Brève présentation de l'état d'avancement des travaux 2007 de la section Mère du Collège Mère – Nouveau-Né

Président: J.M. FOIDART

1. Au cours de l'année 2007, le Collège Mère – Nouveau-Né a finalisé le rapport d'activité relatif au **"Perinatal referral pattern in Belgium"**.

Des recommandations précises ont été formulées afin de demander à l'autorité de prendre diverses initiatives destinées à améliorer la qualité des soins des nouveau-nés et des grossesses à haut risque.

Ces recommandations ont fait l'objet d'une évaluation par le Groupement des Gynécologues Obstétriciens de Langue Française de Belgique (GGOLFB) et par la Vlaamse Vereniging voor Obstetrie en Gynaecologie (VVOG).

Les propositions consensuelles des organisations scientifiques des obstétriciens de Belgique permettent l'inclusion dans le rapport final de recommandations approuvées par les organisations scientifiques et professionnelles par les universités et le Collège (cf rapport d'activité 2007 II)).

2. Un des acquis majeurs de cette activité du Collège au cours de l'année 2006 et 2007 a été la recommandation importante d'établir un cadastre épidémiologique des naissances en Belgique.

Du côté flamand, le SPE est une organisation communautaire fonctionnant depuis une quinzaine d'années et qui permet une épidémiologie périnatale exhaustive et de qualité.

Au niveau francophone, la banque de données périnatales de l'ONE ne recouvre que 90 % des données, n'est pas exhaustive et ne présente donc pas tous les critères indispensables à la présentation de données quantitatives et exhaustives. C'est la raison pour laquelle le Collège a très fortement recommandé l'organisation d'une épidémiologie périnatale en Wallonie et à Bruxelles qui fonctionne selon les mêmes critères que ceux du SPE.

A l'initiative du GGOLFB et avec la participation de la Société Belge de Pédiatrie, une ASBL intitulée CEpiP a été créée. Elle est l'équivalent du SPE. Elle est budgétisée par des fonds communautaires et exerce son activité selon des critères et des items identiques à ceux du SPE. L'objectif sera de pouvoir obtenir une épidémiologie périnatale francophone exhaustive et de qualité, de mettre en place des liens structurels avec le SPE afin d'harmoniser complètement les critères de collecte de données, de vérification des données et des procédures. Ceci devrait permettre la constitution d'une épidémiologie périnatale belge analysable globalement selon des critères identiques et dont les modalités de fonctionnement seront superposables.

3. Outre cette activité, le Collège Mère – Nouveau-Né s'est penché sur la **problématique des césariennes**. L'inflation des taux de césarienne dans tous les pays d'Europe n'épargne pas la Belgique. Trois enquêtes, une du KCE, une autre de l'agence intermutuelliste et la troisième du SPF démontrent une tendance significative à une augmentation semestrielle

des taux de césarienne dans les maternités belges. Les diverses raisons de cette inflation sont complexes et nécessitent une analyse complète. Le Collège s'est attaqué à ce problème au cours de l'année 2007 en réalisant:

- une étude bibliographique de la très vaste littérature anglo-saxonne, américaine, anglaise, canadienne et européenne consacrée à ce sujet;
- une enquête prospective auprès de l'ensemble des praticiens gynécologuesobstétriciens diplômés et des candidats spécialistes en gynécologie-obstétrique des universités francophones et flamandes.

Un ensemble de 15 situations cliniques ont été décrites. Chaque fois, il est demandