replicating Effective Programs (REP) framework is one example of a successful approach, although largely within the context of HIV prevention interventions.[877] Recent work has also focused on knowledge transfer, often incorporating learning from the body of knowledge on diffusion of innovation.[869] The literature confirms that there is no magic solution to guarantee uptake and assimilation of guidelines into clinical practice.

Against this background, the *WHO Guidelines on Hand Hygiene in Health Care* have been developed with the ultimate objective of changing the behaviour of individual HCWs to optimize compliance with hand hygiene at the recommended moments and to improve patient safety. For this objective to be fulfilled, a successful dissemination and implementation strategy is required to ensure that practitioners are aware of the guidelines and their use.[728,878]

Ensuring that guidelines are transformed from a static document into a living and influential tool that impacts on the target practice requires a carefully constructed strategy to maximize dissemination and diffusion.[868] Fraser describes implementation as being concerned with the *movement of an idea that works* across a large number of people (the target population). Based on the best available scientific evidence and underpinned by both the long-standing expertise of Geneva's University Hospitals to promote multimodal hand hygiene promotion campaigns[60] and learning from the England & Wales National Patient Safety Agency (NPSA) *clean**your**hands* campaign, the WHO Hand Hygiene Implementation Strategy has been constructed to provide users with a ready-to-go approach to translate the *WHO Guidelines on Hand Hygiene in Health Care* into practice at facility level.

The WHO Multimodal Hand Hygiene Improvement Strategy consists of a Guide to Implementation and a range of tools constructed to facilitate implementation of each component. The Guide to Implementation accompanies the *WHO Guidelines on Hand Hygiene in Health Care* and outlines a process for fostering hand hygiene improvement in a health-care facility. The implementation strategy has been informed by the literature on implementation science, behavioural change, spread methodology, diffusion of innovation, and impact evaluation. At its core is a multimodal strategy consisting of five components to be implemented in parallel; the implementation strategy itself is designed to be adaptable without jeopardizing its fidelity and is intended therefore for use not only in virgin sites, but also within facilities with existing action on hand hygiene. The five essential elements are: system change, including availability of alcohol-based handrub at the point of patient care and/or access to a safe, continuous water supply and soap and towels; training and education of health-care professionals; monitoring of hand hygiene practices and performance feedback; reminders in the workplace; and the creation of a hand hygiene safety culture with the participation of both individual HCWs and senior hospital managers. Depending on local resources and culture, additional actions can be added, in particular patient involvement (see Part V).

21.2 Essential steps for implementation at heath-care setting level

The Guide to Implementation details the actions and resources necessary to ensure each component of the multimodal strategy can become assimilated into existing infection control and safety programmes. The Guide is structured around five sequential steps which are recommended to reflect an action plan at facility level (Figure I.21.1). The target for this approach is a facility where a hand hygiene improvement programme has to be initiated from scratch.

Step 1: Facility preparedness – readiness for action
Step 2: Baseline evaluation – establishing the current situation
Step 3: Implementation – introducing the improvement activities
Step 4: Follow-up evaluation – evaluating the implementation impact
Step 5: Action planning and review cycle – developing a plan for the next 5 years (minimum)

Step 1 is to ensure the preparedness of the institution. This includes getting the necessary resources in place and the key leadership to head the programme, including a coordinator and his/her deputy. Proper planning must be done to map out a clear strategy for the entire programme.

Step 2 is to conduct baseline evaluation of hand hygiene practice, perception, knowledge, and infrastructure available.

Step 3 is to implement the improvement programme: availability of an alcohol-based handrub at the point of care and staff education and training are vitally important. Well-publicized events involving endorsement and/or signatures of commitment of leaders and individual HCWs will draw great dividends.

Follow-up evaluation to assess the effectiveness of the programme naturally comes next as Step 4.

Finally, Step 5 is to develop an ongoing action plan and review cycle. The overall aim is to inculcate hand hygiene as an integral part of the hospital culture. A more comprehensive outline of activity within each step is presented in Figure I.21.2.

Each step in the cycle builds on the activities and actions that occurred during the previous step, and clear roles and responsibilities are outlined within the strategy. The steps are presented in a user-friendly guidebook, designed to be a working resource for implementers and leads in infection control, safety, and quality. Throughout the five steps, activities are clearly articulated and the accompanying tools to aid implementation are clearly signposted. At the end of each step, a checklist is presented and implementers are instructed to ensure all recommended activities have been completed prior to moving to the next step. Central to the implementation strategy is an action plan, recommended to be constructed within Step 1, to guide actions throughout each subsequent step.

Rather than a linear process, the five steps are intended to be dealt with in a cyclical manner, with each cycle repeated, refined, and enhanced over a minimum 5-year period. A key feature of an implementation strategy is evaluation and this is a permanent feature of the WHO multimodal strategy during Steps 2 and 4. Implementation, evaluation, and feedback activities should be periodically rejuvenated and repeated and become part of the quality improvement actions to ensure sustainability. Following the full implementation of the strategy for the first time, the plan of activities and long-term steps should be based on lessons learnt about key success factors and on areas that need further improvement. Therefore, the choice to privilege some specific activities and/or steps might be performed.

21.2.1 Basic requirements for implementation

In situations where the complete implementation strategy is not considered feasible, perhaps because of limited resources and time, implementers can focus on minimum implementation criteria to ensure essential achievement of each component of the multimodal strategy. The eight criteria are listed in Table I.21.1.

21.3 WHO tools for implementation

The Guide to Implementation is accompanied by an Implementation Toolkit (called Pilot Implementation Pack during the testing phase and illustrated in Figure I.21.3) including numerous tools (Table I.21.2) to translate promptly into practice each of the five elements of the WHO Multimodal Hand Hygiene Improvement Strategy. These tools focus on different targets: operation, advocacy, and information; monitoring; hand hygiene product procurement or local production; education; and impact evaluation. The latter is an essential activity to measure the real impact of the improvement efforts at the point of care. The same tools used for the baseline evaluation should be used to allow a comparison of standardized indicators such as hand hygiene compliance, perception and knowledge about HCAI and hand hygiene, and availability of equipment and infrastructure for hand hygiene. The Guide to Implementation includes details on each tool and instructions on how and when to use it. The practical toolkit represents a very helpful and "ready-to-go" instrument enabling facilities to start immediately their hand hygiene promotion without the need to decide upon the best scientific approach to be selected.

21.4 "My five moments for hand hygiene"

In this section, a new model intended to meet the needs for training, observation, and performance reporting across all health-care settings worldwide is described.[1] This model is also integrated in various tools included in the WHO Multimodal Hand Hygiene Improvement Strategy (see Part I, Sections 21.1–21.3).

The concept of "My five moments for hand hygiene" aims to: 1) foster positive outcome evaluation by linking specific hand hygiene actions to specific infectious outcomes in patients and HCWs (positive outcome beliefs); and 2) increase the sense of self-efficacy by giving HCWs clear advice on how to integrate hand hygiene in the complex task of care (positive control beliefs). Furthermore, it reunites several of the attributes that have been found to be associated with an increased speed of diffusion of an innovation such as *relative advantage* by being practical and easy to remember, *compatibility* with the existing perception of microbiological risk, *simplicity* as it is straightforward, *trialability* as it can be experimented with on a limited basis, and specifically tailored to be *observable.*[879] The fact that the concept uses the number 5 like the five fingers of the hand gives it a 'stickiness factor', i.e. the capacity to "stick" in the minds of the target public and influence its future behaviour, that could make it a carrier of the hand hygiene message and help it to achieve the tipping point of exponential popularity.[880] Since its development in the context of the Swiss National Hand Hygiene Campaign[881] and its integration in the WHO Multimodal Hand Hygiene Improvement Strategy, the concept of "My five moments for hand hygiene" has been widely adopted in more than 400 hospitals worldwide in 2006–2008, of which about 70 have been closely monitored to evaluate impact and lessons learnt.

21.4.1 Concept features and development

Requirement specifications for a user-centred hand hygiene concept.

The main specifications for the concept are given in Table I.21.3. Importantly, it aims for minimal complexity and a harmonious integration into the natural workflow without deviation from an evidenced-based preventive effect. The resulting concept applies across a wide range of care settings and health-care professions without losing the necessary accuracy to produce meaningful data for risk analysis and feedback.

Furthermore, the concept is congruent in design and meaning for trainers, observers, and observed HCWs. This sharing of a unified vision has a dual purpose. First, it avoids an expert–lay person gap and leads to a stronger sense of ownership[882] and second, it reduces training time and cost for observers. Additionally, the robustness of the concept reduces inter-observer variation and guarantees intra-hospital, inter-hospital, and international comparisons and exchange.

21.4.1.1 Health care-associated colonization and infection: the prevention targets

The important concepts of colonization and infection associated with health-care practices have been discussed in depth in Part I.7.

In summary, four negative outcomes constitute the prevention targets for hand hygiene: 1) colonization and exogenous infection of patients; 2) endogenous and exogenous infection in patients; 3) infection in HCWs; and 4) colonization of the health-care environment and HCWs.

21.4.1.2 The core element of hand transmission

During daily practice, HCWs' hands typically touch a continuous sequence of surfaces and substances including inanimate objects, patients' intact or non-intact skin, mucous membranes, food, waste, body fluids, and the HCW's own body. With each hand-to-surface exposure, a bidirectional exchange of microorganisms between hands and the touched object occurs and the transient hand-carried flora is thus continually changing. In this manner, microorganisms can spread throughout a health-care environment and between patients within a few hours.[126,883]

The core elements of hand transmission are stripped down to their simplest level in Figure I.21.4. Effective hand cleansing can prevent transmission of microorganisms from surface "A" to surface "B" if applied at any moment during hand transition between the two surfaces. Typically, surface "A" could be a door handle colonized by MRSA and surface "B" the skin of a patient. Another example would be surface "A" being the patient's groin and surface "B" being an open vascular access hub. If transmission of microorganisms between "A" and "B" would result in one of the four negative outcomes detailed above, the corresponding hand transition time between the surfaces is usually called "hand hygiene opportunity". It follows clearly that the necessity for hand hygiene is defined by a core element of hand transmission consisting in a donor surface, a receptor surface, and hand transition from the first to the second.

21.4.1.3 Conceptualization of the risk: patient zone and critical site

To meet the objective of creating a user-centred concept for hand hygiene, the evidence-based hand transmission model (see Part I.7) was translated into a practical description of hand hygiene indications. The terms *zone*, *area*, and *critical site* were introduced to allow a "geographical" visualization of key moments for hand hygiene (Figure I.21.4a). Focusing on a single patient, the health-care setting is divided into two virtual geographical areas, the *patient zone* and the *health-care area* (Figures I.21.4a and I.21.4b).

The *patient zone* contains the patient X and his/her immediate surroundings. This typically includes the intact skin of the patient and all inanimate surfaces that are touched by or in direct physical contact with the patient such as the bed rails, bedside table, bed linen, infusion tubing and other medical equipment. It further contains surfaces frequently touched by HCWs while caring for the patient such as monitors, knobs and buttons, and other "high frequency" touch surfaces. The model assumes that the patient's flora rapidly contaminates the entire patient zone, but that the patient zone is being cleaned between patient admissions. Importantly, the model is not limited to a bedridden patient, but applies equally to patients sitting in a chair or being received by physiotherapists in a common treatment location. The model also assumes that all objects going in or out of the patient zone are cleaned. If this is not the case, they might constitute an alternative transmission route.

The *health-care area* contains all surfaces in the health-care setting outside the patient zone of patient X, i.e. other patients and their patient zones and the health-care facility environment. Conceptually, the health-care area is contaminated with microorganisms that might be foreign and potentially harmful to patient X, either because they are multiresistant or because their transmission might result in exogenous infection.

Within the patient zone, *critical sites* are associated with infectious risks (Figure I.21.4a): critical sites can either correspond to body sites or medical devices that have to be protected against microorganisms potentially leading to HCAI (called *critical sites with infectious risk for the patient*), or body sites or medical devices that potentially lead to hand exposure to body fluids and bloodborne pathogens (called *critical sites with body fluid exposure risk*), or both precited risks simultaneously (called *critical sites with combined risk*). Drawing blood for example concerns a *critical site with combined risk* that is at the same time associated with an infectious risk for the patient and a body fluid exposure risk for the HCW.

Critical sites either 1) pre-exist as natural orifices such as the mouth and eyes, etc.; 2) occur accidentally such as wounds, pressure ulcers, etc.; 3) are care-associated such as injection sites, vascular catheter insertion sites, drainage exit sites, etc.; or 4) are device-associated such as vascular catheter hubs, drainage bags, bloody linen, etc..

The added value of critical sites lies in their potential use in visual material and training: risk-prone tasks become geographically located and hence more palpable. On the behavioural level, manipulation of critical sites corresponds to either *"a clean/aseptic procedure"* or *"a body fluid exposure procedure"*, and in the case of simultaneous risk, to *"a clean/aseptic and body fluid exposure procedure"*.

21.4.2 The concept and its practical application

"My five moments for hand hygiene" explained

The geographical representation of the zones and the critical sites (Figure I.21.5a) is useful to introduce "My five moments for hand hygiene". The correlation between these moments and the indications for hand hygiene according to the present guidelines is given in Table I.21.4. To further facilitate ease of recall and expand the ergonomic dimension, the five moments for hand hygiene are numbered according to the habitual care workflow (Figure I.21.5b).

Moment 1. Before touching a patient

From the two-zone concept, a major moment for hand hygiene is naturally deduced. It occurs between the last hand-to-surface contact with an object belonging to the *health-care area* and the first within the *patient zone* – best visualized by crossing the virtual line constituted by the patient zone (Figure I.21.5a). Hand hygiene at this moment will mainly prevent colonization of the patient with health care-associated microorganisms, resulting from the transfer of organisms from the environment to the patient through unclean hands, and exogenous infections in some cases. A clear example would be the temporal period between touching the door handle and shaking the patient's hand: the door handle belongs to the health-care area outside the patient zone*,* and the patient's hand belongs to the patient zone. Therefore hand hygiene must take place after touching the door handle and before shaking the patient's hand. If any objects are touched within the patient zone after opening the door handle, hand hygiene might take place either before or after touching these objects, because the necessity for hand hygiene before touching objects within the patient zone is not supported by evidence; in this case the important point is that hand hygiene must take place before touching the patient.

Moment 2. Before a clean/aseptic procedure
Once within the patient zone, very frequently after a hand exposure to the patient's intact skin, clothes or other objects, the HCW may engage in a *clean/aseptic procedure on a critical site with infectious risk for the patient,* such as opening a venous access line, giving an injection, or performing wound care. Importantly, hand hygiene required at this moment aims at preventing HCAI. In line with the predominantly endogenous origin of these infections, hand hygiene is taking place between the last exposure to a surface, even within the patient zone and immediately before access to a critical site with infectious risk for the patient or a critical site with combined infectious risk. This is important because HCWs customarily touch another surface within the patient zone before contact with a critical site with infectious risk for the patient or a critical site with combined infectious risk.

For some tasks on *clean sites* (lumbar puncture, surgical procedures, tracheal suctioning, etc.), the use of gloves is standard procedure. In this case, hand hygiene is required before donning gloves because gloves alone may not entirely prevent contamination (see Part I, Section 23.1).[73,884]

Moment 3. After body fluid exposure risk
After a care task associated with a risk to expose hands to body fluids, e.g. after accessing a critical site with body fluid exposure risk or a critical site with combined infectious risk (*body fluid site)*, hand hygiene is required instantly and must take place before any next hand-to-surface exposure, even within the same patient zone. This hand hygiene action has a double objective. First and most importantly, it reduces the risk of colonization or infection of HCWs with infectious agents that may occur even without visible soiling. Second, it reduces the risk of a transmission of microorganisms from a "colonized" to a "clean" body site within the same patient.[885] This routine moment for hand hygiene concerns all care actions associated with a risk of body fluid exposure and is not identical to the – hopefully very rare – case of accidental visible soiling calling for immediate handwashing.

Disposable gloves are meant to be used as a "second skin" to prevent exposure of hands to body fluids. However, hands are not sufficiently protected by gloves, and hand hygiene is strongly recommended after glove removal (see Part I, Section 23.1). Hence, to comply with the hand hygiene indication in Moment 3, gloves must be removed and subsequently cleansed.

Moment 4. After touching a patient
When leaving the patient zone after a care sequence, before touching an object in the area outside the patient zone and before a subsequent hand exposure to any surface in the health-care area*,* hand hygiene minimizes the risk of dissemination to the health-care environment, substantially reduces contamination of HCWs' hands with the flora from patient X, and protects the HCWs themselves.

Moment 5. After touching patient surroundings
The fifth moment for hand hygiene is a variant of Moment 4: it occurs after hand exposure to any surface in the patient zone, and before a subsequent hand exposure to any surface in the health-care area, but without touching the patient. This typically extends to objects contaminated by the patient flora that are extracted from the patient zone to be decontaminated or discarded. Because hand exposure to patient objects, but without physical contact with the patients, is associated with hand contamination, hand hygiene is still required.

Coincidence of two moments for hand hygiene

Two moments for hand hygiene may sometimes fall together. Typically, this occurs when moving directly from one patient to another without touching any surface outside the corresponding patient zones. In this situation, a single hand hygiene action will cover the two moments for hand hygiene, as moments 4 and 1 coincide. Another example of such a simultaneous moment would be the direct access to a central venous line as a first hand-to-surface exposure after entering the patient zone. In this example, moments 1 and 2 coincide.

Two patients within the same patient zone

Health-care settings and situations have very different features across the world. It may happen that two or more patients are in such close contact that they occupy the same physical space and touch each other frequently. For example, this situation could be represented by a mother with her newborn child, or two patients sharing a single bed or bedding space. In these cases, the application of the patient zone and the actual compliance with the five moments is conceptually and practically difficult. Nevertheless, the two close patients may be viewed as occupying a single patient zone. Hand hygiene is certainly still required when entering or leaving the common patient zone and before and after critical sites according to their specific nature, but the indication for hand hygiene when shifting intact skin contact between the two patients is probably of little preventive value because they are likely to share the same microbial flora.

21.4.2.1 Understanding the visual message

A critical feature to facilitate the understanding and communication of "My five moments for hand hygiene" lies in its strong visual message (Figure I.21.5b). The objective is to represent the ever-changing situations of care into pictograms that could serve a wide array of purposes in health-care settings. The main visual focus depicts a single patient in the centre to represent the point of care of any type of patient. The patient zone, health-care area, critical sites and moments for hand hygiene action are arranged around and on this patient to depict the infectious risks and the corresponding moments for hand hygiene action in time and space. This visual representation is congruent with the point of care concept.

Some limitations can be envisaged in this model and are discussed elsewhere.[1]

21.4.2.2 Training

There are important interpersonal differences when it comes to learning styles. Some individuals respond well to conceptual grouping and will readily understand the risk-based construct of zones and critical sites and the five moments for hand hygiene. The rationale of the current concept is a strong motivator. With these trainees, it is helpful to insist on the main reason for each of the five moments for hand hygiene. Other people respond better to circumstantial cues. For them, it is useful to list the most frequent examples occurring in their specific health-care settings. The five moments' model also offers many possibilities for the development of training tools, including on-site accompanied learning kits, computer-assisted learning, and off-site simulators. It is of importance to understand that HCWs often execute quite sophisticated medical tasks without conscious cognitive attention. Their behaviour is triggered by multiple cues in the environment that are unconsciously processed. To build hand hygiene into their automatic behaviour for these situations, they may need training in a given environment with multiple cues for action. "My five moments for hand hygiene" would serve as solid basic building blocks for such training. It is crucial to determine the delimitation of patient zones and critical sites with local staff in their unique setting, which has the added benefit of increasing process ownership by the concerned staff.

21.4.2.3 Monitoring

Direct observation is the gold standard to monitor compliance with optimal hand hygiene practice. The five moments model can be a valuable aid to observation in several ways. Many care activities do not follow a standard operating procedure, so it is difficult to define the crucial moment for hand hygiene. The five moments' concept lays a reference grid over these activities and minimizes the opportunities for inter- observer variation. Once HCWs are proficient in the five moments concept and its application, they are able to become observers with minimal additional effort, thus reducing training costs.[1] Furthermore, the concept solves the typical problems of clearly defining the denominator as an opportunity and the numerator as a hand hygiene action (see Part III, Section 1.2).

21.4.2.4 Reporting

Reporting results of hand hygiene observation to HCWs is an essential element of multimodal strategies to improve hand hygiene practices.[58,60] Based on the five moments, it is possible to report risk-specific hand hygiene performance in full agreement with training and promotional material. The impact of feedback is thus increased, as the different moments can be individually discussed and emphasized.

21.5 Lessons learnt from the testing of the WHO Hand Hygiene Improvement Strategy in pilot and complementary sites

Since 2006, the WHO Hand Hygiene Improvement Strategy (see Part I, Sections 21.1–21.4) has been tested in a number of health-care settings around the world to generate information on feasibility, validity, and reliability of the interventions, to provide local data on the resources required to carry out the recommendations, and to obtain useful information for the revision and adaptation of the proposed implementation strategies.[62]

Before and during implementation, the Pilot Implementation Pack tools were translated into the six official languages of WHO (Arabic, Chinese, English, French, Russian, and Spanish) and also into some local languages (e.g. Armenian, Bengali, and Urdu). Eight hospitals were selected in seven countries (Table I.21.5.1) located in the six WHO regions (Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean, and the Western Pacific) to participate in the pilot test phase with technical support and careful monitoring from the First Global Patient Safety Challenge team. Field testing has been made also possible through the support of the WHO Regional Patient Safety Focal Points and the WHO representatives at country level, as well as collaboration with expert technical and academic partners and professional associations. Diversity was built into the selection of pilot sites to ensure comparability of the results across the six regions, and they represented a range of facilities in developed, transitional, and developing countries.

All sites identified a project and deputy coordinator and formed a committee mandated to give advice and take decisions on the project plan. The instructions included in the Guide to Implementation and the steps proposed in the action plan were carefully followed in all sites, and all implementation tools were used at the suggested steps (see Part I, Sections 21.1–21.3). Therefore, hand hygiene promotion was conducted according to the WHO strategy, and baseline and follow-up evaluation included the detection of hand hygiene compliance, alcohol-based handrub consumption, perception of hand hygiene by senior managers and HCWs, HCWs' knowledge, and structures related to hand hygiene.

At the same time, a wide range of different health-care settings worldwide also requested to use the WHO Hand Hygiene Improvement Strategy and tools. For this reason, a web-based community forum was established where any health-care facility could enrol in order to access all the tools included in the Pilot Implementation Pack and to ask questions related to implementation. In this way, any health-care facility has been able to participate in field testing as a "complementary test site" (CTS). For logistic and economic reasons, support offered by the WHO to a CTS is limited and mainly web-based. Through the web community, experiences and solutions related to the implementation have also been shared with other test sites.

This has provided a discussion forum exclusively for CTSs and an opportunity for mutual support and exchange during the implementation process.

Pilot testing has been completed in most sites and results have been made available. Similarly, a process of evaluation has been undertaken in some CTSs (Section 21.5.2). Data and lessons learnt from testing have been of paramount importance to revise the content of the present *Guidelines* and to confirm the validity of the final recommendations. Furthermore, when appropriate, they enabled modification and improvement of the suite of implementation tools.

Sections 21.5.1 and 21.5.2 briefly summarize the experience and lessons learnt from the official pilot sites and a number of CTSs. In Section 21.5.1, the specificities of each pilot site regarding implementation and impact and sustainability at local and national/regional levels have been highlighted in brief paragraphs and the lessons are summarized in Table I.21.5.2. A detailed and exhaustive report will be published separately after a careful scrutiny of all data and information available. Specific information about critical aspects of the local production of alcohol-based handrubs is detailed in Section 12.2.

21.5.1 Implementation in pilot sites

WHO African Region (AFR)
Mali - Hôpital du Point G

Hôpital du Point G, an acute-care, 456-bed university health-care facility serving the population of Bamako and its surroundings and being a referral hospital for the entire country, was selected as the pilot site representing the African region. No infection control expertise was available before the enrolment. A pharmacist underwent training in infection control and learnt how to produce the WHO formulation I at the University of Geneva Hospitals and became the project co-ordinator.

The preparation phase was very intensive, in order to set up the conditions for implementation. A committee was established to advise on action plan and take decisions; the hospital directorate showed strong leadership in the promotion and support to the project kick off. Nine units (two surgical, gynaecology and obstetrics, urology, nephrology, infectious diseases, internal medicine, and accident and emergency) representing 13 wards and 224 HCW were selected for pilot testing. The WHO strategy was faithfully implemented fulfilling all steps, starting from December 2006. The WHO-recommended formulation based on ethanol, produced locally from sugar cane and included in the hospital budget, was manufactured at the hospital pharmacy and bottled in 100 ml pocket bottles; a cleaning/recycling process was put in place. At very low cost, 3700 bottles were produced and quality control tests confirmed accordance with the optimal quality parameters in all samples (see also Part I, Section 12.2).

The baseline infrastructure survey identified severe deficiencies in hand hygiene facilities and products. Although clean water was permanently available, only a minority of patient rooms was equipped with sinks (sink:bed ratio equal to 1:22) and no soap and towel were available. This partly explains the very low overall level of hand hygiene compliance (8.0%) among 1932 observed opportunities at baseline. Compliance markedly differed among professional categories, ranging from an average of 3.2% for nursing assistants to 20.3% for doctors and an average of 4.4% for nurses. Compliance also varied among medical specialities, with the lowest level observed in intensive care (2.4%). The level of HCWs knowledge was also very low, with limited understanding of the pathogen transmission dynamics, of the concept of colonization and of the infection risk. Interestingly, according to the baseline perception surveys, the level awareness of the epidemiologic importance of HCAI and of its impact was higher among senior managers than among HCWs.

Implementation of hand hygiene promotion was launched on 2 November 2007 in an official ceremony chaired by the Minister of Health, the WHO representative in Mali and the hospital director, and involving all HCWs. During the event, chairs and HCWs were invited to sign a giant bottle of alcohol-based handrub as a symbol of their commitment, and information leaflets and T-shirts with the project logo were distributed. During the following months, visual posters featuring the WHO project, hand hygiene indications and the technique for handwashing and handrubbing were displayed in study wards. Following the launch, five three-hour education sessions using WHO materials and including feedback of baseline survey results were organised for all study ward HCWs. All participants were given a 100 ml individual pocket bottle of alcohol-based handrub and trained to use it in practice. From this time on, alcohol-based handrub has been regularly distributed by the pharmacy to the study ward head nurses upon return of the empty bottles.

Interestingly, the improvement of critical deficiencies in infrastructure for handwashing was not considered by the hospital directorate as a top priority for improving practices because of resource and cultural issues. Firstly, improving sink:bed ratio is associated with economic constraints at UHPG. Secondly, HCWs consider that sinks in patient rooms are for patient use and are therefore usually reluctant to use them. Thirdly, in patient rooms, soap bars would very likely be taken by patients and/or visitors and to install wall-mounted liquid soap dispensers would be too expensive.

At follow-up evaluation (six months after implementation kick off) hand hygiene compliance increased to 21.8% and handrubbing became the quasi-exclusive hand hygiene technique (93.3%). Improvement was observed among all professional categories and medical specialties, especially as far as indications “after body fluid exposure risk” and “after touching a patient” are concerned. Knowledge scores the following educational sessions increased significantly ($p<.05$) among professionals. The HCWs perception survey highlighted the importance of each component of the strategy for successful promotion.

The project was strongly supported by the hospital directorate which engaged, together with key staff members, in an in depth evaluation of the results of the pilot phase in order to enable sustainability, expansion and further improvement. Hand hygiene promotion and measurement activities have been included in the annual management plans for the entire hospital. Locally adapted posters are in preparation and innovative methods for hand hygiene promotion among most resistant professional categories and for patient involvement will be part of the forthcoming boostering phase of the campaign. The study successful results about the feasibility of the strategy implementation and practice improvement have motivated the Mali government to expand the production of the alcohol-basedhandrub and the dissemination of the strategy to the national level.

WHO Region of the Americas (AMR)/Pan American Health Organization (PAHO)
Costa Rica: Hospital Nacional de Niños (HNN)

The strategy was implemented from March 2007 to September 2008 in 12 wards (290 beds) of HNN, a paediatric hospital in San José, Costa Rica. All steps of the action plan were completed and the facility is now developing a review cycle and a five-year plan to ensure sustainability.

The alcohol-based handrub was produced according to the WHO recommendations by a private company, which accepted to donate the product and the dispensers. The validation of the local production of the WHO-recommended formulation took much longer than expected because of several initial failures at the quality control test level (see Part I, Section 12.2). An engineer reviewed the hospital plan to place the new dispensers at the point of care according to local safety criteria. The system change was critical to the improvement of hand hygiene practices, because alcohol-based handrubs were not previously widely available and, in some areas of the hospital, significant infrastructure deficiencies (sink to bed ratio <1:10) constituted an important barrier.

Observers for hand hygiene monitoring underwent two days of intensive training and were subsequently validated. An official ceremony, chaired by the minister of health, was organized to launch the hand hygiene promotion campaign (Step 3). Giant dolls in the shape of a handrub bottle were prepared and used to market the improvement for promotional purposes. HNN committed also to patient involvement and families were informed of the pilot project and encouraged to use the alcohol-based handrub when caring for their children.

Educational activities with feedback of data collected during the baseline period (Step 2) were organized with the participation of all HCWs from the test units. Overall, 1421 and 1640 hand hygiene opportunities were detected at baseline and follow-up (after 5 months of implementation), respectively. Overall compliance increased from 25.2% to 52.2%. The key success factors of implementation in this site were the high-level, medical leadership and the pragmatic, continuous action by head nurses. Strong support from the government not only facilitated the excellent pilot implementation of the WHO strategy, but also led to its national scale-up with a National Call to Action made by the minister of health to all hospitals in the country.

The Costa Rica experience has had a catalytic influence on other countries in AMR. The expertise of the pilot project team has been successfully exploited by the WHO Regional Office for the Americas (AMRO) in collaboration with PAHO, which has coordinated training initiatives involving other countries. Argentina, Brazil, Colombia, Ecuador, Peru, and Trinidad and Tobago are now preparing to adopt the WHO strategy.

WHO South-East Asia Region (SEAR)
Bangladesh, Chittagong Medical College Hospital (CMCH)

CMCH has been implementing the WHO Hand Hygiene Improvement Strategy since September 2007 in five wards (neonatal care, surgery, orthopaedics, and paediatric and adult ICUs). Given the critical conditions of the hospital (162% bed occupancy, no infection control professional, no data on HCAI and antimicrobial resistance, significant infrastructural deficiencies), there was much scepticism at the time of the pilot enrolment about the feasibility of the project and its worthiness in the presence of other major priorities. To overcome these obstacles, the hospital directorate took the decision to make a major investment in the project. From the CMCH staff, one doctor and one nurse were selected as pilot project coordinators and trained in Lahore and then in Chittagong with the support of the WHO country office. A multidisciplinary infection control committee including the departmental heads of all relevant units was established. The alcohol-based handrub, based on the WHO recommended formulation II (isopropyl alcohol) was manufactured locally by the national Essential Drug Company Ltd. A survey was undertaken to establish the best position for the alcohol-based handrub dispensers to meet the point of care concept. Sinks (1 for every 15 beds) were installed in all of the pilot wards, as only the nursing station and doctors rooms had a sink. In order to improve inadequate water supply, two deep tube wells were sunk and major water supply lines were improved.

Following a preliminary assessment, which clearly highlighted that no hand hygiene action was regularly performed by HCWs because of absence of sinks, running water and soap in the wards, outside the doctors' rooms and the nurses' stations, the decision was taken not to undertake baseline hand hygiene observations and to consider compliance equal to 0% at baseline. Specific challenges to the observation of compliance were the high bed occupancy (two patients per bed in some wards) and overcrowding that made it difficult to apply the patient zone concept, the complexity of the WHO method, and cultural sensitivities to be observed. However, baseline HCW perception surveys yielded some interesting findings. Bearing in mind the infrastructural deficiencies with respect to sink availability, it is significant that during the pre-pilot phase 83.5% and 44.5% of respondents, respectively, stated that their hand hygiene compliance exceeded 50% (most respondents estimated it to be between 80% and 100%) and that they had received formal training in hand hygiene. In addition, 87.8% considered that the performance of hand hygiene required a major effort, and 54.7% stated that the availability of alcohol-based handrub at the point of care would have no or little effect on the improvement of hand hygiene practices.

To launch the implementation phase, a high profile event was held at the hospital with the attendance of the WHO representative, the minister of health, senior ministerial officials, and public and private hospital representatives. Five hundred persons attended the event. In the wards, alcohol-based handrub was made available through wall dispensers and pocket bottles distributed to all HCWs. Posters translated into Bengali were displayed throughout the wards at the locations of alcohol-based handrub dispensers, above washbasins, and between each bed space, and large-size versions of the posters were positioned at the ward entrance. All ward-based staff, both doctors and nurses, were trained to follow the *Guidelines* with refresher courses every fortnight. Some perception difficulties emerged in the use of the WHO educational concepts and tools (see Table I.21.5.2) and a simplified "two moments" approach was adopted. Evaluation of the implementation impact with the use of the WHO surveys has been undertaken (Step 4) and data are under analysis.

The project has led to very beneficial actions beyond hand hygiene improvement both at CMCH and at national level. The CMCH infection control committee is well established and meets regularly every month – or more often if necessary – and plans to expand the WHO strategy to the entire hospital. It is in the process of developing an antibiotic utilization policy, to conduct a prevalence study, and has already pilot infection registers on wards. An audit on surgical procedures is planned to investigate the appropriateness of surgical instruments reprocessing and of surgical hand preparation.

The Joint Secretary Hospital of the Ministry of Health and Family Welfare (MOHFW) visited CMCH during implementation of the pilot and has called for a national roll-out of the pilot project without delay. The MOHFW thus expressed its strong commitment to strengthen infection control across the country, in particular by ensuring that each hospital has a functioning infection control team and propoer access to handwashing facilities by installing one washbasin per 10 beds in all hospitals. Alcohol-based handrub will be procured on a national scale and its use promoted as the gold standard for hand hygiene of non-soiled hands. The proposed timeframe is for roll-out during the financial year 2008–2009 with consolidation during 2009–2010, and a specific budget has already been allocated that includes the strengthening of human resources. The WHO country office will support the MOHFW in the adaptation and updating of guidelines and norms required for the success of the initiative.

WHO European Region (EUR)
Italy: network of 41 ICUs

In November 2006, the Italian ministry of health decided to join the "Clean Care is Safer Care" initiative by launching a national campaign organized by a national coordinating centre for HCAIs (Agenzia Sanitaria e Sociale Regionale Emilia-Romagna) and funded by the National Centre for Disease Control (Centro Nazionale per la Prevenzione e il Controllo delle Malattie, CCM).

Participation in the campaign was proposed to all of the 21 Italian regions and public hospitals. Overall, 190 hospitals from 16 regions joined the campaign, accounting for 315 hospital wards, mostly ICUs and surgical and medical units. The entire range of tools included in the WHO Pilot Implementation Package was translated into Italian and the printed material distributed. One national and four regional training courses for coordinators and observers were organized; the WHO strategy and action plan were entirely adopted (see Part I, Section 21).[886] A web platform was created on the CCM web site for tool downloading, technical questions, and interactive discussion among the sites. One hundred sixty one hospitals reported their findings and experience to the national coordination centre and sent the databases of all surveys included in the WHO strategy. Preliminary analysis of hand hygiene observations related to 66 953 opportunities detected at baseline in 172 hospitals indicate that overall compliance was 43% and that, in 71% of hand hygiene actions, handwashing was the technique used.

Given the high level of data collection accuracy and adherence to the WHO strategy in the Italian campaign, a network of participating ICUs was selected to become the pilot site for EUR according to pre-established criteria (Table I.21.1). Forty-one ICUs from eight regions were eligible, and most of them implemented hand hygiene promotion between October 2007 and January 2008 and conducted baseline and follow-up evaluations during 3–6 months before and after the implementation. Thirty ICUs sent the complete set of baseline and follow-up data of all WHO surveys.

Observations related to 9 828 and 9 302 opportunities were carried out at baseline and follow-up, respectively, with an equal distribution of professional categories and types of indication. Overall, a significant improvement in hand hygiene compliance (from 55% to 69%) was detected following implementation of the hand hygiene strategy. Comparing baseline with follow-up, use of handrubs to perform hand hygiene increased from 36.9% to 60.4% of hand hygiene actions. This is reflected in the structure surveys results from 30 ICUs which indicate that permanent availability of alcohol-based handrubs improved from 70% to 100% and that pocket bottles were available to each HCW in 92% of cases at follow-up (vs 52% at baseline). Improvement was more striking among nurses and nursing students (compliance increased from 58% to 73% and from 52% to 69%, respectively); compliance increased from 48% to 59% among medical doctors and from 56% to 69% among auxiliary nurses. A comparison of the knowledge questionnaire results at baseline and follow-up (1238 vs 802 respondents, respectively) identified areas that need further improvement, e.g. the understanding of the dynamics of microrganism transmission and the role of different sources of infection. In contrast, there was an interesting, positive correlation between the increase of hand hygiene compliance before patient contact (from 49% to 65%) and before an aseptic/clean task (53% to 70%) and the improvement of knowledge at follow-up when answering questions related to these two indications.

According to the perception questionnaire (1116 vs 902 respondents at baseline and follow-up, respectively), the percentage of HCWs who underwent training on hand hygiene increased from 39.7% to 86.6%, respectively. Most respondents attributed the highest scores (6 and 7 of a 7-point Likert scale) to every component of the WHO strategy when asked about the importance of the strategy components in determining their hand hygiene performance improvement.

Working group discussions with 24 pilot ICU coordinators using the CTS evaluation interview template (see Part I, Section 21.5.2) provided very interesting information on the implementation strategy feasibility and invaluable suggestions for improvement (Table I.21.5.2). The discussion was very instructive, particularly to identify actions for securing the sustainability of the hand hygiene promotion programme. In most pilot hospitals, staff working on the wards not involved in the pilot testing requested hand hygiene promotion to be extended to their settings. The campaign is becoming hospital-wide in many institutions and additional health-care facilities have spontaneously joined the national campaign.

WHO Eastern Mediterranean Region (EMR)

For several reasons, more than one pilot site was selected in EMR. Although all sites have committed to undertake all activities included in the action plan for the implementation of the WHO Hand Hygiene Improvement Strategy, they are at different stages of implementation.

Kingdom of Saudi Arabia

Two different health-care settings agreed to participate in the pilot testing in Riyadh, Saudi Arabia. In both sites, a hand hygiene campaign was undertaken in 2005, following the ministerial pledge to the First Global Patient Safety Challenge and the launch of a national campaign. In connection with the latter, all hospitals affiliated to the Ministry of Health were provided with alcohol-based handrubs as the gold standard for hand hygiene according to the WHO strategies. Since 2007, hand hygiene promotion has been further reinforced with participation in the testing of the WHO strategy. In both cases, the hospital bore the entire cost of implementation.

- **King Abdulaziz Medical City (KAMC), Riyadh***,* is a 960-bed teaching hospital delivering high-quality primary, secondary and tertiary health-care services for the Saudi Arabia National Guard. The infection control committee appointed the coordinator and his deputy and also identified infection control practitioners and infection control "champions" (focal points) to implement the activities.

  The KAMC ICUs (seven units: adult, paediatric, neonatal, burn, adult and paediatric cardiovascular, and medical cardiac) and two surgical units were selected to be the pilot wards based on the acuity of care provided, the high risk of microorganism transmission, and the high number of hand hygiene opportunities. Alcohol-based handrub was already available at KAMC, but during the campaign preparation phase a new product was selected among several proposed according to WHO criteria, and the number of fixed dispensers located at the point of care was increased. The goal of the campaign was to reach at least 90% or above compliance with hand hygiene practices.

  Through the use of a specific form, evaluation of the quality of the hand hygiene technique was added to the range of other WHO surveys at baseline and follow-up. Each unit had a champion in charge of carrying out the surveys, coordinating staff training on hand hygiene, and liaising with the campaign coordinator and his deputy. Champions had also to be prepared to meet specific, challenging situations in their interaction with HCWs and others, such as surprise, apprehension of the unknown, scepticism, cynicism, and strong resistance.

  Feedback was given to HCWs, leaders, and key players during the launch day when the promotion campaign was inaugurated. Formal reports on local compliance data were distributed to the respective area directors. The campaign was launched on 13 April 2008 with an official ceremony by the hospital director and other high-level authorities and an advertisement on the KAMC web site. A leaflet was prepared to inform the patients and invite them to participate in the campaign by asking HCWs to perform hand hygiene. An original aspect of implementation at KAMC was the organization of mobile stands inside and around the hospital, which moved to a different location every two to three hours in order to reach all HCWs and patients. These stands, managed by the infection control practitioners, displayed WHO and non-WHO posters and documents on hand hygiene. Stand visitors could watch the WHO training film and were taught the correct technique to perform hand hygiene antisepsis. Throughout a two-month period, 23 training sessions were organized with the participation of 530 staff members from the pilot units. Several promotional tools and posters were adapted from the WHO versions or newly produced in English and Arabic (Table I.21.5.1).

  Overall, 1840 and 1822 hand hygiene opportunities were detected at baseline and follow-up (after three months since implementation), respectively. Overall compliance increased from 45.1% to 59.4% with improvement greatest among nurses (43.9 vs 62.8%). Compliance rates with Moment 3 (after body fluid exposure risk) and Moment 4 (after touching a patient) were high during both observation periods (82.9% vs 85.0% and 67.7% vs 76.2%, respectively). Compliance with Moment 2 (before clean/aseptic procedure) achieved the greatest increase (45.8% vs 84%); improvement was also detected with Moment 1 (before touching a patient) (29.4% vs 58.1%, respectively) and Moment 5 (after touching patient surroundings) (13.2% vs 30.0%, respectively).

- **King Saud Medical Complex (KSMC), Riyadh***,* is a 1446-bed teaching hospital delivering primary, secondary, and tertiary care, under the government of the Saudi Arabia Ministry of Health. It consists of four hospitals: a general hospital, maternity hospital, children's hospital, and a dental centre.

  In September 2007, a hand hygiene committee was created to plan and carry out the activities related to the project. Together with four infection control professionals, three infection control nurses were identified to play the role of trainers for the education sessions and observers. Sessions "train the trainers" were organized and led by the coordinator and deputy coordinator.

  The WHO strategy was implemented hospitalwide, but the observation of hand hygiene practices was carried out only in selected areas. Alcohol-based handrub dispensers were already installed in all wards and departments, but the decision was taken to introduce the WHO formulation. A local company was appointed by the ministry of health to produce different samples of alcohol-based handrub according to the WHO Guide to Local Production. Four types of solutions were produced: one corresponded to the WHO formulation 1 (based on ethanol), while the other three were the same formulation but with some modifications such as a different fragrance or emollient. All four formulations were made in the form of a solution, and all four products were quality control-tested at the University of Geneva Hospitals in Switzerland and found to be consistent with WHO requirements for the final concentrations of the ingredients. Following the reception of these results, the test of acceptability and tolerability of these products among HCWs was carried out according to the WHO method. The best tolerated and most appreciated product was selected and distributed in wall dispensers at the point of care.

Hand hygiene observations were conducted monthly and during the baseline period. KSMC overall hand hygiene compliance was 56%. Feedback of results of the surveys conducted during the baseline period, in particular hand hygiene compliance, was given to all decision-makers on 19 May 2008.

Great emphasis was placed on education at this pilot site. From September 2007 to October 2008, the members of the hand hygiene committee managed to lead 56 sessions during which 998 HCWs were trained in the concepts promoted by the First Global Patient Safety Challenge, in particular, “My five moments for hand hygiene”. In addition, a weekly training session was scheduled every Sunday and attendance was a contract requirement for new staff and for staff renewing their contracts. In 2008, 1297 HCWs participated in these sessions. Much effort was dedicated to producing a large range of new posters on hand hygiene with more visual impact and adapted to the local culture. These were distributed in large quantities across all wards.

Monthly observations during the implementation period (from May to September 2008) documented an increase of the average compliance rate to 75%, with specific departments reaching rates as high as 88.8%.

Pakistan, Institute of Medical Sciences (PIMS)

Three ICUs – medical (9 beds), surgical (14 beds), and neonatal (17 beds) – were selected for pilot testing the WHO Hand Hygiene Improvement Strategy at PIMS, a tertiary referral hospital with 1055 beds. Alcohol-based handrubs have been in use at PIMS since the emergency situation following the 2005 earthquake. In keeping with the WHO project, the WHO-recommended formulation based on isopropanol was produced at PIMS where it replaced the alcohol-based handrub previously purchased from a commercial source at a much higher price (US$ 3.00 per 500 ml vs US$ 1.85 per 500 ml).

Baseline structure evaluation pointed out no relevant deficiency related to handwashing: sink-to-patient ratio was about 1:3, and clean, running water was regularly available. In contrast, alcohol-based handrubs were available (intermittently) in only one of the three ICUs. A high level of awareness of the impact of HCAI and of the importance of hand hygiene was demonstrated by the 123 HCWs responding to the perception survey. It is widely reported that most HCWs believe that compliance in their hospital is higher than 50%. At PIMS, among 755 observed opportunities, the overall hand hygiene compliance at baseline was 34.7% with no significant differences between the major professional categories. Compliance was highest with Moment 1, before touching a patient (60.0% by nurses and 55.5% by doctors), and there was a remarkable difference in the compliance with Moment 4, after touching a patient, between nurses (48.8%) and doctors (22.9%).

On 11 August 2008, a training workshop on hand hygiene was held at PIMS to train the trainers and key individuals involved in the project, and the implementation phase was launched. All staff members of the pilot ICUs were subsequently trained and the WHO hand hygiene posters were made available in Urdu to overcome language barriers. An interesting specificity of the promotion campaign at PIMS was that training was not limited only to regular staff, but was simplified also and offered to the so-called “janitors”, illiterate support employees who are in charge of clinical and human waste disposal and the emptying of urinary bags. The adaptation of educational messages to their level of knowledge was a very challenging task.

The WHO project implementation in ICUs had an overall, positive impact at PIMS because an infection control doctor and three full-time infection control nurses were appointed, and an infection control committee was established. For the first time, proper surveillance of HCAI was also established in the Neonatal ICU using WHO tools. As a result of this project, HCAI has now become a high priority as a part of quality and patient safety agenda of the hospital. In addition, given the substantial cost savings and the potential availability of additional funds, it is planned that the production of the WHO formulation will be expanded for distribution to other wards and departments. In addition, the previous health secretary at the federal ministry of health has expressed an interest to train 100 000 health visitors throughout Pakistan and distribute alcohol-based handrub to them. It is also anticipated that by the end of the project, the WHO representative and the federal ministry of health will explore the feasibility of the production of the WHO formulation on a national scale using public/private partnership.

WHO Western Pacific Region (WPR)
China, Hong Kong Special Administrative Region (SAR): four pilot hospitals

The implementation of the WHO Hand Hygiene Improvement Strategy started in Hong Kong SAR in 2006, a few months after the pledge signature in October 2005. Four pilot hospitals with 20 study wards in total have progressively enrolled since April 2006. Enrolled wards were surgery, internal medicine, adult ICUs, orthopaedics, and geriatrics. Each hospital selected a coordinator and a team of infection control professionals to carry out the project. Aspects specific to the study design for Hong Kong SAR pilot hospitals included that each test ward be associated with a control ward of the same type, and the conduct of a long-term follow-up of hand hygiene compliance measurement.

During the preparation phase, much energy was devoted to setting up the local production of the WHO formulations in the perspective of ensuring cost–effectiveness and large-scale production. Production was put out to tender, and the company proposing the lowest price (including the purchase of plastic fixed dispensers and pocket bottles) was selected. The quality of the final products was ascertained at Geneva’s University Hospitals (see Part I, Section 12.2). The WHO tolerability and acceptability survey (double-blind, randomized, cross-over design) was carried out, and 65% of HCWs indicated a preference for one of the two WHO alcohol-based handrub formulations in use, although some considered it to have an unpleasant odour. All 41 Hong Kong SAR public hospitals are currently purchasing the WHO formulations from the selected local company at the price of US$ 0.50 for the 100 ml bottle and US$ 1.60 for the 500 ml dispenser. Compliance at baseline (April–October 2006) was 20.7% and 22.2% in study and control wards, respectively. Such low rates are surprising in Hong Kong SAR, when considering the major achievements with hand hygiene compliance only a few years previously at the time of the severe acute respiratory syndrome (SARS) outbreak.

Implementation in the test wards of the Hong Kong SAR pilot hospitals involved original aspects of adaptation of the WHO strategy and tools. Education was carried out by presentations targeted to the different professional categories. Different scenarios simulating real care situations were presented to staff, and solutions and explanations were given. All possible efforts were made to enhance HCWs access to alcohol-based handrubs by increasing the number of dispensers at the point of care in test wards, distributing the new products in pocket bottles as well with special belts and clip holders, and making powder-free gloves available in test wards. A question and answer (Q&A) leaflet was prepared, responding to all HCWs' concerns about the use of alcohol-based handrubs (e.g. skin damage, fire safety, bottle contamination), and topics were discussed with HCWs according to the needs. Feedback about hand hygiene performance was given to HCWs individually and immediately after observation. A competition was announced to identify the best slogan to promote "Clean Care is Safer Care" in Chinese. To boost implementation, emphasis was placed on role modelling after the first and the second follow-up periods.

Three periods of follow-up observations were carried out every 3-4 months. In the first period (October 2006–March 2007), overall compliance rates were 56.6% and 18.3% in the test and control wards, respectively. In test wards, compliance improved in all professional categories apart from doctors (15.5% compliance at baseline) who showed no improvement and a significantly lower compliance at all follow-up measurements (mean 23.4%). Between July 2007 and January 2008, the hand hygiene campaign was announced hospitalwide in all pilot hospitals, with an official launch ceremony. All the above-mentioned actions were extended to all wards and no longer limited to test wards only. After the hospitalwide roll-out, compliance rates in test wards remained 52.4%, whereas it increased to 43.8% in the control wards. On 21 January 2008, following the success of the WHO strategy implementation in the pilot hospitals, the Hospital Authority, Hong Kong SAR, launched a national campaign aiming to create an institutional safety climate and improving hand hygiene in 38 public hospitals. At that time a big banner (15 m wide and 9 m hight) was posted up outside the Hospital Authority Head Office for increasing public awareness of the importance of hand hygiene. Most of these hospitals are currently displaying a giant banner on hand hygiene at their entrance to show their participation and using the WHO Implementation Strategy, toolkit, and methodology. It is also of note that the strategy was adapted and successfully implemented in seven home-care facilities in Hong Kong SAR.

21.5.2 Lessons learnt from complementary test sites

Since the start of the testing phase of the WHO Multimodal Hand Hygiene Implementation Strategy, complementary test sites (CTS) were able to access the entire range of tools included in the Pilot Implementation Pack following registration through an interactive web platform created for this purpose. Although CTS did not receive direct monitoring by the First Global Patient Safety Challenge team, a process of evaluation has been undertaken when the implementation phase reached an advanced stage. A structured framework was developed including three levels: level I, the mapping exercise; level II, quantitative evaluation; and level III, qualitative evaluation. The mapping exercise was conducted with the use of an online form and allowed to collect general information about the health-care settings, their progress in the implementation of the WHO Strategy and which tools had been adopted or adapted. Sites at advanced/semi-advanced stages of implementation and which had used most of the WHO tools underwent evaluation levels II and III through a semi-structured telephone interview with the coordinators. The interview included both open and ranking questions (7-point Likert scale) on different components of the WHO Strategy and the Pilot Implementation Pack. The objective was to receive feedback on the drawbacks and advantages of the implementation of the strategy, feasibility of alcohol-based handrub local production, and the validity and obstacles encountered in the use of the tools. For the purpose of quantitative evaluation, the coordinators were requested to send the available data on key indicators e.g. hand hygiene compliance, alcohol-based handrub and soap consumption, as well as the results of the knowledge/perception/structure surveys. Level II evaluation is ongoing.

A total of 114 complete responses were received for the level I survey and concerned both single sites and networks of health-care settings. Forty-seven coordinators from the advanced and semi-advanced sites, representing 230 health-care settings from Egypt, France, Italy, Malta, Malaysia, Mongolia, Spain, and Viet Nam, participated in the level II and III evaluation.

21.5.2.1 Comments on the WHO Multimodal Hand Hygiene Improvement Strategy and the Guide to Implementation

General comments by most coordinators on the WHO Multimodal Hand Hygiene Improvement Strategy indicate that it is comprehensive and detailed, and its action plan very helpful to guide practically the local implementation. For these reasons, it was considered to be a successful model suitable to be used also for other infection control interventions. However, there is a strong need for a summarized/simplified version. Some coordinators raised concerns about the complexity of the strategy and the Pilot Implementation Pack, especially in contexts with limited human resources, while others requested more details on implementation in poorly-resourced countries. As the main focus of the strategy is on hospitals, adaptation to other types of health-care settings was strongly suggested. The overall median score attributed to the usefulness of the Guide to Implementation to help understand the rationale behind the strategy, the step-wise approach to implementation, the objectives and application of the tools was 6 (range 4-7). The section on sustainability was considered worthy of expansion with more detail by some individuals.

Some examples of the local adaptation of the strategy are the local production of posters, brochures, training films, badges and gadgets, organization of focus groups on glove use, use of the fingerprint method for educational purposes, and the involvement of patients and visitors in hand hygiene promotion.

21.5.2.2 Comments on specific elements of the WHO Strategy

System change*.* System change was considered a very important component of the WHO Strategy (median score 7, range 4-7). As far as handwashing was concerned, in some cases where major infrastructure deficiencies were present (e.g. lack of sinks and paper towels), these could not be completely overcome, mainly due to lack of resources.

Forty-six CTS adopted locally-produced WHO-recommended handrub formulations produced either at the hospital pharmacy or in a centralized facility. In the sites where handrub was already in use, the system was strengthened through the increase in the number of dispensers and the use of different types of dispensers.

Reported long-term obstacles to system change included staff subconsciously resistant to using handrub (mainly for self-protection reasons), leakage problem with liquid solutions, rumours about handrubs causing skin cancer, and allergic reactions.

Education. This component was considered of major importance for the success of the campaign and the WHO tools were widely used with the addition of local data in most cases. HCWs who had previously received less education expressed the most interest. In many cases, traditional educational sessions with slide-shows were used, but other methods such as interactive sessions and practical sessions on hand hygiene technique were also adopted. The "My five moments for hand hygiene" concept was perceived as the key winning message of the Strategy and the visual impact of the educational tools and the training film were highly appreciated.

Major obstacles were the limited time availability of HCWs beyond the work shifts and the reluctance of doctors to attend training sessions.

The median score attributed to the importance of education was 7 (range 5-7). Scores given to the usefulness of the different WHO educational tools were as follows: training film, 7 (range 5-7); slide presentation, 6 (range 5-7); hand hygiene brochure, 7 (range 5-7); pocket leaflet, 7 (range 5-7); and the 9 recommendations leaflet, 7 (range 5-7).

Observation and feedback. All sites adopted the WHO observation method and found it relatively easy to apply due to the precise instructions included in the Manual for Observers. The median score attributed to both the importance of observation and feedback and the usefulness of the Manual for Observers was 7 (ranges 4-7 and 1-7, respectively). Observers were mainly infection control nurses. Nevertheless, difficulties were experienced for their validation and the time availability for this task, particularly when limited manpower was available.

Feedback was noted as being very important to raise awareness and to acknowledge the results achieved. The method used most frequently was a slide presentation during educational sessions; in some cases, immediate compliance feedback and a written report were given to staff and the hospital directorate. In some facilities, the reaction of HCWs to reported low rates of compliance was not positive; in others, when data were disseminated to other units, they generated much interest to take part in the implementation.

The other WHO tools for evaluation (structure, perception and knowledge surveys) were used in some sites. Although their usefulness to gather a more comprehensive understanding of hand hygiene practices was acknowledged, it was also pointed out that it was too time-consuming to perform the surveys, some questionnaires are too long, and some questions are difficult to understand. In some sites, a combined knowledge/perception questionnaire was developed locally.

Reminders in the workplace. WHO posters were used in all sites and adapted locally in some cases. They were also useful for patients and visitors and led to spontaneous patient participation. Perishability was one concern and, in some sites, posters were plasticized to overcome this problem. The median score attributed to the importance of reminders was 6 (range 3-7;) median scores attributed to the WHO posters were as follows: "5 Moments", 7 (range 6-7); "How to Handrub", 6 (range 5-7); and "How to Handwash", 6 (range 5-7).

Patient safety climate. Some coordinators pointed out that the implementation of the hand hygiene campaign acted as a trigger to introduce other patient safety topics. Support from top managers and the directorate varied from strong practical support to more moral and verbal support among the different sites. No active patient participation was reported. The median score attributed to the importance of the promotion of a safety culture was 6 (range 2-7); scores attributed to the usefulness of the tools to secure managerial support were: information sheets, 5 (range 3-7); advocacy sheet, 4 (range 2-6); and senior managers' letter template, 5 (range 2-7).

Table I.21.1
Basic requirements for implementation

Multimodal strategy	Minimum criteria for implementation
1A. System change: alcohol-based handrub	Bottles of alcohol-based handrub positioned at the point of care in each ward, or given to staff
1B. System change: access to safe continuous water supply and towels	One sink to at least every 10 beds Soap and fresh towels available at every sink
2. Training and education	All staff involved in the test phase receive training during Step 3 A programme to update training over the short-, medium- and long-term is established
3. Observation and feedback	Two periods of observational monitoring are undertaken during Steps 2 and 4
4. Reminders in the workplace	“How to” and “5 Moments” posters are displayed in all test wards (e.g. patients’ rooms; staff areas; out-patient/ambulatory departments)
5. Institutional safety climate	The chief executive, chief medical officer/medical superintendent and chief nurse all make a visible commitment to support hand hygiene improvement during Step 3 (e.g. announcements and/or formal letters to staff)

Table I.21.2
Type of tools* available to implement the WHO Multimodal Hand Hygiene Improvement Strategy

Type of tool	Tool
Informational/technical	*WHO Guidelines on Hand Hygiene in Health Care* A summary of the Guidelines The Global Patient Safety Challenge document Information sheets WHO-recommended hand antisepsis formulation – guide to local production Alcohol-based handrub production planning and costing tool
Educational	Slide presentation on HCAI and hand hygiene for HCWs and observers Training films Pocket leaflet Hand hygiene brochure Manual for observers
Promotional (marketing/reminder tools)	How to handrub poster How to handwash poster “My Five Moments” poster Clean hands poster Clean environment poster Clean practices poster Clean products poster Clean equipment poster Sample letter to chief nurses/senior medical staff
Evaluation and monitoring	Facility situation analysis Country situation analysis Senior executive manager perception survey HCW perception survey Ward structure survey Soap and handrub consumption survey Hand hygiene observation survey HCW knowledge survey How to use Epi-Info Baseline and follow-up data summary report framework Alcohol-based handrub tolerability and acceptability survey

* Most tools are freely available at: http://www.who.int/gpsc/en/

Table I.21.3
Requirement specifications for a user-centred hand hygiene application concept

Consistent with evidence-based risk assessment of HCAI and spread of multi-resistant microorganisms
Integrated into a natural care workflow
Easy-to-learn
Logical clarity of the concept
Applicable in a wide range of health-care settings
Minimising the density of the need for hand hygiene
Maximal know-how congruence between trainers, observers, and HCWs

Table I.21.4
"My five moments for hand hygiene": explanations and link to evidence-based recommendations

Moment	Endpoints of hand transmission	Prevented negative outcome
1. Before touching a patient	Donor surface: any surface in the *health-care area* Receptor surface: any surface in the *patient zone*	Patient colonization with health-care microorganisms; exceptionally, exogenous infection
2. Before clean/ aseptic procedure	Donor surface: any other surface Receptor surface: *critical site with infectious risk for the patient* or *critical site with combined infectious risk*	Patient endogenous infection; exceptionally exogenous infection
3. After body fluid exposure risk	Donor surface: *critical site with body fluid exposure risk* or *critical site with combined infectious risk* Receptor surface: any other surface	HCW infection
4. After touching a patient	Donor surface: any surface in the *patient zone* <u>with</u> touching a patient Receptor surface: any surface in the *health-care area*	HCW colonization; environment contamination
5. After touching patient surroundings	Donor surface: any surface in the *patient zone* without touching the patient Receptor surface: any surface in the *health-care area*	HCW cross-colonization; environment contamination

Table I.21.4
"My five moments for hand hygiene": explanations and link to evidence-based recommendations (Cont.)

Moment	Examples of care situations when the moment occurs	WHO recommendation (ranking for scientific evidence[a])	Comments: changes since Advanced Draft of these guidelines
1. Before touching a patient	Shaking hands, helping a patient to move around, getting washed, taking pulse, blood pressure, chest auscultation, abdominal palpation	Before and after touching patients (IB)	The two moments before and after touching a patient were separated because of their specific sequential occurrence in routine care, unequal negative outcome in case of failure to adhere, and usual adherence level
2. Before clean/ aseptic procedure	Oral/dental care, secretion aspiration, skin lesion care, wound dressing, subcutaneous injection; catheter insertion, opening a vascular access system; preparation of food, medication, dressing sets	Before handling an invasive device for patient care, regardless of whether or not gloves are used (IB)	This concept was enlarged to cover all transfer of microorganisms to vulnerable body sites potentially resulting in infection
		If moving from a contaminated body site to a clean body site during patient care (IB)	Since it is not possible to determine these body sites objectively, this indication was not retained as a separate item, but covered by within *patient zone* moments
3. After body fluid exposure risk	Oral/dental care, secretion aspiration; skin lesion care, wound dressing, subcutaneous injection; drawing and manipulation any fluid sample, opening draining system, endotracheal tube insertion and removal; clearing up urines, faces, vomit; handling waste (bandages, napkin, incontinence pads); cleaning of contaminated and visibly soiled material or areas (lavatories, medical instruments)	After removing gloves (IB)	After body fluid exposure risk covers this recommendation; see text for further comments
		After contact with body fluids or excretions, mucous membranes, non intact skin, or wound dressings (IA)	This risk was generalized to include all tasks that can potentially result in hand exposure to body fluids. A paradox of body fluid exposure was resolved by including the notion of exposure risk instead of actual exposure.
		If moving from a contaminated body site to a clean body site during patient care (IB)	See comment 2 in Moment 2 (before clean/aseptic procedure)
4. After touching a patient	Shaking hands, helping a patient to move around, getting washed, taking pulse, taking blood pressure, chest auscultation, abdominal palpation	Before and after touching patients (IB)	See comment in Moment 1(before touching a patient)
5. After touching patient surroundings	Changing bed linen, perfusion speed adjustment, monitoring alarm, holding a bed rail, clearing the bedside table	After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient (IB)	Retained to cover all situations where the patient's immediate and potentially contaminated environment is touched but not the patient

[a] Ranking system for evidence (see Part II): category IA, strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies; category IB, strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and a strong theoretical rationale.

Table I.21.5.1

Pilot sites for the testing of the WHO Guidelines on Hand Hygiene in Health Care and its strategy and tools

WHO region	Country	City	Hospital	Hospital wards	Status of the testing at finalization of guidelines (October 2008)	Local tool preparation and/or adaptation
AFR	Mali	Bamako	Hôpital du Point G	Pilot testing complete in nine units including medicine, surgery, emergency, anaesthesia and intensive care, gynaecology and obstetrics	Concluded	• Leaflet for hand hygiene campaign launch • WHO-recommended formulation • Promotional tee-shirts
AMR	Costa Rica	San Jose	Hospital Nacional de Niños	Targeted on subset of wards, including infectious disease	Step 5	• Training film • Hand hygiene song • Posters • WHO-recommended formulation
SEAR	Bangladesh	Chittagong	Chittagong Medical College Hospital	Five wards representing 450 beds	Step 4	• Translation into Bengali of most WHO tools • Simplified 2-moments observation tool including the case of 2 patients per bed • WHO- recommended formulation
EUR	Italy	National network	Network of 41 ICUs	ICUs selected according to the following criteria: - Having a reliable system for HCAI surveillance (HELICS protocol; surveillance system for MRSA bacteraemia) - Explicit consent to provide requested data (results from all WHO surveys and HCAI rates) - No other major prevention project concurrently to the strategy implementation - Compliance with the time line agreed with WHO	Concluded	• Guide to Implementation summary • Posters • Use of the fingertip method to educate HCWs • Gadgets

Table I.21.5.1

Pilot sites for the testing of the WHO Guidelines on Hand Hygiene in Health Care and its strategy and tools (Cont.)

WHO region	Country	City	Hospital	Hospital wards	Status of the testing at finalization of guidelines (October 2008)	Local tool preparation and/or adaptation
EMR	Saudi Arabia	Riyadh	King Saud Medical Complex	Hospitalwide	Step 5	• Campaign original logo • Posters and banners displayed outside the hospital • Pens, mugs, t-shirts, round big buttons with campaign logo • Screen saver • DVD, educational brochures and pocket leaflets for HCWs, patients (adults and children) and visitors translated into 4 different languages (arabic, english, tagalog, urdu) • Demonstrations of the hand hygiene technique • Use of finger tip printculture to educate HCWs and patients • Drawing book for children with cartoons related to the campaign • WHO-recommended formulation with alternative fragrances and emollients • National hand hygiene guidelines • Hand hygiene guideline summary for the HCWs during pilgrimage season
	Saudi Arabia	Riyadh	King Abdulaziz Medical City	Nine pilot areas including 7 ICUs and 2 surgical wards	Concluded	• Banners and posters • Brochures for HCWs • Brochures for patients • Pocket leaflets for HCWs • Badges, pens and mugs
	Pakistan	Islamabad	Pakistan Institute of Medical Sciences (PIMS)	Medical, surgical and neonatal ICUs	Step 4	• Translation of posters into Urdu • WHO-recommended formulation
WPR	China	Hong Kong SAR	Four pilot hospitals: Queen Mary Hospital, Caritas Medical Centre, Tuen Mun Hospital, Yan Chai Hospital	Selection of tests and control wards in the four hospitals	Concluded	• Giant banners for the outside wall of the hospital • Cartoons and other posters • Q&A leaflet responding to HCWs' concerns about the use of alcohol-based handrubs • WHO-recommended formulation

Table I.21.5.2

Lessons learnt from testing in pilot sites

Country	Site	Lessons learnt and suggestions for improving the WHO strategy
Mali	Hôpital du Point G	• Strong support from the WHO country office was critical to overall pilot success, particularly for ministerial engagement and proposed scale-up activities • Active support from the hospital directorate was critical to the project endorsement and development • Difficulties were experienced with some questions' comprehension and the collection of the perception questionnaires. These should be shortened and simplified • Procurement of some ingredients and dispensers for the WHO-recommended formulation was not possible within the country. • Finding an effective method for the distribution of handrub pocket bottles has been a challenging issue, especially because of the risk of being taken along outside the hospital • Successful implementation at this pilot site has been critical to demonstrate the feasibility of the WHO Multimodal Hand Hygiene Improvement Strategy in a setting with limited resources in the African region
Costa Rica	Hospital Nacional de Niños	• The national pledge was a strong driver for action • Strong support from WHO regional and country offices has been critical to overall pilot success, particularly for proposed scale-up activity • Strong medical and nurse leadership at the facility level was also a key factor of success • Translation and adaptation of tools and the sourcing of alcohol-based handrub were significantly more time-consuming than originally planned and resulted in delays • Strengthening local capacity to verify quality of the WHO formulation would significantly speed up the process for regional scale-up • Strengthening local capacity for monitoring and evaluation, particularly data analysis, would yield significant regional and country benefits • Advocacy could be strengthened and assist in securing donor funding, particularly having a strong case for the intervention and associated advocacy materials • There were initially numerous aesthetic concerns relating to the alcohol-based hanrubs, particularly the perception of "dead microbes" remaining on hands as a disincentive to use the handrub • There were recycling and environmental concerns related to alcohol- based handrub dispensers. Bottle reprocessing offered a solution

Table I.21.5.2

Lessons learnt from testing in pilot sites (Cont.)

Country	Site	Lessons learnt and suggestions for improving the WHO strategy
Bangladesh	Chittagong Medical College Hospital	• The national pledge was a strong driver for action • Strong support form WHO regional and country offices has been critical to overall pilot success, particularly in relation to proposed scale-up activity • Facility preparation, especially installation of handwash basins, took more time than expected. Local procurement of heavy duty sanitary equipments such as lever operated pillar taps was not possible. • The close collaboration of a doctor and a nurse as project coordinators was essential to effectively develop and maintain hand hygiene behavioural change among all HCW and patient attendants • At the facility level, commitment by the director, strong support by the head of the newly formed infection control committee, and strong medical and nurse leadership were significant drivers for improvement • Production of a handrub at the para-statal Essential Drug Company Ltd (EDCL) was effective and facilitates the process to add alcohol-based handrubs to the government approved essential medical and surgical requisition list, aspect which is important for budget implication of the national scale-up • The handrub quality control, performed by the EDCL, in future should be complemented through a WHO quality control mechanism • The Guide to Implementation was a very useful basis for all discussions between WHO headquarters and the country and facility leads • The five-step approach was adhered to but adaptations were made based on real-life application, in particular usability was considered an area requiring improvement (need for a simpler guide) • Strengthening local capacity for monitoring and evaluation, particularly data analysis, would yield significant regional and country benefits • In many cases, relatives provide routine physical care to their patient and are being encouraged to use the sinks and handrubs. Need to provide patients and relatives with information on HCAI or hand hygiene. • Comment boxes are present in hospitals and subject to regular review, demonstrating high-level commitment and a culture supportive of patient perspectives • The “Five moments-2” concept was considered complicated, especially as far as observation is concerned • Initial cultural sensitivities have emerged as regards observation – staff did not like being observed • Perception, knowledge, and structure questionnaires raised questions in relation to their cultural suitability • The training film was not used due to lack of easy access to equipment and and re-shooting the film in a Bangladesh hospital is planned to aid scale-up • It was not possible to procure locally durable, economic and purpose-designed wall mounted handrub dispensers and procurement abroad would have delayed the project by at least 6 months. Instead liquid soap dispenser were procured • With the installation of sinks in the wards, soap use (and with it some theft) increased. Due to a normative annual budgeting and procurement cycle of the hospital consumables, difficulties to supply increased amounts of soap to the wards were experienced • Local production of heavy duty flip-top dispenser head or spray head for pocket-carry bottle was not possible. Instead large numbers of spare flip-top heads were procured • Paper towels and paper towel holder were procured from local markets • Staff feedback on the WHO formulation was positive, though an unpleasant smell after application was reported
Italy	Network of ICUs	• Strong support from the national coordination centre and the regional coordinators has been critical to the overall success of the national campaign and the testing in the ICU network • The fact that the campaign was in partnership with a WHO campaign generated a lot of stimulation and motivation to participate and achieve the intended objectives • The strategy approach was particularly appreciated as a very suitable model for practical implementation of recommendations. Recommendation was made to use the same model for other interventions • The Guide to Implementation is complex and the burden of activities to be carried out is arduous. A summary of the guide was produced by the national coordination centre and considered very helpful • Feedback was considered very important to raise HCWs’ awareness and to maintain a high level of support and attention by senior managers throughout the programme roll-out • The five moments approach, the visual impact of WHO educational tools, and the training film were considered to be the key determinants of the success of educational sessions • Difficulties were experienced to attract the medical audience • The knowledge questionnaire is difficult to understand; an Improvement in the formulation of questions 16 and 21 and the removal of question 26 were suggested. • Difficulties were experienced in the use of the Epi Info databases provided by WHO and therefore it was necessary to make corrections and adaptations

Table I.21.5.2
Lessons learnt from testing in pilot sites (Cont.)

Country	Site	Lessons learnt and suggestions for improving the WHO strategy
Saudi Arabia	King Saud Medical Complex	• Strong infection control team and support from the hospital directorate were keys to the success • In general, the WHO strategy requires considerable investment, particularly in human resources. This is not very clear in the Guide to Implementation • WHO should offer training on using Epi Info for data entry and especially data analysis • When the WHO formulation (liquid) was introduced, some HCWs expressed their preference for gel products • The knowledge questionnaire is difficult to understand in many places, especially questions 23, 24, and 25
Saudi Arabia	King Abdul Aziz Medical City	• Leadership is an important success factor. • Assessing shared beliefs and values regarding the issue of patient safety is highly important in order to create a safety culture • A patient-centred/customer-focused approach would be beneficial. • It is important to build on system thinking and not individual thinking • More training is needed for co-ordinators on: behavioural theories; change management; and project management principles • A post description is needed to facilitate co-ordinator selection. • Some questions regarding the perceptions and knowledge questionnaires are redundant and others are difficult to understand and need re-wording • A “facilitators guide” together with the PowerPoint presentation can be very helpful. The presentation should include slides that assess the feelings (emotions) of the HCWs, i.e. photos of infections, experiences of people who were infected, etc. • The “Let us do it Together” form to assess the “how to” perform hand hygiene (psychomotor) should be added to the other WHO tools • A standardized “sample” reporting format is needed where metrics are shown in a consistent manner • An Excel sheet could be helpful for the calculation of product consumption • Communication is the key component of success: to provide ideas on the topic in a very helpful and informative manner (communications management plans) • A small guide is needed on how to overcome resistance to change • Coordinators and project facilitators should be trained on how to address HCWs’ resistance, i.e. surprise, apprehension of the unknown, scepticism, cynicism, complacency, strong resistance, etc.
Pakistan	Pakistan Institute of Medical Sciences (PIMS)	• The success of this project was possible due to strong commitment of PIMS senior management. • The project is very demanding in terms of time to be dedicated to education, because of shortage of permament members of staff and high turnover of medical and nursing students • Language barriers exist (especially among non-medical staff), and there is a need for translation of the WHO material into the local language (currently been undertaken) • There are difficulties to identify some tasks as “aseptic”, e.g. dental/oral care; therefore, the wording of Moment 2 is not adequate • Availability and production of good quality 100 ml flip-top bottles to dispense alcohol-based hand rub was challenging • Providing a dedicated room with adequate temperature control and storage facilities for the production and storage of alcohol was a difficult task • The Guide to Implementation was complex and difficult to understand • Delay to obtain quality control information of locally produced WHO formulation from Geneva because of restriction of sending liquid sample by postal and couriers services • Staff were delighted at the introduction of the WHO formulation as the commercial product previously in use had a very high incidence of dermatitis • No religious issues were raised on the use of the alcohol-based handrub product
Hong Kong SAR	Four pilot hospitals	• Barriers to implement system change: HCWs’ concerns about the use of alcohol-based handrubs (potential skin damage, fire safety, and pocket bottle contamination) and the perception that hands are clean only after handwashing. • Difficulties to allocate time to attend the education sessions • No hand hygiene compliance improvement was observed among doctors. The WHO strategy should include suggestions and ideas how to induce behavioural change in different professional categories

Figure I.21.1
Visual representation of the 5-Step Implementation Strategy

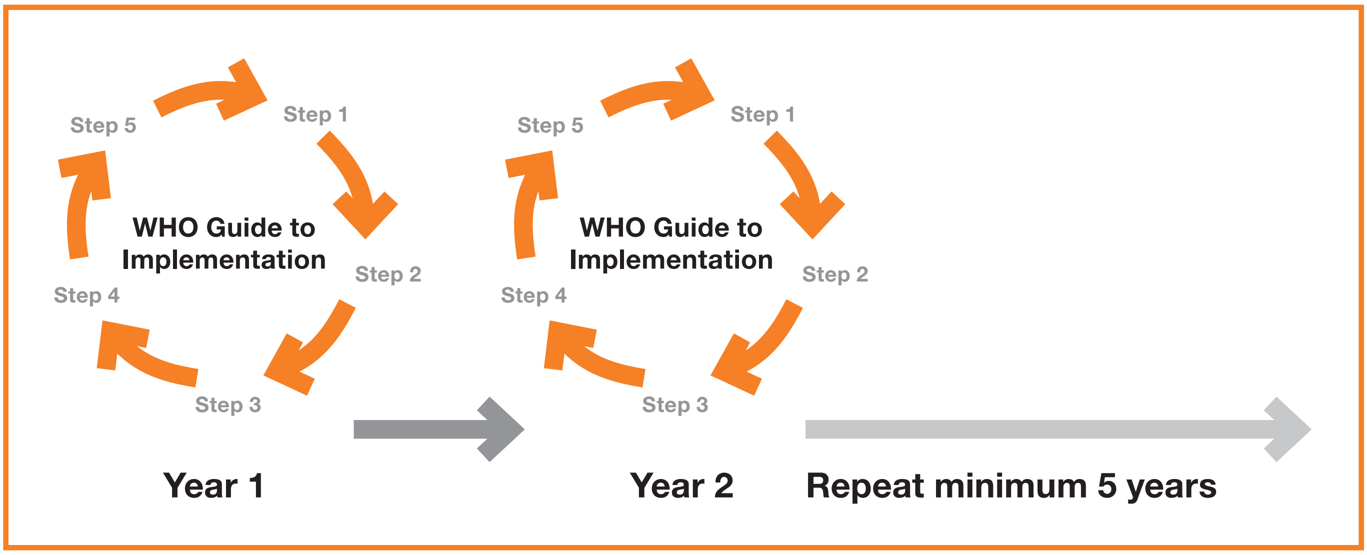


Figure I.21.2
Action plan step-by-step

Step 1: Facility Preparedness	**Step 2: Baseline Evaluation**	**Step 3: Implementation**	**Step 4: Follow-up Evaluation**	**Step 5: Developing Ongoing Action Plan and Review Cycle**
Activities	**Activities**	**Activities**	**Activities**	**Activities**
• Identify coordinator	• Baseline Assessments: undertake	• Launch the strategy	• Follow-up assessments: undertake	• Study all results carefully
• Identify key individuals/ groups	• Senior managers perception survey	• Feedback baseline data	• Health-care worker knowledge survey	• Feedback of follow-up data
• Undertake Facility Situation Analysis	• Health-care worker perception survey	• Distribute posters	• Senior executive managers perception survey	• Develop a five year action plan
• Complete alcohol-based handrub production, planning and costing tool	• Ward structure survey	• Distribute alcohol-based handrub	• Health-care workers perception and campaign evaluation survey	• Consider scale-up of the strategy
• Train observers/trainers	• Local production or market procurement of handrubs	• Distribute other WHO materials from the Pilot Implementation Pack	• Facility Situation Analysis	
• Procure raw materials for alcohol-based handrub (if necessary)	• Data entry and analysis	• Educate facility staff	• Data entry and analysis	
• Collect data on cost-benefit	• Hand hygiene observations	• Undertake practical training of facility staff	• Hand hygiene observations	
• Evaluate computer equipment	• Health-care worker knowledge survey	• Undertake handrub tolerance tests	• Monthly monitoring of use of products	
• Undertake training on data entry and analysis	• Monitor use of soap and alcohol	• Complete monthly monitoring of usage of products		

Figure I.21.3

The Pilot Implementation Pack (now named "Implementation Toolkit") comprising tools corresponding to each component of the WHO Multimodal Hand Hygiene Improvement Strategy

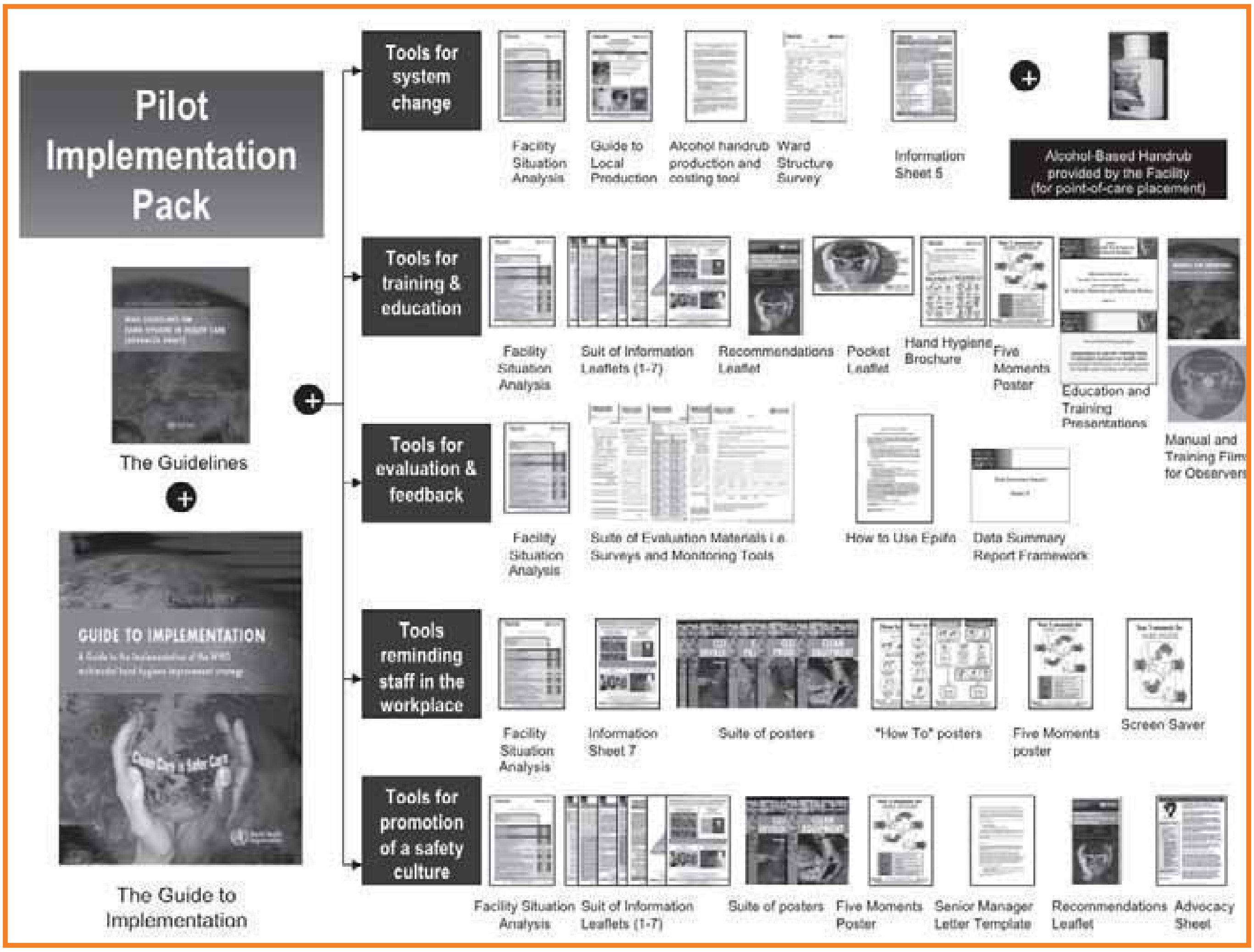
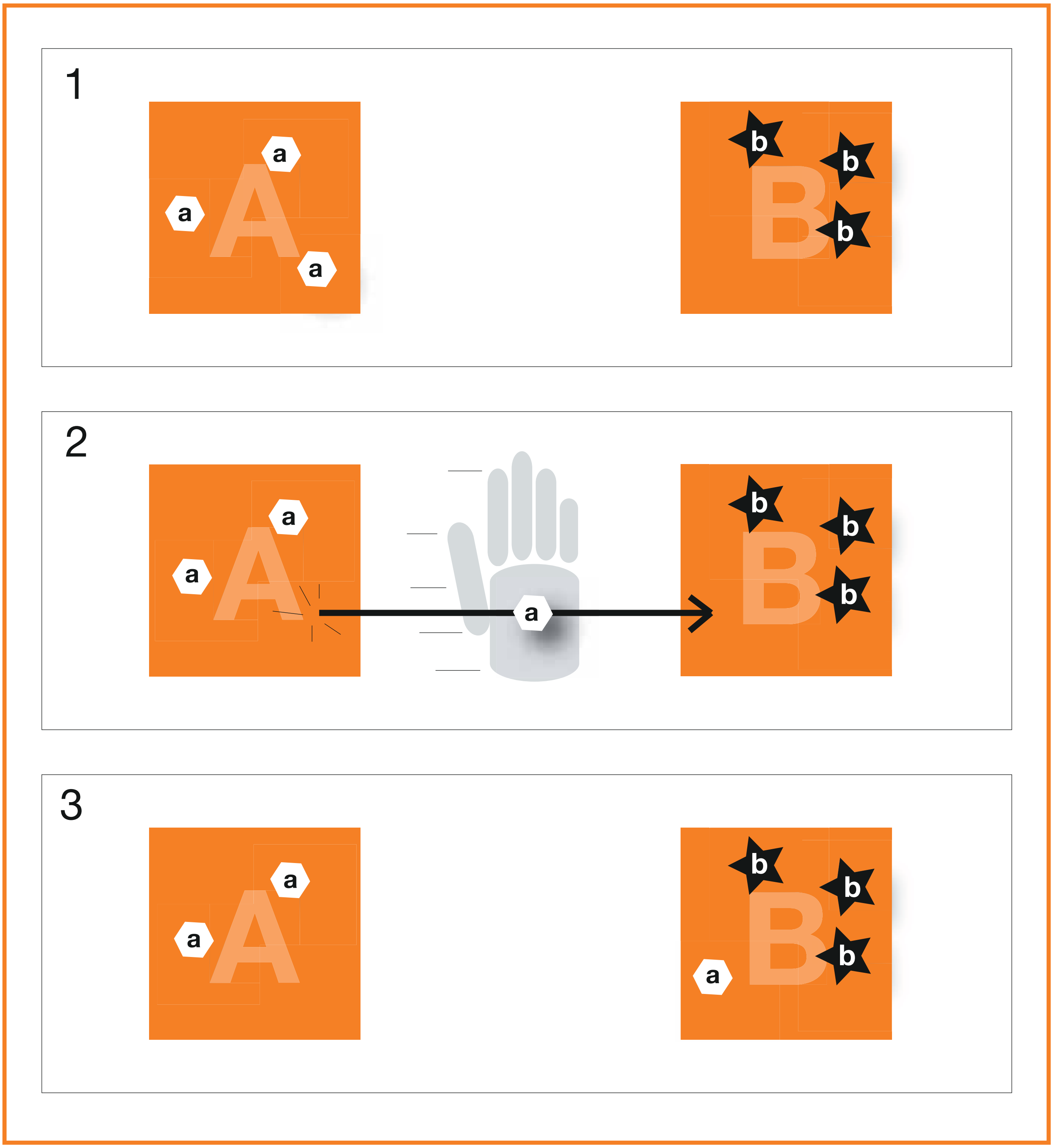


Figure I.21.4
Core elements of hand transmission



1) Donor surface "A" contains microorganisms "a"; receptor surface "B" contains microorganisms "b".
2) A hand picks up a microorganism "a" from donor surface "A" and carries it over to receptor surface "B", no hand hygiene action performed.
3) Receptor surface "B" is now cross-contaminated with microorganism "a" in addition to original flora "b". The arrow marks the opportunity for hand hygiene, e.g. the time period and geographical dislocation within which hand hygiene will prevent cross-transmission; the indications for hand hygiene are determined by the need to protect surface "B" against colonisation with "a" – the preventable negative outcome in this example.

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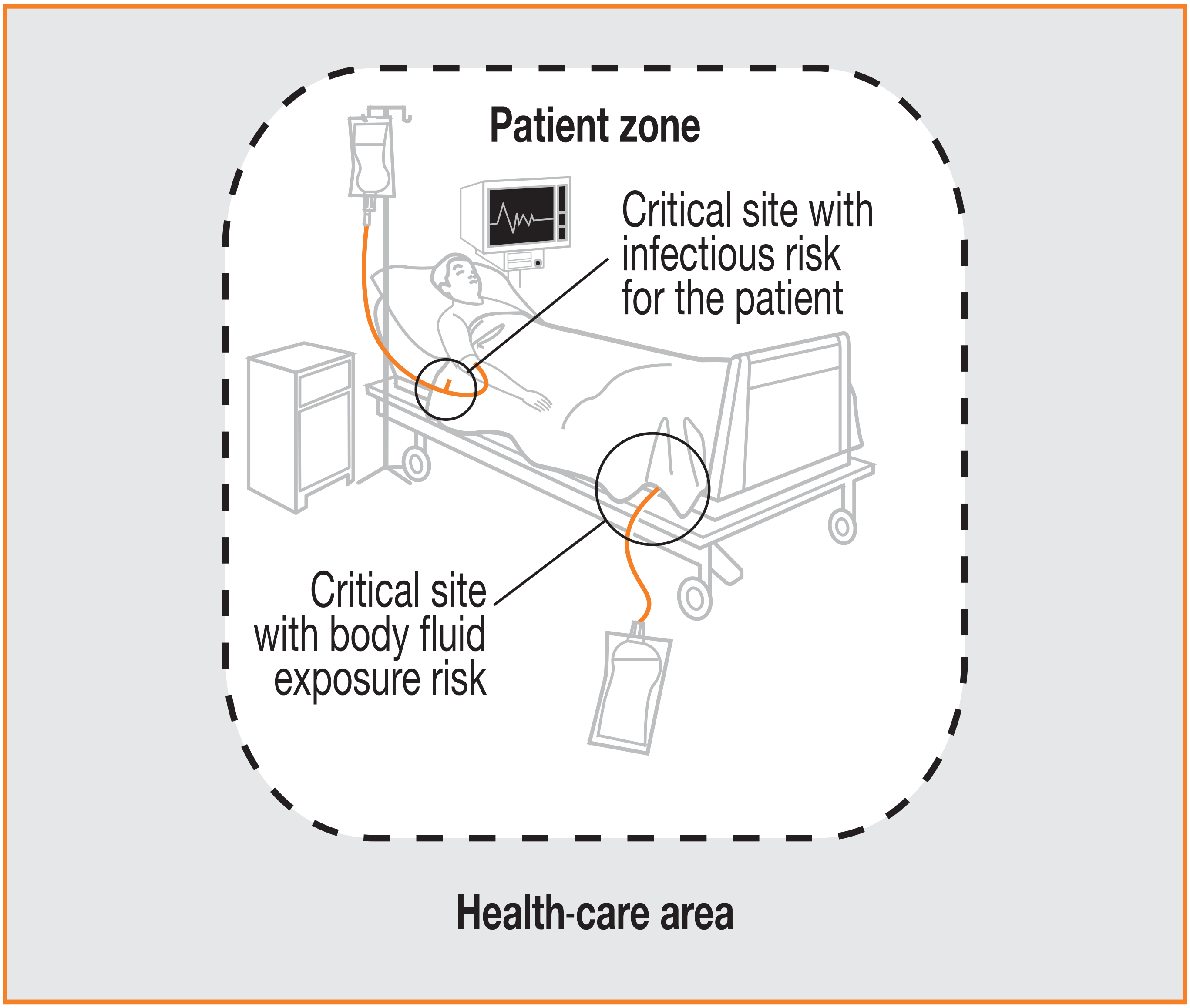
Figure I.21.5a
Unified visuals for "My five moments for hand hygiene"



The *patient zone* is defined as the patient's intact skin and his/her immediate surroundings colonized by the patient flora and the *health-care area* as containing all other surfaces.
Symbols for *critical sites with infectious risk for the patient* and *critical sites with body fluid exposure risk*, two critical sites for hand hygiene within the patient zone (Figure I.21.5a).
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Figure I.21.5b
Unified visuals for “My five moments for hand hygiene”

The *patient zone, health-care area,* and *critical sites* with inserted time-space representation of “My five moments for hand hygiene” (Figure I.21.5b).
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22.

Impact of improved hand hygiene

Evaluation of the effectiveness of hand hygiene guidelines or recommendations on the ultimate outcome, i.e. the HCAI rate, is certainly the most accurate way to measure the impact of improved hand hygiene, but it represents a very challenging activity. Indeed, guideline implementation should not be evaluated per se but in relation to the availability of clear instructions on how to translate it into practice and, ideally, the existence of related tools and impact of their implementation. As an illustration, in a sample of 40 hospitals in the USA, Larson and colleagues found that although most HCWs were aware of the hand hygiene guidelines with alcohol-based handrub available in all facilities, a multidisciplinary implementation programme was conducted in only 44.2% of the hospitals.[728] The impact was quite disappointing: mean hand hygiene compliance rates were no higher than 56.6%, and the correlation of lower infection rates with higher compliance was demonstrated only for bloodstream infections. The authors concluded that a real change following guideline dissemination is not achievable unless fostered by factual multidisciplinary efforts and explicit administrative support.

Difficulties to deal with this challengig issue depend firstly on the diversity of methodologies used in available studies, and this is well reflected in the very different conclusions that can be drawn from systematic reviews on the topic.[887,888]

The lack of scientific information on the definitive impact of improved hand hygiene compliance on HCAI rates has been reported as a possible barrier to appropriate adherence with hand hygiene recommendations. However, there is convincing evidence that improved hand hygiene through multimodal implementation strategies can reduce infection rates. In addition, although not reporting infection rates, several studies showed a sustained decrease of the incidence of multidrug-resistant bacterial isolates and patient colonization following the implementation of hand hygiene improvement strategies.[428,655,687,701] Failure to perform appropriate hand hygiene is considered the leading cause of HCAI and spread of multi-resistant organisms, and has been recognized as a significant contributor to outbreaks.

At least 20 hospital-based studies of the impact of hand hygiene on the risk of HCAI have been published between 1977 and June 2008 (Table I.22.1).[60,61,121,181,182,195,196,489,494,645,657,659,663,667,713-718,852] Despite study limitations, most reports showed a temporal relation between improved hand hygiene practices and reduced infection and cross-transmission rates.

Maki[195] found that HCAI rates were lower when antiseptic handwash was used by HCWs. Doebbeling and colleagues[659] compared hand antisepsis using a chlorhexidine-containing detergent to a combination regimen that permitted either handwashing with plain soap or use of an alcohol-based handrub. HCAI rates were lower when the chlorhexidine-containing product was in use. However, because relatively little of the alcohol rub was used during periods when the combination regimen was in operation and because adherence to policies was higher when chlorhexidine was available, it was difficult to determine whether the lower infection rates were attributable to the hand hygiene regimen used or to the differences in HCW compliance with policies.

A study by Larson and colleagues[713] found that the frequency of VRE infections, but not MRSA, decreased as adherence of HCWs to recommended handwashing measures improved. This strategy yielded sustained improvements in hand hygiene practices. The intervention lasted eight months, and a follow-up survey six months after the end of the intervention showed a sustained improvement in hand hygiene practices. More recently, several studies demonstrated a clear impact of improved hand hygiene on MRSA rates.[489,494,718] In a district hospital in the United Kingdom, the incidence of hospital-acquired MRSA cases significantly decreased after a successful hand hygiene promotion programme.[489] Similarly, in Australia, a hospitalwide, multifaceted programme to change hand hygiene culture and practices led to a 57% reduction of MRSA bacteraemia episodes as well as a significant reduction of the overall number of clinical isolates of MRSA and ESBL-producing *E. coli* and *Klebsiella* spp.[494] The programme was subsequently expanded to another six health-care institutions and then to the entire state of Victoria. After 24 months and 12 months of follow-up, respectively, MRSA bacteraemia and the number of MRSA clinical isolates significantly decreased both in the 6 pilot hospital and statewide (see Table I.22.1).[719] In another study, the intervention consisted of the hospitalwide introduction of an alcohol-based gel and MRSA surveillance feedback through charts.[718] Significant reductions of MRSA bacteraemia and MRSA central line-associated bacteraemia were observed hospitalwide and in the ICU, respectively, with a follow-up of 36 months. In this study, however, it is difficult to define the actual role of hand hygiene to reduce MRSA bacteraemia, because charts were a strong component of the intervention and, at the same time general infection control measures were intensified and the use of antibiotic-coated central venous catheters was initiated in the ICU.

In 2000, a landmark study by Pittet and colleagues[60] demonstrated that implementing a multidisciplinary programme to promote increased use of an alcohol-based handrub led to increased compliance of HCWs with recommended hand hygiene practices and a reduced prevalence of HCAI. Individual bottles of handrub solution were distributed in large numbers to all wards, and custom-made holders were mounted on all beds to facilitate access to hand antisepsis. HCWs were also encouraged to carry a bottle in their pocket. The promotional strategy was multimodal and involved a multidisciplinary team of HCWs, the use of wall posters, the promotion of bedside handrubs throughout the institution, and regular performance feedback to all HCWs (see http://www.hopisafe.ch for further details on methodology). HCAI rates, attack rates of MRSA cross-transmission, and consumption of handrub were measured in parallel. Adherence to recommended hand hygiene practices improved progressively from 48% in 1994 to 66% in 1997 (*P* <0.001). While recourse to handwashing with soap and water remained stable, the frequency of handrubbing markedly increased over the study period (*P* <0.001), and the consumption of alcohol-based handrub solution increased from 3.5 litres to 15.4 litres per 1000 patient-days between 1993 and 1998 (*P* <0.001). Importantly, increased recourse to handrubbing was associated with a significant improvement in compliance in critical care,[334] suggesting that time constraint bypassing was critical. The increased frequency of hand antisepsis was unchanged after adjustment for known risk factors of poor adherence. During the same period, both overall HCAI and MRSA transmission rates decreased (both *P* <0.05). The observed reduction in MRSA transmission may well have been affected by both improved hand hygiene adherence and the simultaneous implementation of active surveillance cultures for detecting and isolating patients colonized with MRSA.[889] Follow-up evaluation 8 years after the beginning of the programme revealed continuous improvement with hand hygiene practices, increased recourse to alcohol-based handrub, and stable HCAI rates; it also highlights the cost–effectiveness of the strategy.[61] The experience from Geneva's University Hospitals constitutes the first report of a hand hygiene campaign demonstrating a sustained improvement over several years; some recent further studies reported a positive impact of hand hygiene promotion with a prolonged follow-up (up to 3 years).[494,714,717,718]

More recently, a number of studies assessed the effectiveness of hand hygiene improvement to prevent HCAI in neonatal care. Following the implementation of hand hygiene multimodal strategies, Lam and colleagues[648] and Won and colleagues[714] demonstrated a significant decrease of overall HCAI rates in neonatal ICUs, whereas Pessoa-Silva and colleagues[657] observed only a decrease in very low-birth-weight neonates (Table I.22.1). A significant reduction of HCAI was also observed in adult ICU patients in a hospital in Argentina.[716] Other investigations showed an impact of improved hand hygiene on specific types of HCAI such as rotavirus[715] and surgical site infections in neurosurgery[717] (Table I.22.1). Furthermore, a recent review of the literature related to the effectiveness of handwashing against SARS transmission concluded that nine of 10 epidemiological studies showed a protective effect of hand hygiene, but this result was only significant in three in a multivariate analysis.[890]

In several other studies in which hand hygiene compliance was not monitored, multidisciplinary programmes that involved the introduction of an alcohol-based handrub were associated with a decrease in HCAI and cross-transmission rates.[429,489,645,735] The beneficial effects of hand hygiene promotion on the risk of cross-transmission have also been reported in surveys conducted in schools or day-care centres,[454,891-896] as well as in community settings.[248,249,449,754,815,830,897-900]

While none of the studies conducted in the health-care setting represented randomized controlled trials, they provide substantial evidence that increased hand hygiene compliance is associated with reduced HCAI rates. Indeed, only very few studies concluded that hand hygiene promotion had no impact on HCAI. A very early study from Simmons and colleagues showed that interventions aimed at improving handwashing practices in ICUs failed to improve them substantially and therefore to reduce HCAI.[667] A very recently published two-year, prospective, controlled cross-over trial by Rupp and colleagues has attracted much attention, including from the lay press. The authors observed that a significant and sustained improvement in hand hygiene adherence following the introduction of an alcohol-based handrub did not lead to a substantial change in device-associated infection rates and infections due to multidrug-resistant pathogens.[707] Nevertheless, it is crucial to note that although the study was, in general, well-designed and conducted, it presents key limitations that have led to harsh criticism following its publication,[901-903] including lack of screening for cross-transmission, lack of statistical power, and use of an alcohol-based handrub that fails to meet the EN 1500 standards for antimicrobial efficacy.

Methodological and ethical concerns make it difficult to set up randomized controlled trials with appropriate sample sizes that could establish the relative importance of hand hygiene in the prevention of HCAI. The studies so far conducted, although semi-experimental and of good quality in most cases, could not determine a definitive causal relationship owing to the lack of statistical significance, the presence of confounding factors, or the absence of randomization. Given that multimodal strategies are the most preferred methods to obtain hand hygiene improvement,[60,713,719,728] additional research on the relative effectiveness of the different components of these strategies would be very helpful to successful achievement of a sustainable impact.[809,904]

The unique large, randomized controlled trial to test the impact of hand hygiene promotion clearly demonstrated reduction of upper respiratory pulmonary infection, diarrhoea, and impetigo among children in a Pakistani community, with positive effect on child health.[249,449] Although it remains important to generate additional scientific and causal evidence for the impact of enhanced adherence with hand hygiene on infection rates in health-care settings, these results strongly suggest that improved hand hygiene practices reduce the risk of transmission of pathogenic microorganisms.

Table I.22.1

Association between improved adherence with hand hygiene practice and health care-associated infection rates (1975– June 2008)

Year	Authors	Hospital setting	Major results	Duration of follow-up
1977	Casewell & Phillips[121]	Adult ICU	Significant reduction in the percentage of patients colonized or infected by *Klebsiella* spp.	2 years
1989	Conly et al.[663]	Adult ICU	Significant reduction in HCAI rates immediately after hand hygiene promotion (from 33% to 12% and from 33% to 10%, after two intervention periods 4 years apart, respectively)	6 years
1990	Simmons et al.[667]	Adult ICU	No impact on HCAI rates (no statistically significant improvement of hand hygiene adherence)	11 months
1992	Doebbeling et al.[659]	Adult ICUs	Significant difference between rates of HCAI using two different hand hygiene agents	8 months
1994	Webster et al.[181]	NICU	Elimination of MRSA, when combined with multiple other infection control measures. Reduction of vancomycin use. Significant reduction of nosocomial bacteremia (from 2.6% to 1.1%) using triclosan compared to chlorhexidine for handwashing	9 months
1995	Zafar et al.[182]	Newborn nursery	Control of a MRSA outbreak using a triclosan preparation for handwashing, in addition to other infection control measures	3.5 years
2000	Larson et al.[713]	MICU/NICU	Significant (85%) relative reduction of VRE rate in the intervention hospital; statistically insignificant (44%) relative reduction in control hospital; no significant change in MRSA	8 months
2000	Pittet et al.[60,61]	Hospitalwide	Significant reduction in the annual overall prevalence of health care-associated infections (42%) and MRSA cross-transmission rates (87%). Active surveillance cultures and contact precautions were implemented during same time period. A follow-up study showed continuous increase in handrub use, stable HCAI rates and cost savings derived from the strategy.	8 years
2003	Hilburn et al.[645]	Orthopaedic surgical unit	36% decrease of urinary tract infection and SSI rates (from 8.2% to 5.3%)	10 months
2004	MacDonald et al.[489]	Hospitalwide	Significant reduction in hospital-acquired MRSA cases (from 1.9% to 0.9%)	1 year
2004	Swoboda et al.[852]	Adult intermediate care unit	Reduction in HCAI rates (not statistically significant)	2.5 months

Table I.22.1

Association between improved adherence with hand hygiene practice and health care-associated infection rates (1975– June 2008) (Cont.)

Year	Authors	Hospital setting	Major results	Duration of follow-up
2004	Lam et al.[648]	NICU	Reduction (not statistically significant) in HCAI rates (from 11.3/1000 patient-days to 6.2/1000 patient-days)	6 months
2004	Won et al.[714]	NICU	Significant reduction in HCAI rates (from 15.1/1000 patient-days to 10.7/1000 patient-days), in particular of respiratory infections	2 years
2005	Zerr et al.[715]	Hospitalwide	Significant reduction in hospital-associated rotavirus infections	4 years
2005	Rosenthal et al.[716]	Adult ICUs	Significant reduction in HCAI rates (from 47.5/1000 patient-days to 27.9/1000 patient-days)	21 months
2005	Johnson et al.[494]	Hospitalwide	Significant reduction (57%) in MRSA bacteraemia	36 months
2007	Thi Anh Thu et al.[717]	Neurosurgery	Reduction (54%, NS) of overall incidence of SSI. Significant reduction (100%) of superficial SSI; significantly lower SSI incidence in intervention ward compared with control ward	2 years
2007	Pessoa-Silva et al.[657]	Neonatal unit	Reduction of overall HCAI rates (from 11 to 8.2 infections per 1000 patient-days) and 60% decrease of risk of HCAI in very low birth weight neonates (from 15.5 to 8.8 episodes/1000 patient-days)	27 months
2008	Rupp et al.[707]	ICU	No impact on device-associated infection and infections due to multidrug-resistant pathogens	2 years
2008	Grayson et al.[719]	1) 6 pilot hospitals 2) all public hospitals in Victoria (Australia)	1) Significant reduction of MRSA bacteraemia (from 0.05/100 patient-discharges to 0.02/100 patient-discharges per month) and of clinical MRSA isolates 2) Significant reduction of MRSA bacteraemia (from 0.03/100 patient-discharges to 0.01/100 patient-discharges per month) and of clinical MRSA isolates	1) 2 years 2) 1 year

ICU: intensive care unit; NICU: neonatal ICU; MRSA: methicillin-resistant *S aureus*; VRE: vancomycin-resistant *Enterococcus* spp; MICU: medical ICU; HCAI: health care-associated infection; SSI: surgical site infection;
NS: not significant.
Source: adapted from Pittet, 2006[885] with permission from Elsevier.

23.

Practical issues and potential barriers to optimal hand hygiene practices

23.1 Glove policies

23.1.1 Reasons for glove use

Prior to the emergence of HIV and the acquired immunodeficiency syndrome (AIDS) epidemic, gloves were essentially worn primarily by HCWs either caring for patients colonized or infected with certain pathogens or exposed to patients with a high risk of hepatitis B. Since 1987, a dramatic increase in glove use has occurred in an effort to prevent the transmission of HIV and other bloodborne pathogens from patients to HCWs.[905] The National Institute for Occupational Safety and Health Administration in the USA (NIOSHA) mandates that gloves be worn during all patient-care activities involving exposure to blood or body fluids that may be contaminated with blood,[906] including contact with mucous membranes and non-intact skin. In addition, gloves should be worn during outbreak situations, as recommended by specific requirements for Personal Protective Equipment (PPE).[58,423,906] The broad scope of these recommendations for glove use potentially leads to inevitable, undesirable consequences, such as the misuse and the overuse of gloves; therefore, there is a need to define glove use indications with greater precision.

Medical glove use by HCWs is recommended for two main reasons: 1) to reduce the risk of contaminating HCWs' hands with blood and other body fluids; 2) to reduce the risk of germ dissemination to the environment and of transmission from the HCWs to the patient and vice versa, as well as from one patient to another.[701,884,907,908]

Single-use (also called disposable) examination gloves, either non-sterile or sterile, are usually made of natural rubber latex or synthetic non-latex materials such as vinyl, nitrile and neoprene (polymers and copolymers of chloroprene). Because of the increasing prevalence of latex sensitivity among HCWs and patients, the FDA has approved a variety of powdered and powder-free latex gloves with reduced protein contents, as well as synthetic gloves that can be made available by health-care institutions for use by latex-sensitive HCWs and for patients with latex hypersensitivity.[909] Several new technologies are emerging (e.g. impregnated glove materials that release chlorine dioxide when activated by light or moisture to produce a disinfecting micro-atmosphere),[910] but none of them has so far led to changes in glove use recommendations.[49] The correct and consistent use of existing technologies with documented effectiveness is encouraged before new technologies are introduced. The main feature of examination gloves to bear in mind is that they are meant to be single-use and to be discarded.[907,911,912] In most cases, they are non-sterile.

Sterile surgical gloves are required for surgical interventions. Some non-surgical care procedures, such as central vascular catheter insertion, also require surgical glove use. In addition to their sterile properties, these gloves have characteristics of thickness, elasticity and strength that are different from other medical gloves (either sterile or non-sterile).

Medical gloves are designed to serve for care purposes only and are not appropriate for housekeeping activities in health-care facilities. Other specific types of gloves are intended for these types of non-care activities.

In published studies, the barrier integrity of gloves has varied considerably based on the type and quality of glove material, intensity of use, length of time used, manufacturer, whether gloves were tested before or after use, and the method used to detect glove leaks.[913-920] In some published studies, vinyl gloves more frequently had defects than did latex gloves, the difference being greatest after use.[913,914,917,921] Intact vinyl gloves, however, provide protection comparable to that provided by latex gloves.[913] Limited studies suggest that nitrile gloves have leakage rates close to those of latex gloves.[922-925] Although recent studies suggest that improvements have been made in the quality of gloves,[919] the laboratory and clinical studies cited above provide strong evidence that hands should still be decontaminated or washed after glove removal.[73,123,139,204,520,914]

23.1.2 Glove efficacy

The efficacy of gloves in preventing contamination of HCWs' hands has been confirmed in several clinical studies.[72,110,139] One study found that HCWs who wore gloves during patient contact contaminated their hands with an average of only 3 CFUs per minute of patient care, compared with 16 CFUs per minute for those not wearing gloves.[72] Two other studies of HCWs caring for patients with *C. difficile* or VRE found that wearing gloves prevented hand contamination among a majority of those having direct contact with patients.[110,139] Wearing gloves also prevented HCWs from acquiring VRE on their hands when touching contaminated environmental surfaces.[139] Preventing gross contamination of the hands is considered important because handwashing or hand antisepsis may not remove all potential pathogens when hands are heavily contaminated.[88,278] Furthermore, several studies provide evidence that wearing gloves can help reduce transmission of pathogens in health-care settings.[701,884] In a prospective controlled trial that required HCWs routinely to wear vinyl gloves when handling any body substances, the incidence of *C. difficile* diarrhoea among patients decreased from 7.7 cases/1000 patient discharges before the intervention to 1.5 cases/1000 discharges during the intervention.[422] The prevalence of asymptomatic *C. difficile* carriage also decreased significantly on "glove" wards, but not on control wards. In ICUs with VRE or MRSA epidemics, requiring all HCWs to wear gloves to care for all patients in the unit (universal glove use) appeared to contribute to the control of outbreaks.[926-928] These data must be interpreted in the light of the actual direct impact on patient care, however, and some additional considerations need to be discussed.[49,929] Glove use is not sufficient to prevent germ transmission and infection if not rigorously accompanied by previous and successive further preventive measures.[930] The benefit of gloves is strictly related to the conditions of usage; the appropriateness of the latter strongly influences the actual reduction of germ dissemination and infection cross-transmission.

Hand hygiene is the most important measure to protect patients, HCWs and the environment from microbial contamination. Hand hygiene indications exist regardless of glove use, even if they influence glove wearing. A study highlighted the risk related to universal gloving as regards multidrug-resistant organism transmission: universal gloving can lead to a significant increase of device-related infections.[884]. Furthermore, wearing gloves does not provide complete protection against the acquisition of infections caused by HBV and HSV.[913,931,932] These studies provide definitive evidence that gloves must be removed after care of a single patient and during the care of a patient, when moving from any body site to another such as non intact skin, mucous membrane or invasive medical device within the same patient, and that hand cleansing must be performed after glove removal. Bacterial flora colonizing patients may be recovered from the hands of up to 30% of HCWs who wear gloves during patient contact.[123,139] Doebbeling and colleagues[520] conducted an experimental study in which the artificial contamination of gloves was undertaken with conditions close to clinical practice. The authors cultured the organisms used for artificial contamination from 4–100% of the gloves and observed counts between 0 and 4.7 log on hands after glove removal. In a recent study identifying neonatal-care activities at higher risk for hand contamination, the use of gloves during routine neonatal care did not fully protect HCWs' hands from bacterial contamination with organisms such as *Enterobacteriacae, S. aureus,* and fungi.[73] In such instances, pathogens presumably gain access to the caregivers' hands via small defects in gloves or by contamination of hands during glove removal.[123,520,913,914]

23.1.3 Glove use and hand hygiene

The impact of wearing gloves on compliance with hand hygiene policies has not been definitively established, as published studies have yielded contradictory results.[49,216,661,672,739] Several studies found that HCWs who wore gloves were less likely to cleanse their hands upon leaving a patient's room,[661,688,739,908,930] and two established an association between inappropriate glove use and low compliance with hand hygiene.[908,930] In contrast, three other studies found that HCWs who wore gloves were significantly more likely to cleanse their hands following patient care.[216,672,802,933] Most of these studies were focused on hand hygiene performance after glove removal only and did not consider other indications. One study found that the introduction of gloves increased overall compliance with hand hygiene, but the introduction of isolation precautions did not result in improved compliance.[934] For example, compliance with glove changing when moving between different body sites in the same patient was unsatisfactory, as well as compliance with optimal hand hygiene practices. Furthermore, although some studies demonstrated a high compliance with glove use, they did not investigate its possible misuse.[683,689,935,936] Surveys conducted at facilities with limited resources showed that low compliance with recommendations for glove use and its misuse is not only associated with shortage of supply, but also with a poor knowledge and perception of the risk of pathogen transmission.[695,937-940] Other studies pointed out the practical difficulty to combine hand hygiene and glove use.[689,759] In one study, glove use compliance rates were 75% or higher across all HCW groups except doctors, whose compliance was only 27%.[128] HCWs should be reminded that failure to remove gloves between patients or when moving between different body sites of the same patient may contribute to the transmission of organisms.[73,927,930,932,941] In two reports, failure to remove gloves and gowns and to wash hands when moving between patients was associated with an increase in MRSA transmission during the SARS outbreak.[942,943]

Whether hand hygiene should be performed before donning non-sterile gloves is an unresolved issue and therefore this moment should not be recommended as an indication for hand hygiene. In this connection, a study found that volunteers did not contaminate the outside of their gloves significantly more often when they did not wash their hands before donning gloves, compared with the level of glove contamination that occurred when they washed their hands first.[944] The study did not determine whether or not HCWs transmitted pathogens to patients more frequently when they did not wash their hands before donning gloves.

23.1.4 Appropriate and safe use of gloves

The use of gloves in situations when their use is not indicated represents a waste of resources without necessarily leading to a reduction of cross-transmission.[884,930] The wide-ranging recommendations for glove use have led to very frequent and inappropriate use in general, far exceeding the frame of real indications and conditions for appropriate glove use that remain poorly understood among HCWs. Careful attention should be paid to the use of medical gloves according to indications[907] for donning, but also for their removal. Moreover, numerous conditions regulate glove use and are aimed at preventing glove contamination and further consequences.

General indications for gloving and for glove removal are listed in Table I.23.1 and practical examples of care situations with indication for glove use are included in the pyramid (Figure I.23.1). It is important that HCWs are able to: 1) identify clinical situations when gloves are not indicated; 2) differentiate these from situations where gloves should be worn; and 3) correctly select the most appropriate type of gloves to be worn. Indications including indirect health-care activities, such as preparing parenteral nutrition or handling soiled waste, are also shown in the figure. In general, the moment for glove removal meets the recommendations for single use, i.e. related to a single patient and to a single care situation within the same patient.

Conditions for glove use also imply the existence of a glove use procedure. Proper glove use requires continuous reasoning and a behavioural adjustment according to the care situation (Table I.23.2). These conditions are associated with equipment procurement and management (supply, availability, storage, and disposal) and with rigorous sequences and techniques for glove donning and removal (Figures I.23.2 and I.23.3). Conditions for glove use in health care are as crucial as the identification of indications. Indications represent a frame to limit the start and end of glove use. Importantly, gloves must be donned immediately before the contact or the activity that defines the indication and removed immediately after this contact or activity is over.[945]

Glove use does not obviate the need to comply with hand hygiene.[884] 1) When the hand hygiene indication occurs before a contact requiring glove use, handwashing or handrubbing must be performed before donning gloves to prevent glove contamination and possible cross-transmission in case of glove damage or improper use/efficacy. 2) Gloves must be removed to perform handwashing or handrubbing to protect a body site from the flora from another body site or skin area previously touched within the same patient. 3) Hand hygiene must be performed immediately after glove removal to prevent HCW contamination and further transmission and dissemination of microorganisms. It should be noted that handwashing with soap and water is necessary when gloves are removed because of a tear or a puncture and the HCW has had contact with blood or another body fluid; this situation is considered to be equivalent to a direct exposure to blood or another body fluid.

Further crucial conditions for appropriate glove use are their mechanical and microbiological integrity. Medical gloves should be kept in their original package or box until they are donned;[945] this requires that gloves are available at the point of care as well as alcohol-based handrubs. Moreover, it is appropriate to have more than one type of gloves available, thus allowing HCWs to select the type that best suits their patient-care activities as well as their hand size. When removed, gloves should be discarded and disposed of; ideally, gloves should not be washed, decontaminated, or reprocessed for any reuse purpose.

These conditions are essential to prevent germ transmission through contaminated gloves to the patient and the HCW, and their further dissemination in the environment. When gloving is required continously because contact precautions are in place, all these conditions are difficult to integrate as part of usual care activities. Indeed, while the general indication to don gloves should remain until the contact with the patient and his/her immediate surroundings is completed, indications for glove removal, hand hygiene and, again, further indications for gloving may occur.

23.1.5 Factors potentially interfering with glove use

The use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves.[946] Following the use of powdered gloves, some alcohol-based hand rubs may interact with residual powder on HCWs' hands, resulting in a gritty feeling on hands. In facilities where powdered gloves are commonly used, a variety of alcohol-based hand rubs should be tested following removal of powdered gloves in order to avoid selecting a product that causes this undesirable reaction.[520,914] As a general policy, health-care settings should preferably select non-powdered gloves for both examination and surgical purposes.

23.1.6 Caveats regarding washing, decontaminating and reprocessing gloves

Manufacturers are not responsible for glove integrity when the principle of "single usage" is not respected. Any practice of glove washing, decontamination or reprocessing is not recommended as it may damage the material integrity and jeopardize the glove's protective function. Although these practices are common in many health-care settings, essentially in developing countries, where glove supply is limited,[947] no recommendation exists concerning the washing and reuse of gloves, nor the washing or decontamination of gloved hands followed by reuse on another patient.

In one study, washing gloved hands between patient treatments using 4% chlorhexidine and 7.5% povidone-iodine liquid soaps for 30 seconds eradicated all organisms inoculated from both glove surfaces.[948] Another study describes a significant reduction of bacterial count on perforated gloves to permit their reuse for non-sterile procedures after cleansing of the gloved hand using an alcohol-based preparation with chlorhexidine.[949] Although the microbial efficacy of glove washing and decontamination is demonstrated, the consequences of such processes on material integrity still remain unknown. More research on glove integrity after washing, decontaminating, and reprocessing is necessary to answer numerous unsolved issues before arriving at consistent recommendations. To this end, we call upon the manufacturers of gloves for medical application to concentrate on this issue and to conduct research to develop recyclable gloves for both examination and surgical use, and to provide also information about safe reprocessing methods for the reuse of gloves in resource-limited settings.

Cleansing gloved hands to allow for prolonged use on the same patient may result in considerable savings of disposable examination gloves. Some evidence exists that cleansing latex-gloved hands using an alcohol-based handrub solution is effective in removing micro-organisms and shows increasing contamination rates of hands only after 9–10 cycles of cleansing.[950,951] However, cleansing plastic-gloved hands with an alcohol-based formulation leads to early dissolving of the plastic material. If there is an intention to proceed with the process of glove decontamination, this should be started only after performing a local study using the type of gloves and products provided at the facility. It should be noted that this process may be applied only in the framework of contact precautions implementation[907] and as long as gloves are not soiled with blood and other body fluids. As a consequence, this limited context for glove decontamination probably does not represent an effective response to the serious problem of glove shortage in developing countries.

In conclusion, no evidence-based recommendation currently exists regarding glove reprocessing. While this may be an interesting option at facilities where supply is insufficient, all consequences of the reprocessing should be anticipated and measured before putting it into practice. A reprocessing method has been suggested by the Johns Hopkins Program for International Education in Reproductive Gynaecology and Obstetrics (JHPIEGO).[952] This process is not standardized nor validated, and no recommendation of this or any other reprocessing process can be expressed in the absence of good quality research. This protocol firstly includes a situation analysis assessment and some criteria for opting for reprocessing gloves in order to minimize the risks and to optimize the results. Before planning or continuing the reprocessing of used gloves, every health-care facility should first undertake an assessment of factors leading to the shortage of single-use gloves, such as budget constraints or interrupted supply chains. Efforts should focus on reducing the need for gloves by avoiding wastage caused by unnecessary use and by providing a secure stock of good quality single-use surgical and examination gloves, together with a budget for regular restocking. Opting for glove reprocessing without having made these assessments would amount to contributing to the maintenance of inappropriate glove use. Health administrators are encouraged to purchase good quality disposable gloves and replenish stocks in time. In addition, clinic managers and supervisors should check that gloves are not wasted, and HCWs should be educated to appropriate use of gloves (see Figure I.23.1).

In institutions with limited resources, some authors suggest that if the necessity for the reprocessing of single-use gloves persists after a thorough evaluation, the reprocessing of previously decontaminated and thoroughly cleaned surgical gloves using sterilization (autoclaving) or high-level disinfection (steaming) can produce an acceptable product; when combined with double gloving, this may constitute a temporary tolerable practice.[952,953] However, the practice could be retained only if basic criteria, such as glove quality, are satisfied and the selected processes and technologies for reprocessing are reliable and under control. A universal problem is the introduction of equipment, technology, and method with no evaluation of associated needs. In this case, their reliability and safety are not guaranteed.[929] If reprocessing does take place, the institution should develop clear policies to define clinical situations where gloves are needed, when the use of reprocessed gloves can be tolerated, and when gloves should be discarded and not reprocessed (e.g. when holes are detected). Only surgical latex gloves may be reused either as surgical gloves using double gloving or as gloves for examination purposes. Some authors recommend that latex rubber surgical gloves should be discarded after three reprocessing cycles because gloves tear more easily with additional reprocessing.[954,955] Examination gloves should never be reprocessed because of their particular composition properties, thinness, and inelasticity.

Systematic research is urgently needed to evaluate reprocessing methods and to develop and validate a process that leads to a product of acceptable quality. Furthermore, well-conducted cost–benefit studies are required to evaluate the potential benefits of reprocessing gloves and the general need for investing in preventive measures. Through an analysis of the financing structures of health-care delivery systems in developing countries, incentives for investment in the prevention of HCAIs from the individual, institutional, and societal perspectives can be identified.

The practice of autoclaving used plastic gloves in case of shortage and of autoclaving new plastic gloves meant for examination for use as surgical gloves has been described.[956] The reprocessing at 125 °C leads to gloves sticking together, and separation causes tears and holes. The authors found 41% of recycled gloves with impaired integrity.[956] Another potential hazard is often witnessed in developing countries: many reprocessing units use powder inside reprocessed latex gloves to prevent material sticking together and to facilitate reuse. The consequences of use of powdered latex gloves in terms of the development of latex allergies and impaired working conditions leading to sickness in HCWs are well documented.[957]

In general, one of the major risks of reprocessing gloves is that they could show a higher rate of non-apparent holes and tears after the reprocessing cycle than new ones. A study by Tokars et al. showed that surgeons wearing a single layer of new surgical gloves had blood contact in 14% of the procedures, and blood contact was 72% lower among surgeons who double gloved.[958] Therefore, double gloving in countries with a high prevalence of HBV, HCV and HIV for long surgical procedures (>30 minutes), for procedures with contact with large amounts of blood or body fluids, for some high-risk orthopaedic procedures, or when using reprocessed gloves is considered an appropriate practice.

The illegal recovery and recycling of discarded gloves from hospital waste dumping sites, often using dubious and uncontrolled reprocessing methods, can constitute an additional health hazard and is of growing concern in countries with limited resources. Hospitals are therefore encouraged to destroy each glove before discarding.

In brief, the opinion of international experts consulted by WHO is that glove reprocessing must be strongly discouraged and avoided, mainly because at present no standardized, validated, and affordable procedure for safe glove reprocessing exists. Every possible effort should be made to prevent glove reuse in health-care settings, and financial constraints in developing countries leading to such practices should be assessed and tackled. Institutions and health-care settings should firmly avoid the reuse of gloves. In circumstances where the reprocessing of gloves has been carefully evaluated but cannot be avoided, a clear policy should be in place to limit reprocessing and reuse of gloves until a budget is allocated to ensure a secure supply of single-use gloves. Policies for exceptional reprocessing should ensure a process that follows strict procedures for collection, selection and reprocessing, including instructions for quality/integrity control and discarding of unusable gloves.

23.1.7 Conclusions

Medical glove use is an evidence-based measure to protect patients, HCWs, and the environment. The recommendations for glove use must be implemented regardless of the type of setting and the resources available. Nevertheless, glove misuse is observed regularly worldwide, irrespective of the underlying reasons. Even in institutions where gloves are widely available, HCWs often fail to remove gloves between patients or between contact with various sites on a single patient, thus facilitating the spread of microorganisms.[154,744,952,959,960] Knowledge dissemination and practical training on the appropriate use of gloves are the foremost interventions leading not only to best practices, but also to resource saving. Deficient glove procurement in terms of quantity and quality causes inappropriate and unsafe practices such as glove misuse and overuse and may lead to uncontrolled reprocessing.[929,947] No evidence-based recommendations for glove reuse or reprocessing exist other than those described above. Medical gloves are meant to be disposable and for single use. They are intended to complement hand hygiene and are effective as long as they are used according to the proper indications. Hand hygiene still remains the basic and most effective measure to prevent pathogen transmission and infection.

In no way does glove use modify hand hygiene indications or replace hand hygiene by washing with soap and water or handrubbing with an alcohol-based handrub.

Gloves represent a risk for pathogen transmission and infection if used inappropriately.

23.2 Importance of hand hygiene for safe blood and blood products

Providing a safe unit of blood to a patient who requires blood transfusion is a multistep process. It includes identifying safe blood donors for blood donation, safe blood collection without harming the blood donor and the donated blood, screening of donated blood for HIV, hepatitis B and C, and syphilis, processing the blood into blood products, and issue of blood or blood product to the patient, when prescribed.

Appropriate hand hygiene practice is crucial to the safety of blood and blood products at all stages in the transfusion chain during which the donated blood units are handled. The microbial contamination of blood or blood products may occur at the time of blood collection or during the processing into blood products, labelling, storage and transportation, or during administration of blood at the patient bedside. This can have fatal consequences for the recipients of the transfusion. Serious consequenses of microbial contamination can be avoided by giving particular attention to the hand hygiene of the donor care staff at the time of blood collection and by thorough cleansing of the venepuncture site on the donor arm.

Furthermore, blood collection staff frequently needs to collect blood in environments that are especially challenging. Special care must be exercised in hand hygiene while collecting blood in outdoor situations where access to running water is limited.

It is essential that all those who work in areas where blood is handled pay strict attention to hand hygiene. Standard operating procedures should be available to staff, detailing exactly how hands should be decontaminated in order to protect blood donors, patients, and the staff themselves, as well as the blood and blood products. Figure I.23.4 depicts the crucial steps during blood collection, processing, and transfusion with an associated risk for the contamination of blood or blood products attributable to poor hand hygiene of the staff involved in these processes. At each step, there are several critical procedures, including meticulous hand hygiene, which ultimately lead to the safety of blood and blood products.

23.3 Jewellery

Several studies have shown that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings.[961-963] A study by Hoffman and colleagues[962] found that 40% of nurses harboured Gram-negative bacilli such as *E. cloacae, Klebsiella* spp., and *Acinetobacter* spp. on skin under rings and that some nurses carried the same organism under their rings for months. In one study involving more than 60 ICU nurses, multivariable analysis revealed that rings were the only significant risk factor for carriage of Gram-negative bacilli and *S. aureus* and that the organism bioburden recovered correlated with the number of rings worn.[964] Another study showed a stepwise increased risk of contamination with *S. aureus*, Gram-negative bacilli, or *Candida* spp. as the number of rings worn increased.[153] In a Norwegian study comparing hand flora of 121 HCWs wearing a single plain ring and 113 wearing no rings, there was no significant differences in the total bacterial load or rates of carriage of *S. aureus* or non-fermentative Gram-negative rods on hands, but personnel wearing rings were more likely to carry *Enterobacteriaceae* (P=0.006).[965] Among 60 volunteers from perioperative personnel and medical students, Wongworawat & Jones[966] found no significant difference in bacterial counts on hands with or without rings when an alcohol product was used, but there were significantly more bacteria on ringed hands when povidone-iodine was used for handwashing (P<0.05). Furthermore, Rupp and colleagues[707] reported that having longer fingernails and wearing rings were associated with increased numbers and species of organisms on hands. In addition, at least one case of irritant dermatitis under the ring has been reported as a result of wearing rings.[967]

A survey of knowledge and beliefs regarding nosocomial infections and jewellery showed that neonatal ICU HCWs were not aware of the relationship between bacterial hand counts and rings, and did not believe that rings increased the risk of nosocomial infections; 61% regularly wore at least one ring to work.[960]

Whether the wearing of rings results in greater cross-transmission of pathogens remains unknown. Two studies found that mean bacterial colony counts on hands after handwashing were similar among individuals wearing rings and those not wearing rings.[963,968] One study compared the impact of wearing rings on the efficacy of several different products in 20 subjects who wore a ring on one hand and no ring on the other: an alcohol-based formulation; a waterless, alcohol-chlorhexidine lotion; and a povidone-iodine scrub. There were no significant differences in bacterial counts when the two alcohol-based formulations were used, but there were higher counts on the ringed hands (p<0.05) after povidone-iodine scrub[966].

Further studies are needed to establish if wearing rings results in a greater transmission of pathogens in health-care settings. Nevertheless, it is likely that poorly maintained (dirty) rings and jewellery might harbour microorganisms that could contaminate a body site with potential pathogens. Rings with sharp surfaces may puncture gloves. Hand hygiene practices are likely to be performed in a suboptimal way if voluminous rings or rings with sharp edges or surfaces are worn. Jewellery may also be a physical danger to either patients or the HCW during direct patient care, e.g. a necklace may be caught in equipment or bracelets may cause injury during patient handling.

The consensus recommendation is to strongly discourage the wearing of rings or other jewellery during health care. If religious or cultural influences strongly condition the HCW's attitude, the wearing of a simple wedding ring (band) during routine care may be acceptable, but in high-risk settings, such as the operating theatre, all rings or other jewellery should be removed.[969] A simple and practical solution allowing effective hand hygiene is for HCWs to wear their ring(s) around their neck on a chain as a pendant.

23.4 Fingernails and artificial nails

Numerous studies have documented that subungual areas of the hand harbour high concentrations of bacteria, most frequently coagulase-negative staphylococci, Gram-negative rods (including *Pseudomonas* spp.), *Corynebacteria*, and yeasts.[63,534,970] Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails.[971,972] Even after careful handwashing or surgical scrubs, HCWs often harbour substantial numbers of potential pathogens in the subungual spaces.[154,973,974] In particular, the presence of fingernail disease may reduce the efficacy of hand hygiene and result in the transmission of pathogens. A cluster of *P. aeruginosa* SSIs resulted from colonization of a cardiac surgeon's onychomycotic nail.[523]

A growing body of evidence suggests that wearing artificial nails may contribute to the transmission of certain health care-associated pathogens. HCWs who wear artificial nails are more likely to harbour Gram-negative pathogens on their fingertips than those who have natural nails, both before and after handwashing[154,534,974,975] or handrub with an alcohol-based gel.[154] It is not clear if the length of natural or artificial nails is an important risk factor, since most bacterial growth occurs along the proximal 1 mm of the nail, adjacent to subungal skin.[154,972,974] An outbreak of *P. aeruginosa* in a neonatal ICU was attributed to two nurses (one with long natural nails and one with long artificial nails) who carried the implicated strains of *Pseudomonas* spp. on their hands.[976] Case patients were significantly more likely than controls to have been cared for by the two nurses during the exposure period, suggesting that colonization of long or artificial nails with *Pseudomonas* spp. may have played a role in causing the outbreak. HCWs wearing artificial nails have also been epidemiologically implicated in several other outbreaks of infection caused by Gram-negative bacilli or yeast.[159,167,977] In a recent study, multiple logistic regression analysis showed the association of an outbreak of extended-spectrum beta-lactamase-producing *K. pneumoniae* in a neonatal ICU resulting from exposure to an HCW wearing artificial fingernails.[155] A cluster of five cases of *S. marcescens* bacteraemia in haemodialysis was associated with a nurse who used an artificial fingernail to open a vial of heparin that was mixed to make a flush solution. The strains isolated from the five patients and the nurse were indistinguishable.[856] Allergic contact dermatitis resulting in months of sick leave has been reported in an office worker with artificial nails.[978]

Long, sharp fingernails, either natural or artificial, can puncture gloves easily.[123] They may also limit HCWs' performance in hand hygiene practices. In a recent survey among neonatal ICU HCWs, 8% wore artificial fingernails at work, and knowledge among them about the relationship between Gram-negative bacterial hand contamination and long or artificial fingernails was limited.[960]

Jeanes & Green[979] reviewed other forms of nail art and technology in the context of hand hygiene in health care, including: applying artificial material to the nails for extensions; nail sculpturing; protecting nails by covering them with a protective layer of artificial material; and nail jewellery, where decorations such as stones may be applied to the nails or the nails are pierced. In addition to possible limitations of care practice, there may be many potential health problems, including local infection for individuals who have undergone some form of nail technology.[979]

Each health-care facility should develop policies on the wearing of jewellery, artificial fingernails or nail polish by HCWs. These policies should take into account the risks of transmission of infection to patients and HCWs, rather than cultural preferences.

Consensus recommendations are that HCWs do not wear artificial fingernails or extenders when having direct contact with patients and natural nails should be kept short (≤ 0.5 cm long or approximately ¼ inch long).

23.5 Infrastructure required for optimal hand hygiene

Compliance with hand hygiene is only possible if the health-care setting ensures the adequate infrastructure and a reliable supply of hand hygiene products at the right time and at the right location in alignment with the concept of "My five moments for hand hygiene" (Part I, Section 21.4).[1] An important cause of poor compliance may be the lack of user-friendliness of hand hygiene equipment, as well as poor logistics leading to limited procurement and replenishment of consumables. The latter is one of the most commonly cited obstacles to hand hygiene improvement in developing countries (reports of workshops hosted by the WHO Regional Offices for Africa (AFRO) and South-East Asia (SEARO) in 2007, see http://www.who.int/gpsc/in/). As an example, very low overall hand hygiene compliance (8%) was shown in a university hospital in Mali where, at the same time, a survey on infrastructure for hand hygiene demonstrated that no alcohol-based handrub was available. Only 14.3% of patient rooms were equipped with sinks, and soap and towels were available at only 47.4% of sinks.[980] In developed countries, Suresh & Cahill[981] described several deficiencies in the structural layout of hand hygiene resources that hinder their usage: poor visibility, difficulty of access, placement at undesirable height, and wide spatial separation of resources that are used sequentially.

Other parts of these *Guidelines* have already described the need for clean water for handwashing and have elaborated on the advantages of handrubs over handwashing, namely, the freedom from the requirement of sinks and the possibility to clean hands at the point of care. While describing the overall infrastructure necessary, this section is particularly focused on soap and handrub dispensers.

23.5.1 General guidelines

All health-care settings should have written guidelines describing the appropriate placement of sinks and soap and handrub dispensers. Furthermore, the delegated responsibility with regards to supply of hand hygiene products, replenishment of consumables, and maintenance of the dispensers should be clearly described and communicated.

23.5.2 Sinks

While not all settings have a continuous water supply, tap water (ideally drinkable, is preferable for handwashing (see Part I, Section 11.1). In settings where this is not possible, water "flowing" from a pre-filled container with a tap is preferable to still-standing water in a basin. Where running water is available, the possibility of accessing it without the need to touch the tap with soiled hands is preferable. This may be achieved by taps that are opened by using an elbow or foot. In settings without budget restrictions, sensor-activated taps may be used for handwashing, although it must be noted that the system reliability is paramount since its failure completely prevents any access to handwashing facilities. In summary, manual or elbow- or foot-activated taps could be considered the optimal standard within health-care settings. Their availability is not considered among the highest priorities, however, particularly in settings with limited resources. Of note, recommendations for their use are not based on evidence.

To avoid water splashes, the water stream should not be directed straight into the drain, and taps should be fitted with an aerator screen. The mesh of the aerator screen should be sufficiently wide to ensure that no water remains on top of the aerator screen, as this may lead to bacterial contamination and consequent spread of microbes.[982]

23.5.3 Dispensers

In most health-care facilities, alcohol-based handrub dispensers have historically been located close to the sink, often adjacent to the wall-mounted liquid soap. Part of their function was to dispense pre-set amounts of handrub (mostly 1. 5 ml, half of what was needed according to older guidelines). Frequently, these dispensers were designed to allow the user to apply handrub without using their contaminated hands to touch the dispenser (elbow-activated). While wall-mounted dispensers at the sink seemed a logical place to start promoting hand antisepsis with rubs over handwashing, the main advantage of handrubs is the fact that they can (and should) be used at the point of care, for example at the end of the bed. Placement of handrubs exclusively at the sink therefore disregards one of their unique features and is not aligned with promoting hand hygiene at the five moments when it is required in health care.

The advantages and disadvantages of the different dispenser systems are discussed below and summarized in Table I.23.3. Although the same wall-mounted dispensers are used frequently for handrubs and liquid soaps, this section will focus on handrub dispersion. It is obvious that economic constraints as well as local logistics have a major influence on the choice of dispensing system. Furthermore, in many settings, the different forms of dispensers, such as wall-mounted and those for use at the point of care, should be used in combination to achieve maximum compliance. Some of the prerequisites for all dispensers and their placement are given in Table I.23.4. Some examples of dispensers for use at the point of care are shown in Figure I.23.5.

23.5.3.1 Wall-mounted systems

Wall-mounted soap dispensing systems are recommended to be located at every sink in patient and examination rooms, when affordable. Wall-mounted handrub dispensers should be positioned in locations that facilitate hand hygiene at the point of care, in accordance with the concept of the "My five moments for hand hygiene". Careful consideration should be given to the placement of these dispensers in areas with patients who are likely to ingest the product, such as disoriented elderly patients, psychiatric patients, young children, or patients with alcohol dependence. In patient areas where beds are geographically in very close proximity, common in developing countries, wall-mounted, alcohol-based handrubs can be placed in the space between beds to facilitate hand hygiene at the point of care. Some institutions have customized dispensers to fit on carts or intravenous-pools to ensure use during care delivery.

Splashes on the floor from wall-mounted dispensers have been reported as a potential problem, as this may lead to the discolouration of certain floor surfaces or even result in the floor surface becoming slippery. Some manufacturers in developed countries offer dispensers with a splash-guard intended to catch splashes and droplets to avoid these problems.

Dispensers should be mounted on the wall in a manner that allows unrestricted, easy access (i.e. not in corners or under hanging cupboards). They should be used preferably with disposable, transparent containers of a standardized size, thus allowing the use of products from different suppliers (e.g. Euro-dispenser for standardized 500 ml and 1000 ml bottles). The product should be placed in the dispenser in such a way that the label and content is visible to ensure timely replacement of empty containers by housekeeping or maintenance staff. Dispersion of the handrub should be possible in a "non-touch" fashion to avoid any touching of the dispenser with contaminated hands, e.g. "elbow-dispensers" or pumps that can be used with the wrist.[58] Despite the fact that ease of access may lead to increased use, as shown by Larson and colleagues[654] when comparing the frequency of handrub use of manually operated and touch-free dispensers in a paediatric ICU, robust mechanical systems are preferable over electronic "non-touch systems" that are more susceptible to malfunction, more costly, and frequently only usable with the supplier's own hand hygiene formulation. In general, the design and function of the dispensers that will ultimately be installed in a health-care setting should be evaluated, because some systems were shown to malfunction continuously, despite efforts to rectify the problem.[983]

23.5.3.2 Table-top dispensers (pumps)

A variation of wall-mounted dispensers are holders and frames that allow placement of a container that is equipped with a pump. The pump is screwed onto the container in place of the lid. It is likely that this dispensing system is associated with the lowest cost. Containers with a pump can also be placed easily on any horizontal surface, e.g. cart/trolley or night stand/bedside table. Several manufacturers have produced dispenser holders that allow positioning of the handrub onto a bed frame, thus enabling access to the handrub at the point of care. A disadvantage of these "loose" systems is the fact that the bottles can be moved around easily and may be misplaced, resulting in decreased reliability. Where possible, the combination of fixed (wall-mounted) and loose dispensers should be used.

23.5.3.3 Pocket or clip-on dispensers

Studies that compared the use of personal alcohol-based handrub dispensing systems with the traditional wall-mounted dispenser and sinks were unable to show a sustained effect on hand hygiene compliance,[709] possibly because the increased availability of hand hygiene products is only a single intervention within a broad multimodal approach. Individual, portable dispensers are ideal if combined with wall-mounted dispensing systems, to increase point-of-care access and enable use in units where wall-mounted dispensers should be avoided or cannot be installed. Also, wall-mounted systems can be used for back-up, as many of the pocket bottles or clip-ons are frequently not transparent and may be found to be empty when required. In some of these systems, the amount of handrub may be so small (10–20 ml) that several containers per HCW are needed each day. Costs and dependency on a single manufacturer and its products may be a problem especially with the clip-on system. Because many of these systems are used as disposables, environmental considerations should also be taken into account. In some situations, concern has been expressed about the potential contamination of the external surface of the bottle. However, this is considered to be almost theoretical and negligible because of the excess spillage of the disinfectant and the overall short time until replacement.

23.5.3.4 Automated wall-mounted dispensers

These types of systems have emerged from the non-medical setting, are aesthetically appealing, and are presently being marketed in many health-care settings. Such systems are truly non-touch and easy to use. Barrau and colleagues[984] compared a wall-mounted, hand-activated sprayer system with "bottles on a table", suggesting a possible benefit of the sprayer system. The study had several flaws, among them the low volume of product dispensed, which may be associated with lower efficacy.[985] On average, less than 0.8 ml was supplied for a one-time handrub, an amount less than three times than that currently recommended. In addition to the costs of the dispensers and the problem of their maintenance, many of these systems have to be filled with the manufacturer's own handrub, which is generally more expensive than other products distributed in 500 ml and 1000 ml standardized containers. In general, the maintenance is more complicated and the chance of malfunction is higher in automated systems.

23.5.3.5 Indicators/surveillance

Within the health-care setting, simple structure and performance indicators may be used to evaluate:

- the number of dispensers filled compared with the total number of dispensers in a unit;
- the number of dispensers in working order compared with the total number of dispensers in a unit ;
- the proportion of patient and treatment rooms with dispensers present at the point of care;
- the number of sinks in patient and treatment rooms and sink/bed ratio;
- the proportion of sinks equipped with soap and single-use towels.

Recently, special dispensers with electronic surveillance systems have been made commercially available. While measures of use are not validated in observational studies and do not allow conclusions about individual HCW adherence to hand hygiene indications, particularly the five moments, these electronic devices, in combination with other measures, may help to collect information about soap and handrub use, including the effect of quality improvement and educational initiatives.[986]

23.6 Safety issues related to alcohol-based preparations

23.6.1 Fire hazard issues

Alcohols are flammable. Flashpoints of alcohol-based handrubs range from 17.5°C to 24.5°C, depending on the type and concentration of alcohol present.[484,540] Therefore, risk assessment and minimization is crucial and alcohol-based handrubs should be stored away from high temperatures or flames in accordance with National Fire Protection Agency recommendations in the USA.

Although alcohol-based hand rubs are flammable, the risk of fires associated with such products is very low. For example, none of 798 health-care facilities surveyed in the USA reported a fire related to an alcohol-based handrub dispenser. A total of 766 facilities had accrued an estimated 1430 hospital-years of alcohol-based handrub use without a fire attributed to a handrub dispenser.[987]

In Europe, where alcohol-based handrubs have been used extensively for many years, the incidence of fires related to such products has been extremely low.[484] A recent study[988] conducted in German hospitals found that handrub usage represented an estimated total of 25 038 hospital-years. The median volume usage was between 31 litres/month (smallest hospitals) and 450 litres/month (largest hospitals), resulting in an overall usage of 35 million litres for all hospitals. A total of seven non-severe fire incidents was reported (0.9% of hospitals). This is equal to an annual incidence per hospital of 0.0000475%. No reports of fire caused by static electricity or other factors were received, nor any related to storage areas. Indeed, most reported incidents were associated with deliberate exposure to a naked flame, e.g. lighting a cigarette.

One recent report from the USA described a flash fire that occurred as a result of an unusual series of events, which consisted of an HCW applying an alcohol gel to her hands then immediately removing a polyester isolation gown and touching a metal door before the alcohol had evaporated.[989] Removing the polyester gown created a large amount of static electricity that generated an audible static spark when she touched the metal door, igniting the unevaporated alcohol on her hands.[989] This

incident underscores the fact that, following the application of alcohol-based handrubs, hands should be rubbed together until all the alcohol has evaporated.
In the USA, shortly after publication of the 2002 CDC/HICPAC hand hygiene guideline, fire marshals in a number of states prohibited the placement of alcohol-based handrub dispensers in egress corridors because of a concern that they may represent a fire hazard. On 25 March 2005, the Center for Medicare and Medicaid Services adopted a revised version of the USA National Fire Protection Agency's Life Safety Code that allows such dispensers to be placed in egress corridors. The International Fire Code recently agreed to accept alcohol-based handrubs in corridors. In addition, the CMS 3145-IFC (Fire Safety Requirement for Certain Health Care Facilities, Alcohol-Based Hand Sanitizer and Smoke Detector Amendment) was published in March 2005, addressing this issue.[990]

23.6.2 Other safety-related issues

Accidental and intentional ingestion and dermal absorption of alcohol-based preparations used for hand hygiene have been reported.[599,778-780] Acute, severe alcohol intoxication resulting from accidental ingestion of an unknown quantity of alcohol-based handrub was recently reported in the United Kingdom, resulting in the unconsciousness of an adult male patient (Glasgow Coma Scale 3).[778,781] This unusual complication of hand hygiene may become more common in the future, and security measures are needed. These may involve: placing the preparation in secure wall dispensers; labelling dispensers to make the alcohol content less clear at a casual glance and adding a warning against consumption; and the inclusion of an additive in the product formula to reduce its palatability. In the meantime, medical and nursing staff should be aware of this potential risk.

Alcohol toxicity usually occurs after ingestion. It is primarily metabolized by an alcohol dehydrogenase in the liver to acetone. Symptoms and signs of alcohol intoxication include headache, dizziness, lack of coordination, hypoglycaemia, abdominal pain, nausea, vomiting, and haematemesis. Signs of severe toxicity include respiratory depression, hypotension, and coma. Among alcohols, isopropyl alcohol appears to be more toxic than ethanol, but less so than methanol. Blood isopropyl alcohol levels of 50 mg/dl are associated with mild intoxication and 150 mg/dl with deep coma. Apparently, isopropyl alcohol has no adverse effects on reproduction and is not genotoxic, teratogenic, or carcinogenic.[991]

In addition to accidental ingestion, alcohols can be absorbed by inhalation and through intact skin, although the latter route (dermal uptake) is very low. Any absorption exceeding certain levels may result in toxicity and chronic disease in animals[992] and humans.[780] Recently, the Health Council of the Netherlands[993] suggested to classify ethanol as carcinogenic and to include it in skin notation because of the fear of an increased risk of breast and colorectal cancer in persons with an occupational exposure to ethanol. While the Dutch Social and Economic Council advised the Ministry of Social Affairs and Employment to consider an exception for the use of alcohol-based handrubs in health-care settings, the Ministry of Social Affairs and Employment rejected such an exception and set the maximum amount of occupational absorbed ethanol at such a low level that the decision could possibly lead to a ban of ethanol-containing handrubs in the Netherlands if upheld. Obviously, such a decision would be disastrous for health-care settings and could induce other countries to consider similar measures. Indeed, while there are no data to show that the use of alcohol-based handrub may be harmful – and studies evaluating the absorption into blood show that it is not – reduced compliance with hand hygiene will lead to preventable HCAIs.

Data used by the Dutch Heath Council estimated the absorption level after spraying of the total body under occlusive circumstances and after exposure times of up to 24 hours, although this is obviously not relevant for the application of handrubs. Furthermore, they estimated a worst case dermal uptake of 30 mg ethanol after a single application to hands and forearms, and a daily uptake of 600 mg/day after 20 applications per day, an estimate that has been proven wrong by several new studies.[782,784,994,995]

In practice, absorption of ethanol from a handrub would be by a combination of dermal absorption and inhalation. In a study using a solution of 44% ethanol sprayed on the skin and left for 15 minutes, there was no positive identification of ethanol in any of the blood samples taken (limit of detection was 9 mg/litre).[994] Turner and colleagues evaluated the dermal absorption through HCW's intact skin[599]: 3 ml of an isopropyl alcohol-containing handrub (52.6% (w/w) isopropyl alcohol) were applied to HCWs' hands every 10 minutes over a 4-hour period. A blood sample was taken 5 minutes after the final application of handrub and blood isopropyl alcohol levels were measured. In 9 out of 10 participants, a rise in the blood isopropyl alcohol level was noted at very low levels (the highest observed level was 0.18 mg/dl), much less than the levels achieved with mild intoxication (50 mg/dl).

More recently, Miller and colleagues conducted two studies in which large amounts of an ethanol-based handrub were used very frequently over periods of several hours; they found that blood alcohol levels at the end of the trial periods were below the level of detection.[782,995] Brown and colleagues exposed HCWs to intensive use (30 times/hour) of ethanol- and isopropanol-based handrub solutions and found only extremely low concentrations of ethanol in the blood (far too low to cause symptoms) and that blood isopropanol levels were undetectable.[783] Similarly, insignificant levels of ethanol were detected in the breath of a few study participants and no trace of isopropanol. Kramer and colleagues studied the intensive use of handrub solutions containing 55–95% ethanol and found that blood ethanol concentrations were far below levels that would result in any noticeable symptoms. For example, the highest median blood ethanol concentration after intensive use of a 95% ethanol hand rub was 20.95 mg/litre, whereas levels of 200–500 mg/litre are needed to impair fine motor coordination, and levels of 500–1000 mg/litre are needed to impair judgement.[784]

The presence of ethanol in the blood of human beings can also have other origins. Ethanol can be found in ripe fruit with concentrations of 0.6% or higher as a product of fermentation by natural yeasts.[996] A very small amount of ethanol is present as an endogenous substance in the blood, probably resulting from microbial production in the gastrointestinal tract. Studies have shown concentrations ranging from 0 mg/litre to1.6

mg/litre.[997,998] In rare instances, much higher endogenous concentrations have been reported (> 800 mg/litre) in Japanese subjects with serious yeast infections; endogenous ethanol appears to have been produced after they had eaten carbohydrate-rich foods.[997]

Studies to measure both alcohol and acetone levels in subjects chronically exposed to topical alcohols are required to investigate further this issue. Based on work emerging from the United Kingdom,Table I.23.5 lists the risks and recommended mitigation measures.[999,1000]

Table I.23.1
Indications for gloving and for glove removal

	Indication
Glove use	1) before a sterile condition 2) anticipation of a contact with blood or another body fluid, regardless of the existence of sterile conditions and including contact with non-intact skin and mucous membrane 3) contact with a patient (and his/her immediate surroundings) during contact precautions
Glove removal	1) as soon as gloves are damaged (or non-integrity suspected) 2) when contact with blood, another body fluid, non-intact skin and mucous membrane has occurred and has ended 3) when contact with a single patient and his/her surroundings, or a contaminated body site on a patient has ended 4) when there is an indication for hand hygiene

Table I.23.2
A question-frame to capture practical conditions for appropriate and safe glove use

Before donning gloves	When to wear gloves	When to remove gloves
– Is there any indication for glove use? – What is this indication? – What type of gloves is required? – Are gloves still in their original packaging? – When does the exact moment to put on gloves apply? – How do they protect the patient, the HCW, the environment? – Is any hand hygiene action indicated before donning gloves? – If any indication for hand hygiene, was handwashing or handrubbing performed? – Was it performed immediately before donning gloves? – Have both hands to be gloved? – Has the gloving technique been respected?	– Does the indication for use of gloves still remain? – Does any indication for glove removal occur?	– When does the exact moment for removing glove apply? – Has the technique to remove gloves been respected? – Have gloves been properly disposed? – Has hand hygiene been performed immediately after glove removal? – Have hands been washed if soiled with blood or another body fluid after glove removal?

Table I.23.3
Advantages and disadvantages of different dispensing methods

Dispenser type	Advantages	Disadvantages
Wall- and bed-mounted dispensers	• HCWs know where they are – can allow attainment of hand hygiene in alignment with the "Five moments" concept • Can be operated by a no-touch system (if elbow-operated) • Standardized with regard to refill (freedom to choose other suppliers) • Visible for staff, patients and visitors	• Not always placed in convenient locations; in some units they will not align with the requirements of the "Five moments" concept • Dependent on good service (refilling and maintenance) • Patients and visitors can access and ingest (e.g. areas where patients are confused and paediatric wards) • Splashes on floor that stain certain floor surfaces
Table-top dispensers (pumps)	• Use at point of care allowing attainment of hand hygiene in alignment with the "Five moments" concept • Low costs	• No fixed location • Patients and visitors can access and ingest (e.g. elderly and paediatric wards) • No-touch difficult
Pocket- and clip-on dispensers	• Constant access by HCWs – increased perception of self-efficacy among HCWs • No access for patients and visitors for safety purposes	• Can run-out at point of care, thus require back-up and facilitated access in wards for refill • Costs • Dependent on supplier (clip-on) • Environmental concerns and disposal if containers are not reused
Automated-wall mounted	• Faster and "aesthetically appealing" • No touch	• Unusable when out of order • Standardized amount of product preset • Costs of maintenance • Dependent on supplier

Table I.23.4
Characteristics to be considered as a prerequisite for all dispensers and their placement

Prerequisite	Comment
Easy and unobstructed access	Allow enough space around the dispenser; e.g. do not place under cupboards or next to other objects that hinder/obscure free access
Logical placement	HCWs should know intuitively where dispensers are placed. They should be as close as possible, (e.g. within arm's reach) to where patient contact is taking place, to avoid to have to leave the care/treatment zone
Wide availability	Available in all patient rooms (possibly at the bedside) and in all examination rooms and other points of care
Standardized (with regard to fillings/ containers)	Standardization should ensure that dispensers can be used with products of multiple brands, instead of only fitting the product of a single manufacturer A "Euro-dispenser" has been developed that holds European standard 500 ml and 1000 ml containers
"No-touch" system	To allow use by contact with clean body part (e.g. elbow dispenser, pump on a bottle operated by a clean wrist). This is with the exception of pocket bottles or systems worn on HCWs' uniforms
Disposable reservoir	Dispensers should generally have a disposable reservoir (container/bottle) that should not be refilled. If reusable reservoirs have to be used, they should be cleaned and disinfected according to the instructions in Section 12
Avoid contamination	Dispensers should be constructed in such a way that contaminated hands do not come into contact with parts of the delivery system of the dispenser and/or those parts unable to be cleaned

Table I.23.5

Summary of risks and mitigation measures concerning the use of alcohol-based hand hygiene preparations

Risk	Mitigation
Fire	• Involve fire officers, fire safety advisers, risk managers, and health and safety and infection control professionals in risk assessments prior to embarking on system change • Risk assessment should take into account: – the location of dispensers – the storage of stock – the disposal of used containers/dispensers and expired stock • Storage: store away from high temperatures or flames • Drying: following application of alcohol-based handrubs, hands should be rubbed together until all the alcohol has evaporated (when dry, hands are safe)
Storage	• Local and central (bulk) storage must comply with fire regulations regarding the type of cabinet and store, respectively • Production and storage facilities should ideally be air-conditioned or cool rooms • No naked flames or smoking should be permitted in these areas • National safety guidelines and local legal requirements must be adhered to for the storage of ingredients and the final product • Care should be taken when carrying personal containers/dispensers, to avoid spillage onto clothing, bedding or curtains and in pockets, bags or vehicles • Containers/dispensers should be stored in a cool place and care should be taken regarding the securing of tops/lids • The quantity of handrub kept in a ward or department should be as small as is reasonably practicable for day-to-day purposes • A designated 'highly flammables' store will be required for situations where it is necessary to store more than 50 litres (e.g. central bulk storage) • Containers and dispenser cartridges containing handrub should be stored in a cool place away from sources of ignition. This applies also to used containers that have not been rinsed with water
Disposal	• Used containers and dispensers will contain gel residues and flammable vapours • Rinsing out used containers with copious amounts of cold water will reduce the risk of fire and the containers may then be recycled or disposed of in general waste
Location of dispensers	• Handrub dispensers should not be placed above or close to potential sources of ignition, such as light switches and electrical outlets, or next to oxygen or other medical gas outlets, because of the increased risk of vapours igniting • The siting of handrub dispensers above carpets is not recommended, because of the risk of damage and lifting/warping of carpets. • Consideration should be given to the risks associated with spillage onto floor coverings, including the risk of pedestrian slips
WHO Formulation	• The WHO-recommended formulation handrub should not be produced in quantities exceeding 50 litres locally or in central pharmacies lacking specialized air conditioning and ventilation • Since undiluted ethanol is highly flammable and may ignite at temperatures as low as 10 °C, production facilities should directly dilute it to the concentrations outlined in the Guide to Local Production (http://www.who.int/gpsc/tools/InfSheet5.pdf) • The flashpoints of ethanol 80% (v/v) and isopropyl alcohol 75% (v/v) are 17.5 °C and 19 °C, respectively
Spillage	• Significant spillages should be dealt with immediately by removing all sources of ignition, ventilating the area, and diluting the spillage with water (to at least 10 times the volume) • The fluid should then be absorbed by an inert material such as dry sand (not a combustible material such as sawdust), which should be disposed of in a chemical waste container • Vapours should be dispersed by ventilating the room (or vehicle), and the contaminated item should be put in a plastic bag until it can be washed and/or dried safely
Fighting a large (i.e. bulk storage) alcohol fire	• Water or aqueous (water) film-forming foam (AFFF) should be used; other types of extinguishers may be ineffective and may spread the fire over a larger area rather than put it out
Ingestion	• In areas where there is thought to be a high risk of ingestion, a staff-carried product is advised • If a wall-mounted product is used, consideration should be given to small bottles • If bottles with a greater capacity than 500 ml are used, consideration should be given to providing them in secured containers • Consideration should be given to the labelling of the handrubs, including an emphasis on the sanitizing properties and warning of dangers associated with ingestion • National and local toxicology specialists should be involved in developing and issuing national/local guidance on how to deal with ingestion (based on products available within a country)

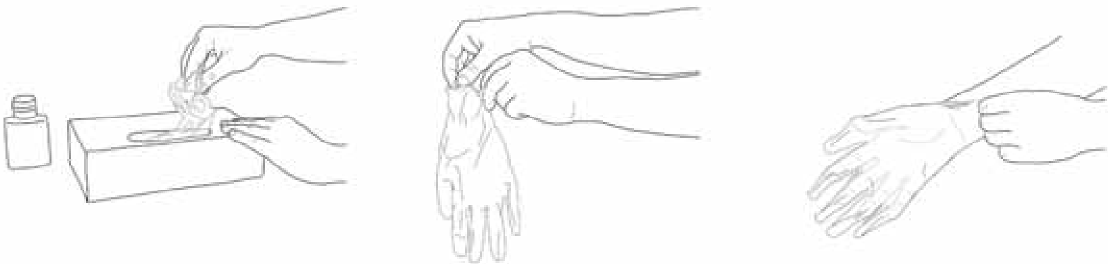
Figure I.23.1
Situations requiring and not requiring glove use

Gloves must be worn according to STANDARD and CONTACT PRECAUTIONS. The pyramid details some clinical examples in wich gloves are not indicated, and others in which examination or sterile gloves are indicated. Hand hygiene should be performed when appropriate regardless indications for glove use.

Figure I.23.2
How to don and remove non-sterile gloves

When the hand hygiene indication occurs before a contact requiring glove use, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water.

I. HOW TO DON GLOVES:



1. Take out a glove from its original box

2. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)

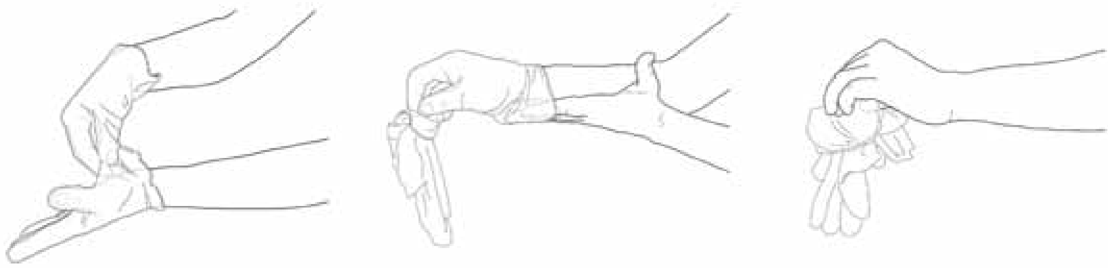
3. Don the first glove

4. Take the second glove with the bare hand and touch only a restricted surface of glove corresponding to the wrist

5. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand, thus permitting to glove the second hand

6. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use

II. HOW TO REMOVE GLOVES:



1. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out

2. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist. Remove the second glove by rolling it down the hand and fold into the first glove

3. Discard the removed gloves

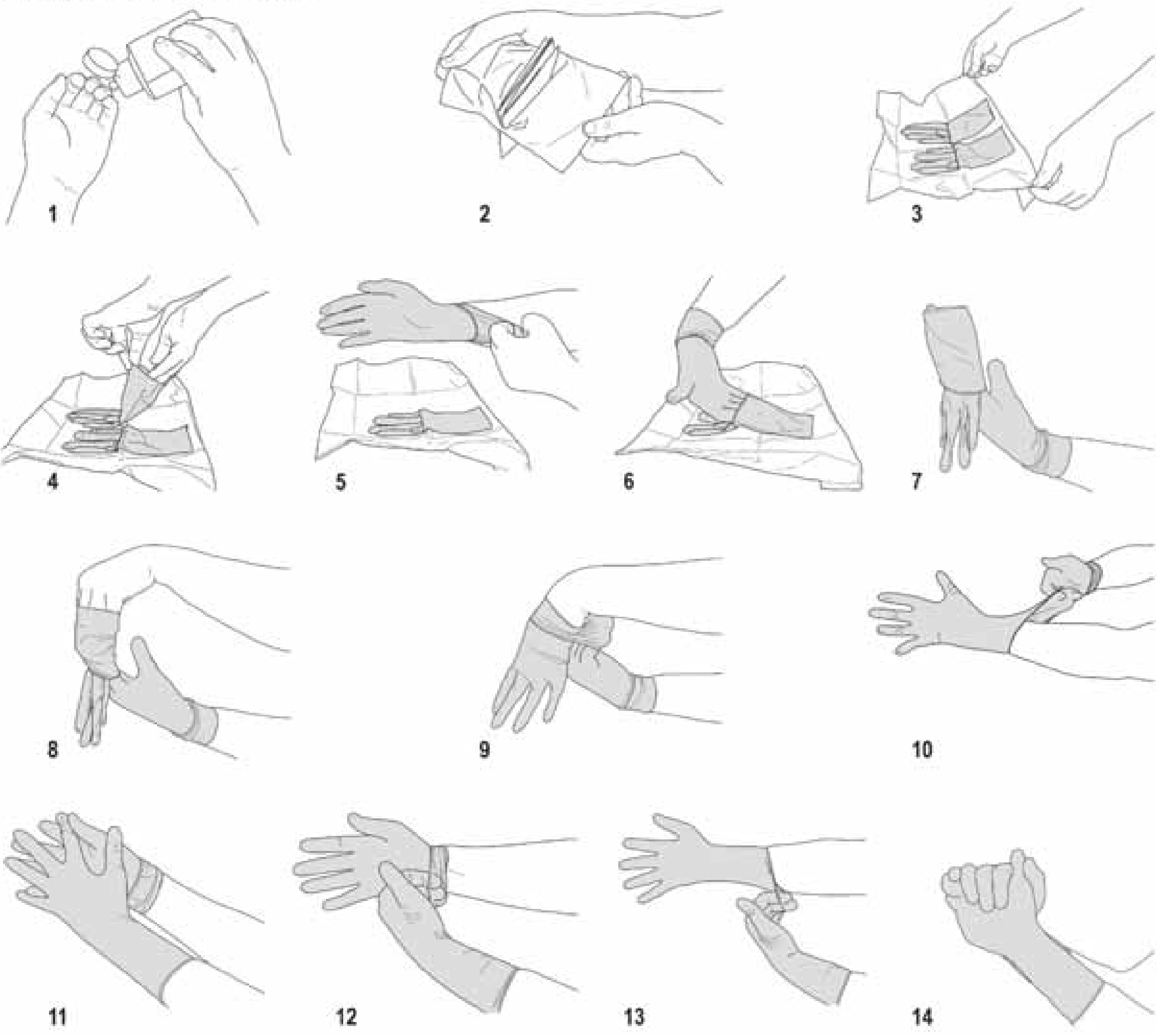
4. Then, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water

Figure I.23.3

How to don and remove sterile gloves

The purpose of this technique is to ensure maximum asepsis for the patient and to protect the health-care worker from the patient's body fluid(s). To achieve this goal, the skin of the health-care worker remains exclusively in contact with the inner surface of the glove and has no contact with the outer surface. Any error in the performance of this technique leads to a lack of asepsis requiring a change of gloves.

I. HOW TO DON STERILE GLOVES



1. Perform hand hygiene before an "aseptic procedure" by handrubbing or hand washing.
2. Check the package for integrity. Open the first non-sterile packaging by peeling it completely off the heat seal to expose the second sterile wrapper, but without touching it.
3. Place the second sterile package on a clean, dry surface without touching the surface. Open the package and fold it towards the bottom so as to unfold the paper and keep it open.
4. Using the thumb and index finger of one hand, carefully grasp the folded cuff edge of the glove.
5. Slip the other hand into the glove in a single movement, keeping the folded cuff at the wrist level.

6-7. Pick up the second glove by sliding the fingers of the gloved hand underneath the cuff of the glove.

8-10. In a single movement, slip the second glove on to the ungloved hand while avoiding any contact/resting of the gloved hand on surfaces other than the glove to be donned (contact/resting constitutes a lack of asepsis and requires a change of glove).

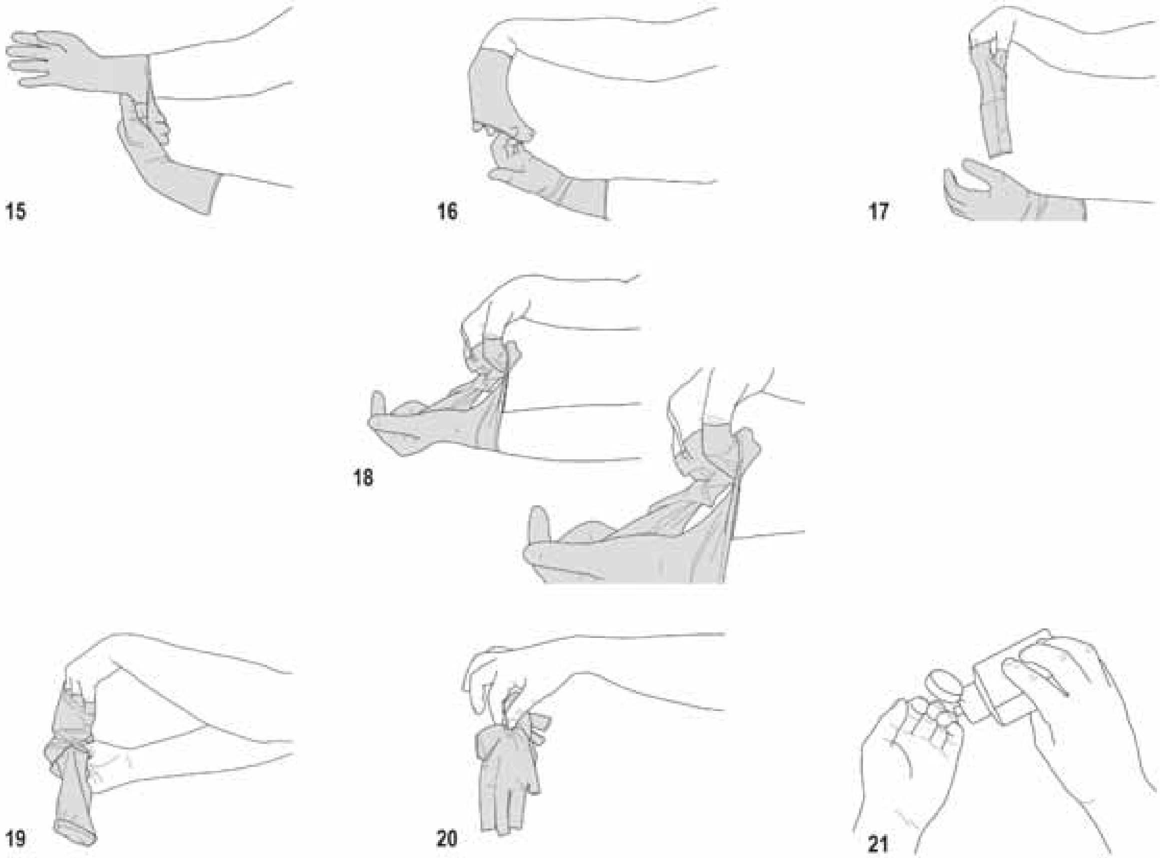
11. If necessary, after donning both gloves, adjust the fingers and interdigital spaces until the gloves fit comfortably.

12-13. Unfold the cuff of the first gloved hand by gently slipping the fingers of the other hand inside the fold, making sure to avoid any contact with a surface other than the outer surface of the glove (lack of asepsis requiring a change of gloves).

14. The hands are gloved and must touch exclusively sterile devices or the previously-disinfected patient's body area.

Figure I.23.3
How to don and remove sterile gloves (Cont.)

II. HOW TO REMOVE STERILE GLOVES



15-17. Remove the first glove by peeling it back with the fingers of the opposite hand. Remove the glove by rolling it inside out to the second finger joints (do not remove completely).

18. Remove the other glove by turning its outer edge on the fingers of the partially ungloved hand.

19. Remove the glove by turning it inside out entirely to ensure that the skin of the health-care worker is always and exclusively in contact with the inner surface of the glove.

20. Discard gloves.

21. Perform hand hygiene after glove removal according to the recommended indication.

NB: Donning surgical sterile gloves at the time of a surgical intervention follows the same sequences except that:

- it is preceeded by a surgical hand preparation;
- donning gloves is performed after putting on the sterile surgical gown;
- the opening of the first packaging (non-sterile) is done by an assistant;
- the second packaging (sterile) is placed on a sterile surface other than that used for the intervention;
- gloves should cover the wrists of the sterile gown.

Figure I.23.4
Blood safety: crucial steps for hand hygiene action

Collection of blood from blood donors →	Production of blood products →	Storage and transport →	Issue of safe blood and blood products to patients
• Hand hygiene* • Sterile blood collection bags • Donors' arm cleansing • Gloves**	• Hand hygiene* • Clean equipment • Gloves**	• Hand hygiene* • Gloves** for safe handling • Correct temperature to avoid physical damage and bacterial overgrowth	• Hand hygiene* • Gloves** for safe handling • Safe bedside transfusion procedures

* Hand hygiene before and after the procedure.
** Clean non-sterile gloves.

Figure I.23.5
Different types of dispensers at the point of care

Pocket bottle with clip

Pocket bottle

Figure I.23.5

Different types of dispensers at the point of care (Cont.)

Dispenser fixed to the medicine trolley

Euro dispenser with spill tray

Pump dosing device for placement on the container/bottle

Pocket bottles (snap-cap and pump) and clip-on dispensers

24.
Hand hygiene research agenda

Although the number of published studies dealing with hand hygiene has increased considerably in recent years, many questions regarding hand hygiene products and strategies for improving HCW compliance with recommended policies remain unanswered. Table I.24.1 lists a number of areas that should be addressed by researchers, scientists and clinical investigators. Table I.24.2 includes a series of open questions on specific unsolved issues that require research activities and field testing. Some of the research questions will be covered by studies conducted within the framework of the World Alliance for Patient Safety.

Table I.24.1
Hand hygiene research agenda

Area	In both developed and developing countries	More focus on developing countries
Education and promotion	Survey on perceptions among HCWs regarding indications for hand hygiene Identify more effective ways to educate HCWs regarding patient-care activities that can result in hand contamination and cross-transmission Assess the key determinants of hand hygiene behaviour and promotion among the different populations of HCWs Evaluate the impact of different definitions and approaches to the "Five moments" Explore avenues to implement hand hygiene promotion programmes in undergraduate courses Study the impact of religion and culture on population-based education on hand hygiene behaviour Identify effective methods and models for patient participation in the promotion of hand hygiene compliance among HCWs in different cultural or social contexts Document benefits and disadvantages of patient empowerment/participation in the promotion of hand hygiene in health-care settings, in particular, its impact on hand hygiene compliance Implement and evaluate the impact of the different components of multimodal programmes to promote hand hygiene Ascertain the impact of social marketing on hand hygiene compliance Develop and evaluate methods to obtain management support Evaluate hand hygiene practices in traditional medicines and explore the possibility of promoting hand hygiene among practitioners	Test different strategies for hand hygiene promotion in developing countries Conduct cost–benefit, cost utility, and cost–effectiveness analyses of improving hand hygiene in developing countries

Table I.24.1
Hand hygiene research agenda (Cont.)

Area	In both developed and developing countries	More focus on developing countries
Agents, indications, choice of hand hygiene product, technique, hand care	Identify the most suitable agents for hand hygiene based on a set of valid criteria	Study skin adverse events in different ethnic groups and in tropical climates
	Determine the role of alcohol-based handrub (gloving + handrubbing vs gloving + handwashing) to prevent the transmission of spore-forming pathogens	
	Determine if preparations with sustained antimicrobial activity (based on various components, e.g. triclosan, chlorhexidine, silver) are more effective to reduce infection rates than those whose activity is limited to an immediate effect when used for hygienic hand antisepsis	
	Develop and field-test devices to facilitate the optimal application of hand hygiene agents	
	Develop hand hygiene agents with lower skin irritancy potential	
	Study the possible advantages and interactions of hand care lotions, creams, and other barriers with hand hygiene agents	
	Conduct market research on handrub products and their cost at country level	
	Determine if bar soap is acceptable; if yes, establish if single-use, small pieces should be recommended	
	Establish appropriate duration (90 seconds vs 3 minutes) of surgical hand preparation, in particular, using alcohol-based handrubs	
	Establish whether there is a need to perform a second handrub for surgical procedures of more than a two-hour duration and, if so, determine the duration of the handrubbing.	
	Establish which skin areas must be cleansed (up to the wrist, forearm or elbow?) during surgical hand preparation	
	Determine the effect of changing the sequence of steps or reducing the number of steps for hand decontamination on efficacy	
	Ascertain the need for handrubbing before using non-sterile examination gloves	
	Establish a feasible method (e.g. disinfecting gloves) for performing hand hygiene between patients for HCWs who are gloved for designated procedures (e.g. phlebotomists)	
	Assess the effect of glove use on compliance with hand hygiene	
	Investigate the impact of wearing a watch on the efficacy of hand hygiene	

Table I.24.1
Hand hygiene research agenda (Cont.)

Area	In both developed and developing countries	More focus on developing countries
Laboratory-based and epidemiological research and development	Conduct experimental studies to understand different aspects of transmission, colonization and infection – role of casual contact and the environment (surface contamination) in the transmission of pathogens, transmission dynamics from colonization to infection, etc.	
	Develop and evaluate new standardized protocols to test the efficacy of hand hygiene agents considering, in particular, short application times and volumes that reflect actual use in health-care facilities	
	Establish if hand antisepsis prior to donning non-sterile examination gloves reduces transmission of pathogens to patients	
	Conduct further studies to determine the relative efficacy of alcohol-based solutions vs gels and other formulations in reducing transmission of HCAI	
	Compare the utility of different methods (new devices, surrogate markers, etc.) to assess hand hygiene compliance that allow frequent feedback on performance	
	Compare the results of hand hygiene monitoring methods using different denominators (e.g. indications vs opportunities)	
	Determine the percentage increase in hand hygiene adherence required to achieve a predictable risk reduction in infection rates	
	Assess compliance with recommendations for surgical hand preparation	
	Conduct further studies to determine the consequences of soap contamination	
	Evaluate contamination of tap/faucet water at the sink with P. aeruginosa and non-fermenting Gram-negative bacilli and its role in hand contamination	
	Evaluate the frequency of recontamination (when rinsing) after surgical hand scrub and its impact on surgical infection rates	
	Conduct additional in vitro and in vivo studies of both alcohol-based formulations and antimicrobial soaps to establish the minimal level of virucidal activity required to interrupt direct contact transmission of viruses in health-care settings	
	Evaluate the effectiveness of handrubbing or handwashing to interrupt transmission of pathogens such as noroviruses	
	Identify the most appropriate surrogate virus for human norovirus for use in laboratory studies of hand hygiene agents	
	Gather evidence on reduced susceptibility to antiseptic agents and evaluate whether resistance to antiseptics influences the prevalence of antimicrobial resistance	
	Determine the actual risk of triclosan-inducing resistance in in-use situations	
	Establish sample size requirements for studies designed to answer different research questions in hand hygiene epidemiology and research	

Table I.24.1
Hand hygiene research agenda (Cont.)

Area	In both developed and developing countries	More focus on developing countries
System	Determine the effect of quality (or lack of it) and temperature of water on hand hygiene Develop and evaluate models for inexpensive and sustained supply of products in different countries Develop a cost-utility tool for large-scale production, storage, and distribution of alcohol-based handrubs Establish correlations between hand hygiene compliance rates (ideally by direct observation), product consumption, and HCAI rates Investigate the potential for aerosolization of water-borne pathogens associated with air dryers	Establish the requisite quality of water for handwashing Establish the most appropriate method to keep water safe for care and hand hygiene purposes when it needs to be stored at point of use (containers) Establish the recommended number of sinks per bed Evaluate the cost–benefit of glove reuse in settings with limited/poor resources

Table I.24.2
Unsolved issues for research and field testing

Area	Outstanding questions to be resolved
Water quality and its availability in health care	Should water for handwashing be drinkable or simply the cleanest possible? Should water requirements be differentiated according to the resources available in different settings? Are the water quality requirements at the tap/faucet in the operating room different from those in the rest of the health-care setting? Should high-risk populations (e.g. immunosuppressed) who need guaranteed high standards of water quality be identified?
Soap	What is the potential for actual soap contamination during use? What is the best storage method between uses?
Hand drying	What quality of paper should be used for hand hygiene? What should be the standards for paper? Is there a preferred type of paper? Does the quality of paper have an impact on hand hygiene compliance? What are the best approaches when single-use towels are not available? Use of recycled paper for hand drying: • What type of in vitro studies may be appropriate to assess the level of contamination of recycled paper? • Could there be an impact of the type of paper (recycled vs not-recycled) on HCAI or colonization rates by multidrug-resistant pathogens? • What is the cost–benefit of using recycling paper?
Antimicrobicidal activity of products	When handling norovirus, is handrubbing or handwashing preferred? Is there an impact of resistance to antiseptics on the prevalence of antibiotic-resistant strains?
Use of gloves	Should hand hygiene be recommended before donning non-sterile gloves? What are the cost–benefits of glove reuse in settings with limited/poor resources? How many times could gloves be reused? What type of gloves could be reused? Could gloves be decontaminated between different patients? How? Should the reuse of gloves definitely be forbidden: during outbreaks; if there is direct contact with blood or body fluids; and during the care of patients colonized and/or infected with multidrug-resistant pathogens? In other situations?
Surgical hand antisepsis	What are the different types of surgical hand antisepsis currently performed in different countries? What elements are to be included in a standardized protocol to define the status quo? What is the appropriate time for surgical hand preparation? A 5-minute or a 3-minute scrub? Are times < 2 minutes inappropriate?
Hand hygiene promotion	Is there a consequential impact of low budget, educational interventions on compliance with hand hygiene in countries with limited resources? What are the cognitive determinants of hand hygiene behaviour?

PART II.

CONSENSUS RECOMMENDATIONS

Ranking system for evidence

The consensus recommendations listed below (Part II, Sections 1–9) are categorized according to the CDC/HICPAC system, adapted as follows:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies

Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and a strong theoretical rationale.

Category IC. Required for implementation, as mandated by federal and/or state regulation or standard.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale or a consensus by a panel of experts.

1. Indications for hand hygiene

A. Wash hands with soap and water when visibly dirty or visibly soiled with blood or other body fluids (IB) or after using the toilet (II).[179,248,249,287,339,899,1001-1005]

B. If exposure to potential spore-forming pathogens is strongly suspected or proven, including outbreaks of *Clostridium difficile,* hand washing with soap and water is the preferred means (IB).[419-421,432]

C. Use an alcohol-based handrub as the preferred means for routine hand antisepsis in all other clinical situations described in items D(a) to D(f) listed below, if hands are not visibly soiled (IA).[60,221,329,333,484-487,665] If alcohol-based handrub is not obtainable, wash hands with soap and water (IB).[60,195,196]

D. Perform hand hygiene:

a. before and after touching the patient (IB);[50,52,73,88,110,114,121,125,126,1006]
b. before handling an invasive device for patient care, regardless of whether or not gloves are used (IB); [1007]
c. after contact with body fluids or excretions, mucous membranes, non-intact skin, or wound dressings (IA);[50,125,127,179]
d. if moving from a contaminated body site to another body site during care of the same patient (IB);[73,88,125-127]
e. after contact with inanimate surfaces and objects (including medical equipment) in the immediate vicinity of the patient (IB);[73,111,112,114,125-127,129,130]
f. after removing sterile (II) or non-sterile gloves (IB).[73,123,139,520,1008]

E. Before handling medication or preparing food perform hand hygiene using an alcohol-based handrub or wash hands with either plain or antimicrobial soap and water (IB).[1001-1004]

F. Soap and alcohol-based handrub should not be used concomitantly (II).[617,1009]

2. Hand hygiene technique

A. Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry (IB).[201,814] (The technique for handrubbing is illustrated in Figure II.1)

B. When washing hands with soap and water, wet hands with water and apply the amount of product necessary to cover all surfaces. Rinse hands with water and dry thoroughly with a single-use towel. Use clean, running water whenever possible. Avoid using hot water, as repeated exposure to hot water may increase the risk of dermatitis (IB).[255,586,587] Use towel to turn off tap/faucet (IB).[151,220,222,1010,1011] Dry hands thoroughly using a method that does not recontaminate hands. Make sure towels are not used multiple times or by multiple people (IB).[75,115,257,671] (The technique for handwashing is illustrated in Figure II.2).

C. Liquid, bar, leaf or powdered forms of soap are acceptable. When bar soap is used, small bars of soap in racks that facilitate drainage should be used to allow the bars to dry (II).[265,266,640,1012-1015]

3. Recommendations for surgical hand preparation

A. Remove rings, wrist-watch, and bracelets before beginning surgical hand preparation (II).[962,965,966,968,1016] Artificial nails are prohibited (IB).[154,167,534,974,977]

B. Sinks should be designed to reduce the risk of splashes (II).[235,552]

C. If hands are visibly soiled, wash hands with plain soap before surgical hand preparation (II). Remove debris from underneath fingernails using a nail cleaner, preferably under running water (II).[63]

D. Brushes are not recommended for surgical hand preparation (IB).[247,261,463,511,545-547]

E. Surgical hand antisepsis should be performed using either a suitable antimicrobial soap or suitable alcohol-based handrub, preferably with a product ensuring sustained activity, before donning sterile gloves (IB).[162,227,282,336,463,482,524,525]

F. If quality of water is not assured (as described in Table I.11.3) in the operating theatre, surgical hand antisepsis using an alcohol-based handrub is recommended before donning sterile gloves when performing surgical procedures (II).[250,282,463,482]

G. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, typically 2–5 minutes. Long scrub times (e.g. 10 minutes) are not necessary (IB).[284,378,380,460,511,512,525,541,542]

H. When using an alcohol-based surgical handrub product with sustained activity, follow the manufacturer's instructions for application times. Apply the product to dry hands only (IB).[562,564] Do not combine surgical hand scrub and surgical handrub with alcohol-based products sequentially (II).[617]

I. When using an alcohol-based handrub, use sufficient product to keep hands and forearms wet with the handrub throughout the surgical hand preparation procedure (IB).[328,557,568] (The technique for surgical hand preparation using alcohol-based handrubs is illustrated in Figure I.13.1.)

J. After application of the alcohol-based handrub as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves (IB).[463,482]

4. Selection and handling of hand hygiene agents

A. Provide HCWs with efficacious hand hygiene products that have low irritancy potential (IB).[219,220,262,264,329,548,549,572,607]

B. To maximize acceptance of hand hygiene products by HCWs, solicit their input regarding the skin tolerance, feel, and fragrance of any products under consideration (IB).[221,329,488,549,598,608,610,633,1017]

C. When selecting hand hygiene products:

   a. determine any known interaction between products used to clean hands, skin care products, and the types of glove used in the institution (II);[342,946]
   b. solicit information from manufacturers about the risk of product contamination (IB);[160,643,644]
   c. ensure that dispensers are accessible at the point of care (see Part I.1 for the definition) (IB);[335,486]
   d. ensure that dispensers function adequately and reliably and deliver an appropriate volume of the product (II);[60,983]
   e. ensure that the dispenser system for alcohol-based handrubs is approved for flammable materials (IC);
   f. solicit and evaluate information from manufacturers regarding any effect that hand lotions, creams, or alcohol-based handrubs may have on the effects of antimicrobial soaps being used in the institution (IB);[342,563,1018]
   g. cost comparisons should only be made for products that meet requirements for efficacy, skin tolerance, and acceptability (II).[464,488]

D. Do not add soap (IA) or alcohol-based formulations (II) to a partially empty soap dispenser. If soap dispensers are reused, follow recommended procedures for cleansing.[161,358]

5. Skin care

A. Include information regarding hand-care practices designed to reduce the risk of irritant contact dermatitis and other skin damage in education programmes for HCWs (IB).[618,624]

B. Provide alternative hand hygiene products for HCWs with confirmed allergies or adverse reactions to standard products used in the health-care setting (II).

C. Provide HCWs with hand lotions or creams to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing (IA).[549,607,623-626]

D. When alcohol-based handrub is available in the health-care facility for hygienic hand antisepsis, the use of antimicrobial soap is not recommended (II).

E. Soap and alcohol-based handrub should not be used concomitantly (II).[617]

6. Use of gloves

A. The use of gloves does not replace the need for hand hygiene by either handrubbing or handwashing (IB).[73,123,139,520,913,914,931]

B. Wear gloves when it can be reasonably anticipated that contact with blood or other potentially infectious materials, mucous membranes, or non-intact skin will occur (IC).[906,1019,1020]

C. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient (IB).[73,114,123,139,520,941,1021]

D. When wearing gloves, change or remove gloves during patient care if moving from a contaminated body site to either another body site (including non-intact skin, mucous membrane or medical device) within the same patient or the environment (II).[72,123,139]

E. The reuse of gloves is not recommended (IB).[956] In the case of glove reuse, implement the safest reprocessing method (II).[952]

7. Other aspects of hand hygiene

A. Do not wear artificial fingernails or extenders when having direct contact with patients (IA).[154,155,159,856,976,977]

B. Keep natural nails short (tips less than 0.5 cm long or approximately ¼ inch) (II).[976]

8. Educational and motivational programmes for health-care workers

A. In hand hygiene promotion programmes for HCWs, focus specifically on factors currently found to have a significant influence on behaviour, and not solely on the type of hand hygiene products. The strategy should be multifaceted and multimodal and include education and senior executive support for implementation.(IA)[60,651,657,676,701,708,713,725,732,767,802,809,813,814,816,820,834,939,1022]

B. Educate HCWs about the type of patient-care activities that can result in hand contamination and about the advantages and disadvantages of various methods used to clean their hands (II).[60,657,663,666,670,715,716,727,814,939,1022]

C. Monitor HCWs' adherence to recommended hand hygiene practices and provide them with performance feedback (IA).[60,633,651,657,663,666,670,676,686,687,715,939]

D. Encourage partnerships between patients, their families, and HCWs to promote hand hygiene in health care settings (II).[803-805]

9. Governmental and institutional responsibilities

9.1 For health-care administrators

A. It is essential that administrators ensure conditions are conducive to the promotion of a multifaceted, multimodal hand hygiene strategy and an approach that promotes a patient safety culture by implementation of points B–I below.

B. Provide HCWs with access to a safe, continuous water supply at all outlets and access to the necessary facilities to perform handwashing (IB).[939,981,1023]

C. Provide HCWs with a readily accessible alcohol-based handrub at the point of patient care (IA).[60,485,486,615,647,665,855,1024,1025]

D. Make improved hand hygiene adherence (compliance) an institutional priority and provide appropriate leadership, administrative support, financial resources, and support for hand hygiene and other infection prevention and control activities (IB).[60,657,708,713,728]

E. Ensure HCWs have dedicated time for infection control training, including sessions on hand hygiene (II).[732,1026]

F. Implement a multidisciplinary, multifaceted and multimodal programme designed to improve adherence of HCWs to recommended hand hygiene practices (IB).[60,713,719]

G. With regard to hand hygiene, ensure that the water supply is physically separated from drainage and sewerage within the health-care setting, and provide routine system monitoring and management (IB).[228]

H. Provide strong leadership and support for hand hygiene and other infection prevention and control activities (II).[713]

I. Alcohol-based handrub production and storage must adhere to the national safety guidelines and local legal requirements (II).

9.2 For national governments

A. Make improved hand hygiene adherence a national priority and consider provision of a funded, coordinated implementation programme, while ensuring monitoring and long-term sustainability (II).[875,1027-1029]

B. Support strengthening of infection control capacities within health-care settings (II).[1026,1030,1031]

C. Promote hand hygiene at the community level to strengthen both self-protection and the protection of others (II).[248,249,451-454,899]

D. Encourage health-care settings to use hand hygiene as a quality indicator (Australia, Belgium, France, Scotland, USA) (II).[726,727]

Figure II.1
How to handrub

Figure II.2
How to handwash

PART III.

PROCESS AND OUTCOME MEASUREMENT

1.

Hand hygiene as a performance indicator

Monitoring hand hygiene adherence serves multiple functions: system monitoring, incentive for performance improvement, outbreak investigation, staffing management, and infrastructure design.[60,648,651,663,666,670,676,684,686,713,714] It has to be kept in mind, however, that hand hygiene performance is only one node in a causal tree leading to the two major infectious outcomes: HCAI and health care-associated colonization with multi-resistant microorganisms. As a process element in this causal chain, hand hygiene performance itself is influenced by many factors, not least the structural aspects related to the quality and availability of products such as alcohol-based handrub at the point of care.

The correct moment for hand hygiene is usually termed "opportunity". According to an evidence-based model of hand transmission,[1,885] the opportunity corresponds to the period between the moment in which hands become colonized after touching a surface (either environment or patient) and the moment in which hands touch a receptor surface. This transition can potentially result in a negative infectious outcome. Opportunities constitute the denominator in the calculation of compliance with optimal hand hygiene. As a consequence, measurement technologies and methods can be divided into two main categories: those with a measured denominator, and those without.

An ideal indicator of hand hygiene performance would produce an unbiased and exact numerical measure of how appropriately HCWs practise hand hygiene so that its preventive effect on negative infectious outcomes is maximized. Ideally, such an indicator implies a technology that does not interfere with the behaviour of those observed, assesses the microbiological outcome of each hand cleansing action in real time, and reliably captures each moment requiring hand hygiene even during complex care activities. Furthermore, the method used should not require excessive staffing time and other incurred costs to provide sufficient data to exclude selection bias and underpowering. Bias and insufficient sample size represent the two major threats to meaningful monitoring outputs (see Part III, Section 1.1 below).

Today, such an ideal method does not exist. All current measurement approaches produce approximate information on real hand hygiene performance, each with certain advantages and disadvantages (Table III.1.1).

Hand hygiene performance in health care can be monitored directly or indirectly. Direct methods include direct observation, patient assessment or HCW self-reporting. Indirect methods include monitoring consumption of products, such as soap or handrub, and automated monitoring of the use of sinks and handrub dispensers.

1.1 Monitoring hand hygiene by direct methods

Detection of hand hygiene compliance by a validated observer (direct observation) is currently considered the gold standard in hand hygiene compliance monitoring.[58] It is the only method available to detect all occurring hand hygiene opportunities and actions and to assess the number of times and appropriate timing when hand hygiene action would be required in the sequence of care. Observations are usually performed by trained and validated observers who observe care activity directly and count the occurring hand hygiene opportunities and determine the proportion being met by hand hygiene actions. It is essential that hand hygiene opportunities, indications, and actions are clearly defined (see Part III, Section 1.2). The validation of observers is essential for the quality of observation data (see under 1.2.3).

Opportunities for hand hygiene action using alcohol-based handrubs can be distinguished from those requiring handwashing with soap and water. If pre-established in the selected methodology, direct observations allow to collect more detailed information. This can comprise glove use, handrubbing technique, application time, and other quality parameters that affect hand hygiene efficacy such as the wearing of jewellery and fingernail status (see Part I, Sections 23.4 and 23.5). Whereas routine monitoring needs to be kept simple and straightforward, observations for research purposes can be even more detailed. A major drawback of direct observation is the large effort required (trained and validated staff and many working hours). For example, with a typical average density of 10 hand hygiene opportunities per hour, a total observation time of 80 hours is required to obtain 500 opportunities.

Causes of potential bias arising from hand hygiene direct observation are listed in Table III.1.2. The most important are observation, observer, and selection bias. Observation bias is generated by the presence of an observer who influences the behaviour of the observed HCWs towards a higher compliance or by an increased attention to the topic under study. In a recent study, compliance found to be 45% with overt observations was in reality only 29% when observations were covert.[736] Observation bias can also induce increased recourse to hand hygiene action at inappropriate times during the sequence of care, i.e. not associated with true improvement in compliance. If observational surveys are conducted periodically, this bias would be equally distributed among all observations.[831] Observation bias might be eliminated by keeping observations covert. Such observations, however, are not recommended in conjunction with promotional interventions because they can induce mistrust in the observed HCWs. Furthermore, hiding the true reason for the presence of an observer can hardly be maintained in the case of repeated observations. If a baseline observation is covert, then the results of overt follow-up observations would be confounded by the change in method. The observation bias can also be attenuated by desensitizing HCWs through the frequent presence of observers or an unobtrusive conduct during observation sessions. Some investigators call this effect the "Hawthorne effect" following ergonomic studies in the early 20th century at the Hawthorne factory of Western Electrics in the USA.[334,810,1032,1033] On the other hand, this effect can be used deliberately to stimulate hand hygiene compliance in a promotional intention, rather than to obtain objective quantitative results.[334,810,1033] Obtaining a sustained and never-ending Hawthorne effect associated with improved compliance with hand hygiene and decreased infection and cross-transmission rates could certainly represent an ideal perspective.[810]

Observer bias refers to the systematic error introduced by inter-observer variation in the observation method (Table III.1.2). To reduce this bias, observers have to be validated. It is noteworthy that even the same observer can unconsciously change his/her method over time.

Selection bias results from systematically selecting HCWs, care settings, observation times, or health-care sectors with a specific hand hygiene behaviour. In practical terms, this bias can be minimized by randomly choosing locations, times during the day, and HCWs.

Another threat to meaningful hand hygiene compliance results is the inclusion of a small sample size. In a comparative quantitative analysis of hand hygiene performance during two different periods, a large enough sample is needed to exclude the influence of chance. A sample size calculation should therefore be performed at the design stage of every hand hygiene monitoring scheme. For example, to show a difference between 40% and 60% compliance in two different measurements with a power of 90% and an alpha error of 5%, twice 140 (140x2) opportunities have to be observed. The sample size increases to twice 538 (538x2) opportunities when a difference between 40% and 50% is to be detected. Another more innovative statistical approach for measuring improvement over time and determining whether statistical improvement has really occurred is described in Appendix 4. However, because this method has not yet been applied to the analysis of hand hygiene data, further research is needed to consolidate its use in this field.

If hand hygiene monitoring is used for comparison between health-care sectors or periods, confounding factors should be included in the dataset and corrected for by stratification, adjustment, or by keeping them unchanged between the monitoring sets. Typical confounders in this field are professional category, time of day, and health-care setting. Critical reviews of observation methods have been published.[809,1034,1035]

Patients could be observers of HCWs' hand hygiene compliance. In two studies, patients were encouraged to find out if HCWs had washed their hands before patient contact.[804,805] Patient monitoring of hand hygiene compliance is not well documented, however, and has never been objectively evaluated.[1036] Patients may not feel comfortable in a formal role as observers and are not always physically or mentally able to execute this task.[737,1037]

Self-assessment by HCWs can be carried out. It has been demonstrated, however, that self-reports of compliance do not correlate well with compliance measured by direct observation, and self-assessment markedly overestimates compliance with hand hygiene.[218,220,666,667,676,733]

1.2 The WHO-recommended method for direct observation

Observation is a sophisticated activity requiring training, skill and experience. Observers have to be aware of the multiple potential biases introduced with the observation process and they can help to minimize these by gaining a full understanding of the methodology. A stringent adherence to the same methodology over space and time is required.

WHO proposes a standardized hand hygiene observation method based on an approach validated through several studies.[60,652,686,738] All relevant theoretical and practical aspects related to this method are detailed in the Hand Hygiene Reference Technical Manual that is included in the Implementation Toolkit (available at http://www.who.int/gpsc/en/). An "Observation form" for data collection, consistent with the proposed method and including concise user instructions, is also availabletogether with a "Compliance calculation form" to facilitate the immediate performance feedback. Observation of hand hygiene practices is an essential component of the WHO Hand Hygiene Improvement Strategy (See Part I, Sections 21.2 and 21.3).

1.2.1 Profile and task of observers

The task of observers is to observe HCWs during their usual care activity and to assess their compliance with the recommended indications for hand hygiene. To be able to accomplish this task, observers have to be able to understand the logic of care. Ideally, they have training and experience in patient care as professionals.

1.2.2 Training of observers

Observers have to be trained according to the principles of "My five moments for hand hygiene" and, ideally, have become excellent monitors of the application of hand hygiene during health-care delivery. Their excellence should be confirmed through observations performed by a senior observer, if feasible, depending on the setting. They have then to be instructed in hand hygiene observation according to the present methodology. This should take a relatively short time if they have already proved to be proficient in the application of the five moments.

1.2.3 Validation of observers

Once knowledgeable in the use of the observation form and process, observers must be validated either by parallel observation jointly with a confirmed observer, or by being tested through the use of the WHO Training Film included in the WHO Implementation Toolkit (available at http://www.who.int/gpsc/en/). In the first case, two observers engage in an observation session during a real-life care situation and each completes an observation form separately while observing the same HCW and the same care sequence. Results are then compared and discordant notifications discussed. This process is repeated until concordance is reached in the number and nature of each occurring hand hygiene opportunity. It is recommended that the person in charge of validation remains the same for all new potential observers in a given setting. It is advisable to perform validation in each care setting that is to be monitored by the future observer. The WHO Training Film provides visual examples of the five moments for HCWs and observers. Observers can be trained and tested through the use of the scenarios, which include different sequences of health care where hand hygiene is necessary. Observers are asked to complete the form while watching the film, and the trainer can then judge their performance by comparing the results with the those provided in a slide show presentation that accompanies the film. The subsequent discussion is usually very valuable for learning purposes. If a time grid of opportunities can be established in a scenario, kappa statistics can be calculated to quantify the level of coincidence between two observers.

1.2.4 Understanding the five moments for hand hygiene

The concept of "My five moments for hand hygiene" has been created as a robust framework for understanding, training, measuring, and communicating hand hygiene performance.[1] Understanding this concept (see Part I, Section 21.4) is a prerequisite for any future observer. It is a simple concept that should not leave any knowledge gap between the insight of observers and observed HCWs once they are adequately trained in hand hygiene. It is essential, however, that local specificity related to the application of the "five moments" is established and known by everyone. For example, the delimitation of the patient zone in a given setting needs to be specifically determined.

Health-care activity must be imagined as a succession of tasks during which the HCWs' hands touch different types of surfaces prior to and after patient contact. Each contact is a potential source of contamination for HCW's' hands.

A crucial point specific to observations is the distinction between indications and opportunities, which is more extensively described in the Hand Hygiene Reference Technical Manual. The *indication* is the reason why hand hygiene is necessary at a given moment to effectively interrupt microbial transmission during care, and it corresponds to precise moments in patient care. Very close to the concept of indication, the term *opportunity* is much more relevant to the observer: it determines the need to perform the hand hygiene action, whether the reason (the indication that leads to the action) be single or multiple. From the observer point of view, the opportunity exists whenever one of the indications for hand hygiene occurs and is observed. Several indications may arise simultaneously and create a single opportunity. Very importantly, the opportunity constitutes the denominator for calculating compliance, i.e. the proportion of times that HCWs perform hand hygiene action of all observed moments when this was required.

For this purpose, hand hygiene action is defined as either rubbing hands with an alcohol-based handrub accepted by the institution or handwashing with soap and water. Neither the duration nor other quality aspects of hand hygiene such as the quantity of product used, glove use, length of fingernails, or the presence of jewellery are assessed.

It is important to understand that hand hygiene actions not corresponding to an opportunity, and therefore "additional" and not required, should not be taken into account by the observer.

1.2.5 Understanding the observation form

Observations are noted on a paper form using a pencil and rubber. Each form represents a separate observation session. Experience shows that this material is ergonomic for observations. The surface of a sheet of paper provides the necessary overview of the past evolution of observed activity in several, simultaneously observed HCWs. Using a pencil and an eraser, errors can easily be corrected.

The form has three main sections: 1) a header contains information on the institutional level (country, city, hospital, site identity); 2) a second header contains information on the session (observer identity, date, start and end time, duration, period number, session number, form number, department, service name, ward name); and 3) four columns below the header represent the sequence of actions for different HCWs observed during the same session. Each column is usually dedicated to one HCW and therefore the form can include up to four HCWs. Alternatively, in situations with low activity, each column can be dedicated to a different professional category and therefore the HCWs belonging to the same professional category can be grouped within one column. This method can be practical when the observer chooses to observe more than four HCWs during the same session. This results, however, in a loss of the possibility to calculate a per person density of hand hygiene opportunities and individual feedback after the session. The header of each column contains information about the observed HCW (professional category, code, number). The rest of the column consists of equal blocks that are incrementally numbered from 1 to 8 from top to bottom. Each block represents one of the sequentially occurring opportunities for hand hygiene. For each opportunity, the observer notes in the corresponding block all the applicable indications and if hand hygiene was executed by handrubbing, handwashing or missed.

1.2.6 Determining the scope of an observation period

Before starting an observation period, the investigators and project coordinators must determine the scope of observations. Possible scopes are listed in Table III.1.3. If the scope is to build a comparison between two or more observation periods to assess the evolution of hand hygiene compliance over time, special attention should be paid to control for the potential confounding factors. This can be achieved by predefining a target number of opportunities by profession, wards, and time of day. To minimise inter-observer variability, the observer or the team of observers should remain the same across the different periods of the project. The best unit for calculation is the denominator, i.e. opportunities for hand hygiene, because this will directly influence the results.

1.2.6.1 Selection of location and time

A representative mix of wards and time of day should be sought. Naturally, observers tend to undertake their activity at times and in locations with a high density of care to gather a higher number of opportunities more quickly. Observers have to be aware that changing the method of selecting time and location for observations between observation periods can lead to bias because there is usually an association between density of opportunities and compliance. Therefore, we suggest to establish a rough location plan and timetable ahead of planned observations that will be remain stable over observation periods.

1.2.6.2 Selection of HCWs

Once location and time are determined, observers have to choose the HCWs to be observed during a session. Selection bias should be minimized by choosing at random. In the case of repeated observation periods in particular, observers may know the intrinsic performance of individual HCWs and this could easily influence the overall observation result by always selecting HCWs with extreme behaviour.

1.2.6.3 Starting, continuing, and concluding an observation session

Once a health-care situation is identified, the observer may introduce himself/herself by indicating unobtrusively the scope of his/her presence. The way in which this introduction is handled depends on local social and medical culture. A balance should be sought between increased observation bias through a too overt presence and inducing the feeling of being cheated in the observed by pretending to be there for another scope. This includes also a discreet positioning of the observer.

After completing the form header, each observed opportunity is noted on the form (see above). Only opportunities for which the entire time between the two delimiting hand-to-surface exposures can be observed are noted.

During the observation session, the observer must not interfere with observed staff. The session should be concluded after 20 minutes ± 10 minutes according the duration of care activity. The observer may want to give feedback to the observed HCW(s) about the observed hand hygiene performance. This depends on the scope of the observation, but it was found to be very efficient and appreciated by HCWs.

1.2.7 Analysis

Following data entry (Epi Info databases for entering data collected according to the WHO-recommended method for direct observation are available), the simplest form of results is the overall compliance. This is calculated by dividing the number of observed hand hygiene actions performed when an opportunity occurs, by the total number of opportunities. It has been found useful to stratify compliance by institutional sector, professional category, and indication (moment) for hand hygiene using the ‘My five moments for hand hygiene’ as strata.[1]

1.2.8 Reporting of results

Feedback of results to those concerned is a very powerful promotional tool and should firstly address groups with a strong internal identity. A short delay between observation activity and reporting of results might increase the effect of feedback. Continual feedback of unchangingly bad results without any intervention should be avoided, as it may lead to “desensibilization” and demotivation.

Special attention should be given to the potentially low number of observed opportunities when using percentages to report compliance. Low numbers occur especially with stratified results. It is good practice to calculate 95% confidence intervals and include these in graphics. For instance, for 30 opportunities with a compliance of 50%, the confidence interval would stretch from 31% to 69% compliance. With 100 opportunities and 50% compliance, the confidence interval would shrink to 40–60%, and for 200 and 50% compliance opportunities to 43–57%. Finally, observations can be reported to HCWs directly after each session, which produces an immediate impact. For statistical methods to measure hand hygiene compliance over time see also Appendix 4.

1.3 Indirect monitoring of hand hygiene performance

In the quest for less expensive monitoring approaches, experts have used the consumption of hand hygiene products such as paper towels,[1038] alcohol-based handrub or liquid soap[60,334,429,486,489,713,803,852] to estimate the number of hand hygiene actions. To make these monitoring techniques more meaningful, the quantity of handrub was translated into a number of hand hygiene actions by using the average amount per action as a divider. The missing denominator of the need for hand hygiene actions was either ignored by only following the evolution over time, or substituted by a surrogate measure such as patient days or workload indicators drawn from a computerized database of nursing activities.[851]

Some studies[60,334,486] have shown that the consumption of products used for hand hygiene correlated with observed hand hygiene compliance, whereas others have not.[1039] Thus, the use of this measure as a surrogate for monitoring hand hygiene practices deserves further validation. Other studies found that feedback based on measured soap and paper towel consumption did not have an impact on hand hygiene.[802,1038]

Methods based on product consumption cannot determine if hand hygiene actions are performed at the right moment during care or if the technique is correct. The advantages, however, are that they are simple, can be continuous, and provide a global picture that remains unaffected by selection or observer bias and, most likely, observation bias. The amount of alcohol-based handrub used by health-care settings has been selected as one of the indicators. Nevertheless, it has to be considered that this measure may not exactly reflect the product consumption by HCWs, but could include the amount used by visitors or patients, especially if the dispensers are located also in public areas of the health-care setting and they are wall-mounted.

1.4 Automated monitoring of hand hygiene

The use of sinks and handrub dispensers can be monitored electronically.[699,710,852,986] Systems that are even able to identify HCWs when using a sink or a handrub dispenser are under development. These methods allow precise quantitative results on hand hygiene activity to be obtained, with the only costs being the installation and maintenance of the system. Changes over time can be assessed. Some studies have attempted to measure the need for hand hygiene by monitoring patient room entries and linking each entry to the use of a sink or a handrub dispenser. For the moment, no comparative studies exist to validate the appropriateness of electronic detection of hand hygiene opportunities.

Wireless devices placed inside handrub or soap dispensers can provide useful information regarding patterns of hand hygiene frequency. A recent study evaluated wireless devices that were placed inside handrub dispensers on a general medical ward and in a surgical intensive care unit.[1040] During a 3-month trial period, 17 304 hand hygiene episodes using handrub were recorded on the medical ward for a rate of 9.4 hand hygiene episodes/patient-day. A total of 50 874 hand hygiene episodes using handrub were recorded in the ICU for a rate of 47.7 hand hygiene episodes/patient-day. Average usage was highest between 10:00 and 19:00; the lowest was at 05:00. By mapping the location of each device, it was observed that dispensers located in rooms with patients on contact precautions were used significantly less often than those located in other rooms on the ward (*P* = 0.006).

Table III.1.1
Advantages and disadvantages of various hand hygiene monitoring approaches

Monitoring approach	Advantages	Disadvantages
Direct observations by expert observers	• Only way to reliably capture all hand hygiene opportunities • Details can be observed • Unforeseen qualitative issues can be detected while observing hand hygiene	• Time-consuming • Skilled and validated observers required • Prone to observation, observer, and selection bias
Self-report by health-care workers	• Inexpensive	• Overestimates true compliance • Not reliable
Direct observations by patients	• Inexpensive	• Potential negative impact on patient–HCW relationship • Reliability and validity required and remains to be demonstrated
Consumption of hygiene products such as towels, soap, and alcohol-based handrub	• Inexpensive • Reflects overall hand hygiene activity (no selection bias) • Validity may be improved by surrogate denominators for the need for hand hygiene (patient-days, workload measures, etc.)	• Does not reliably measure the need for hand hygiene (denominator) • No information about the appropriate timing of hand hygiene actions • Prolonged stocking of products at ward level complicates and might jeopardize the validity • Validity threatened by increased patient and visitor usage • No possibility to discriminate between individuals or professional groups
Automated monitoring systems	• Absence of observer may reduce observation bias • May potentially produce valuable detailed information about hand hygiene behaviour and infectious risks	• Scarce real world experience so far • Potential ethical issues with tracking of individual activity • Unknown impact on staff and patient behaviour • Systems may be costly and failure-prone

Table III.1.2
Potential bias in hand hygiene observation

Bias	Description
Observation bias	Presence of an observer induces better than usual hand hygiene behaviour
Observer bias	Observers systematically interpret the observation method and definitions for hand hygiene opportunities and actions in their own way; consequently, their results are different from those of other observers
Selection bias	Observers systematically select certain times, care situations, health-care sectors, HCWs or opportunities for their observations; consequently, their results do not reflect the overall hand hygiene compliance

Table III.1.3
Potential scope of hand hygiene observations

• Compare the evolution of compliance over time in the same institution or sector
• Compare different sectors
• Perform a baseline measurement of compliance in an institution
• Perform formal observations with immediate feedback to the observed HCW for training purposes
• Establish the impact of system changes and multimodal interventions on compliance (before/after study)
• Compare the quality of care in different hospitals
• Evaluate hand hygiene practices in the framework of an outbreak investigation

2.

Hand hygiene as a quality indicator for patient safety

Patient safety has become the touchstone of contemporary medical care. Medical errors and adverse events occur with distressing frequency, as outlined persuasively in the USA Institute of Medicine's *To err is human.*[1041] HCAIs are second only to medication errors as a cause of adverse events in hospitalized patients. Hospital infection control provides a mature template for patient safety with a long track record of research, evidence-based practice standards, and practice improvement efforts. Moreover, infection control professionals and hospital epidemiologists have pioneered real-time methods to detect the occurrence of HCAI and monitor compliance with infection control standards. Nonetheless, as documented in these WHO guidelines, compliance with hand hygiene – the pillar of infection control – remains woeful in the vast majority of health-care institutions. The current emphasis on hand hygiene by the WHO World Alliance for Patient Safety and many regulatory and accrediting agencies reflects the slow progress of the health professions in meeting even modest performance standards.

Donabedian's quality paradigm of structure, process and outcome[1042,1043] provides a useful framework for considering efforts to improve hand hygiene compliance. Clearly, if sinks and alcohol dispensers are not readily accessible (faulty structure) and hand hygiene is not performed (inadequate process), the risk of infection and its attendant morbidity, mortality, and cost (outcomes) will increase. Quality indicators can be developed according to Donabedian's framework.

Hazard analysis critical control point (HACCP) is another valuable method to examine the system of patient care as it relates to hand hygiene. Originally developed to provide astronauts with pathogen-free food, HACCP is now widely employed in good manufacturing practice, food and drug safety, and blood banking. In brief, the method identifies error-prone aspects of systems (critical control points), evaluates the risk they pose, and designs them out. Critical control points are scored according to their probability of occurrence, probability of avoiding detection, and severity of downstream impact. Failure mode and effects analysis is closely related to HACCP and is being exploited increasingly in patient safety. A desirable feature of both HACCP and failure mode and effects analysis is their emphasis on system errors and their consequences. An empty alcohol dispenser, failure to educate staff in proper hand hygiene technique, and failure to practise hand hygiene after glove removal are serious failures at key points in the patient-care system. When multidisciplinary care teams map their institution's system for hand hygiene, they not only identify error-prone critical control points and barriers to compliance, but also identify which aspects of the system are most critical to improve and monitor. This collaborative approach to identifying key quality indicators vastly improves these indicators' local credibility and relevance and provides a guide to ongoing improvement and auditing efforts.

Failures at critical control points in the hand hygiene system can be seen as problems in the reliability of the system. The concept of reliability is the bedrock of modern manufacturing (e.g., it transformed the quality of automobile production), but has been applied to health care only recently. Reliability looks at the defect or failure rate in key aspects of production (i.e. patient care). Industry often seeks to achieve defect rates of one per million or less (a component of so-called six-sigma reliability). While such a high degree of reliability seems impossible in many aspects of health care, it is worth noting that most institutions have hand hygiene defect rates of six per ten opportunities or greater. Moreover, these rates do not even reflect current thinking about rigorous reliability, in which the entire system either performs correctly or does not. For example, defect-free care of a central venous catheter would require selection of the optimal insertion site, perfect hand hygiene, maximal barrier precautions, correct skin preparation, and prompt removal of the catheter as soon as it is no longer needed. Failure at any one of these steps means "no credit". Clearly, current defect rates in the hand hygiene system are no longer tolerable. Even in a setting with severely constrained resources, basic hand hygiene can and should be performed very reliably with a defect rate of less than 5–10%.

Although health-care providers – particularly managers in relatively complex organizations – will find it valuable to understand and apply Donabedian's quality paradigm, HACCP, failure mode and effects analysis, and reliability theory, it should be relatively easy for health-care providers in virtually every setting to start evaluating, improving, and monitoring the reliability of the hand hygiene infrastructure and practice immediately. Table III.2.1 provides a variety of structure and process quality indicators that are derived directly from these WHO guidelines. Health-care providers and multidisciplinary teams (in collaboration with quality improvement and infection control experts where available) may want to begin by considering some of these indicators. The emphasis is on structure and process because the ultimate outcomes – reduced infection and antibiotic resistance rates – are likely to be linked closely with improvements in structure and process, are more time-consuming to measure, and may not be immediately discernible. Many indicators in Table III.2.1 are relatively easy to measure and provide real-time feedback to caregivers and managers.

For example, at the most basic level, are user-friendly, clear policies in place, and are these accessible to HCWs in the workplace? Is the design of the work space, including the placement of sinks, alcohol-based handrub dispensers, and other hand hygiene equipment and supplies, conducive to compliance? Are the alcohol-based handrub dispensers conveniently placed near every bed space (or are they hiding behind the ventilator)? Are the sinks fully operational, and are soap and clean towels always available? Are alcohol-based handrub dispensers full and operational? Are appropriate education programmes available to all HCWs, including trainees and rotating personnel, and is continuing education provided on a regular basis? What is the actual attendance at these programmes and are they mandatory? Can HCWs answer basic questions about hand hygiene (either by survey or web-based learning modules), such as the indications and rationale for hand hygiene and the efficacy and relative merits of various hand hygiene products and procedures? It is particularly important to verify the competency of all HCWs in performing hand hygiene procedures – a critical certification step that is applied all too rarely, especially to doctors. Can HCWs actually demonstrate proper technique when washing hands or using alcohol-based handrubs? Are hand lotions always available to HCWs and conveniently placed?

These types of questions are asked in technical tools included in the WHO Multimodal Hand Hygiene Improvement Strategy and conceived for evaluation such as the WHO Facility Situation Analysis and the WHO Questionnaire on Ward Structure for Hand Hygiene (Implemenmtation Toolkit, available at http://www.who.int/gpsc/en/).

Quick, simple real-time checks of the health-care environment can be extremely useful for monitoring barriers to compliance, e.g. checks to see if alcohol-based handrub dispensers are full and operational.

Random audits of actual practice are indispensable (see Part III, Section 1.1). While hand hygiene practice can be considered a process of care, when it is not performed appropriately it can also be viewed as an important intermediate step in the chain leading to the colonization and infection of patients. Moreover, audit and feedback of compliance data is a major component of any multifaceted behaviour change programme. Simple graphics of compliance rates (or, alternatively, defect rates) should be prominently displayed where they can be seen during routine work. Data should be incorporated into HCW's education and fed back in real time.

Efforts to improve hand hygiene performance will be more successful if they take advantage of basic behavioural science principles. Sustained improvement requires *knowledge* – do providers understand the indications and rationale for hand hygiene? Are HCWs *enabled* to do the right thing by ensuring that sinks or alcohol-based handrubs are available at the point of care, and has this been verified by observing HCWs' work habits? Are staffing ratios adequate, or are HCWs so harassed that they cannot perform even the most basic procedures reliably? Are they *motivated*, and do they have a strong sense of *self-efficacy*? How do they view the unit or department's *social norms* regarding hand hygiene? Can they identify an opinion leader in their unit or department who takes the lead in education and the promotion of hand hygiene? If HCWs are educated, competent, have convenient access to hand hygiene facilities and supplies, and have sufficient staffing, are they held *accountable* for defects in their performance?

The ultimate customer, of course, is the patient. Patients and their families can be given a "tip sheet" to help them understand their role as partners in patient safety. They should be encouraged to point out lapses in hand hygiene technique without fear of retribution. Surveys can help HCWs determine if patient perceptions match their own view of their performance (see Part V, Section 6).

In conclusion, hand hygiene is an important indicator of safety and quality of care delivered in any health-care setting, because there is substantial evidence to demonstrate the correlation between good hand hygiene practices and low HCAI rates (see Part I, Section 22). It is embedded in the HCAI planks of the 5 Million *Lives* Campaign (http://www.ihi.org/IHI/Programs/Campaign/) and is emphasized in the WHO Collaborating Centre on Patient Safety Solutions as one of the highest priority solutions to improve patient safety (www.who.int/patientsafety/solutions/patientsafety/en/).

Table III.2.1

Examples of quality indicators which may be used in relation to hand hygiene in health-care settings (not including pre-surgical hand preparation)

Indicators*	Measure option**	Measure option**	Suggested frequency**
Structure			
Hand hygiene policies located near the point of care			
Hand hygiene education and training program, including behaviour change strategies, at least annually			
Functioning sinks with clean, running water available in clinical rooms/wards/treatment areas for hand washing	One per ward	Sink to bed ratio	Annual or more frequent depending on results and action
Sinks equipped with liquid soap in clinical areas	100% to zero		Monthly/weekly/daily
Sinks equipped with bar soap/soap flakes in clinical areas[1]	100% to zero		Monthly/weekly/daily
Bar soap/flakes on a dish that drains excess liquid			
Sinks equipped with single use/disposable towels in clinical areas[2]	100% through none		Monthly/weekly/daily
Liquid soap dispensers in working order	100% through none		Monthly/weekly/daily
Beds with alcohol-based handrub dispensers within arm's reach, e.g. affixed to bed	100% through none		
Alcohol-based handrub pocket bottles carried by staff	all staff through 75%, 50%, 25%, zero		Monthly/weekly/daily
Alcohol-based handrub bottle affixed to trolleys for use in clinical areas	100% through zero	Bottle to trolley ratio	Monthly/weekly/daily
Alcohol-based handrub bottle affixed to wall in rooms/cubicles/treatment rooms	100% through zero	Bottle to room ratio	Monthly/weekly/daily
Alcohol-based handrub dispensers in working order	100% through zero		Monthly/weekly/daily
Supply of alcohol-based handrub pocket bottles available in clinical areas			
Hand care lotion bottles in rooms/cubicles/treatment rooms	100% through zero	Bottle to room ratio	Monthly/weekly/daily
Posters (5 Moments) in rooms/cubicles/treatment rooms	100% through zero	Poster to room ratio	Monthly/weekly/daily
Posters How to rub/rinse in rooms/cubicles/treatment rooms	100% through zero	in rooms/cubicles/treatment rooms	Monthly/weekly/daily
Glove boxes in patient rooms/cubicles/treatment rooms	100% through zero	Bottle to room ratio	Monthly/weekly/daily
Clean gloves in a range of sizes available for use at the point of care/each bed space	100% through zero	Glove stock to bed ratio	Monthly/weekly/daily
Hand hygiene monitoring and feedback (at least monthly) showing adherence data of staff and leadership, including prominent display of clear graphs presenting trends over time			

Table III.2.1

Examples of quality indicators which may be used in relation to hand hygiene in health-care settings (not including pre-surgical hand preparation) (Cont.)

Indicators*	Measure option**	Measure option**	Suggested frequency**
Process			
Correct answers by staff to a complete, standard list of knowledge questions on hand hygiene	100% through zero	random choice of x staff, overall and individual %s of knowledge	Bi-annually
Staff fully in compliance with institutional hand hygiene policy			
Healthcare workers do not wear artificial finger nails or extenders	100% through zero	random choice of x staff, % of staff wearing or not wearing	Quarterly/weekly
Healthcare workers perform all three key hand hygiene procedures (hand washing, handrub, glove removal) correctly			
Healthcare worker hand hygiene compliance with Five Moments	100% through zero	% by ward/department	Depends on score, aim annual or more frequently
Healthcare worker performance in relation to correct technique for hand hygiene	100% through zero	% by ward/department	Depends on score
Volume of product usage (soap and alcohol-based handrub)		Mls per bed day	Need to set benchmarks. Measure monthly
Soap and alcohol-based handrubs are not used concomitantly		random choice of x staff, % times used or not used concomitantly	Quarterly/weekly
Where alcohol-based handrubs are available antimicrobial soap is not in use	100% through zero	% by ward/department	Quarterly/weekly
Multimodal strategy implemented			Annual
Outcome			
Infection rates monitored			Monthly/quarterly, if surveillance in place
Transmission rates for epidemiological pathogens (including antibiotic resistant pathogens) monitored	As above		Monthly/quarterly if surveillance in place
Product tolerance and acceptability analysis			Annual
Product cost comparations/benefit analysis			Annual

* Those in bold indicate the first criterion that should be considered

** The suggested measure options are not based on evidence, but on expert consensus and local experiences

[1] Where liquid soap not available

[2] Where disposable towels not available measure availability of freshly laundered dry cloth towels

3.

Assessing the economic impact of hand hygiene promotion

3.1 Need for economic evaluation

Several choices are usually available to endeavour to deal with health problems. These choices are often referred to as interventions. Identification of interventions is usually based on whether they lead to the desired outcomes or not i.e. does the chosen intervention reduce death or disability, or improve the quality of life to the desired extent? This simplistic approach is often adequate as the first step. However, when more than one intervention is available, which may be often the case, it is necessary to choose the one that provides a greater return on "investment". In particular, when resources are limited, a choice has to be made in favour of the one that provides the most output (reduction in disease, death or disability) at the lowest cost.

Economic evaluation refers to "the comparative analysis of alternative courses of action in terms of both costs and consequences. The basic task of any economic evaluation is to identify, measure, value, and compare the costs and consequences of the alternatives being considered".[1044] Thus, two features always characterize any economic analysis. The first deals with obtaining information on inputs and outputs (often called costs and consequences) of the interventions. The linkage between costs and consequences usually facilitates the reaching of a rational decision. The second feature concerns available choices. An inherent assumption underlying this characteristic is that resources are scarce and only the most efficacious ones should be deployed. A full economic evaluation thus means measuring the costs and consequences of two or more interventions or between an intervention and the status quo at the least.

In addition to hand hygiene, several infection control interventions are available. According to Graves and colleagues,[1045] "those who set budgets for infection control in hospitals and decide how those budgets should be allocated between infection control programmes must address two questions. First, should current rates of HCAI be reduced, and if so, by how much? Second, which infection control strategies are cost effective and/or productively efficient?" Answers to these questions can be found by studying how economic costs and health benefits change with different infection control strategies.[1046] The framework below provides basic information on how two of the more common types of economic evaluation are carried out to select health interventions (Figure III.3.1).

3.2 Cost–benefit and cost–effectiveness analyses

Figure III.3.1 illustrates two competing interventions, A and B. Intervention A is the intervention of interest, e.g. hand hygiene using alcohol-based handrub, and intervention B is the comparator, e.g. hand hygiene using soap and water. Intervention B does not necessarily have to be an "active programme"; a second option of maintaining the status quo could even be considered, i.e. doing nothing. The consequences of both interventions would be reduction of HCAIs. While the identification of various types of cost are similar across most economic evaluations, the overall process of economic evaluation can be of two types: cost–benefit analysis or cost–effectiveness analysis.

3.2.1 Cost–benefit analyses

Cost-benefit analyses (CBA) measure both the costs and the consequences of alternatives.[1044] The results of these analyses may be presented in the form of a ratio of monetary costs to monetary benefits or as a simple sum. A typical example of a CBA would be to compare the costs and benefits of performing hand hygiene using soap with that of an alcohol-based handrub. While there is extensive evidence on the added advantages of alcohol-based handrubbing as part of a multimodal promotion strategy in reducing the transmission and disease rates, few studies have compared costs of alternative interventions using a CBA approach. Haddix and colleagues[1047] state that "CBA is often the most appropriate approach when a policy-maker has a broad perspective and is faced with one or more of the following situations: (1) must decide whether to implement a specific programme; (2) required to choose among competing options; (3) has a set budget and must choose and set priorities from a group of potential projects; or (4) the interventions under consideration could produce a number of widely differing outcomes."

3.2.2 Cost–effectiveness analyses

Analyses in which costs are related to a single common effect or consequence which may differ in magnitude between alternative programmes are referred to as cost–effectiveness analyses (CEA). Compared with CBA, in a typical CEA the consequence or summary measure is expressed in costs per unit of health outcome, e.g. costs per quality-adjusted life year (QALY) saved, per life saved or per life year gained.[1047] A typical example may be extension of life after renal failure. Two interventions that could be compared may be renal dialysis and kidney transplantation. The outcome of interest for both these interventions is common, i.e. life years gained. Normally, we would compute the differential costs and consequences and then lean towards the intervention with the least cost. This measure is called an incremental cost–effectiveness ratio (ICER). If kidney transplantation costs US$ 50 000 and extends life by 10 years, this would generate an ICER of US$ 5000 for each life year gained. Similarly, we could compute the costs of dialysis and compare the ICERs of the two interventions in order to make a decision.

Cost utility analysis is one form of CEA that uses QALYs instead of merely looking at costs per life year gained. The QALY concept attempts to place values (derived from population-based exercises) on different states of health. QALYs allow for the comparison of different health outcomes as health positions or "utility" value placed by society. To do this, any state of health or disability is assigned a utility value on a scale ranging from 0 (immediate death) to 1 (state of perfect health). QALYs thus measure health positions and are a linear measure. There are perhaps some issues with their use, as they discount health gains among the elderly more severely and treat each movement as of equal value. Such movements are probably non-linear, however, with people valuing slight improvements when they are ill more than they value similar improvement increments from gains in fitness at the top end of their recovery.

The ability to compare directly the dollar cost of different health outcomes is sometimes attractive to the decision-maker. For the policy-maker, the health intervention that produces the greatest QALYs at the least cost is often seen to be more attractive.

Cost utility is a difficult but interesting area to explore. This is because most health infections are transient states and assigning health utility states over a long term may be less meaningful. Using QALYs, which are rather static instruments, may be less applicable to infection-related illnesses, as these may come and go, thereby making assessments difficult. The DALY (disability-adjusted life year) is another outcome measure used in CEA that combines life years gained in full health and life years gained in less than perfect health (seen as a disability) in one combined measure. The DALY has been used when examining health deficiencies or the burden of disease in the international literature – particularly that relating to less developed countries. Thus one might estimate the DALYs lost related to various illnesses, e.g. eye disease, or infections, e.g. pneumonia.

3.2.3 Analyses perspective

Regardless of whether a CBA or CEA is performed, the analyses perspective is a crucial element in decision-making. Perspectives available for either analysis include societal, payer, hospital or individual. Costs and consequences within the analyses will differ based on the perspective chosen; the results will thus also vary based on the perspective chosen. Most studies to date have focused mainly on the hospital or institution and have not captured costs and consequences from a broader perspective.[1048] A societal perspective is more useful for policy-makers and governments who need to allocate budgets and choose between different health programmes or interventions.

3.3 Review of the economic literature

Despite the availability of established methods of economic evaluation, few prospective studies have been conducted to establish the cost–benefit or cost–effectiveness of hand hygiene in health-care settings. The Agency for Health Care Research and Quality in their recent review of quality improvement prevention strategies for HCAI concluded that "the evidence for quality improvement strategies to improve adherence to preventive interventions for HCAI is generally of suboptimal quality, consisting primarily of single-centre, simple before–after studies of limited internal and external validity. Thus, we were unable to reach any firm conclusions regarding actionable quality improvement strategies to prevent HCAIs".[1049]

In general, studies have compared the costs of hand hygiene promotion programmes versus the potential cost savings from preventing HCAIs using a business case analytic approach. Unlike a CBA or CEA, a business case analysis usually provides an explanation of a provider's expenditures for a programme over a short period (often1–3 years), including the effects of any offsetting savings.[1050] Ritchie and colleagues reviewed all economic studies relating to the overall impact of alcohol-based hand hygiene products in health care[1025] and concluded that, while further research is required to measure the direct impact of improved hand hygiene on infection rates, the potential benefit of providing alcohol-based handrubs is likely to outweigh costs, and their wide-scale promotion should continue. The review also recommended that those planning local improvements should note that multimodal interventions are more likely to be effective and sustainable than single-component interventions and, although these are more resource-intensive, they have a greater potential to save costs over the long term.

Examples of typical costs incurred and cost savings associated with implementing hand hygiene programmes in institutions are provided below. Furthermore, evidence is provided on the costs and cost savings from a hospital/institutional perspective through the use of a business case approach. While some studies presented here have shown cost savings, it should be noted that business cases usually fail to deliver projected cost savings in the short or near term.[1051] This is mainly because hospitals are known to have high fixed costs (up to 85%).[1052] This leaves the administration with limited scope to demonstrate savings from a small percentage of remaining variable costs.

3.4 Capturing the costs of hand hygiene at institutional level

The costs of hand hygiene promotion programmes include costs of hand hygiene installations and products, plus costs associated with HCW time and the educational and promotional materials required by the programme. These can be categorized into fixed and variable costs. Examples of fixed costs include those associated with buildings, equipment and new installations, salaried staff, and overhead costs such as heating, air conditioning, and water. Examples of variable costs include products needed for handwashing, including soap, water, and materials used for drying hands (e.g. towels), while the costs of hand antisepsis using an alcohol-based handrub include the cost of the handrub product plus dispensers and pocket-sized bottles, if made available. In general, non-antimicrobial soaps are often less expensive than antimicrobial soaps. In health-care settings, mainly in resource-poor countries, basic handwashing equipment such as sinks and running water is often not available or of limited quality. In calculating costs for hand hygiene, these substantial construction costs need also to be taken into account. In addition, overhead costs for used water and maintenance need to be added to the calculation.

The cost per litre of commercially prepared alcohol-based handrubs varies considerably, depending on the formulation, the vendor, and the dispensing system. Products purchased in 1.0–1.2 litre bags for use in wall-mounted dispensers are the least expensive; pump bottles and small pocket-sized bottles are more expensive; and foam products that come in pressurized cans are the most expensive. Presumably, a locally-produced solution composed of only ethanol or isopropanol plus 1% or 2% glycerol would be less expensive than commercially produced formulations. Boyce estimated that a 450-bed community teaching hospital in the USA spent US$ 22 000 (US$ 0.72 per patient-day) on 2% chlorhexidine-containing preparations, plain soap, and an alcohol-based hand rinse.[1053] When hand hygiene supplies for clinics and non-patient care areas were included, the total annual budget for soaps and hand antiseptic agents was US$ 30 000 (about US$ 1 per patient-day).

Annual hand hygiene product budgets at other institutions vary considerably because of differences in usage patterns and varying product prices. Countries/states/regions/localities with centralized purchasing can achieve economies on a scale that can result in considerable cost reduction of products. A recent cost comparison of surgical scrubbing with an antimicrobial soap versus brushless scrubbing with an alcohol-based handrub revealed that costs and time required for pre-operative scrubbing were less with the alcohol-based product.[328] In a trial conducted in two ICUs, Larson and colleagues[329] found that the cost of using an alcohol-based handrub was half that of using an antimicrobial soap for handwashing (US$ 0.025 vs US$ 0.05 per application, respectively). In another study conducted in two neonatal ICUs, investigators looked at the costs of a traditional handwashing regimen using soap, use of an alcohol-based handrub supplemented by a non-antimicrobial soap, use of hand lotion, and nursing time required for hand hygiene.[646] Although product costs were higher when the alcohol-based handrub was used, the overall cost of hand hygiene was lower with the handrub because it required less nursing time.

3.5 Typical cost-savings from hand hygiene promotion programmes

To assess the cost savings of hand hygiene promotion programmes, it is necessary to consider the potential savings that can be achieved by reducing the incidence of HCAIs. One of the easiest ways to assess the cost savings is to estimate the excess hospital costs associated with the excess patient days caused by HCAIs. In a recent study by Stone and colleagues, costs of catheter-related bloodstream infection (CR-BSI), surgical site infection (SSI), ventilator-associated pneumonia (VAP), and hip SSIs were estimated and found to be a minimum of US$ 5500 per episode. The authors further reported that CR-BSI caused by MRSA may cost as much as US$ 38 000 per episode.[1054] Table III.3.1 provides a summary of the costs of the four most common HCAIs based on a systematic review of literature published by Stone and colleagues for periods 1990–2000 and 2001–2004.[15,1055]

In addition to the costs reported above, there are several hidden costs that are not included in the calculation of these figures. These costs could instead be referred to as lost "opportunities for saving". Stone and colleagues provide several examples. An unscheduled revisit to the operating room for incision and drainage after an SSI can limit the number of procedures that can be performed in a day. Hold-ups often cause delays and postponement of scheduled procedures. Another example of a hidden cost includes the dissatisfaction of the patient and the referring doctor. Research suggests that dissatisfied customers often have the tendency to tell more people about the deficiencies in their care. Hence, the loss of existing customers (patients) means higher replacement costs associated with attracting and receiving new patients. These include costs for marketing and registering new patients into the medical records system and the costs of countering any negative publicity and building renewed trust.

Thus, it is not surprising that the excess hospital costs associated with only four or five HCAIs of average severity may equal the entire annual budget for hand hygiene products used in inpatient care areas. Just one severe SSI, lower respiratory infection, or BSI may cost the hospital more than the entire annual budget for antiseptic agents used for hand hygiene.[1053] For example, in a study conducted in a Russian neonatal ICU, the authors estimated that the excess cost of one health care-associated BSI (US$ 1100) would cover 3265 patient-days of hand antiseptic use (US$ 0.34 per patient-day).[687] The authors estimated that the alcohol-based handrub would be cost saving if its use prevented approximately 3.5 BSIs per year or 8.5 pneumonias per year. In another study, it was estimated that cost savings achieved by reducing the incidence of *C. difficile*-associated disease and MRSA infections far exceeded the additional cost of using an alcohol-based handrub.[429]

Several studies provided some quantitative estimates of the cost savings from hand hygiene promotion programmes.[60,181] Webster and colleagues[181] reported a cost saving of approximately US$ 17 000 resulting from the reduced use of vancomycin following the observed decrease in MRSA incidence over a 7-month period. Similarly, MacDonald and colleagues reported that the use of an alcohol-based hand gel combined with education sessions and performance feedback to HCWs reduced the incidence of MRSA infections and expenditures for teicoplanin (used to treat such infections).[489] For every UK£ 1 spent on alcohol-based gel, UK£ 9–20 were saved on teicoplanin expenditure.

Including both direct costs associated with the intervention (increased use of handrub solution, poster reproduction, and implementation) and indirect costs associated with HCW time, Pittet and colleagues[60] estimated the costs of the programme to be less than US$ 57 000 per year for a 2600-bed hospital, an average of US$ 1.42 per patient admitted. Supplementary costs associated with the increased use of alcohol-based handrub solution averaged US$ 6.07 per 100 patient-days. Based on conservative estimates of US$ 100 saved per infection averted, and assuming that only 25% of the observed reduction in the infection rate has been associated with improved hand hygiene practice, the programme was largely cost effective. A subsequent follow-up study performed in the same institution determined the direct costs of the alcohol-based handrub used, other direct costs, indirect costs for hand hygiene promotion, and the annual prevalence of HCAI for 1994–2001.[490] Total costs for the hand hygiene programme averaged Swiss francs (CHF) 131 988 between 1995 and 2001, or about CHF 3.29 per admission. The prevalence of HCAI decreased from 16.9 per 100 admissions in 1994 to 9.5 per 100 admissions in 2001. Total costs of HCAIs were estimated to be CHF 132.6 million for the entire study period.

The authors concluded that the hand hygiene programme was cost saving if less than 1% of the reduction in HCAIs observed was attributable to improved hand hygiene practices. An economic analysis of the "clean***your***hands" hand hygiene promotional campaign conducted in England and Wales concluded that the programme would be cost beneficial if HCAI rates were decreased by as little as 0.1%. The impact of the "clean***your***hands" campaign is the subject of a 4-year research programme which will look at the effectiveness of the various components of the multimodal approach.

A quasi-experimental study in Viet Nam to assess the impact of the introduction of an alcohol- and chlorhedixine-based hand santizer for hand antisepsis on SSI rates among neurosurgical patients revealed a reduction in the infection rate by 54% and a reduction in post-operative length of stay and antimicrobial use from 8 days to 6 days ($P<=0.001$).[717] Although no costs were provided in this study, it is reasonable to assume that the reduction in hospital stay allowed the hospital to generate additional revenue by filling beds with new admissions (increased volume). Antibiotic costs were also reduced because of earlier discharge for these patients.

Despite the fact that the above-mentioned studies strongly suggest a clear benefit of hand hygiene promotion, budget constraints are a fact, particularly in developing countries, and cost–effectiveness analysis might be used to identify the most efficient strategies. To achieve this goal, data on the incidence of HCAI and the resulting opportunity costs, as well as on the cost and effectiveness of competing infection control strategies, are required.[1045] Because these variables may vary by and large according to the region and institution, local studies may be necessary to help choose the best strategies.[1045] Well-conducted local studies may suggest other infection control interventions of even greater cost benefit, depending on the socioeconomic and cultural environments of the health-care system. Although a business case approach may be beneficial to the hospital management in determining the cost of the infection control programmes, it is necessary to conduct economic evaluation from a broader perspective, i.e. societal, so as to reflect the values of all members of society and not just the preferences of select individuals who manage hospital services. This approach will allow policy-makers and payers to choose between infection control interventions that offer the greatest quality output per unit of cost. Clearly, hand hygiene would be an intervention of interest for many developing nations that are often faced with several competing priorities compounded with limited resources.

3.6 Financial strategies to support national programmes

Interventions designed to improve hand hygiene across a country may require significant financial and human resources, particularly multifaceted campaigns. Costs must be balanced in terms of anticipated reduction in HCAI. The economies of scale achieved by centralized design and production of supporting materials will logically result in less cost to the overall health economy. This approach was used in the "clean***your***hands" campaign conducted in England and Wales (described in the box below). Countries without centralized distribution networks might not achieve sufficient economies of scale to make such an approach feasible without additional massive investment from the commercial sector. Similar approaches have been used by some other countries and have met with success. For instance, according to the WHO recommendations, Hong Kong SAR has adopted a centralized system for the production and distribution of alcohol-based hand rub to all its hospitals. This strategy has not only resulted in economies of scale by lowering the cost of the product, i.e. alcohol-based hand rub (see Part I ,Section 12), it has also fostered a spirit of campaign and competition, achieved standardization across health entities, and provided a foundation for evaluation of its success in the future.

Taking into account the many financial constraints in resource-poor countries and the considerably high cost investment required (e.g. secure water supply and sinks), the investment in programmes using alcohol-based handrubs as the primary or sole means of hand hygiene seems to be an obvious solution. It should nevertheless be taken into account that investment in the infrastructure of health-care facilities, such as secure water supply and sinks, is necessary in the long run to improve the quality of health-care delivery as a whole. This investment can show benefits other than an improvement in hand hygiene practices.

Case-study:
England and Wales national programme, a programme with potential benefits

National programmes can achieve economies of scale in terms of the production and distribution of materials. In England and Wales, the NPSA "cleanyourhands" campaign is a collaboration between national government bodies and the commercial sector in the development, piloting, evaluation, and implementation of the programme. The national procurement body for the National Health Service (NHS) and the national NHS Logistics Authority, which has expertise in distributing products across the NHS, have worked in partnership with the NPSA to ensure the campaign achieves its objectives. The Logistics Authority is responsible for the distribution of the alcohol-based handrubs and the campaign materials to every hospital implementing the campaign.

The NPSA campaign is funded centrally for its first year; thereafter, all campaign materials will be produced and funded by commercial companies on the national alcohol-based handrub contract. The companies will fund this by paying a licence fee in proportion to their turnover on the contract.

At the outset, the six main sources of possible financial benefits to the wider health-care economy resulting from a successful campaign were identified as those relating to:
- reduced hospital costs;
- reduced primary care costs;
- reduced costs incurred by patients;
- reduced costs of informal carers;
- productivity gains in the wider economy;
- reduced costs associated with litigation and compensation.

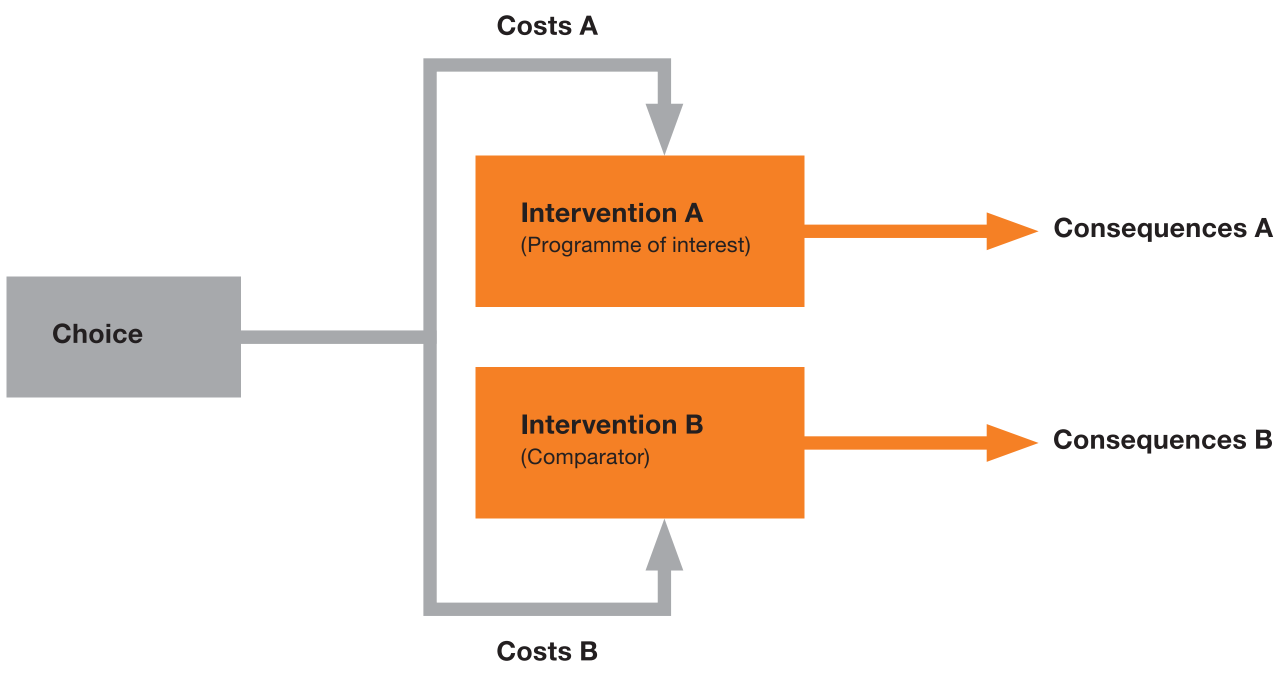
Though there are some up-front costs for hospitals associated with implementing the campaign, for a 500-bed hospital it would cost around UK£ 3000 initially to put alcohol-based handrub at each bedside. The analysis suggested that the campaign would deliver net savings from the outset. An Excel spreadsheet for self-completion by an individual health-care institution has been produced, which allows for the input of local data and will indicate likely cost savings over time (Appendix 4). Even if financial savings were not to be realized, the likely patient benefits in terms of lives saved and relatively modest costs mean that the intervention would still be highly cost effective compared with many other NHS activities. The economic evaluation went on to suggest that the campaign would be cost saving even if the reduction in hospital-acquired infection rates were as low as 0.1%.

Table III.3.1
Costs of the most common health care-associated infections in the USA

Type of infection	Attributable costs in US$		Range	
	Mean	Standard deviation	Minimum	Maximum
Bloodstream infection	36 441	37 078	1 822	107 156
Surgical site infection	25 546	39 875	1 783	134 602
Ventilator-associated pneumonia	9 969	2 920	7 904	12 034
Urinary tract infection	1 006	503	650	1 361

Reproduced from Cosgrove SE & Perencevich EN with permission from Lippincott Williams & Wilkins.[1056]

Figure III.3.1
Basic types of economic evaluation



PART IV.

TOWARDS A GENERAL MODEL OF CAMPAIGNING FOR BETTER HAND HYGIENE A NATIONAL APPROACH TO HAND HYGIENE IMPROVEMENT

1. Introduction

Guidelines do not implement themselves,[1057] and simple dissemination strategies have been described as unlikely to have any impact at all on implementation.[1058,1059] Health-care policy-makers and strategists have therefore looked towards nationally coordinated and centralized health improvement programmes as an acknowledged method of tackling significant health-related problems. National programmes do not necessarily employ campaign approaches; however, national health improvement programmes have been shown in many cases to use elements of campaigning and mass media involvement to good effect. This part reviews the increasing shift towards national hand hygiene improvement programmes, with or without campaigning, as a method of spreading hand hygiene improvement strategies in health care.[1060] It concludes with an account of current national hand hygiene improvement programmes, drawing on the progress made by them and lessons learnt from the countries that have embarked on such an approach. Based on the experiential learning and the current literature, a blueprint is presented for developing, implementing, and evaluating a national hand hygiene improvement campaign within health care.

2. Objectives

The present guidelines recommend a multifaceted system and behaviour change intervention as the most reliable method to improve hand hygiene in health care. To accompany the guidelines and aid implementation at a local level, a comprehensive Guide to Implementation and a suite of facilitative tools have been developed. This part is concerned with how to develop a successful improvement programme at a national level that will aid in implementation at a local level. It reviews the literature on national health improvement programmes and campaigns and explores the applicability of such an approach in relation to hand hygiene. Behaviour change interventions in the health-care context are increasingly utilizing the popular media within an integrated campaign framework and this has been shown to have numerous benefits, not least in terms of cost–effectiveness.[1061] The background, risks, and benefits of national approaches to hand hygiene improvement are described within the context of general public health or health improvement campaigning. This part further highlights the developments of national hand hygiene improvement campaigns in the time period since the launch of the WHO First GlobalPatientSafetyChallenge, and the publication of the 2006 Advanced Draft of the guidelines, and concludes by presenting a blueprint for national campaigns.

3.
Historical perspective

The First Global Patient Safety Challenge of the WHO World Alliance for Patient Safety (www.who.int/gpsc) entitled "Clean Care is Safer Care" has followed a classic approach to health improvement. It calls for a concerted global effort to effect policy and intervention strategies to enhance patient safety through implementation of a simple, low-cost health improvement (improved compliance with hand hygiene in health care) to contribute to the prevention of HCAI. Achievement of its aims has required action on a country-by-country basis, and has involved lobbying for national political action on hand hygiene improvement. This section positions hand hygiene improvement in health care as one component of an infection control/quality and safety health improvement programme. National health improvement programmes are historically associated with numerous benefits, including the avoidance of fragmentation, cost inefficiency, and duplication of effort.[1062]

Hand hygiene improvement in health care has not been seen conventionally as a public health issue, though it does concern a health issue of significance to a subset of the population, i.e. those receiving treatment in a health-care setting. With in excess of 700 million people hospitalized annually, and an overall prevalence of HCAI ranging from around 5% in the developed world up to 20% in some developing countries, the burden of associated disease is significant.[479,835] Thus, there is an argument for the application of public health strategies to change HCW behaviour to impact positively on the health of patients. Historically, public health behaviour change campaigns have focused on persuasion as a major tool.[1063]

Until recently, national hand hygiene improvement programmes in health-care settings were not widely reported. With the emergence of the WHO First Global Patient Safety Challenge and its three-pronged approach of gaining political commitment, raising awareness, and offering technical support to further the improvement agenda, national campaigning has come to prominence as one inspirational component of a comprehensive infection control strategy. Ministers of health signing a statement of commitment to address HCAI as part of this Patient Safety Challenge agree specifically to "developing or enhancing ongoing campaigns at national or sub-national levels to promote and improve hand hygiene among health-care providers".

The Millennium Development Goals (MDGs), agreed to by all countries worldwide and all leading development institutions, offer a blueprint for improvement. The goals have galvanized remarkable efforts to meet the needs of the world's poorest populations.[1064] The MDGs are time-bound, have political support, and are ambitious in their scope. These are common features of successful health improvement campaigns.

4.

Public campaigning, WHO, and the mass media

Public campaigning is central to a number of WHO programmes. In *The World Health Report 2002,*[1065] WHO reported on a series of comprehensive approaches that have been implemented at the national level to reduce specific risks in health care, taking into account a variety of interventions including the dissemination of information to the public, mainly through media outreach. The use of mass media within public health campaigns forms one component of broader health promotion programmes and can be useful in wide-scale behaviour change.[1061,1066,1067]

As many international and national health campaigns have demonstrated, the media play a key role in mobilizing public support, influencing behavioural change, and setting the local political agenda. A 2001 Cochrane review[1068] showed that the use of the mass media was a way of presenting information about important health issues, targeted by those who aim to influence the behaviour of health professionals and patients. The review concluded that the mass media should be considered as one of the tools that may influence the use of health-care interventions. Their usefulness in changing knowledge, awareness and attitudes makes mass media campaigning a potentially significant component of attempts to impact on hand hygiene behaviour change strategies, since hand hygiene compliance is predicated upon knowledge, attitudes, and beliefs of HCWs. Mass media campaigns are usually designed to generate a specific outcome in a relatively large number of individuals within a specific period of time and through an organized set of communication activities.[1066] With the growth in telecommunications, television and the Internet are increasingly used as channels for promoting behaviour change[1069] and could play a role in hand hygiene-related mass media campaigns, particularly if they target national and local opinion leaders.

4.1 National campaigns within health care

National health improvement programmes are designed to mobilize action at local levels to implement accepted methods to change behaviour and improve health care. Such programmes rely on carefully constructed improvement and spread methodologies, with the prominent model of the PDSA cycle[1070] incorporating quality improvement principles as a central component.

As one approach to health improvement, there is a considerable body of evidence to support the positive impact of campaigning on health-related behaviours,[1071,1072] although campaigns are not without their critics.[1066,1073] The Institute for Healthcare Improvement (IHI) in the USA turned to the campaign approach at a national, regional, and facility level to achieve a goal of transformational improvements in health care, using learning from electoral politics to reach a large number of health-care facilities across the country.[1074] In describing the subsequent IHI 100 000 Lives Campaign (Table IV.9.1), Berwick and colleagues[1075] outline a need to create a sense of urgency and pace. This campaign, one of the largest attempts to mobilize health care to focus on issues of quality and safety, holds much relevance when considering hand hygiene improvement in health care.

A feature of conventional campaigns, reflected in the IHI approach, is their association with a focused and time-bound effort.[1063] The IHI campaign was constructed around specific targets and deadlines; it also won support from national professional organizations, creating what they describe as a powerful national infrastructure to drive change and transform health-care quality. IHI identified the target (described as conceptually simple interventions) and the deadline and provided tools and resources for implementation. Berwick and colleagues[1075] emphasize, however, that the ultimate results rest with the participating hospitals to reliably introduce the interventions and engage boards, executives, frontline clinicians, patients, and families.

National-level campaigns to improve antibiotic use in Europe and the USA have been reported in the literature.[1076] Such campaigns have targeted the population level and employed techniques of mass media distribution. Similar to hand hygiene improvement campaigns in health care, antibiotic campaigns are multifaceted and are concerned with cost–effectiveness. According to Goossens and colleagues, only two countries in Europe have undertaken and evaluated national antibiotic-use campaigns and reported demonstrable success.[1076] The USA has seen a dramatic reduction in the use of antibiotics by paediatricians.[1077] In conclusion, these authors call for a wider use of the campaign approach and the incorporation of social marketing, together with cultural adaptation and population targeting.

Campaigns are likely to be more successful when they are accompanied by concomitant structural changes that provide the opportunity structure for the target audience to act on the recommended message.[1063] These authors also suggest that accompanying campaigns with reinforcing “legislation and regulation” can influence the campaign impact and sustainability. An illustration of the impact of legislation and regulation can be seen in England and Wales where the national *clean**your**hands* campaign (Table IV.9.1) received considerable leverage with a parallel national target to reduce MRSA rates by 50%.[1078]

5.

Benefits and barriers in national programmes

National political commitment to a health issue increases awareness and helps leverage additional resources.[1072] Translation of national political commitment into action yields benefits, and these can be quantified in terms of avoiding a fragmented and cost-inefficient duplication of effort.[1062,1079] The focus should be on producing practical tools that can be implemented across entire health-care systems. Pragmatic adaptations to these national programmes are described as necessary in order to achieve maximum local ownership, which is critical to ensuring successful implementation.

Dawson and colleagues[1080] describe the ongoing oral polio vaccine campaign in India as an example of a mass population-based intervention that illustrates both the benefits and problems of mass campaigning. The authors highlight the importance of establishing procedures for reviewing policy formulation and implementation and emphasize monitoring and evaluation, with explicit, clear lines of responsibility for all aspects of the programme. Evaluation is central to mass health-care improvement.[1027,1081] The necessary expertise and resources are essential in ensuring robust evaluation. Tilson Pietrow and colleagues[1082] describe a number of new challenges for international health programmes of the 21st century and conclude that health communication programmes will be under increasing scrutiny in terms of evaluation and documentation of their impact, cost–effectiveness, and sustainability. Data to facilitate impact assessment, while crucial to determine success, are not always available in many published studies[1083] and, where available, it is often difficult to prove a definite correlation between the campaign and the desired outcome.[1084]

The NHS for England and Wales, where a national patient safety alert[1031] was issued instructing organizations to implement alcohol-based handrub at the point of care, provides further evidence of the role of regulation. Its action was supported by built-in monitoring mechanisms via the national health watchdog (Health Care Commission), which examines whether, and to what extent, organizations have implemented both the campaign and the near-patient handrubs.

When deciding on the suitability of a national approach to improvement in relation to hand hygiene, politicians or leaders need to consider a number of factors that can influence success. Characteristics of national strategies will be influenced by the key drivers for improvement[868] which, in the context of infection control in the developed world, relate to the growing need to reassure patients and the public that care provided is clean and safe.

Improvement is a dynamic process, and success will be affected by internal as well as external factors.[1085] Improvement must be preceded by an analysis and understanding of existing patient safety and infection control structures, policies and programmes – and this is emphasized by the WHO World Alliance for Patient Safety toolkit for the implementation of hand hygiene strategies. Political commitment and national ownership of programmes are essential but, inevitably, those strategies that are dependent on social and political dynamics are subject to risk. The integration of all levels of a health improvement programme is crucial; national and hospital programmes should be harmonized. At the hospital level, chief executive officers (CEOs) should be made aware of any recommendations/requirements for hand hygiene promotion campaigns that are issued by organizations that accredit or license health-care facilities. Accreditation can be a powerful driver for health improvement and is cited as a powerful driver for improvement across many WHO regions (see, for example, AFRO Workshop Report 2007 and SEARO Workshop Report 2007, available at http://www.who.int/patientsafety/gpsc/en). The benefits and barriers associated with national improvements will be influenced by how health care is regulated and operated nationally, regionally, and locally.[1085]

Wachter and colleagues[1027] in their critique of the IHI "100 000 Lives Campaign" describe the modus operandi of the campaign as being one of leveraging "unprecedented" social pressure for participation, pressure that was constructed upon a set of realistic goals for improvement. Risks to success associated with national-level health improvements are further explored within the context of the campaign, with the need for regular communication, clear role definitions, and a clear national agenda emerging as critical factors for success.[1074]

If a decision is taken to integrate campaigning into a national health improvement programme, cultural and contextual alignment should be considered. Pillsbury and colleagues,[1086] in their reflection on a campaign to raise community awareness about reproductive and sexual health, highlight a lack of research into understanding local behaviours. They emphasize the importance of evaluating the local understanding and appropriateness of messages used; some of the African examples cited by them illustrate the risks associated with communication strategies where messages do not "talk" to the audience.

6.

Limitations of national programmes

National hand hygiene improvements must acknowledge that hand hygiene is not the sole measure necessary to reduce infection.[49] An acknowledgment of the importance of other factors such as environmental hygiene, crowding, staffing levels and education is emphasized by Jumaa as part of a total infection control improvement package.[51] Indeed, vertical programmes based on single interventions or diseases are under close scrutiny in terms of their effectiveness and impact, and there is a growing movement towards horizontal programmes that build capacity across the entire health system. The First Global Patient Safety Challenge, "Clean Care is Safer Care", and its main output, these *WHO Guidelines on Hand Hygiene in Health Care*, support this premise and emphasize that hand hygiene is one of a range of interventions designed to reduce the transmission of pathogenic microbes in health-care settings. Countries currently implementing national hand hygiene improvement programmes have emphasized that an initial focus on hand hygiene improvement can open doors to a broader focus on infection control improvement and result in renewed or intensified focus on infection control practices themselves (http://www.who.int/gpsc/country_work/Bangladesh_pilot_report_Jan_2008.pdf) .

Much of the literature relating to hand hygiene improvement in health-care settings is concerned with developed countries, and it is accepted that the threat from infection in developing countries is high. The extra hurdles faced by developing countries in terms of technical and human resource capacities have been cited as potential barriers to national health improvement programmes.[1087] In addition, the limited or non-existent public health infrastructure, including access to basic sanitation, and the wider geographical and cultural influences cannot be overlooked. Improving hand hygiene compliance within health care in developing countries must therefore take account of these constraints. The work of Curtis and colleagues[1088] provides testimony to the fact that it is possible to mount national programmes, including campaigns to improve hand hygiene, in developing countries. In these settings, however, taking account of local constraints, context, and cultures is paramount; this observation is equally relevant in the developed world.[868] Pillsbury and colleagues[1086] describe a community-based nongovernmental organization approach in Africa that has successfully promoted sexual and reproductive health messages. The importance of connecting with locally based groups described in this account mirrors the work of Curtis and colleagues[1088] with women's nongovernmental organizations described as ideally positioned to connect the target audience with the body of scientific information concerning the desired health behaviour. Credibility of the messenger is key, and the cultural context – including establishing beliefs on the importance of hand hygiene as a contributor to HCAI within the target audience – is an important starting point in the development of any mass campaign.[1089]

Mah and colleagues[872] suggest that it is possible for individual institutions (or even wards) to run successful, participatory campaigns to improve hand hygiene with a moderate budget. The involvement of industry sponsorship is suggested as a means of securing financial resources and, when channelled centrally, may yield more promising returns, particularly from an economy-of-scale perspective.

7.

The relevance of social marketing and social movement theories

Part I, Section 20.3, provides a comprehensive account of the applicability of social marketing to hand hygiene improvement. In a systematic review of hand hygiene behavioural interventions,[872] Mah and colleagues found synergies in many modern-day approaches to hand hygiene improvement and the ethos of social marketing. Scott and colleagues[1089] extol consumer marketing as a new approach that might overcome some of the conventional limitations associated with hand hygiene behaviour change outside health care. Social marketing might add value to the global drive for better hand hygiene in health care, exactly because it has been applied in both developed and developing countries.[1090] Mah and colleagues[872] suggest that social and behavioural theories and models are underused in the design of current hand hygiene promotion interventions. They counter the commonly held belief that social marketing is cost-intensive and conclude that social marketing is not necessarily an expensive activity due to its scalability. One of the chief advantages of nationally coordinated campaigns with pooled financial input is that it ensures resource provision that maximizes economies of scale and utilizes the expertise of the marketing world in spreading hand hygiene improvement messages within health care.

In contrast to the evidence relating to social marketing, the relevance of social movement theories to hand hygiene improvement, or health improvement generally, is an unresolved issue. Social movement theories concerned with large-scale societal change have gained prominence within health improvement literature in recent years and embody much of what is aspired to by health policy-makers striving to improve practices in health care. However, Brown and colleagues[1091] urge caution in drawing conclusions regarding the usefulness of such a comparison and emphasize that social movements are defined by the emergence of informal networks based on shared beliefs and solidarity that mobilize around issues of conflict and usually involve some form of protest. These possibilities of applying social movement theories within general spread strategies offer a new angle to hand hygiene improvement in health care, and this might hold relevance in terms of pursuing a global hand hygiene improvement movement. Within the context of broader patient safety improvements and the need to mobilize HCWs in a different way of working, there may be benefits in the concept.
Bate and colleagues[1092] argue that social and organizational change do have similarities with health-care improvement and conclude that those considering large-scale change in health care might benefit from consideration of change from a perspective of social movements. There is no literature specifically reviewing hand hygiene campaigns and social movement theories, and this gap in the literature may benefit from further study.

Social movements tend to occur spontaneously, and this contrasts sharply with current examples of national hand hygiene improvements that rely on centrally constructed programmes of change implemented in a coordinated manner using accepted methodologies of health improvement spread. Whether it is possible to create a contagious hand hygiene improvement movement using the vehicle of national programmes is only recently being addressed, and emerging results of the impact of these approaches are expected in the coming years.

7.1 Hand hygiene improvement campaigns outside of health care

While there is little available published literature on national hand hygiene improvement strategies in health care, the Global Public–Private Partnership for Handwashing with Soap (GPPHWS) illustrates a comprehensive strategy for improving hand hygiene in the community. The partnership was catalysed around a bold objective: to establish large-scale national programmes on handwashing,[1088] which involved putting into place a number of collaborative efforts for success at the national level including between government, academia, the private sector, and external support agencies. The partnership relied on the identification of a national coordinator at the governmental level.[1088]

Within a developing country context, Scott and colleagues[1089] have used a social marketing approach to consider motivations, environmental factors, and habits that mitigate against the desired behaviour within their target audiences. This approach has been rolled out in Ghana and a number of other countries. In developing countries, this public–private partnership[1093] has attempted to tackle the problems across nations exacerbated by low compliance with hand hygiene in the community, rather than in the health-care setting. This campaign involves close working with the private sector with the aim of developing and executing far-reaching improvement strategies. Transferring such an approach to hand hygiene in health care will raise ethical issues relating to partnerships working with corporate bodies. This may not necessarily be a barrier, and WHO is ideally placed to act as a catalyst to this end.

A list of critical factors that are necessary to drive forward this improvement has been drawn up: political will; policies and strategies that enable improvement; finance; coalition and partnerships; local governments and local action; and external support agencies. Fewtrell and colleagues[1094] emphasize the importance of selecting interventions for developing countries based on local desirability, feasibility, and cost–effectiveness. These factors will differ in a number of ways across developed and developing countries, not least in the absence of robust public health infrastructure in developing nations. Finally, they emphasize also the importance of making intelligent choices of interventions for specific settings.[1094]

These non-health-care programmes to improve handwashing behaviour appear to be feasible and sustainable, especially when they incorporate traditional hygiene practices and beliefs[1095] and take into consideration locally appropriate channels of communication.[1096] Consumer and market studies were effectively employed to understand the nature of the market, consumer attitudes, behaviours, and most appropriate promotional strategies and communication channels. These programmes have achieved an effective partnership between private industry and the public sector to promote handwashing with non-branded soap; therefore, many of the strategies employed require further consideration by those involved in developing national campaigns on hand hygiene improvement in health care.

8.

Nationally driven hand hygiene improvement in health care

Lessons from the Global Public–Private Partnership for Handwashing with Soap suggest that mass behaviour change is achievable and that commercial marketing techniques can be applied to good effect, even on a large scale.[1096] Hand hygiene improvement in health care presents unique challenges: the target audience is not the public or patients with or at risk of a disease, but the HCW. Unlike other health improvement campaigns, the target behaviour (hand hygiene compliance) contributes to the prevention of numerous episodes of infection and not a single disease. The published literature illustrates few examples of national campaigns aimed at improving hand hygiene within a health-care context, thus reflecting the novelty of such approaches. However, WHO has monitored the development of national campaigning over the past five years and has recorded a rapidly increasing number of new initiatives (http://www.who.int/gpsc/national_campaigns/en/). The first documented campaign, *clean**your**hands* (Table IV.8.1), was launched in England and Wales in 2004. It is centrally coordinated and funded, has political backing, and involves the provision of campaign materials to support local implementation of a multimodal hand hygiene improvement strategy. The campaign is the subject of a five-year research evaluation project,[1028,1097] with early indications suggesting a change in hand hygiene behaviour. Although not without its critics,[787] the campaign has demonstrated the possibilities of running an integrated behaviour change programme on hand hygiene at a national level.

Since 2004, a further 25 countries have been identified as running or preparing to embark on national programmes. A network of hand hygiene campaigning nations is in an embryonic stage, coordinated through the WHO World Alliance for Patient Safety.[857] This network will continue to centralize lessons learnt and share examples through its National Campaigns web platform.

9.

Towards a blueprint for developing, implementing, and evaluating a national hand hygiene improvement programme within health care

Based on the current evidence and experience from existing national hand hygiene improvement programmes (including national campaigns), this part concludes with an outline of the steps required in the development of a national strategy for action on hand hygiene improvement. Central to the strategy is the process required to progress from an initial desire to focus on hand hygiene improvement down to the actions required at a local health-care facility level to implement the WHO multimodal strategy. The WHO Implementation Strategy incorporates the evidence relating to implementation effectiveness within its core Guide to Implementation and accompanying toolkit for improvement (http://www.who.int/gpsc/country_work/en/). Table IV.9.1 presents a detailed framework for action, summarized in Figure IV.1.

10.

Conclusion

Avoidable harm continues to occur to patients receiving health care, because of the unreliable systems and strategies that mitigate against optimal hand hygiene compliance. As part of the continued global effort to ensure that no patient is unavoidably harmed through lack of compliance with hand hygiene, consideration should be given to nationally-coordinated programmes (in some cases campaigns) to promote and sustain hand hygiene improvement, keeping the issue in the national spotlight[1072] and ensuring effective implementation of guidelines that have an impact on hand hygiene at the bedside. Noar[1066] emphasizes that even taking into account the numerous caveats associated with campaigning, it is likely that targeted, well-executed mass media health campaigns can have some effects on health knowledge, beliefs, attitudes, and behaviour. The existence of guidelines does not in itself improve hand hygiene compliance. Therefore, the added impetus provided by a nationally coordinated campaign or programme, with some form of monitoring and evaluation, targets and regulation, has been demonstrated to provide a powerful adjunct to local implementation. In particular, to raise awareness of the issue and elevate it to a level of prominence that might not be realized in the absence of a nationally coordinated activity. For hand hygiene improvements to succeed within an integrated safety and infection control agenda, national-level approaches should be considered.

Table IV.8.1
The public information component of two national campaigns focusing on the prevention of health care-associated infection

Campaign	Interventions and tools	Target audiences	Implementing bodies	Significant results
"cleanyourhands" England and Wales[1029] (September 2004 to date)	A multimodal campaign based on social marketing and sustainable methodology aimed at educating and providing prompts. It includes: Implementation guide with supporting resources for HCWs with ongoing support through e-bulletins and local visits A series of three posters: the core campaign posters; the staff champion posters; the patient posters Patient leaflets, badges, stickers to encourage patient involvement Printed information materials including staff leaflet, multi-purpose panels and pump indicators A media kit A campaign web site Screen saver Media launches of the campaign involving local celebrities Conferences National televised debate	HCWs Senior management within health-care settings Patients Hospital visitors Partner organizations	NPSA NHS Trusts Department of Health Welsh Assembly Government	100% of all acute trusts in England and Wales signed up to the campaign 80% of trusts say hand hygiene is a top priority Use of alcohol handrub and soap has risen threefold Initiated patient empowerment pilot Expanded programme to non-acute sector

Table IV.8.1

The public information component of two national campaigns focusing on the prevention of health care-associated infection (Cont.)

Campaign	Interventions and tools	Target audiences	Implementing bodies	Significant results
"100 000 Lives" USA[863] (December 2004-June 2006)	Information calls on the campaign and on each intervention Campaign brochure Sign-up process: system, state and regional events Media kits, media events "Getting started" kits Campaign web site Information to existing partners on enrolling new partners Publicity of the successes of participating hospitals in implementing the campaign	Health-care providers Partner organizations Patients	IHI Hospitals Systems	3000 hospitals joined the campaign Target lives saved achieved according to IHI data sources

Table IV.9.1
Framework for action

Step	Actions/issues for consideration	References	WHO implementation tools
1. Readiness for action	**Considerations:** • Patient Safety Strategy: — Is there an existing or planned regional (WHO) strategy on patient safety, hand hygiene improvement and infection control? — Is the WHO country office driving infection control/hand hygiene improvement? — Is there national political support/ leadership for patient safety, hand hygiene improvement, and infection control? — Is there a national patient safety agenda? — Is there a national infection control agenda? — Is hand hygiene improvement integrated/ embedded within broader patient safety agenda? — Is hand hygiene part of an accountability/ governance framework; does it link with accreditation? • Commitment to "Clean Care is Safer Care": — Has a national political pledge of support to "Clean Care is Safer Care" been signed? — Do national or regional policies/guidelines exist on hand hygiene improvement in health care? — Is the WHO strategy consistent with national policies/guidelines on infection control/hand hygiene? • Is there broad support from policy-makers, professionals and the public to prioritize effort and resource on hand hygiene at a national level? • Will the programme be coordinated through the ministry of health or via another mechanism (e.g. regional or district authorities or a network of experts)? • Do hand hygiene campaigns outside of health care already exist; can links be made?	*798,1072,1074,1088,1094*	• Pledge briefing pack • Country situation analysis • Facility situation analysis • Perception surveys • WHO guide to local production of alcohol-based handrub • *WHO Guidelines on Hand Hygiene in Health Care* • WHO Guide to Implementation of the multimodal strategy and associated toolkit • Break-even cost analysis tool

Table IV.9.1

Framework for action (Cont.)

Step	Actions/issues for consideration	References	WHO implementation tools
	• Infrastructure and resources: — Are national data available on the economic cost of HCAI? — Are national data available on likely costs of a hand hygiene programme? — Is there a HCAI national/local surveillance system in place or anticipated? — Is technical infection control expertise available to coordinate the campaign? — Are required products affordable/available (soap and alcohol-based handrub)? — Is national or donor funding available for the short, medium or long-term? — Are partnerships with commercial sectors feasible? — How feasible will it be to produce, adapt and translate (where necessary) the WHO implementation toolkit? — How feasible will it be to produce the WHO alcohol-based handrub formulation nationally (if limited, affordable access to commercial sector products)? — Does the national infrastructure support rapid spread of improvement? **Once a decision is made to run a national programme, proceed to step 2**		
2. Identify roles and responsibilities	**Actions:** 1. Establish a national task force, headed by an influential, technically competent (in infection control or patient safety) national lead and deputy to coordinate and champion the campaign (credibility of the messenger in conveying scientific information to the target audience is key) 2. Develop terms of reference for the task force relating to implementation of hand hygiene improvement programmes at local level, as an integral part of national infection control strategy 3. Task force membership should comprise national safety and infection control professionals and national bodies for infection control 4. Task force membership should include ministry of health officials concerned with infection control/safety 5. Brief/sensitize a task force on all aspects of the improvement, including local implementation using the WHO Guide and technical and advocacy toolkit	*1086*	• WHO Guidelines on Hand Hygiene in Health Care • WHO Guide to Implementation of the multimodal strategy and associated toolkit • Regional advocacy guide on hand hygiene

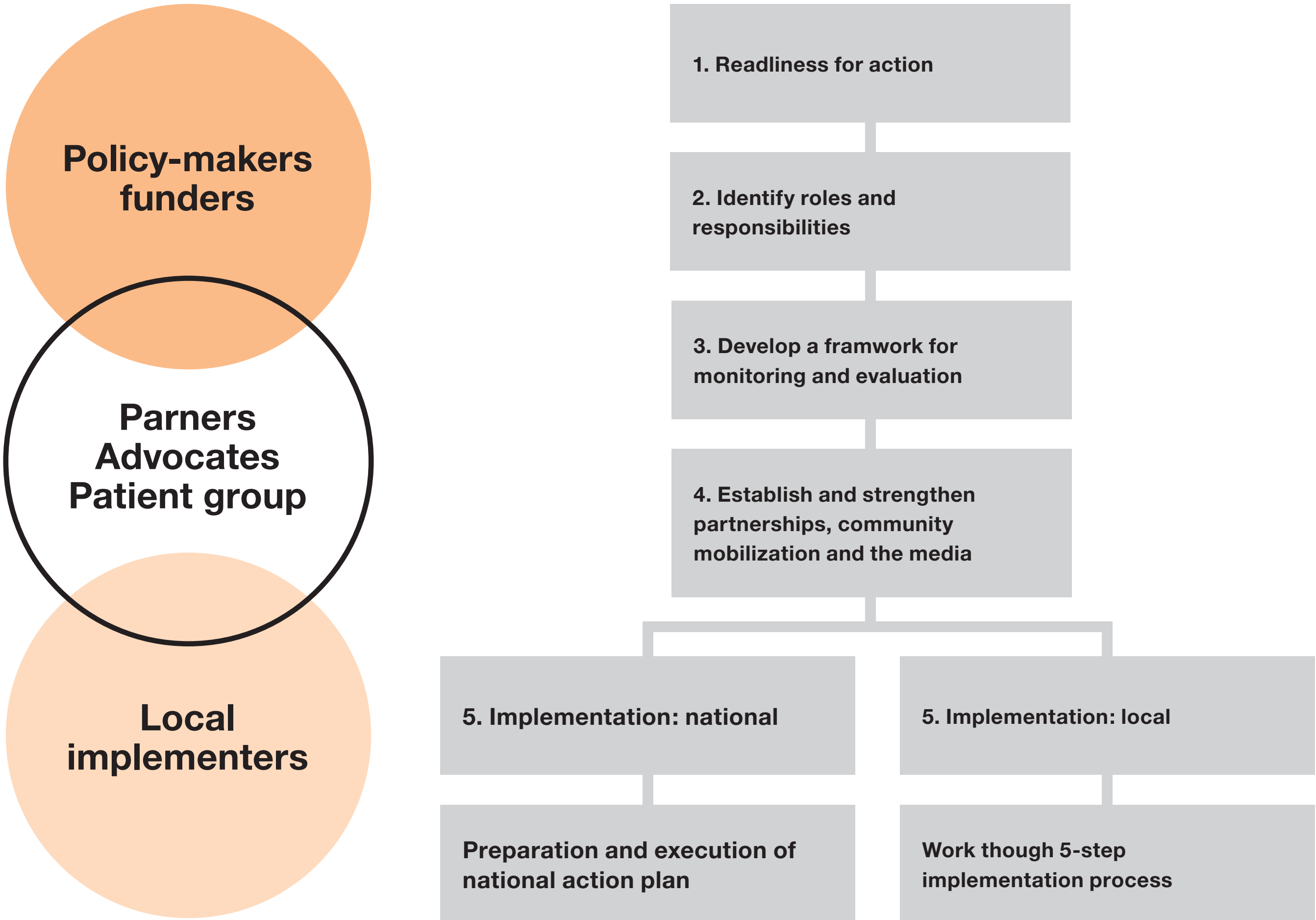
Table IV.9.1
Framework for action (Cont.)

Step	Actions/issues for consideration	References	WHO implementation tools
3. Develop a framework for monitoring and evaluation	**Considerations:** • What will the realistic deadline be for action? • What realistic targets will be used (e.g. reduction in infection, increase in compliance and product usage) • What parameters/baseline data are available to measure the impact of the programme? • Is there a system for accreditation and regulation? How will the hand hygiene improvement fit into this system?	1074,1075,1088	• WHO Guide to Implementation and associated toolkit • Evaluation tools (facility situation analysis; hand hygiene compliance; health care-associated infection rates; soap consumption; alcohol-based handrub consumption; knowledge surveys; perception surveys; ward structure surveys)
4. Establish and strengthen partnerships, community mobilization, and the media	**Considerations:** • Which agencies/professional bodies, coalitions, voluntary organizations, partners, and nongovernmental organizations will be involved? • Will patient and public engagement feature in the programme? • How will marketers and the mass media be involved to ensure local hygiene practices and beliefs are taken into account? • Will behavioural/industrial psychologists be involved in the communications and promotions activity to ensure alignment with local culture?	1072,1086,1098	• Regional Advocacy Guide for Hand Hygiene Improvement Strategies
5. Implementation:	**National** **Actions**: 1. Prepare a national action plan, based on steps 1 to 4, including all issues raised in the WHO Guide to Implementation 2. Establish a process for refining the plan in response to learning during implementation **Considerations:** • Consider a national and sub-national meetings for hospital directors, managers, and other key decision-makers (for sensitization, awareness-raising, and building commitment) • Consider awareness-raising activities from national to local: including preparing communications/briefings to circulate to hospitals presenting an outline of the strategy and its benefits • Develop and execute a plan to communicate and implement the strategy • How many and what type of facilities will be involved?	1074,1094	• Regional Advocacy Guide for Hand Hygiene Improvement Strategies • WHO Guide to Implementation

Table IV.9.1
Framework for action (Cont.)

Step	Actions/issues for consideration	References	WHO implementation tools
	• Will a pilot test occur or is mass roll-out anticipated? • Consider holding a training session(s) for infection control teams using the WHO training tools • In parallel, work to ensure infection control and the WHO strategy is incorporated within existing education programmes • Consider creation of networks to support change at the front-line of care		
	Local **Actions**: 1. Local health-care facilities are provided with the WHO Guidelines, Guide to Implementation and toolkit 2. Local health-care facilities work through the five-step implementation process		• Regional Advocacy Guide for Hand Hygiene Improvement Strategies • WHO Guide to Implementation and associated toolkit

Figure IV.1
Action framework



PART V.

PATIENT INVOLVEMENT IN HAND HYGIENE PROMOTION

1.

Overview and terminology

Patient empowerment is a new concept in health care and has now been expanded to the domain of patient safety. In developing countries, this has been influenced significantly by the USA IHI reports on health quality and safety, with a focus on increasing the public's awareness of medical errors and national efforts to actively engage patients in their care.[1041,1099] Even though the term can have different meanings and interpretations, *empowerment* in health care generally refers to the process that allows an individual or a community to gain the knowledge, skills, and attitude needed to make choices about their care. The term *patient participation* is more often used when referring to chronic diseases such as diabetes, in which patients are invited to participate in the ongoing decisions of their care. Patient empowerment is generally required in order for patients to participate. Thus empowerment refers to a process that, ultimately, leads patients to participate in their care.

Although there are many unanswered questions about how to approach patient involvement, this part of the guidelines presents the evidence supporting the use of programmes aiming to encourage patients to take a more active role in their care, especially with regard to hand hygiene promotion, using a three-fold approach:

- review the current literature on patient and HCW empowerment and hand hygiene improvement;
- report on the results of the WHO Global Patient Survey of patients' perspectives regarding their role in hand hygiene improvement;
- propose a multifaceted strategy for empowerment that can be incorporated into a broader, multimodal, hand hygiene improvement strategy.

2.

Patient empowerment and health care

The term chosen to engage and involve patients will depend on what is appropriate for the specific culture of a region or community. *Patient empowerment* might be the preferred term from a patient advocacy point of view. However, the less emotionally charged and challenging term *patient participation* might be a term more acceptable to many HCWs, patients, and cultures. For the purpose of these guidelines, the word *empowerment* is used.

WHO defines empowerment as "a process through which people gain greater control over decisions and actions affecting their health" and should be seen as both an individual and a community process.[1100]

Four components have been reported as being fundamental to the process of patient empowerment: 1) understanding by the patient of his/her role; 2) aquisition by patients of sufficient knowledge to be able to engage with their health-care provider; 3) patient skills; and 4) the presence of a facilitating environment.[1101] Based on these four components, empowerment can be defined as:

A process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation.

3. Components of the empowerment process

3.1 Patient participation

WHO recognizes that the primary responsibility for the delivery of safe care is with the health-care system. Nevertheless, there are now many ways in which patients can become involved in the process of their own health care. Lyons[1102] identifies three key contributions patients can provide: 1) historical background about their health; 2) self-interest and motivation for a beneficial outcome; and 3) being physically present at all times during care and treatment. Their age, culture, background, personality, and level of intelligence have been identified as key characteristics when engaging patients in participation.[1102] To sum up, the opportunity for patients to be involved in their health care has evolved over the last decades from passive to more active. An understanding of this new role by both patient and HCW is the foundation of an empowerment programme.

3.2 Patient knowledge

Patients can be empowered only after having gathered enough information, understanding how to use the information, and being convinced that this knowledge gives them shared responsibility with their HCWs. In their review of materials given to patients, Coulter and colleagues[1103] found that relevant information was often omitted, many doctors adopted a patronizing tone, and few actively promoting a shared approach. Studies have also shown that patients prefer information that is specific, given by their HCWs, and printed for use as prompt sheets if necessary.[1103,1104]

3.3 Patient skills

3.3.1 Self-efficacy

Self-efficacy is defined as an individual's belief that he/she has the capabilities to produce an effect or reach a certain goal.[1105] Individuals with high self-efficacy regarding a given behaviour are more inclined to undertake this behaviour, have greater motivation, and usually undertake more challenging tasks than individuals with low self-efficacy.[1106]

Promoting self-efficacy among patients is fundamental in order to bring them to the stage where they will feel confortable to ask HCWs about hand hygiene. Bandura identified four major ways (dubbed "sources") to improve one's self-efficacy: mastery experiences; vicarious experience; verbal persuasion; and physiological responses. Mastery experiences, considered as the most important, relate to the fact that previous successes will raise self-efficacy. Vicarious experience refers to the increase in one's self-efficacy upon witnessing other individuals completing successfully a task. The third source, verbal persuasion, relates to the impact of encouragement on an individual's perceived self-efficacy. Finally, physiological responses such as moods, emotional states, physical reactions, and stress levels also influence one's perception of self-efficacy.

These skills can be applied to the behaviour of empowering patients to ask about hand hygiene. Knowledge will give mastery experience of the behaviour, role modelling by HCWs will provide vicarious experience, and patients asking their providers to perform hand hygiene will give verbal persuasion. It is likely that the high self-efficacious person will have the skills to invest more effort.[1106]

3.3.2 Health literacy

Health literacy is the ability to understand health information and to use that information to make good decisions about health and medical care. Lower health literacy has been reported among people who are elderly, less educated, poor, and members of minority groups[1107] and is associated with lower health outcomes, increased rates of hospitalization, and higher costs for care.[1101,1108] Health literacy is fundamental to patient empowerment.[1109] However, authors of health education material often attempt to encourage health literacy by simply rewriting existing materials in lay language and fail to recognize that "information" is only one piece of the literacy process.[1110] To solve this problem, an action plan has been set forth to improve literacy in the USA.[1111]

In summary, the skills of self-efficacy and health literacy have been linked to the performance of a task that requires a change in behaviour. High levels of self-efficacy appear to be a motivating factor to perform a task. Health literacy and community partnership provide the structure required by champions of empowerment to deliver the message of engagement to their communities.

3.4 Creation of a facilitating environment and positive deviance

The creation of a facilitating environment can be defined as the process in which patients are encouraged to develop and practise open communication about their care in an environment free of barriers. There are three prerequisites that HCWs require if they are expected to help patients be seen as partners and to facilitate an environment for empowerment.[1112] These are: a) a workplace that has the requisite structure to promote empowerment; b) a psychological belief in one's ability to be empowered; and c) acknowledgement that the relationship and communication of HCWs with patients can be powerful.

An individual cannot create personal empowerment in another individual, but the partnership of HCWs and patients can facilitate the process of empowerment. If patients are given knowledge and resources in an environment of mutual respect and support, then a facilitating environment for empowerment will develop.

Positive deviance is based on the observation that, in most settings, a few at-risk individuals develop uncommon, beneficial practices and, consequently, experience better outcomes than neighbours with similar risks.[1113,1114] Recognition of these individuals and identification and explanation of their uncommon behaviour allows the design of behaviour change activities that can lead to widespread adoption of beneficial behaviour. This approach, which takes advantage of the community's existing assets, was originally developed for combating childhood malnutrition,[1115,1116] but has also been applied to various health-care programmes such as newborn care or reducing the spread of MRSA.[1117,1118] It is now being seen as a means to provide a framework for facilitating empowerment.

Positive deviance could be used to promote hand hygiene and patient empowerment. The strategy involves: 1) social mobilization; 2) information gathering; and (3) behaviour change.

Social mobilization is an opportunity for health-care settings to identify problems and find solutions to increase compliance. This can be done by bringing together the individuals who have a vested interest in the problem. Information-gathering would offer an opportunity for individuals to identify the best ways to involve patients and HCWs. Behavioural change can be developed through a partnership that takes responsibility for implementation. For some communities, the process of positive deviance may reveal a lack of hand hygiene products, cultural barriers to empowerment, or the need to develop networks of champions.

The partnership of HCWs and patients can facilitate the process of empowerment if HCWs recognize patients as equal partners. Positive deviance can be used to find solutions to common local issues within a community and encourage behaviour change.

4.

Hand hygiene compliance and empowerment

Multimodal programmes for increasing hand hygiene compliance are now recommended as the most reliable, evidence-based method for ensuring sustainable improvement.[60,713] WHO has developed and tested a multimodal Hand Hygiene Improvement Strategy (see Part I, Section 21) to translate into practice the present guidelines. Although patient empowerment was already referenced in the 2006 Advanced Draft of the Guidelines[59] and explicitly stated as one of the final recommendations, the emphasis placed upon it within the associated implementation strategy has been limited. WHO is committed to informing and educating patients about the importance of hand hygiene and their potentially powerful role in supporting improvement.[767] This is mirrored across a growing number of countries of the world that are incorporating patient empowerment into their national strategies. (Table V.4.1)

4.1 Patient and health-care worker empowerment

4.1.1 Willingness to be empowered

Miller & Farr[1119] surveyed patients' knowledge of HCAI in the USA by asking if they were satisfied with the information they received about infection control and if they were willing to pay for increased investment in infection control programmes within their hospital. Responses revealed that 70% of patients were concerned about the risk of infection, 69% said the risk was never explained, and 57% said they would be willing to pay for better infection control programmes and information on infections.

The NPSA for England and Wales assessed patients' views on involvement as part of their "*clean**your**hands*" campaign and reported that 71% of respondents wanted to be involved in improving hand hygiene practices.[1029] Similar results were reported by an acute care trust,[1120] where 79% of patients thought that they should be involved in hand hygiene improvements.

A willingness to be empowered is dependent on patient input during the development of the programme. Entwistle and colleagues[1121] reviewed the content of five leading patient safety directives in the USA; they reported that the programmes had been developed without input from patients and lacked information about what the HCWs needed to do and what support should be given to patients. In 2001, the National Patient Safety Foundation Advisory Council in the USA took up the concern about consumer involvement and developed a new programme with input from patients and families, "Patients and Families in Patient Safety: Nothing About Me, Without Me", as a call to action for health-care organizations at all levels to involve patients and families in systems and patient safety problems.[1122]

In 2004, WHO launched the World Alliance for Patient Safety to raise awareness and political commitment to improve the safety of care in all its Member States. A specific area of work, Patients for Patient Safety, was designed to ensure that the wisdom of patients, families, consumers, and citizens, in both developed and developing countries, is central in shaping the work of the Alliance. In 2007, as part of the WHO First Global Patient Safety Challenge, "Clean Care is Safe Care", the development and implementation of an empowerment model for hand hygiene was initiated in collaboration with Patients for Patient Safety. In studies undertaken in the USA and the United Kingdom, McGuckin and colleagues[803-805] reported on patients' willingness to be empowered and involved in hand hygiene by asking their HCWs to clean their hands. They documented that 80–90% of patients will agree to ask in principle, but the percentage of those that actually asked their HCW is slightly lower at 60–70%. A recent survey of consumers on their attitudes about hand hygiene found that four out of five consumers said they would ask their HCW "did you wash/sanitize your hands?" if their HCW educated them on the importance of hand hygiene.[874] A patient's willingness to be involved, empowered or engaged is dependent on the overall environment of the organization and its attitudes toward patient safety and patient involvement.[876,1036,1123,1124]

4.1.2 Barriers to patient empowerment

There are several different theories from various disciplines that provide insight into the barriers of hand hygiene compliance that may apply to patient involvement. These theories include cognitive, behavioural, social, marketing, and organizational theories that may be valuable when considering barriers to be overcome, or a strategy to involve and engage patients.[876] Pittet[789] discusses in some detail the promising effect of the theory of ecological perspective as part of a multimodal programme to increase hand hygiene compliance. In this theory, similar to that of positive deviance,[1115,1116] behaviour is viewed as affecting and being affected by multiple factors, and both influences and is influenced by the social environment. Although further assessment of these theories is needed, they do appear to have a bearing on some of the barriers of patient empowerment. Three barriers that can lessen patient involvement are: 1) intrapersonal; 2) interpersonal; and 3) cultural.[1125]. Intrapersonal factors include psychological vulnerability, acute pain, and illness,[1126] and each can be influenced by a lack of knowledge[1127] and professional domination.[1128] Interpersonal factors centre on the importance of communication and the need to use clear, simple language so that expectations are apparent.[1129] Cultural factors such as cultural marginalization, caused by social pressure, can have a significant impact on "speaking up".[1130] In addition to these barriers, a significant factor often perceived by the patient is the fear of a negative impact/response from their HCWs.[1131] This barrier was explored in an acute care rehabilitation unit where patients are often dependent on their HCWs for activities of daily living. The authors reported that 75% of patients were comfortable asking their HCWs "did you wash/sanitize your hands?"[805] It is important to note that empowerment is a major part of the rehabilitation process and, therefore, this may have been a motivating factor for empowerment in these patients.

Although HCWs are trained and motivated to provide the best care possible, they are often faced with barriers that are more system-related than behavioural. Empowering a patient covers issues that go beyond decision-making and involve more individual interests and cultural parameters. Acknowledging different views on patient empowerment and dealing with them in the context of an organization, culture, or community will be necessary when removing barriers to patient empowerment, involvement or participation in hand hygiene compliance.

Table V.4.1
Countries and territories with national strategies for patient empowerment (as at October 2008)

Country
• Australia
• Belgium
• Canada
• England and Wales (http://www.npsa.nhs.uk/cleanyourhands/in-hospitals/pep)
• Ireland
• Northern Ireland
• Norway
• Ontario (Canada)
• Saudi Arabia
• USA (http://www.jointcommission.org/patientsafety/speakup)

5.

Programmes and models of hand hygiene promotion, including patient and health-care worker empowerment

5.1 Evidence

As only a few studies have been published to assess the efficacy of patient involvement to increase hand hygiene, an evidence-based review of programmes that have empowered, involved or encouraged patient participation in hand hygiene promotion cannot be evaluated by the traditional method focused on quantitative data, linear causality, and "scientific" reliability.[1132] The complex multidisciplinary approach to hand hygiene compliance lends itself to evaluations that are used more in health promotion.[1133] These evaluations use a theory-based approach that explore links between activities, outcomes, and context and take into account the relationship between individuals and their environment.[1134,1135] They determine not only what works, but under what conditions, and the relationship programmes have within an organization. Many organizations, both at the national and local levels, have developed programmes of empowerment for hand hygiene that use various approaches. In most cases, these do not have a strategy for evaluation. Therefore, the following review of programmes that have used empowerment has been limited to published articles and reports in which there was some form of evaluation for hand hygiene as a separate outcome or as part of a multifaceted programme.

5.2 Programmes

Programmes for patient and staff empowerment in the context of hand hygiene improvement can be categorized into educational (including Internet), motivational (reminders/ posters), and role modelling within the context of a multimodal approach.

5.2.1 Educational programmes

Hand hygiene information for patients can be in the form of printed matter, an oral demonstration, or audiovisual means. In their patient empowerment model, McGuckin and colleagues educated patients about hand hygiene by using brochures that asked the patient to be a partner with their HCWs. The materials presented discussed the *who, why, where* and *when* of hand hygiene. This programme has been evaluated in several multicentre studies documenting that 80–90% of patients reported that they had read the educational brochures.[803,804] Petersen and colleagues[1136] developed a promotional campaign that included educational brochures for patients on hand hygiene as well as bottles of alcohol-based hand rub. Although patients were encouraged to speak up about hand hygiene, Petersen and colleagues reported an overall increase of only 10% in compliance, but believed this was attributable to limitations in their observation technique. Using demonstrations as a form of education and empowerment about hand hygiene was evaluated and found to increase awareness and compliance.[1137] Chen & Chiang compared the use of a hand hygiene video to illustrated posters to teach hand hygiene skills to parents of paediatric intensive care patients and to empower them about their role in hand hygiene. They reported a steady sustained increase in compliance and empowerment by parents attributable to a strong motivation to protect their child.[1138] In 2008, the CDC released a podcast on hand hygiene and patient empowerment stating that it is appropriate to ask or remind health-care providers to practise hand hygiene (http://www2a.cdc.gov/podcast/player.asp?=9467). Empowering patients about patient safety issues using Internet sources such as home pages for hospitals or national agencies has become part of many hospital systems as a result of mandatory reporting of quality and safety. When 32 consumer participants were introduced to five Internet sources on quality care in order to educate them about patient involvement, they reported a significant improvement in test scores after exposure to the Internet sources.[1139] The studies described here are from health-care settings in developed countries.

5.2.2 Reminders and motivational messages

Patient empowerment models often include visual reminders for both the HCW and the patient.[803-805] These visual reminders usually include small badges or stickers worn by patients with a message such as "did you wash/sanitize your hands?" A multicentre, one-year evaluation of a model using education and reminders as a route to empowerment, found a statistically significant increase in hand hygiene compliance with the model working equally well for all sizes of hospitals and unit types.[1140] Posters, another form of reminder, are used in hand hygiene programmes and campaigns to educate and empower HCWs as well as patients. An evaluation of 69 hand hygiene posters representing 75 messages found that only 41% framed the message for motivation, empowerment, and health promotion. Similar findings were reported from a poster campaign in a paediatric ICU to encourage both HCWs and patients/visitors to practise hand hygiene.[1141] If the message is framed correctly, posters can serve as a visual reminder and encouragement for both the patient and the HCW to participate in hand hygiene practices. Educational videos, posters, brochures, and visual reminders targeted to educate HCWs and patients were evaluated in three long-term care facilities as part of a comprehensive hand hygiene programme. This combination of HCW education and patient empowerment resulted in an aggregate increase in hand hygiene compliance of 52% and a 32% decrease in infections.[806]

5.2.3 Role modelling

Role modelling in which the HCW behaviour towards hand hygiene is influenced by either peers or superiors has been shown to influence compliance and motivate the patient to be empowered.[732,802,853,872,1142-1145]

McGuckin and colleagues reported an increase in hand hygiene compliance and alcohol-based hand rub use by using "authority figures" as role models for empowerment.[853] The medical director, nurse manager, director of nursing, and infection control professional dedicated to the medical/surgical ICU recorded short audio messages about hand hygiene, such as "we want 100% compliance with hand hygiene in our ICU" and "remember to use sanitizer", that were broadcast at randomly timed intervals from the announcement speakers at the nurses' station. Christensen & Taylor[1142] question the use of empowerment for the ICU patient and suggest that patients need to have control restored before they can be empowered. Lankford and colleagues[802] reported that a HCW's hand hygiene behaviour was influenced negatively when the HCW was in a room with a senior staff member or peer who did not perform hand hygiene. Sax and colleagues[732] identified social pressures that could be considered a form of role modelling as highly ranked determinants of good hand hygiene adherence: the influence of superiors and colleagues on staff and patients.

In summary, programmes and models for empowering patients and HCWs must be developed with an evaluation component that includes both qualitative and quantitative measures to determine not only what works, but under what conditions, and within which organizational context the programme works. Programmes in which there is some evidence of empowering patients and HCWs are usually part of a multifaceted approach and include one or all of the following: educational tools, motivation tools, and role modelling. Many aspects of patient empowerment remain unexplored; for example, the views of HCWs on this topic are largely unknown. Also, as most studies exploring the impact of patient empowerment on HCWs' hand hygiene practices were conducted in settings with low baseline compliance rates, the impact has always been significant and, therefore, the effect on settings with higher baseline compliance remains unknown. In addition, because the studies were short term, any sustainable effect has not been determined. Finally, empowerment programmes require further testing in settings where a multimodal promotion strategy – including system change, monitoring and HCW performance feedback, education, reminders in the workplace, and promotion of the institutional safety climate – is being promoted.

6.

WHO global survey of patient experiences

A WHO survey was undertaken as part of the work of the Patient Involvement Task Force established during the development process of these guidelines, to identify existing gaps in knowledge and to incorporate geographical and culturally diverse perspectives related to patient empowerment and hand hygiene improvement. A two-phase, web-based survey was conducted between March 2007 and January 2008. The survey sought views on infrastructure, barriers and facilitators, existing country strategies, and case-study examples. Detailed results are presented in Appendix 6.

In summary, 459 completed surveys were received, with only 13% from WHO regions other than AMR and EUR. Infrastructure to support hand hygiene varied by region with, as anticipated, major constraints reported in AFR and SEAR. Of the 29% of respondents who reported asking a HCW to wash/sanitize their hands, 25% reported receiving a negative response. One of the key findings is the impact that HCW encouragement seems to have on the likelihood of patients feeling empowered to ask about hand hygiene, with 86% reporting that they would feel comfortable doing so if invited to. This decreased to 52% when not invited, and increased to 72% when presented with a scenario where failure to comply was observed. Furthermore, respondents who had direct experience of an HCAI were more likely to question the HCW (37% among those who had direct experience vs 17% among those who did not). Details of the study design, data analysis, and results of all questions, as well as specific details from case-studies, can be found at http://www.who.int/patientsafety/challenge/en.

7.

Strategy and resources for developing, implementing, and evaluating a patient/health-care worker empowerment programme in a health-care facility or community

Patient/HCW empowerment programmes should form one component of an evidence-based multimodal hand hygiene improvement strategy. Table V.7.1 presents a template of a strategy to develop an empowerment programme in a health-care community by providing several steps for ownership, programme review, development, implementation, and evaluation. Each step identifies a task, or tasks, with the process that is needed to complete each one. Background information and resources are cross-referenced with the text of the guidelines, as well as with Appendix 6 for the survey results.

Table V.7.1
Template of a strategy to develop an empowerment programme)

1. Ownership: develop a shared responsibility		
Task	**Process**	**Guidelines (Part V) Section no.**
Introduce empowerment in the context of hand hygiene improvement to key decision-makers	Present the evidence-based multimodal Hand Hygiene Improvement Strategy to key decision-makers	4, 5
	Discuss WHO commitment for improving hand hygiene (through lobbying for adoption of recommendations in the *WHO Guidelines*)	2
	Highlight better outcomes by using multimodal Hand Hygiene Improvement Strategy approach	3.4, 4
	Share results of the *WHO patient survey* in your region	Appendix 6, Table 2
Determine the most appropriate terminology to describe empowerment in your culture or community	Decide on wording that is positive, not easily misunderstood, and appropriate for your community/ organization. Some of the most common terminology: — patient empowerment — patient involvement — patient participation — patient engagement	1, 2
Establish your core support network	Identify sources for individual and organizational support. Suggestions: — HCWs — community leaders — champions of health-care causes — patient advocates — advisers	3.4
	Form a support/action team responsible for making hand hygiene initiatives top priority	3.4, 4.1.1
	To ensure involvement, implement the step of positive deviance	3.4

Table V.7.1

Template of a strategy to develop an empowerment programme (Cont.)

2. Review existing empowerment models/programmes		
Task	**Empowerment models**	**Guidelines (Part V) Section**
Research existing empowerment programmes for information on how they are structured and implemented. Four types are listed here	Multimodal	4
	Education	5.2.1
	Motivation	5.2.2
	Role modelling	5.2.3
3. Programme development: know your organization		
Task	**Process**	**Guidelines (Part V) Section no.**
Review and understand current knowledge, skills, and attitudes of HCWs and patients at your health-care facility	Establish each team member's role	4
	Evaluate your current knowledge and perception of hand hygiene and target areas to seek additional information – use *WHO Knowledge and Perception Surveys*	4, Appendix 6, Table 6
	Evaluate your team's skills	4
	Evaluate the degree to which you have a facilitating environment for empowerment	4
	Evaluate the willingness of patients and HCWs to participate in empowerment	4.1.1, Appendix 6, Figure 4
	Evaluate the barriers of patients and HCWs to participation in empowerment	4.1.2, Appendix 6, Table 3, Figure 2
	Understand WHO survey expectations	Appendix 6,Table 5
Review and understand patient factors that may present challenges to implementing the programme. Use knowledge and skills to design tasks that overcome challenges	Understanding of self-empowerment	3.1, 4.1.1
	Willingness to be in a partnership with HCWs	4.1.1
	Understand how respect is shown towards HCWs (reinforced directly or subliminally by HCWs)	4.1.2
	Understand cultural barriers that patients may have towards communicating with their HCW	4.1.2
Review and understand HCW factors which may present challenges to implementing the programme. Use knowledge and skills to design tasks that overcome challenges	Attitudes towards patient input	3.1
	Availability and use of printed materials	5.2.1
	Availability and use of visual reminders	5.2.2
	Attitudes towards the message: HCW + patient partnership	5.2.3
	Degree of agreement with the *WHO survey – patient responses*	6.6, Appendix 6, Figure 3, Table 2
Plan and develop educational materials based on your organization's norms	Include patient input in the design and wording of your materials	5.1, Appendix 6, Tables 4 & 5
	Design printed materials	5.2.1, 5.2.2
	Design visual reminders	5.2.2
	All materials should promote the message: HCW + patient partnership	Appendix 6, Tables 4 & 6
	Incorporate insight and local understanding from *WHO survey – patient responses*	Appendix 6, Figure 1, Table 4

Table V.7.1
Template of a strategy to develop an empowerment programme (Cont.)

4. Programme implementation		
Task	**Process**	**Guidelines (Part V) Section no.**
Put your programme designs into action. You should include plans to overcome challenges in patient and HCW factors, and have your educational materials ready	Know your community's or organization's preferences for instruction techniques	4, Appendix 6, Table 2, Figure 3
	Include HCW involvement and partnership	5, Appendix 6, Table 4
	Identify barriers when the programme is under way	4.1.2
	Include *WHO survey – patient preferences*	6, Appendix 6, Tables 3-5
5. Evaluation		
Task	**Methods**	**Guidelines (Part V) Section no.**
Design your evaluation process. Three ideas are listed here.	Theory-based / health promotion	5
	Patient satisfaction survey	5
	Patient as observer of practices	5

PART VI.

COMPARISON OF NATIONAL AND SUB-NATIONAL GUIDELINES FOR HAND HYGIENE

Guidelines for hand hygiene prepared by various other agencies, both prior to and after the publication of the Advanced Draft of these guidelines, are currently available. An analysis of recommendations in guidelines produced by 16 countries was published in 2001.[635] However, several guidelines included in the analysis were not formal publications agreed upon nationally or sub-nationally, and the level of details provided could be expanded more extensively. This section examines the scope, approaches, and recommendations of some national and sub-national guidelines.

Different strategies were used to identify available guidelines. These included using search engines such as Google and electronic resources such as PubMed and the Guideline International Network. Keywords used in the search were "hand hygiene", "hand washing", "handwashing", "hand rubbing", "handrubbing", "hand decontamination" and "guidelines" in various combinations. Requests for hand hygiene guidelines were also made to members of the WHO First Global Patient Safety Challenge core group of experts, national representatives of the European Union hospital infection network (Hospital in Europe Link for Infection Control through Surveillance) and WHO regional offices.

Twenty-one guidelines were obtained for comparison. These included 15 national guidelines from Australia,[1146] Belgium,[1147] Canada,[1148] Egypt,[1149] England,[1150] France,[1151] Germany,[1152] Ireland,[1153] Nepal,[1154] the Russian Federation,[1155] the Netherlands,[1156] Tunisia,[1157] Scotland,[1158] Sweden,[1159] and the USA,[58] and six sub-national guidelines from Ontario[1160] and Manitoba[1161] (Canada), and Liverpool,[1162] Southampton,[1163] Mid Cheshire,[1164] and Bassetlaw[1165] NHS Trusts (England). The documents were analysed using a methodology adapted from the European HARMONY (Harmonisation of Antibiotic Resistance measurement, Methods of typing Organisms and ways of using these and other tools to increase the effectiveness of Nosocomical infection control) project approach,[1166] a tool developed originally to evaluate antibiotic policies in different hospitals and since used in several other infection control-related projects.[1167] The main aspects considered by this method were: information about the guideline's title, year of publication, endorsing body, and mode of publication; aspects related to the guideline development process (e.g. national vs sub-national, developers, target population, and methods for evidence evaluation and recommendation development); type of recommendations, details about indications and technique, and products recommended for hand hygiene; and recommended strategies for hand hygiene improvement and guideline implementation.

Eighteen of the 21 guidelines were available through web sites, 14 of which were in English. These documents were developed either by professional societies involved in infection prevention and in the control of antimicrobial resistance or by governmental agencies such as the ministry of health. In some cases, recommendations on hand hygiene were part of much longer infection control or antimicrobial resistance control guidelines. In the latter documents, details on important issues related to hand hygiene were generally insufficient or the information was made available in different parts of the document or allied publications, thus making difficult the analyses.

The documents varied in their scope, approach to the topic, and content. Some were primarily intended as advisory directives,[58,1146,1150,1152,1153,1159] while the primary focus of others were the technical issues of why, when and how to perform hand hygiene.[1149,1154,1157,1162-1165] Developers of the advisory type of documents focused mainly on evidence-gathering and making general recommendations applicable to different settings and areas. The latter group of documents focused more on specific issues related to implementation such as technical details, popularizing practices, and logistics; they referred to documents in the advisory group for their evidence base. Some documents belonging to the advisory group mentioned and referred to companion materials, such as training guides and other national guidelines, for some details. Several documents contained a long detailed text in addition to the evidence for recommendations.

The extent to which evidence was collected and assessed varied considerably. Only three guidelines described clearly the method used for collecting or selecting evidence. Seven national and two sub-national guidelines graded the evidence for recommendations.[58,1148,1150-1153,1159,1160,1162] However, they used different grading systems and definitions to indicate the strength of evidence and recommendations. The strength and quality of evidence was determined based on expert consensus in three documents.[1148,1152,1159] The evidence grading was performed using the methods adopted by the National Institute for Health and Clinical Excellence (NICE) from the Scottish Intercollegiate Guideline Network (SIGN) for the EPIC (Evidence-based Practice in Infection Control) 2 guidelines.[1150] Published guidelines used as references were assessed using the AGREE (Appraisal of Guidelines' Research and Evaluation) instrument in one document.[1150]

Table VI.1 shows some of the major aspects of the evidence-grading systems used in different documents. There were additional differences in the individual statements. For example, the CDC Category 1A is "strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies" and that of France Category 1 is "strongly supported by well-designed studies and do not pose economical or technical problems". In EPIC 2 guidelines, evidence grades 1 and 2 were further classified into three (e.g. 1, 1^{+}, and 1^{++}). In general, there were three to five grades of evidence and recommendations. The quantum of evidence and details of data from studies presented varied considerably. This probably reflects differences in the rigour in evidence-gathering and assessment.

The recommendations formulated were based on expert consensus for most documents. The validation process was not clear for most guidelines. Seven described internal or external peer reviews and public consultations as the methods of validation.

The guideline documents appeared to be still evolving. Several guidelines stated that they need to be revised periodically based on new evidence and some are currently being revised, e.g. the French and Belgian guidelines (personal communication).

Based on the original CDC evidence document, a "How-to Guide" was made by the same agencies a few years later.[1168] Four guidelines,[1148,1160-1162] one revised guideline,[1150] and the IHI "How-to Guide" document[1168] were published after the publication of the Advanced Draft of these *WHO Guidelines* (October 2005 onwards), although, interestingly, only three of these six documents referred to the WHO publication.[1158,1160,1168]

HCWs were the main target population in all guidelines. Since all were national and sub-national documents, policy-makers (local authorities, institutional authorities, etc.) were also possible intended users, but this was specified only in nine documents.[58,1146,1150,1153,1158,1160-1162,1164] The intended settings were also not exactly specified in most documents. Seven documents mentioned health care in community settings in addition to hospitals.[1146,1158,1160-1162,1164,1165] As far as it is possible to understand, the others are intended to be used primarily for care in hospital settings. Although not clearly specified in many documents, most of the recommendations relate to inpatient care.

Most documents stated that the intended outcome was to produce improvement in hand hygiene so as to contribute to the reduction in pathogen transmission and ultimately HCAIs and/or antimicrobial resistance. However, audit and measurable indicators were mentioned in only nine of them.[58,1148,1150,1151,1153,1158,1160,1162,1164]

Administrative approaches for implementation, such as the emphasis on the binding nature of the document, varied. Fourteen documents recommended the implementation of the guidelines as a priority,[58,1146,1147,1150,1151,1153,1157,1158,1160-1165] and eight stressed adherence to the guideline as a requirement.[1151,1158,1160-1165] All sub-national guidelines make this statement.

Although the general concepts concerning indications and methods to perform hand hygiene practices were similar in essence in all documents, the terminology used to describe various issues differed considerably between documents, thus making exact comparisons difficult. For example, terms such as decontamination and antisepsis were used synonymously in different documents. Several documents included a list of definitions, but the number of terms for which an explanation was provided and even its details varied. Definition of terms used to classify situations where hand hygiene practices were indicated also differed between documents. For example, in some cases, "social" indications meant contacts other than patient care (between HCWs, casual social contact between patient and HCWs, etc.). In some others, the same word was used to include all situations where plain soap and water was recommended as the method, including visible soiling with blood and body fluids. Others did not classify indications, but merely provided lists. In the present evaluation, three types of indications for hand hygiene were considered: social (contacts different from patient care), patient care, and surgical hand preparation. According to this classification, most guidelines appeared to have focused on the latter two types of indication. Five guidelines, three national and two sub-national,[1148,1150,1156,1161,1162] were developed primarily for routine patient care and had only social and routine patient-care indications.

Although indications and methods for hand hygiene were the focus for several national and all sub-national guidelines, the level of detail described varied considerably between documents. In general, the sub-national guidelines tended to have more technical details with easier to understand illustrations than the national documents, which were more advisory in nature. In some documents, the approach was to describe the methods according to indications (for example, "before" and "after" indications and then the appropriate methods) and, in others, the indications for a given method (e.g. all indications requiring handrubbing) of hand hygiene.

Most guidelines advocated hand hygiene for a variety of, but similar, "before" and "after" indications. Some documents advised that the decision for hand hygiene and choice of methods be based on risk assessment by the HCW.[1162,1165] Many guidelines also had "umbrella" indications that could include many different situations for hand hygiene. These meant that it was up to the HCW to decide whether hand hygiene was required or not for individual situations. The indications which were listed were meant to be examples and not to fulfil a complete list, at least in some. There were also differences in wording between documents which led to differences in situations included under one stated indication.

Overall, there is an overlap between stated indications from different documents. An analysis of what was stated in the documents was performed (Table VI.2). Among the indications "before" an activity for routine patient care, performing invasive procedures was the most mentioned. Among indications for hand hygiene "after" procedures during routine patient care, visible soiling of hands, and contact with blood, body fluids, wounds, catheter sites or drainage sites were the most frequently mentioned.

A few documents listed situations where hand decontamination was not required.[1147-1149,1151,1156] The situations included were before nursing care or the physical examination of non-immunocompromised patients, before and after short or social contact with non-immunocompromised patients, and after contact with surfaces not suspected of being contaminated.

Handwashing was the standard for routine patient care in seven documents,[1146,1148,1149,1155,1157,1164,1165] and alcohol-based handrub in seven others.[58,1150-1152,1156,1159,1160] Either handwashing or handrubbing were recommended in seven.[1147,1153,1154,1158,1161-1163] Most guidelines, especially sub-national, provided details of the procedures for hand hygiene and the analyses of their content in this regard are presented in Table VI.3. Handwashing was recommended in all documents for soiled hands. Handwashing with medicated soap was recommended as an alternative.

Several strategies were considered for promotion and implementation of the guidelines. Here again, details were more developed in the sub-national guidelines. In most cases, strategies recommended for implementation and sustainability were based on multiple elements. Ongoing education of HCWs, making materials required for hand hygiene easily available and accessible, monitoring performance, and attention to the skin care of HCWs were stressed to be the most important aspects: at least nine documents had some reference to all of these four issues.[58,1148,1150,1151,1153,1158,1160,1162,1164] One document had only a general discussion on various issues impacting on implementation, but without clear recommendations.[1154] Details provided in various documents were analysed.

Regular training was considered important in 15 guidelines,[58,1146,1148,1150,1151,1153,1154,1157-1162,1164,1165] and some information on areas to be covered was provided in five.[58,1153,1157,1160,1161] Reminders in the workplace were recommended by eight.[58,1153,1158,1160-1164] Wall-mounted dispensers for hand rub were recommended in 11[58,1147,1151-1153,1155,1158,1160,1162-1164] and pocket dispensers in 3.[58,1151,1164] Aspects of skin care were dealt with in 19 documents.[58,1146-1148,1150-1156,1158-1165]

Nine documents recommended monitoring of performance by an audit of hand hygiene, with direct observation being the method suggested in most documents.[58,1148,1150,1151,1153,1158,1160,1162,1164] Audit of product consumption was mentioned in three[58,1150,1153] and tools for audit were provided in three.[58,1153,1160] Feedback to HCWs was mentioned only in six guidelines.[58,1148,1150,1151,1158,1160] Two documents suggested the possibility of administrative actions in the case of non-compliance with hand hygiene recommendations.[1153,1160]

Outlines on how to choose a hand hygiene product were available in eight documents.[58,1151-1153,1158,1160-1162] Roles and responsibilities of stakeholders were considered at least in a very basic manner in eight documents.[1146,1150,1151,1153,1158,1160,1162,1164] Ten guidelines stressed the need for active HCW involvement for successful implementation,[58,1146,1148,1150,1153,1157,1158,1160,1161,1162] and four had recommendations for patient participation.[58,1160,1161,1164] Outlines for the location of handwashing facilities were provided in 13. [1146-1149,1152,1153,1156,1158,1160-1164] Reference to wider safety issues were made in four documents.[58,1153,1158,1160]

Detailed information on costing or cost–effectiveness was not provided in any guideline. Two documents included very basic information on this aspect.[1147,1150]

In summary, although the overall aim of all the documents included in the comparison was to give recommendations for optimal hand hygiene practices, there were wide variations in the scope, goals, content, breadth, and depth of topics covered. Lack of uniformity in terminology further compounded analytical differences. Many documents did not adequately cover several aspects, especially those essential for proper implementation and sustainability. Some of the recommendations were such that the HCW had to make decisions as to when and how to perform hand hygiene.

The *WHO Guidelines on Hand Hygiene in Health Care* were developed in 2005 as an advanced draft and have been finalized as the present document in 2008. This document has taken on board the above-mentioned concerns and bridged most of the gaps. This is the most extensively referenced and comprehensive guidelines for hand hygiene available to date. These guidelines are for use by policy-makers, managers, and HCWs in different settings and geographical areas. In many countries, guideline- and policy-developers are already using these guidelines as a resource for adaptation to local needs and logistics.

Guidelines developed by the CDC in 2002[58] are also used as a reference internationally. Both WHO and CDC guidelines are documents prepared specifically to promote hand hygiene. Both documents reviewed evidence extensively and used a similar grading system. The layout and the issues discussed are also broadly similar and include a wide variety of topics related to hand hygiene While the CDC guidelines are primarily intended for use in the USA and other Western countries, the WHO guidelines were conceived in a more global perspective and, therefore, are not targeted at only developing or developed countries, but all countries regardless of the resources available. Another general, but essential, difference of approach is that the present *WHO Guidelines* have been validated and finalized after a pilot test phase using a specific implementation strategy in different health-care settings worldwide.

Furthermore, in the present guidelines, evidence has been derived from more recent studies, details of how the evidence was collected are provided, and the recommendations are based on extensive international consultations. Although the CDC guidelines were constantly considered as a very valuable framework, many innovative aspects of hand hygiene are dealt with in the present WHO guidelines. For example, there are sections on mathematical modelling to understand the transmission of pathogens in health-care settings, local production of alcohol-based handrubs, religious and cultural aspects of hand hygiene, promotion of hand hygiene on a national scale, and social marketing, and including the detailed analyses of guidelines presented here. More details are also provided on behavioural aspects, infrastructure required for hand hygiene, and safety issues. The WHO guidelines are therefore more extensive. Details of hand hygiene procedures including pictorial representations are made available in the WHO guidelines, and more detailed strategies for promotion for use in a wider range of settings are also discussed.

Both documents present recommendations and indicate the grading of recommendations. Most are similar, but the WHO document (see Part II) has a few that are not considered in the CDC document and *vice versa*. Recommendations for handling medicines and food, and a set of recommendations for national governments provided in the WHO guidelines are examples. The respective strength for some recommendations also differs between the two documents. Outcome measurements are considered at great length in the WHO document. Other aspects such as the promotion of hand hygiene on a large scale and providing information to the public are also given due importance in these guidelines. CDC guidelines provide links to other web sites for further reference.

Table VI.1
Grading of evidence used in different guideline documents

	USA*					England**				France			Canada			Germany					Sweden			Ireland		
	IA	IB	IC	II	N	1	2	3	4	1	2	3	1	2	3	IA	IB	II	III	IV	I	II	III	I	II	III
Randomised controlled trials						√							√													
Well-designed studies	√									√				√		√					√			√		
Suggestive studies		√		√							√						√	√				√			√	
Case-control studies							√																			
Non-analytical studies								√																		
Theoretical rationale		√		√														√				√	√		√	
Most experts				√					√		√				√		√				√					√
Mandated by government			√																	√						
Unresolved Issue					√							√							√							

* CDC guidelines
** EPIC 2 guidelines

Table VI.2

Guidelines mentioning indications for hand hygiene before, after, and between activities

Before an activity	No. of guidelines	References
Performing invasive procedures	18	58,1146-1148,1150-1156,1158-1164
Any direct patient contact	16	58,1146,1148,1150-1154,1158-1165
Preparing, handling, serving or eating food, and feeding a patient	12	1148,1150-1153,1156,1158,1160-1165
Beginning of workshifts	11	1147,1149,1151,1153,1157,1158 ,1159,1161-1164
Care of particularly susceptible patients	10	1147-1149,1151-1154,1156,1158,1164
Contact with catheter sites and drainage sites	10	58,1146,1147,1150-1152,1156,1159,1163,1164
Eating	10	1146,1148,1149,1151,1153,1154,1157,1158,1163 ,1164
Patient contacts that may pose an infection risk to the patient	9	1147,1150-1156,1159,1164
Contact with wounds	8	1147,1151-1153,1156,1159,1161,1163
Using (any) gloves	7	58,1146,1149,1154,1160,1162,1163
Using sterile gloves for invasive procedures (not surgical)	6	58,1152-1154,1157,1163
Direct contact with patients who have antimicrobial-resistant organisms	6	1147,1151,1154,1156,1157,1163
Preparing and giving medication	6	1158,1160-1164
Handling of clean materials	4	1149,1152,1157,1164
Entering the clean part of staff changing rooms of operation areas, sterilization department, or other aseptic areas	2	1152,1158
Use of computer keyboard	1	1158
Caring activities after risk assessment	1	1147
Injections or venepuncture	1	1146
After an activity		
Contact with blood, body fluids, wounds, catheter sites or drainage sites	16	58,1146-1149,1151,1152,1154,1156,1157,1159-1164
Visible soiling of hands	15	58,1147-1159,1162
Glove removal	14	58,1146-1148,1150-1154,1158,1160,1161,1163,1164
Personal body functions	14	58,1146-1149,1152,1153,1156-1158,1161-1164
Contact with infectious patients	13	58,1147-1149,1151-1154,1156,1158,1162-1164
Contact with wounds	11	58,1147-1149,1151-1153,1156,1159,1160,1162
Contact with patient's intact skin	11	58,1150,1151,1153,1154,1156,1158,1160,1162-1164
End of work shift	9	1149,1151-1153,1157,1158,1161,1163,1164
Contact with inanimate objects in the immediate vicinity of the patient	7	58,1147,1151,1153,1158,1160,1162
Microbial contamination	5	1147,1148,1153,1156,1159
Suspected or proven exposure to spore-forming pathogens	1	58
Contact with items known or suspected to be contaminated	1	1161
Using computer keyboard	1	1158
Between activities		
Contact with different patients	9	1147-1151,1155-1157,1164
Moving from a contaminated to a clean body site of the same patient	7	58,1147,1148,1151,1153,1160,1164
Different caring activities on the same patient	4	1148,1151,1162,1164
Contact with different patients in high risk units	3	1147,1153,1164

Table VI.3
Guidelines including specific recommendations regarding hand hygiene techniques

	Routine (n=21)		Surgical (n=16)	
Preparation (removal of rings, bracelets, etc.)	19		13	
Surfaces to be cleaned	18		10	
Brushing technique	—		9	
	Handwashing	Handrubbing	Handwashing	Handrubbing
Recommended	21	19	16	8
Agent	Soap – 21 Liquid (plain or medicated) – 20 Bar soap as alternative – 3	Gel – 4 Other – not specified	Medicated bar or liquid soap	
Number of documents where the following are mentioned				
Quantity of product*	10	10	4	3
Duration	18 (10–15 sec in most)	13 (15–30 sec) Some – until dry	15	6
Drying Disposable/sterile towel	21 21	—	13 12	—

*Some other documents refer to the manufacturers' recommendations.

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APPENDICES

Appendix 1.

Definitions of health-care settings and other related terms

HEALTH SYSTEM: all the activities whose primary purpose is to promote, restore or maintain health

(The World Health Report 2000 – Health systems: improving performance)

DEFINITIONS FROM THE WHO GLOSSARY OF TERMS

(available at: http://www.wpro.who.int/chips/chip04/definitions.htm)

Health infrastructure

- ***General hospital***. A hospital that provides a range of different services for patients of various age groups and with varying disease conditions.

- ***Specialized hospital***. A hospital admitting primarily patients suffering from a specific disease or affection of one system, or reserved for the diagnosis and treatment of conditions affecting a specific age group or of a long-term nature.

- ***District/first-level referral hospital***. A hospital at the first referral level that is responsible for a district or a defined geographical area containing a defined population and governed by a politico-administrative organization such as a district health management team. The role of district hospitals in primary health care has been expanded beyond being dominantly curative and rehabilitative to include promotional, preventive, and educational roles as part of a primary health-care approach. The district hospital has the following functions:

  – it is an important support for other health services and for health care in general in the district;
  – it provides wide-ranging technical and administrative support and education and training for primary health care;
  – it provides an effective, affordable health-care service for a defined population, with their full participation, in cooperation with agencies in the district that have similar concerns.

- ***Primary health-care centre***. A centre that provides services which are usually the first point of contact with a health professional. They include services provided by general practitioners, dentists, community nurses, pharmacists and midwives, among others.

Health workforce

- ***Physicians/doctors***. All graduates of any faculty or school of medicine, actually working in the country in any medical field (practice, teaching, administration, research, laboratory, etc.).

- ***Midwives***. All persons who have completed a programme of midwifery education and have acquired the requisite qualifications to be registered and/or legally licensed to practise midwifery, and are actually working in the country. The person may or may not have prior nursing education.

- ***Nurses***. All persons who have completed a programme of basic nursing education and are qualified and registered or authorized to provide responsible and competent service for the promotion of health, prevention of illness, the care of the sick, and rehabilitation, and are actually working in the country.

- ***Pharmacists***. All graduates of any faculty or school of pharmacy, actually working in the country in pharmacies, hospitals, laboratories, industry, etc.

- ***Dentists***. All graduates of any faculty or school of dentistry, odontology or stomatology, actually working in the country in any dental field.

- ***Other health-care providers (including community health workers)***. All workers who respond to the national definition of health-care providers and are neither physicians/doctors, midwives, nurses, pharmacists, or dentists.

Inpatient. A person who is formally admitted to a health-care facility and who is discharged after one or more days.

Outpatient. A person who goes to a health-care facility for a consultation, and who leaves the facility within three hours of the start of consultation. An outpatient is not formally admitted to the facility.

DEFINITIONS FROM THE EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES

(available at http://www.euro.who.int/observatory/Glossary/TopPage?phrase=D)

Ambulatory care. All types of health services provided to patients who are not confined to an institutional bed as inpatients during the time services are rendered (USAID, 1999). Ambulatory care delivered in institutions that also deliver inpatient care is usually called "outpatient care". Ambulatory care services are provided in many settings ranging from physicians' offices to freestanding ambulatory surgical facilities or cardiac catheterization centres. In some applications, the term does not include emergency services provided in tertiary hospitals (USAID, 1999).

Day care. Medical and paramedical services delivered to patients who are formally admitted for diagnosis, treatment or other types of health care with the intention of discharging the patient the same day.

Long-term care. Long-term care encompasses a broad range of help with daily activities that chronically disabled individuals need for a prolonged period of time. Long-term care is primarily concerned with maintaining or improving the ability of elderly people with disabilities to function as independently as possible for as long as possible; it also encompasses social and environmental needs and is therefore broader than the medical model that dominates acute care; it is primarily low-tech, although it has become more complicated as elderly persons with complex medical needs are discharged to, or remain in, traditional long-term care settings, including their own homes; services and housing are both essential to the development of long-term care policy and systems. Nursing homes, visiting nurses, home intravenous and other services provided to chronically ill or disabled persons.

Social care. Services related to long-term inpatient care plus community care services, such as day care centres and social services for the chronically ill, the elderly and other groups with special needs such as the mentally ill, mentally handicapped, and the physically handicapped. The borderline between health care and social care varies from country to country, especially regarding social services which involve a significant, but not dominant, health-care component such as, for example, long-term care for dependent older people.

Appendix 2.

Guide to appropriate hand hygiene in connection with *Clostridium difficile* spread

Hand hygiene and infection control

Hand hygiene is a crucial action recommended for preventing and controlling the transmission of pathogens within health-care settings to ensure that patients remain safe and that their risks of acquiring infection are minimized. Hand hygiene is an essential practice for all health-care workers (physicians/doctors, midwives, nurses, pharmacists, dentists, and other care providers including community health workers and family members) in order to protect the patients and themselves.

The method employed in ensuring that hand hygiene is effective falls into one of two categories:

- **Handrubbing with an alcohol-based handrub**
  Handrubbing is the gold standard technique to perform hand hygiene on all occasions except for those described for handwashing with soap and water, i.e. handrubbing is the action recommended for health-care workers for the routine, day-to-day decontamination of hands.

- **Handwashing with soap and water:**
  Handwashing still occupies a central place in hand hygiene and should be employed when hands are visibly dirty or visibly soiled with blood or other body fluids; after using the toilet; and when exposure to potential spore-forming pathogens is strongly suspected or proven, including during outbreaks of diarrhoea.

Correct method at the correct moment

Understanding and employing the correct method and technique at the correct moment is highly likely to result in optimum compliance with hand hygiene and maximum safety of patients and staff.

The advantages and disadvantages of both alcohol-based handrubs and handwashing with soap and water can be found throughout the *WHO Guidelines on Hand Hygiene in Health Care*. The following information is intended to support health-care workers and others in understanding and explaining the challenges presented by patients with *C. difficile* infection, particularly in relation to hand hygiene.

Specific challenges posed by patients with diarrhoeal illnesses

Preventing and controlling the spread of all diarrhoea-related bacteria, viruses, and parasites is always important. One of the main actions in this regard is to ensure that hands are *washed thoroughly with soap and water* when they are:
- visibly dirty or visibly soiled with blood or other body fluids;
- after using the toilet;
- when exposure to potential spore-forming pathogens is strongly suspected or proven, including during outbreaks of *C. difficile*.

What is *Clostridium difficile*?

Background information on *C. difficile* is available from a range of scientific and patient support documents. The following information is an overview of what *C. difficile* is and the problems it can cause.

C. difficile is a bacterium (germ) that is present naturally in the bowel of some individuals. It can spread by touching faecally contaminated surfaces and then touching your mouth, e.g. when eating. It can also spread following contact with the faeces of people who have the infection, if the bacterium is ingested through your mouth.

If someone is taking antibiotics to treat an infection, they can kill the good bacteria living in the bowel as well as the bad; when this happens *C. difficile* can grow quickly in the bowel and produce toxins that lead to disease. *C. difficile* is passed out in the faeces of people who are infected, including in the form of spores (a hardy form of the bacterium), which can survive for a long time in patient surroundings on any surface, e.g. toilet areas, clothing, sheets, and furniture, if these items are not regularly and appropriately cleansed. It is possible for anyone to spread the infection (to themselves or others) because they have not performed hand hygiene properly or kept patient surroundings clean. Elderly people and patients with comorbidities or who have had certain medical procedures to the bowel are especially at risk of getting *C. difficile* infection.

Why have there been increasing numbers of cases in certain countries recently?

This is not entirely clear, though it is known that a number of factors may be responsible, including natural changes to the way in which bacteria act in relation to their circumstances; for example, *C. difficile* becoming more resistant to antibiotics in response to their increased and more widespread use. The growing numbers of elderly, sick patients receiving care, the pressures on health-care workers to deliver care, and the way in which services such as cleaning are provided to health-care settings may all have had an impact. New strains of *C. difficile* have evolved in recent years that appear to spread more readily and may cause more severe cases of illness. It is also possible that the recommended practices for preventing and controlling *C. difficile* are not always applied for a number of reasons and may, as a result, be contributing to the current problem. Finally, in some countries where there has been no surveillance of *C. difficile* until now, reports of rising numbers may be explained because they are now looking for it.

Can appropriate infection control practices help prevent and control *Clostridium difficile*?

Yes, they can. It is recommended that gloves be worn (together with gown and application of other contact precautions) and hands washed appropriately if exposure to potential spore-forming pathogens is strongly suspected or proven, including *C. difficile* outbreaks. The method of hand hygiene to be employed must be handwashing using soap and water. Even when gloves have been worn, handwashing is essential. Of note, it is important that the correct technique for handwashing is applied. In all other health-care situations, alcohol-based handrubs remain the preferred method for hand hygiene and the most reliable method to ensure maximum compliance and efficacy to reduce health care-associated infections and cross-transmission of pathogens.

What is the concern about health-care workers using alcohol-based handrubs at the point of care when patients have *Clostridium difficile*?

There is concern because alcohol-based handrubs are known to be less effective on soiled hands generally and, specifically, when there is *C. difficile* infection. This is because of the handrubs' inability to kill the *C. difficile* spores that at times can be present.

Conveying simple messages to health-care workers, through routine training and updates, and reinforcing these during times of outbreaks will help to ensure that the correct methods for hand hygiene are applied at the correct moments. To sum up, these messages are repeated in the diagram.

Routine method for health-care workers dealing with all patients at all times, with the exception of:

- visibly dirty or visibly soiled hands (with blood or other body fluids)
- after using the toilet
- when exposure to potential spore-forming pathogens is strongly suspected or proven, including during outbreaks of *C. difficile*

RUB (use an alcohol-based handrub)

Special measures for health-care workers in the presence of Clostridium difficile (diarrhoea)

- use gloves for all contacts with patients and their surroundings (and wear a gown as part of contact precautions)
- when hands are visibly dirty or visibly soiled with blood or other body fluids after using the toilet
- when exposure to potential spore forming pathogens is strongly suspected or proven, including during outbreaks of C. difficile.

WASH (use soap and water)

Should we remove alcohol-based handrubs from areas where there is *Clostridium difficile* infection?

No. Alcohol-based handrubs are required at the point of care for a number of reasons:

- They are easy to use and therefore more likely to result in greater compliance with the need for hand hygiene by health-care workers.
- They are proven to be effective in killing a range of pathogens and therefore reducing patients' risk of acquiring health care-associated infection.
- They are effective in killing the non-spore form of *C. difficile* which may be present in higher numbers than the spores.
- Sinks for handwashing are not always readily available and, even if they were made available right next to a patient, washing takes at least twice as much time than rubbing – all factors that mitigate against full compliance with hand hygiene. Relying on promoting handwashing only in health care is thought to result in lower compliance, lower efficacy and greater risk of continued spread of pathogens.
- Evidence-based research reinforces the need for the presence of alcohol-based handrubs to ensure maximum patient safety.
- There is no evidence to suggest that their use has been connected with increased *C. difficile* infections.

Thus, alcohol-based handrubs should **NOT** be removed from health-care settings; to remove them would be likely to result in greater risk to patients from health care-associated infections.

Are visibly clean (not soiled) hands still at risk for cross-transmission?

It is very unlikely. Because handwashing with soap and water is recommended when exposure to potential spore-forming pathogens is strongly suspected or proven (this includes outbreaks of *C. difficile),* it is very unlikely that using alcohol-based handrubs on visibly clean hands will put patients at risk of cross-infection. In fact alcohol-based handrubs are effective in killing the non-spore form of *C. difficile* that can also be present. Therefore, appopriate glove use and adopting either means of performing hand hygiene on non-soiled hands will ensure clean, safe hands.

The bottom line is to remember the message that hands should be washed thoroughly with soap and water when they are visibly dirty or visibly soiled with blood or other body fluids.

How often will the spores be present when patients have *Clostridium difficile* infection?

When patients with *C .difficile* have severe diarrhoea, large amounts of spores can be present. This is the basis of all the recommendations featured here. This is also true of specific strains of *C. difficile,* including those that are epidemic in certain countries. Effective hand hygiene at the point of care, together with other well-accepted control measures (in particular, glove use and gowning as part of contact precautions, and individual rooms), helps to manage the problem.

Clostridium difficile figures are very high is some countries, and seem to have become worse. Is this because of alcohol-based handrubs?

There is published evidence that the extensive use of alcohol-based handrubs in hospitals has **not** led to an increase in *C. difficile*.

Does the promotion of alcohol-based handrubs imply the "downgrading" of sinks and handwashing?

No. Guidance usually highlights the fact that handwashing is essential in specific situations (as described above). Although washing hands with soap and water remains an accepted method for routine hand antisepsis, alcohol-based handrubs should be promoted as the gold standard for hand hygiene considering, in particular, their dramatic impact on improving compliance with hand hygiene and ensuring clean, safe hands.

What other key measures should be taken to prevent and control *Clostridium difficile*?

There are several measures, including performing hand hygiene, that should be applied to prevent and control *C. difficile* infection, and these have been published widely. The following is a brief description of these key steps, which should be in place when *C. difficile* infection is present.

- Antimicrobial prescribing is a crucial part of preventing, controlling and managing *C. difficile* infection. Guidance is widely available on this. Antibiotic stewardship is therefore an important part of health-care services to control *C. difficile*, as is the appropriate prescribing of other drugs including antacids and perhaps proton pump inhibitors.
- Patients with, or strongly suspected of having, *C. difficile* infection should be cared for in a single room with a toilet or dedicated commode and other dedicated care equipment until they are symptom-free for at least 48 hours. If single rooms are not available, cohorting of patients with *C. difficile* infection should be considered in conjunction with risk assessment and infection control expertise.
- Patients with *C. difficile* infection should have their surroundings and other areas of concern, e.g. toilet areas, cleaned at least daily using clean equipment and a freshly-made solution containing at least 1000 ppm available chlorine (this can be done by cleaning areas as normal and then using a "bleach" to clean afterwards or by using a combined detergent and chlorine-based solution). It should be noted that non-chlorine-based cleaning agents can promote the formation of *C. difficile* spores. Air drying should be allowed following cleaning.

- Health-care workers should wear gloves and aprons when providing care for patients with *C. difficile* and should discard them immediately after they have been worn for a patient-care activity. Hand hygiene must then be performed. There is evidence that wearing gloves significantly reduces *C. difficile* infection and is therefore crucial, even though handwashing reduces spores and alcohol-based handrubs are effective against non-spore forms of *C. difficile*.

Washing of clothing (including staff uniforms), bed linen, etc. – both in health-care settings using industrial processes and in the home – is also important when someone has *C. difficile* infection. Careful handling of contaminated clothing is essential in order to prevent the spread of any of the bacteria or its spores to hands or other items. Key points to consider for laundering include:

- always hold laundry away from yourself;
- do not sort through laundry unless absolutely necessary and do not shake it;
- perform hand hygiene after handling laundry;
- use normal detergent to wash the laundry;
- dry laundry either in a tumble dryer or on a washing line;
- iron clothes according to their instructions, using a hot steam iron if possible;
- keep clean the machines or sink areas where laundry has been washed.

Organizational steps are also important in aiding prevention and control. An adequate health-care infrastructure should be in place, including:

- a functioning and effective infection prevention and control team;
- functioning and effective communication strategies and information available for patients and visitors;
- written guidance that sets standards and assigns responsibilities, including monitoring of recommended practices against the standards;
- surveillance and education programmes, with multidisciplinary teams working to ensure targeted management and control.

There are also other specific measures that are recommended during outbreaks of *C. difficile* (http://www.cdc.gov/ncidod/dhqp/id_Cdiff.html)[1]

Summary

Preventing and controlling the spread of all diarrhoeal diseases is important. The main message is that hands should be washed thoroughly with soap and water when they are: visibly dirty or visibly soiled with blood or other body fluids; after using the toilet; or when exposure to potential spore-forming pathogens is strongly suspected or proven, including during outbreaks of *C. difficile*.

Performing hand hygiene using an alcohol-based handrub is the recommended and most effective method to clean hands in most patient-care situations. According to recent evidence, alcohol-based handrubs have been a major factor in the reduction of serious infections such as MRSA, for example in the United Kingdom.

It is important that the correct technique for hand hygiene is always applied.

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[1] Vonberg RP et al. Infection control measures to limit the spread of *Clostridium difficile. Clinical Microbiology and Infection,* 2008, 14(Suppl. 5):2-20.

Appendix 3.

Hand and skin self-assessment tool

Rate the current condition of the skin on your hands on a scale of 1–7								
Appearance								
Abnormal: red, blotchy, rash	1	2	3	4	5	6	7	Normal: no redness, blotching, or rash
Intactness								
Many abrasions or fissures	1	2	3	4	5	6	7	Completely intact: no abrasions or fissures
Moisture content								
Extremely dry	1	2	3	4	5	6	7	Normal amount of moisture
Sensation								
Extreme itching, burning, or soreness	1	2	3	4	5	6	7	No itching, burning, or soreness

Sources: adapted from Larson E et al. Physiologic and microbiologic changes in skin related to frequent handwashing. *Infection Control*, 1986, 7:59-63 and Larson E et al. Prevalence and correlates of skin damage on the hands of nurses. *Heart & Lung*, 1997, 26:404-412.

Appendix 4.

Monitoring hand hygiene by direct methods

The power calculations detailed in Part III, Section 1.1 of the *WHO Guidelines for Hand Hygiene in Health Care* are critical for obtaining reliable estimates of the percentage of hand hygiene compliance at the organization level at a single point in time. The objective of these calculations is to determine the sample size necessary to produce results that can be generalized to larger populations and can meet the defined degree of confidence and margin of error. These considerations are similar to those involved in conducting point-in-time research. Examples of this approach can be found in political polling, market research, and educational testing. When measurements are made in the context of an improvement initiative, however, the research questions and approaches to sampling are different. An improvement team is typically interested in answering the following questions: (1) are we making progress toward a goal of increased hand hygiene compliance? and (2) how will we know when we have reached the goal?

Studies aimed at improvement, known as analytical studies,[1] seek only enough data, collected repeatedly at suitable intervals, to detect and track the effectiveness or efficiency of improvement efforts over time. The requirements for data collection and inference under such circumstances are different from those required by clinical or population research aimed at answering questions about efficacy.[2] For instance, you do not need a valid scale to monitor weight loss, only a consistent one. It does not matter if the scale reads a few pounds too light or too heavy; as long as the readings are reasonably consistent: you can successfully track your progress over time, and you will know when you have lost that extra 10 pounds because your daily readings will hover around the desired level. Of course, if your goal is to weigh exactly 150 lb, you will need a scale that is valid as well as reliable.

In the case of improving hand hygiene, the improvement goal typically is to bring compliance (i.e. the percentage of fulfilled hand hygiene opportunities) above 95% by introducing systems improvements, behavioural incentives, education, and other interventions described elsewhere in these guidelines. The challenge for improvers, therefore, is to determine if progress is being made towards the target, and when it has been reached. In order to judge the effects of the interventions, baseline measures should be taken on the units where improvement work is under way; then performance over time can be compared with the baseline and the desired target or goal.

Sampling strategies for tracking improvement initiatives draw from both probability and non-probability sampling techniques. For ministries of health or other agencies that are interested in gauging the impact of an initiative in a region, a province or a health system, it may be desirable or necessary to start the work and track progress in a small sample of institutions or settings. For example, imagine that you have 12 clinics spread out across a region. Rather than collecting detailed data at all 12 clinics every day you might want to select one clinic to pilot test a new strategy for hand hygiene compliance. You could select a clinic to be the pilot, based on your knowledge of the clinics (e.g. Clinic 4 has experience with improvement work and would be more receptive to trying a new project related to hand hygiene compliance). This is what Deming characterized as judgement sampling.[3] Another approach would be to randomly select one of the clinics to be the pilot. To do this you would write the numbers 1–12 on separate pieces of paper (it is best to use the same size of paper) place them in a bowl and stir them around. Without looking at the pieces of paper, reach into the bowl and select one piece of paper. If the number 7 was on this piece of paper then Clinic 7 would be the one that you have randomly selected to be the pilot clinic for our hand hygiene test. Once a unit of analysis has been selected, you will need to make decisions on two key concepts related to improvement studies: (1) the *number of data points* needed to represent accurately the variation in the process and (2) the *number of observations* included in each data point. Both of these concepts are briefly described below.

Whether you are using judgement sampling based on your knowledge of the unit(s) of analysis or simple random sampling where all units of analysis have an equal probability of being selected, you should try to obtain around 20 data points (or subgroups) before analysing the variation in the process. The general assumption behind this guidance is that a relatively stable distribution of the results starts to form when you have 15–25 data points.[4-6] When you have fewer than 15 data points the variation in the process has a tendency to be quite volatile and the probability of improperly representing the current variation due to a type I or type II error increases.[7] Obtaining around 20 data points, therefore, taken within the unit of analysis where improvement efforts are under way, can provide a robust enough estimate to gauge whether improvement is occurring.

When tracking hand hygiene compliance, the preferred measure is typically a percentage where the numerator is the total number of times an HCW was observed to have appropriately washed his or her hands before and after a patient encounter. The denominator is the total number of observations made. When analysing data based on percentages it is advisable to have denominators that are at least in the double digits. The general guidance is that a minimum of 12–15 observations should be in the denominator before a percentage is calculated. For example, if you have only 4 observations in the denominator and 2 of the HCWs (the numerator) properly washed their hands this produces a 50% compliance number (2/4 = 50%). But this is not as robust a 50% calculation as one with a denominator of 18 with 9 HCWs as the numerator. Data collection for improvement not only needs to be based on sound statistical methods but it also needs to be practical and reasonably easy for the data collectors. Those interested in gaining more insight on more precise sampling estimates than those offered in the

general guidelines described above should consult standard references on quality improvement methods.[2]
A practical yet robust data collection plan for tracking the percentage of workers adhering to proper hand hygiene compliance could be set up as follows:

- select a unit of analysis to be the pilot unit or clinic;
- select a random day each week to observe hand hygiene compliance;
- on selected days, collect a minimum of 15 observations of hand hygiene opportunities (the denominator);
- out of these opportunities determine the number of times hand hygiene was completed properly (this is the numerator);
- compute the percentage of hand hygiene compliance for that week;
- repeat this process for the next 15–20 weeks, as work goes forward on improving compliance:
- use a run chart (see below) to assess the success of the improvement efforts.

As measurements will be used to gauge which interventions are successful for improving compliance, the pace of data collection should match the pace of the improvement efforts. If you can collect 12–15 opportunities several times a week, then instead of collecting 1–20 weeks of data you can analyse the data each day or several days a week rather than wait for one data point each week. In this regime, feedback to the improvers will occur more rapidly, and they will be able to make more timely adjustments in their efforts. Important considerations in the decision about how frequently to measure are (1) the ability of the data collectors to gather data more frequently; and (2) having sufficient opportunities to observe hand hygiene compliance so that the denominators are appropriate.

Note that when you repeatedly gather samples over time (e.g. daily or weekly) the sample size increases quickly. For example, if you perform 25 hand hygiene observations each week you will have 100 observations in a month. This provides a very robust and stable distribution of data points for analysis.

Once the data have been obtained, statistical process control (SPC) methods are the preferred way to analyse process performance over time. The basic tools in this branch of applied statistics are run charts and Shewhart control charts. These tools can provide a degree of statistical confidence similar to that achieved by more familiar statistical tests that use *p* values and confidence intervals. Run charts, for example, perform at roughly the 95% confidence interval, while the more robust control chart functions at a level equivalent to the 99% confidence intervall.[7]

A run chart provides a running record of a process over time. It offers a dynamic display of the data and can be used on virtually any type of data (e.g. counts of events, percentages, wait times or physiological test results). Because run charts do not require complex statistical calculations they can easily be understood and constructed, and can be applied by those who lack formal statistical training. Most improvement teams start out with run charts because they are easy to grasp, do not require computers to develop, and provide a good foundation to move eventually to the more robust control charts.

Interpreting run charts for significance involves the application of a set of decision rules based on sequential patterns of observations that refute the assumption that the measures were drawn from a completely random system.[8] Such patterns are based on the notion of "runs." An example is shown in Figure 1. Note that time is displayed on the horizontal axis, while the measure of interest is plotted on the vertical axis. The centreline on the graph is the median. Runs are defined relative to the median. A run consists of one or more consecutive data points on the same side of the median. Data points falling on the median are not counted. In Figure 1 the chart contains 4 runs as shown by the circles drawn around the data clusters. Two data points fall on the median.

Once the number of runs has been determined, the next step is to apply four run chart rules to determine if the data on the chart display random or non-random patters of variation. The run chart rules designed to detect a non-random pattern in the data include:

Rule 1: A shift in the process, or too many data points in a run (6 or more consecutive points above or below the median).

Rule 2: A trend
(5 or more consecutive points, all increasing or decreasing).

Rule 3: Too many or too few runs
(use a table to determine this one).

Rule 4: An "astronomical" data point, which is a point that visually is dramatically higher or lower that all the other data points. This is a judgement call when using the run chart and should be used not to determine statistical significance but rather as a signal that more rigorous analysis with a control chart is needed.

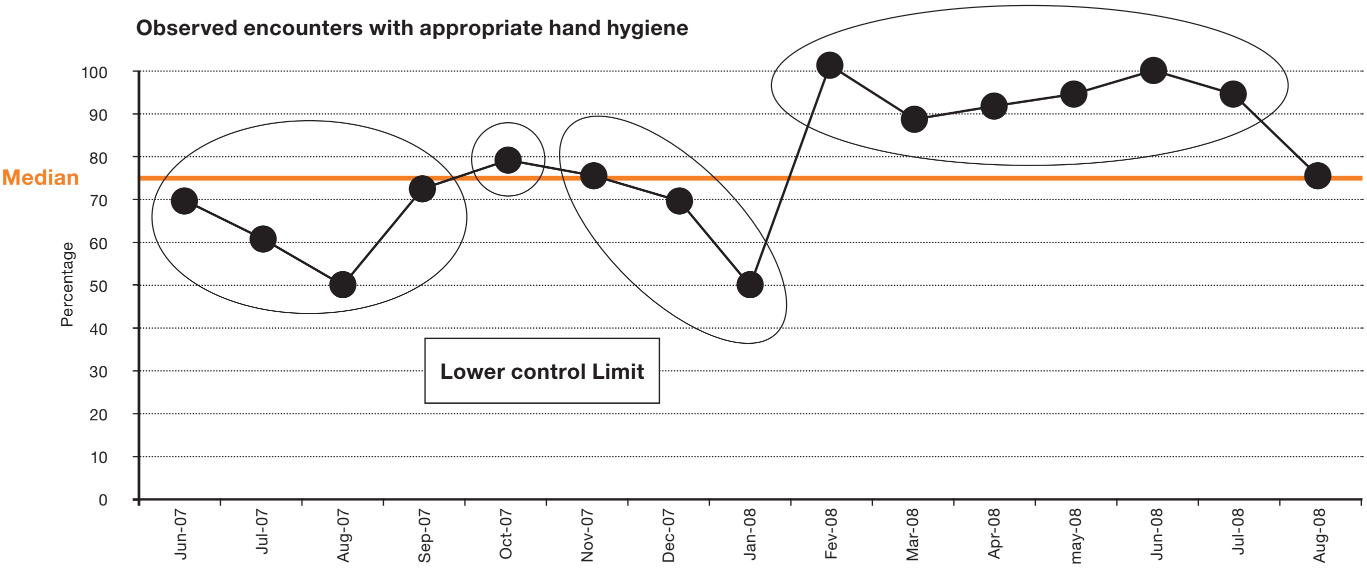
Figure 1 shows that the data have, in fact, shifted upwards. This is determined by seeing that the last run contains 6 consecutive data points above the median, which is a signal of a non-random pattern. In this particular case this is a desirable outcome to observe, because it shows that the intervention the team put in place between January and February of 2008 had the desired effect (i.e. the percentage of hand hygiene compliance increased).

As improvement teams become more comfortable with data collection and analysis, the next logical progression analytically is to place the data on a control chart. Control charts are very similar to the run charts with the following exceptions:

- the median is replaced with the mean;
- the upper and lower control limits (known as sigma limits) are computed;
- more robust statistical tests are applied to the charts to detect what Walter Shewhart (1931) called common and special causes of variation.

The appropriate control chart for hand hygiene compliance is what is known as a p-chart. In this case, the "p" stands for a percentage or proportion (i.e., the percentage of HCWs properly cleaning their hands). There are six other basic control charts that form the foundation for SPC analysis. Given that there is only one way to make a run chart and many ways to make control charts, it is advisable to start out improvement teams by making the run chart. As they gain greater knowledge of and comfort with statistical methods, they can move to the application of control charts. Standard texts will provide the reader with a full background on the theory and application of control charts.[3-7,9-11] A good short treatment of Shewhart chart construction can be found in Mohammed et al.[12].

Figure 1.
Hand hygiene run chart



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Appendix 5.
Example of a spreadsheet to estimate costs

A spreadsheet for completion by an individual health-care institution allows the input of local data and will indicate likely cost savings over time. The example below is used in the England and Wales "clean*your*hands" campaign. Values are for the purposes of example.

Data in coloured cells can be changed	
Upfront costs	
This is the estimated additional upfront cost of	**£2 351**
equipping each bed in your Trust with alcohol rub	
Trust information	
Number of general and acute care beds	500
Occupancy rate	85.4%
Total general and acute care admissions	20 000
Procurement	
Do you intend to use PASA? (choose Yes or No)	Yes
Hand hygiene compliance	
Initial handwashing compliance rate	28.4%
Target handwashing compliance rate (after 5 years)	76.2%
Current usage and spending	
Current annual alcohol rub usage (litres)	100
Current annual alcohol rub spend (£)	810
Current annual alcohol unit cost (£ per litre)	8.10
Current volume per 1000 patient-days (litres)	0.64
Current cost per 1000 patient-days (£)	5.20
PASA unit costs	
£ per litre	6.40
Prospective	
New alcohol gel unit cost	6.40
Volume per 1000 patient-days	6.49
Final annual alcohol gel usage (litres)	1 011
Final annual alcohol gel cost (£, at current unit costs)	8 193
Final annual alcohol gel cost (£)	6 474
Central campaign costs	
Costs of posters, etc. – average cost per bed (£)	2.56

Data in coloured cells can be changed	
HCAI information	
Rate of HCAI (inpatient phase)	7.8%
Achievable reduction in HCAI	9.0%
Target reduction in HCAI	9.0%
Current annual deaths	18
Excess inpatient cost for those with HCAI	3 777
Current estimated HCAIs	1 560
Average QALYs lost (fatal infection)	7
Average QALYs lost (non-fatal infection)	0.007
Additional costs incurred by patients (£)	6.9
Average additional primary care costs (£)	23.5
Average costs of additional informal care (£)	149
Average production gains (£)	408
Discount rates	
Discount rate – financial costs and benefits	3.5%
Discount rate – QALYs	1.5%
Perspective	
Perspective for evaluation (choose hospital or society)	Hospital

PASA = Purchasing and Supply Agency;
QALY = quality-adjusted life year.

Appendix 6.

WHO global survey of patient experiences in hand hygiene improvement

A survey was undertaken during 2007–2008 to ascertain the views of patients in relation to health care-associated infection (HCAI) and, in particular, the role that patients can play in hand hygiene improvement (see the summary included in Part V of *WHO Guidelines on Hand Hygiene in Health Care*).

Details of the study design, preliminary data analysis and results for all questions, as well as specific details from case-studies, can be accessed at: http://www.who.int/patientsafety/challenge/en.

In total, 457 questionnaires were collected during the study period. The geographical distribution of respondents is shown in Table 1.

Table 1.
Respondents by WHO region

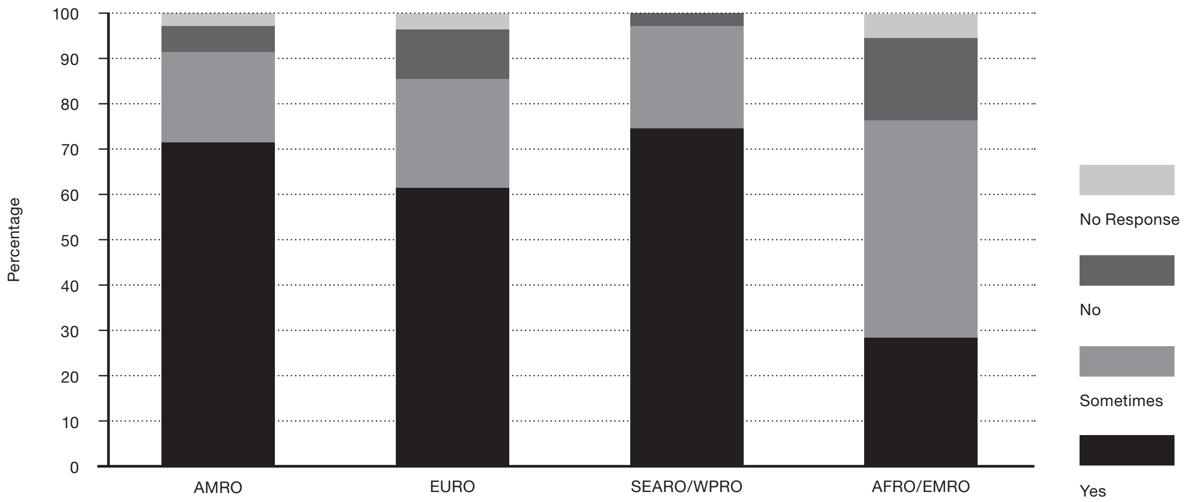
WHO region	No. of respondents	Percentage
The Americas (AMR)	237	52%
Europe (EUR)	161	35%
South East-Asia (SEAR) and the Western Pacific (WPR)*	42	9%
Africa (AFR) and the Eastern Mediterranean (EMR)*	17	4%

* Because of the relatively low number of respondents, the results from SEAR/WPR and AFR/EMR have been merged.

Existing infrastructure

Availability and ease of access to products is the cornerstone of the WHO Hand Hygiene Improvement Strategy, described as "system change" within the *Guidelines'* recommendations. For this reason, respondents were asked to indicate whether such products were readily available (see Figure 1).

Figure 1.
Availability of products by WHO region



The patient experience

I was in a special care unit for three days recently, too sick to think about handwashing, but I never saw even one health-care worker wash/sanitize her hands before coming to my bedside (survey respondent, USA).

Twenty-nine percent of respondents stated that they had asked a health-care workers (HCW) to wash or sanitize his/her hands. Regional analysis shows that the greatest percentage of positive responses was from the Region of the Americas and the least from the European Region (Table 2).

Table 2.
Patient experiences of patient participation by WHO region

Have you ever asked your health-care worker to wash or sanitize his/her hands (Q5)	AMR	EUR	SEAR/WPR	AFR/EMR
Yes	85 (36%)	28 (17%)	16 (38%)	5 (29%)
No	151 (64%)	132 (82%)	26 (62%)	10 (59%)
No response	1 (0.3%)	1 (1%)	0	2 (12%)

Respondents were asked to provide additional information relating to their experiences. Figure 2 illustrates some themes from around the world relating to patient-perceived barriers to involvement.

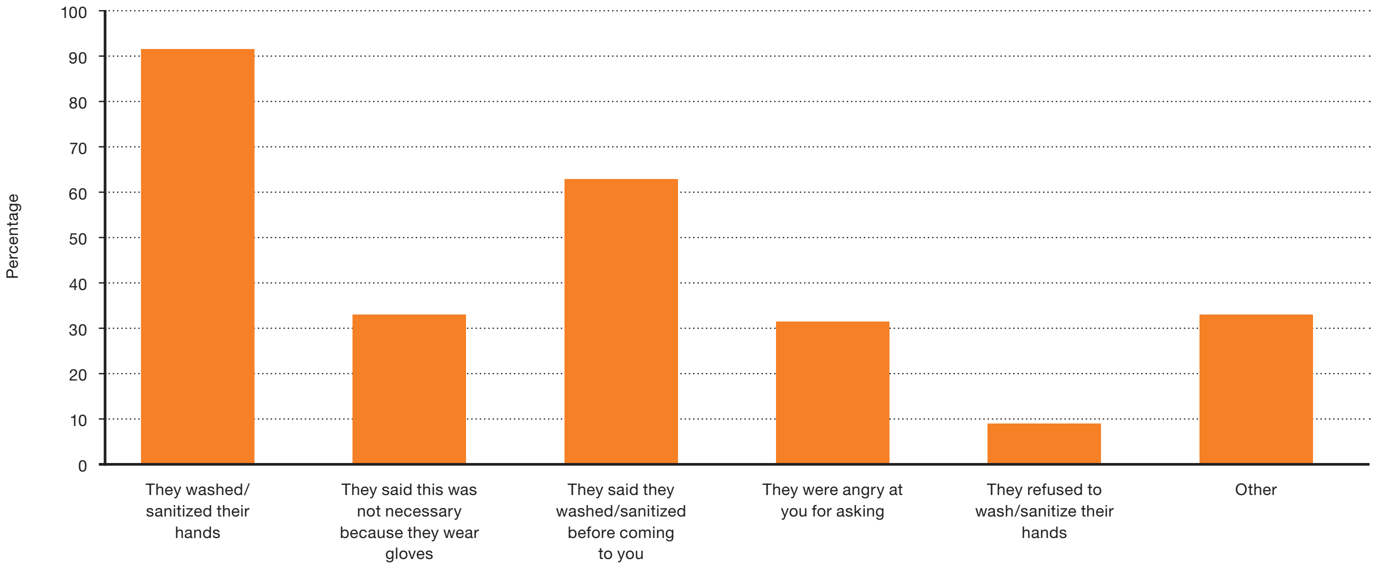
Figure 2.
Free text related to patient-perceived barriers to patient involvement

Heatlh-care worker response

First it is necessary to change the cultural barriers: patients have no right to tell the physicians what to do (survey respondent, Slovenia).

The way in which HCWs communicate risk and the nature of their response to being asked was central to the survey. A sub-analysis of responses (Figure 3) to the question related to the HCW's reaction and/or answer when asked to practice hand hygiene reinforces the importance of ensuring that HCWs are prepared for strategies that include patient participation.

Figure 3.
Response to patient requests for hand hygiene



Expectations

If the doctor said, please remind me, I would find it quite easy to say, you asked me to remind you to wash your hands...it would be similar to my saying why I was there, or giving the doctor an update on medication, etc...that is, just part of the routine (survey respondent, USA).

When presented with scenarios in which a HCW invited the patient to remind them to clean their hands, 86% reported that they would feel comfortable doing so. This decreased to 52% when not invited, and increased to 72% when they were presented with a scenario where failure to comply was observed. These high rates were probably attributable in some part to the hypothetical nature of the questions. Table 3 illustrates overall responses to these scenarios.

Table 3.
Patient expectations in hypothetical situations

	Yes	No	No response
If your doctor, nurse or other person providing health care to you **asked or invited** you to remind them to wash/sanitize their hands before examining you, would you feel able to do this? (Q8)	86%	11%	2%
If your doctor, nurse or other person providing health care to you **did not ask or invite** you to remind them to wash/sanitize their hands before examining you, would you feel able to do this? (Q10)	52%	44%	4.6%
If **you saw** a doctor or nurse taking care of the patient next to you and then coming to you without washing or sanitizing their hands, would you ask them to do so? (Q12)	72%	25%	3%

Patient views on best methods of getting hand hygiene messages across

Massive education – all levels/sectors of society (survey respondent, Australia).

Respondents reported that the most useful method to educate people in their country/community about hand hygiene and infection control was HCWs showing the importance of hand hygiene, e.g. by cleaning their hands in the presence of the patient; 398 of the 459 responders reported that this was either "useful" or "very useful" (Table 4 illustrates this by region).

Table 4.
Best methods of getting message across
(number and percentage of patients who marked the method as either "useful" or "very useful", by WHO region

Method of promoting hand hygiene	Total	AMR	EUR	SEAR/WPR	AFR/EMR
Through HCWs showing its importance, e.g. by cleaning their own hands in the presence of the patient	**398 (87%)**	206 (87%)	142 (88%)	36 (86%)	12 (70%)
Through caregivers giving permission for patient to ask about hand hygiene	**328 (72%)**	170 (71%)	123 (77%)	26 (62%)	8 (47%)
Through a media campaign explaining the facts and encouraging involvement	**342 (75%)**	175 (74%)	123 (77%)	34 (81%)	11 (65%)
Through education in schools and colleges	**344 (75%)**	169 (71%)	131 (82%)	34 (80.5%)	9 (53%)
Through hospital campaigning	**333 (73%)**	167 (70%)	129 (80%)	27 (64%)	9 (53%)
Through clinics or other health-care facilities actively promoting the importance of hand hygiene	**362 (79%)**	184 (77%)	134 (83%)	32 (76%)	11 (64%)
Through the involvement of community and country leaders	**258 (57%)**	116 (53%)	100 (62%)	22 (52%)	8 (47%)
Through visual aids or prompts (e.g. posters)	**331(76%)**	176 (74%)	128 (79%)	34 (81%)	11 (65%)

Risk communication

Inform patients that they are in so much risk in medical care (survey respondent, Republic of Moldova).

Building on this series of questions, the second stage of the survey attempted to explore in more detail some of the issues around risk communication with respondents asked for their views on eight possible methods (Table 5).

Table 5.
How useful do you think the following methods are for encouraging patient participation in hand hygiene improvement?
(*Figures for respondents who replied "useful" or "very useful", and percentages of those from each region who were asked the question*)

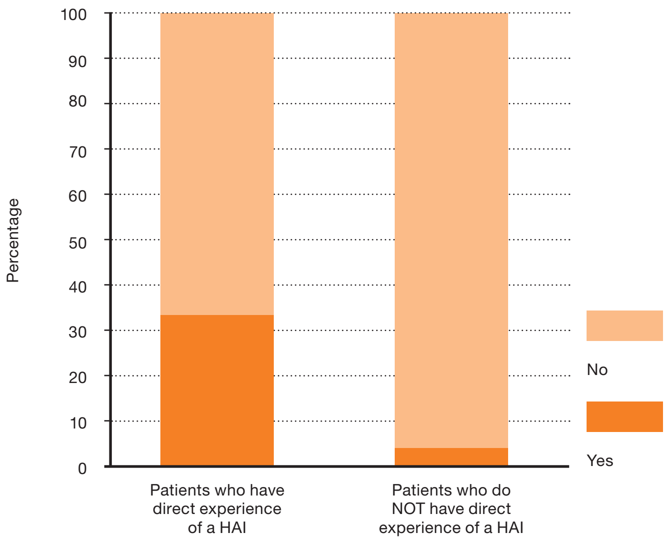
Methods to encourage patient participation	Total	AMR	EUR	SEAR/WPR	AFR/EMR
Open verbal dialogue between patients and health-care providers on the real risk to patients caused by poor hand hygiene	**176 (79%)**	77 (83%)	87 (78%)	7 (78%)	5 (63%)
Open verbal dialogue, as described above, and a clear invitation to patients to remind health-care providers to, for example, clean their hands	**168 (76%)**	81 (87%)	77 (69%)	6 (67%)	4 (50%)
The provision of written information to patients describing the evidence linking low levels of hand hygiene with the development of HCAI	**173 (78%)**	77 (83%)	85 (76%)	6 (67%)	5 (63%)
The provision of written information as described above and a clear invitation to patients to remind health-care providers to, for example, clean their hands	**170 (77%)**	78 (84%)	82 (73%)	6 (67%)	4 (50%)
Explicit communication, including campaigns, describing the risk and the harm (including the risk of mortality) that HCAI can cause, and explaining the role of hand hygiene as an important preventive measure	**187 (84%)**	83 (89%)	92 (82%)	7 (78%)	5 (63%)
Explicit communication, as described above, and a clear invitation to patients to remind health-care providers to, for example, clean their hands	**168 (76%)**	79 (85%)	78 (70%)	7 (78%)	4 (50%)
Providing HCWs with formal training in patient–HCW risk communication to ensure they are receptive to the needs of patients in relation to the prevention of HCAI	**184 (83%)**	83 (89%)	89 (79%)	7 (78%)	5 (63%)
Providing HCWs with formal training in patient–HCW risk communication, as described above, and instructing HCWs to invite patients to ask them to clean their hands.	**179 (81%)**	83 (89%)	84 (75%)	7 (78%)	5 (63%)

Does experience of health care-associated infection influence behaviour?

My family members who have been hospitalized have acquired nosocomial infections – this is a very serious problem in my country
(survey respondent, Mexico).

People who had direct experience of an HCAI were more likely to question the HCW; 37% among those who had direct experience vs 17% among those who did not. Among respondents who identified themselves as not working in any aspect of health care, this is more pronounced: 31% of patients who had had a direct experience of an HCAI had previously asked their HCW to wash/handrub, while only 4% of those who did not have a direct experience had done so (Figure 4).

Figure 4.
Does having a direct experience of a health care-associated infection influence the likelihood that a patient will ask their health-care workers to clean their hands (wash/handrub)?



Comparison of the study with previous work

Data comparing the results of this study with four other studies/ surveys asking for a patients' preference for involvement are shown in Table 6.

Table 6.
Comparison with other studies

Study	Yes, patients should be involved	Would you ask?	HCW permission
England and Wales NPSA (2004)[1]	71%	26%	NA
Ontario (Canada)[2]	32%	42%	NA
USA consumer survey[3]	NA	NA	80%
USA web survey[4]	NA	60% (20)	NA
Current study	NA	52% (29% had actually asked in this survey)	86%

Patient narratives

On the high dependency ward where we had to request that the nursing staff washed their hands, wore aprons and gloves, their attitude was that we were ove reacting
(narrative, United Kingdom).

Respondents who indicated a personal experience of HCAI were asked for their willingness to be contacted. Of these, 123 respondents (27%) stated that they were willing to be contacted; 110 respondents were successfully contacted and a total of 11 completed standard narrative forms were received. At the time the HCAI developed, the patients had been admitted because of a range of underlying medical conditions. Four respondents specifically identified methicillin-resistant *Staphylococcus aureus* (MRSA) as the HCAI. The remaining descriptions included urinary tract infection, wound infection, septicemia, and *C. difficile,* and one patient acquired HIV infection.

Risk communication

We were informed by the ward nurses that Mum had contracted a "little, of no concern" infection. We were given a broadsheet A4 paper with the initials MRSA and what they stood for, there was no other information given to my family whatsoever … 20 hours later she was in a coma and died 11 days later (narrative, United Kingdom).

Building on the earlier questions exploring how best to communicate risks within the context of HCAI, the narrative forms explored both how the individuals had been informed of the acquired infection and whether they had been informed about any risk of HCAI whilst receiving care/treatment (Table 7).

Table 7.
Patient narrative – risk communication

Country	Infection/organism	How told	Informed of risk of HCAI while in hospital?
India	HIV	Report	Not answered
United Kingdom	MRSA	Verbal	No
USA	Septicaemia	Verbal	No
Australia	Urinary tract infection	Not told	No
USA	Urinary tract infection	Not told	No
United Kingdom	MRSA	Verbal	No
USA	MRSA	Not told	No
USA	Septicaemia	Not told	No
USA	Wound	Verbal	No
United Kingdom	C. difficile	Leaflet	No
United Kingdom	MRSA	"Had to ask"	No

Conclusion

The results of this study reinforce a number of findings from previous studies. Many individuals who have had an experience as a patient are interested in the possibilities of participating in hand hygiene improvement among HCWs in health-care settings. Most respondents are interested in and positive about empowerment; however, there were a number of caveats. The following action areas should be considered by any country or facility intent on introducing or strengthening this component of the strategy:

- infrastructure for hand hygiene;
- patient and HCW information and education;
- risk communication;
- alignment with culture.

In particular, the survey reinforces the importance of programme development and the need for any patient empowerment strategy to be at one with the organizational culture and context. The survey results present an endorsement that patient empowerment should form one component of a multimodal hand hygiene improvement strategy.

Limitations of the study

The survey was targeted at individuals having a health-care encounter as a patient. However, distribution channels (WHO Patients for Patient Safety Champions and members of the International Alliance of Patient Organizations) inevitably resulted in sample bias with a high percentage of respondents being both patients and also involved in some way in the health-care sector, which limits the capacity for generalizing these results to the population as a whole. It is probable also that respondents were sensitized to the issues surrounding HCAI during the survey and replied to certain questions in a manner that might be considered as a socially acceptable response. Although limited, the number of responses from the African, South-East Asia, Eastern Mediterranean, and Western Pacific Regions are useful for comparative purposes, and further work will be required in the future to gain a greater understanding of patient perception in these regions.

[1] *Patient empowerment* (pilot web site). London, National Patient Safety Agency, 2008 (http://www.npsa.nhs.uk/cleanyourhands/in-hospitals/pep/, accessed 1 December 2008)

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[4] Aleccia J. *The dirty truth about docs who don't wash: Patients shouldn't be shy about asking providers to hit the sink, experts say*. Microsoft web site, Health page, 2008 (http://www.msnbc.msn.com/id/22827499, accessed 26 November 2008).

ABBREVIATIONS

AFFF	aqueous (water) film-forming foam
AFRWHO	African Region
AFRO	WHO Regional office for Africa
AIDS	acquired immunodeficiency syndrome
AMR	WHO Region of the Americas
AMRO	WHO Regional office for the Americas
ASTM	American Society for Testing and Materials
BSI	bloodstream infection
CBA	cost–benefit analyses
CCM	Centro per il Controllo delle Malattie
CDC	Centers for Disease Control and Prevention
CEA	cost–effectiveness analyses
CEN	Comité Européen de Normalisation / European Committee for Standardization
CEO	chief executive officer
CFU	colony forming unit
CHG	chlorhexidine gluconate
CMCH	Chittagong Medical College Hospital
CoNS	coagulase-negative staphylococci
CR-BSI	cather-related bloodstream infection
CR-UTI	catheter-related urinary tract infection
CTICU	cardiothoracic intensive care unit
CTS	complementary test site
DALY	disability-adjusted life year
DDAC	didecyldimethyl ammonium chloride
EA	ethanol
EDTA	ethylene-diaminetetraacetic acid
EMR	WHO Eastern Mediterranean Region
EMRO	WHO Regional Office for the Eastern Mediterranean
EN / prEN	European norm / European norm in preparation (prenorm)
ESBL	extended-spectrum beta-lactamase
EUR	WHO European Region
EURO	WHO Regional Office for Europe
FDA	Food and Drug Administration
GPPHWS	Global Public Private Partnership for Handwashing with Soap
HACCP	hazard analysis critical control point
HARMONY	Harmonisation of Antibiotic Resistance measurement, Methods of typing Organisms and ways of using these and other tools to increase the effectiveness of Nosocomical infection control
HAV	hepatitis A virus
HBM	Health Belief Model
HBV	hepatitis B virus
HCAI	health care-associated infection
HCP	hexachlorophene soap/detergent
HCW	health-care worker
HELICS	Hospital in Europe Link for Infection Control through Surveillance
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	human immunodeficiency virus
HLC	Health Locus of Control
HNN	Hospital Nacional de Niños
HSV	herpes simplex virus
ICER	incremental cost–effectiveness ratio
ICU	intensive care unit
IHI	Institute for Healthcare Improvement
INICC	International Nosocomial Infection Control Consortium
IPA	isopropanol
IPA-H	isopropanol + humectants
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JHPIEGO	Johns Hopkins Program for International Education on Gynecology and Obstetrics (international health organization affiliated to Johns Hopkins University)
KAAMC	King Abdul Aziz Medical Center
LR	log reduction
MDG	Millennium Development Goal
MIC	minimum inhibitory concentration
MICU	medical intensive care unit
MRSA	methicillin-resistant *Staphylococcus aureus*
MSICU	medical/surgical intensive care unit
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NICU	neonatal intensive care unit
NIH	National Institutes of Health
NIOSHA	National Institute for Occupational Safety and Health Administration
NNIS	National Nosocomial Infection Surveillance
n-P	n-propanol
NPSA	National Patient Safety Agency
OPD	outpatient department
PACU	post-anaesthesia care unit
PAHO	Pan American Health Organization
PASA	Purchasing and Supply Agency
PCMX	para-chloro-meta-xylenol
PDSA	Plan–Do–Study–Act
P-I	povidone-iodine detergent
PICU	paediatric intensive care unit
PMT	Protection Motivation Theory
PPE	Personal Protective Equipment
QAC	quaternary ammonium compound
QALY	quality-adjusted life year
REP	Replicating Effective Programs
RNAO	Registered Nurses Association of Ontario
RSV	respiratory syncytial virus
SARS	severe acute respiratory syndrome
SEAR	WHO South-East Asia Region
SEARO	WHO Regional Office for South-East Asia
SEM	Self-efficacy Model
SICU	surgical intensive care unit
SSI	surgical site infection
TFM	Tentative Final Monograph
TPB	Theory of Planned Behaviour
USA	United States of America
USAID	United States Agency for International Development
UTI	urinary tract infection
VAP	ventilator-associated pneumonia
VRE	vancomycin-resistant enterococci
v/v	volume/volume
WHO	World Health Organization
WPR	WHO Western Pacific Region
WPRO	WHO Regional Office for the Western Pacific

AKNOWLEDGEMENTS

Developed by the Clean Care is Safer Care Team
(Patient Safety Department, Information, Evidence and Research Cluster) with:

Critical contribution to content from:
John Boyce
Saint Raphael Hospital, New Haven, CT; United States of America

Yves Chartier
World Health Organization, Geneva; Switzerland

Marie-Noelle Chraïti
University of Geneva Hospitals, Geneva: Switzerland

Barry Cookson
Health Protection Agency, London; United Kingdom

Nizam Damani
Craigavon Area Hospital, Portadown, Northern Ireland; United Kingdom

Sasi Dharan
University of Geneva Hospitals, Geneva; Switzerland

Neelam Dhingra-Kumar
Essential Health Technologies, World Health Organization, Geneva; Switzerland

Raphaelle Girard
Centre Hospitalier Lyon Sud, Lyon; France

Don Goldmann
Institute for Healthcare Improvement, Cambridge, MA: United States of America

Lindsay Grayson
Austin & Repatriation Medical Centre, Heidelberg; Australia

Elaine Larson
Columbia University School of Nursing and Joseph Mailman School of Public Health, New York, NY; United States of America

Yves Longtin
University of Geneva Hospitals, Geneva; Switzerland

Marianne McGuckin
McGuckin Methods International Inc., and Department of Health Policy, Jefferson Medical College, Philadelphia, PA; United States of America

Mary-Louise McLaws
Faculty of Medicine, University of New South Wales, Sidney; Australia

Geeta Mehta
Lady Hardinge Medical College, New Delhi; India

Ziad Memish
King Fahad National Guard Hospital, Riyadh; Kingdom of Saudi Arabia

Peter Nthumba
Kijabe Hospital, Kijabe; Kenya

Michele Pearson
Centers for Disease Control and Prevention, Atlanta, GA; United States of America

Carmem Lúcia Pessoa-Silva
Epidemic and Pandemic Alert and Response, World Health Organization, Geneva; Switzerland

Didier Pittet
University of Geneva Hospitals and Faculty of Medicine, Geneva; Switzerland

Manfred Rotter
Klinishche Institut für Hygiene und Medizinische Mikrobiologie der Medizinischen Universität, Vienna; Austria

Denis Salomon
University of Geneva Hospitals and Faculty of Medicine, Geneva; Switzerland

Syed Sattar
Centre for Research on Environmental Microbiology, Faculty of Medicine, University of Ottowa, Ottawa; Canada

Hugo Sax
University of Geneva Hospitals, Geneva; Switzerland

Wing Hong Seto
Queen Mary Hospital, Hong Kong Special Administrative Region of China

Andreas Voss
Canisius-Wilhelmina Hospital, Nijmegen;The Netherlands

Michael Whitby
Princess Alexandra Hospital, Brisbane; Australia

Andreas F Widmer
Innere Medizin und Infektiologie, Kantonsspital Basel und Universitätskliniken Basel, Basel; Switzerland

Walter Zingg
University of Geneva Hospitals, Geneva; Switzerland

Technical contributions from:
Vivienne Allan
National Patient Safety Agency, London; United Kingdom

Charanjit Ajit Singh
International Interfaith Centre, Oxford; United Kingdom

Jacques Arpin
Geneva; Switzerland

Pascal Bonnabry
University of Geneva Hospitals, Geneva; Switzerland

Izhak Dayan
Communauté Israélite de Genève, Geneva; Switzerland

Cesare Falletti
Monastero Dominus Tecum, Pra'd Mill; Italy

Tesfamicael Ghebrehiwet
International Council of Nurses; Switzerland

William Griffiths
University of Geneva Hospitals, Geneva; Switzerland

Martin J. Hatlie
Partnership for Patient Safety; United States of America

Pascale Herrault
University of Geneva Hospitals, Geneva; Switzerland

Annette Jeanes
Lewisham Hospital, Lewisham; United Kingdom

Axel Kramer
Ernst-Moritz-Arndt Universität Greifswald, Greifswald; Germany

Michael Kundi
University of Vienna, Vienna, Austria

Anna-Leena Lohiniva
US Naval Medical Research Unit, Cairo; Egypt

Jann Lubbe
University of Geneva Hospitals; Geneva; Switzerland

Peter Mansell
National Patient Safety Agency, London; United Kingdom

Anant Murthy
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; United States of America

Nana Kobina Nketsia
Traditional Area Amangyina, Sekondi; Ghana

Florian Pittet
Geneva; Switzerland

Anantanand Rambachan
Saint Olaf College, Northfield, MN; United States of America

Ravin Ramdass
South African Medical Association; South Africa

Beth Scott
London School of Hygiene and Tropical Medicine, London; United Kingdom

Susan Sheridan
Consumers Advancing Patient Safety; United States of America

Parichart Suwanbubbha
Mahidol University, Bangkok; Thailand

Gail Thomson
North Manchester General Hospital, Manchester; United Kingdom

Hans Ucko
World Council of Churches, Geneva; Switzerland

Editorial contribution from:
Rosemary Sudan
University of Geneva Hospitals, Geneva; Switzerland

Special technical contribution from:
Benedetta Allegranzi
Clean Care is Safer Care Team, Patient Safety Programme, WHO

Peer review from:
Nordiah Awang Jalil
Hospital Universiti Kebangsaan Malaysia, Kuala Lumpur; Malaysia

Victoria J. Fraser
Washington University School of Medicine, St Louis, MO; United States of America

William R Jarvis
Jason & Jarvis Associates, Port Orford, OR; United States of America

Carol O'Boyle
University of Minnesota School of Nursing, Minneapolis, MN; United States of America

M Sigfrido Rangel-Frausto
Instituto Mexicano del Seguro Social, Mexico, DF; Mexico

Victor D Rosenthal
Medical College of Buenos Aires, Buenos Aires; Argentina

Barbara Soule
Joint Commission Resources, Inc., Oak Brook, IL; United States of America

Robert C Spencer
Bristol Royal Infirmary, Bristol; United Kingdom

Paul Ananth Tambyah
National University Hospital, Singapore; Singapore

Peterhans J van den Broek
Leiden Medical University, Leiden; The Netherlands

Editorial supervision from:
Didier Pittet
University of Geneva Hospitals and Faculty of Medicine, Geneva; Switzerland

Patient Safety Programme, WHO
(All teams and members listed in alphabetical order following the team responsible for the publication)

Clean Care is Safer Care:
Benedetta Allegranzi, Sepideh Bagheri Nejad, Pascal Bonnabry, Marie-Noelle Chraiti, Nadia Colaizzi, Nizam Damani, Sasi Dharan, Cyrus Engineer, Michal Frances, Claude Ginet, Wilco Graafmans, Lidvina Grand, William Griffiths, Pascale Herrault, Claire Kilpatrick, Agnès Leotsakos, Yves Longtin, Elizabeth Mathai, Hazel Morse, Didier Pittet, Hervé Richet, Hugo Sax, Kristine Stave, Julie Storr, Rosemary Sudan, Shams Syed, Albert Wu, Walter Zingg

Bloodstream Infections:
Katthyana Aparicio, Gabriela García Castillejos, Sebastiana Gianci, Chris Goeschel, Maite Diez Navarlaz, Edward Kelley, Itziar Larizgoitia, Peter Pronovost, Angela Lashoher

Central Support & Administration:
Sooyeon Hwang, Sean Moir, John Shumbusho, Fiona Stewart-Mills

Communications & Country Engagement:
Vivienne Allan, Agnès Leotsakos, Laura Pearson, Gillian Perkins, Kristine Stave

Education:
Bruce Barraclough, Felix Greaves, Benjamin Ellis, Ruth Jennings, Helen Hughes, Itziar Larizgoitia, Claire Lemer, Douglas Noble, Rona Patey, Gillian Perkins, Samantha Van Staalduinen, Merrilyn Walton, Helen Woodward

International Classification for Patient Safety:
Martin Fletcher, Edward Kelley, Itziar Larizgoitia, Fiona Stewart-Mills

Patient Safety Prize & Indicators:
Benjamin Ellis, Itziar Larizgoitia, Claire Lemer

Patients for Patient Safety:
Joanna Groves , Martin Hatlie, Rachel Heath, Helen Hughes, Anna Lee, Peter Mansell, Margaret Murphy, Susan Sheridan, Garance Upham

Radiotherapy:
Michael Barton, Felix Greaves, Ruth Jennings, Claire Lemer, Douglas Noble, Gillian Perkins, Jesmin Shafiq, Helen Woodward

Reporting & Learning:
Gabriela Garcia Castillejos, Martin Fletcher, Sebastiana Gianci, Christine Goeschel, Helen Hughes, Edward Kelley, Kristine Stave

Research and Knowledge Management:
Maria Ahmed, Katthyana Aparicio, David Bates, Helen Hughes, Itziar Larizgoitia, Pat Martin, Carolina Nakandi, Nittita Prasopa-Plaizier, Kristine Stave, Albert Wu, Lorri Zipperer

Safe Surgery Saves Lives:
William Berry, Mobasher Butt, Priya Desai, Gerald Dziekan, Lizabeth Edmondson, Luke Funk, Atul Gawande, Alex Haynes, Sooyeon Hwang, Agnès Leotsakos, Elizabeth Morse, Douglas Noble, Sukhmeet Panesar, Paul Rutter, Laura Schoenherr, Kristine Stave, Thomas Weiser, Iain Yardley

Solutions & High 5s:
Laura Caisley, Gabriela Garcia-Castillejos, Felix Greaves, Edward Kelley, Claire Lemer, Agnès Leotsakos, Douglas Noble, Dennis O'Leary, Karen Timmons, Helen Woodward

Tackling Antimicrobial Resistance:
Gerald Dziekan, Felix Greaves, David Heymann, Sooyeon Hwang, Sarah Jonas, Iain Kennedy, Vivian Tang

Technology:
Rajesh Aggarwal, Lord Ara Darzi, Rachel Davies, Gabriela Garcia Castillejos, Felix Greaves, Edward Kelley, Oliver Mytton, Charles Vincent, Guang-Zhong Yang

Vincristine:
Felix Greaves, Claire Lemer, Helen Hughes, Douglas Noble, Kristine Stave, Helen Woodward

WHO Collaborating Departments:
WHO Lyon Office for National Epidemic Preparedness and Response, Epidemic and Pandemic Alert and Response, Health Security and Environment Cluster

Blood Transfusion Safety, Essential Health Technologies, Health Systems and Services Cluster

Clinical Procedures, Essential Health Technologies, Health Systems and Services Cluster

Making Pregnancy Safer, Reproductive Health and Research, Family and Community Health Cluster

Policy, Access and Rational Use, Medicines Policy and Standards, Health Systems and Services Cluster

Vaccine Assessment and Monitoring, Immunization, Vaccines and Biologicals, Family and Community Health Cluster

Water, Sanitation and Health, Protection of the Human Environment, Health Security and Environment Cluster

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Conflict of Interest Statement

Development of the WHO Guidelines on Hand Hygiene in Health Care

For the purpose of finalizing the WHO Guidelines on Hand Hygiene in Health Care, *"Declaration of interest"* forms from the technical experts who contributed to the content of the Guidelines were gathered. All 27 of these experts contributed to the development of the Guidelines through their participation in five experts' consultations and core group meetings. There was no conflict of interest disclosed among the experts contributing to the content of the Guidelines apart from four persons who have disclosed the following information:

- Dr John Boyce disclosed that he had contract agreements and consultancies with GOJO, Clorox, Advanced Sterilization Products, Soap and Detergent Association, 3M Corporation, Dial Corporation and Mycrocept. Some arrangements with GOJO and Clorox focused on hand hygiene in health-care settings. He has received funding for research on diverse topics ranging from comparison of alcohol-based hand rub products and frequency of their use in an observational trial conducted in a health-care setting, to assessing the cleanliness of environmental surfaces in a health-care setting (not directly related to hand hygiene) and advice regarding products intended for surgical hand scrub. Dr Boyce has received honorariums from Clorox and Advanced Sterilization Products as a board member for attending annual meetings where hand hygiene was one of the subject areas of discussion.

- Professor Barry Cookson received an education grant from GOJO which was added to funding from a Department of Health, UK, grant .The funds were used to assess the effectiveness of the national hand hygiene campaign being implemented in all NHS Trusts over a period of four years. Professor Cookson has been a consultant for 3M, Biomerieux, Wyeth, Sanofi Pasteur, GlaxoSmithKline Beecham and Momentum on matters not related to hand hygiene or hand hygiene products.

- Dr Ziad Memish disclosed that he has contract agreements with GlaxoSmithKline and Wyeth on research trials on vaccines and has not provided consultancy on any matters related to hand hygiene or hand hygiene products.

- Dr Maryanne McGuckin disclosed that she has contract agreements with Ecolab, GOJO and Medline for the sole purpose of providing their clients (health-care facilities) with enrolment in her hand hygiene compliance and benchmarking programme. She receives compensation from these companies for this service but does not recommend or promote the use of any hand hygiene products. Currently, Dr. McGuckin receives no funding from these companies for her research and development work. She holds shares in Steris as part of an independent portfolio.

With regard to the specific content contribution to Guidelines development, the above-mentioned experts have co-authored or provided input to the following chapters:

I.7. Transmission of pathogens on hands (J. Boyce)
I.8. Models of hand transmission (J. Boyce)
I.9. Relationship between hand hygiene and acquisition of health care-associated pathogens (J. Boyce)
I.13. Surgical hand preparation: state of the art (J. Boyce)
I.23.7. Safety issues related to alcohol-based preparations (J. Boyce)
III.3. Cost-effectiveness of hand hygiene (J. Boyce)

I.1. Monitoring hand hygiene compliance (B. Cookson)
III.3. Cost-effectiveness of hand hygiene (B. Cookson)
VI. Comparison of hand hygiene national guidelines (B. Cookson)

I.17. Religious and cultural aspects of hand hygiene (Z. Memish)

V. Patient involvement in hand hygiene promotion (M. McGuckin)

None of the above-mentioned authors contributed to chapter I.11. "Review of preparations used for hand hygiene", or to chapter I.12 "WHO-recommended handrub formulation".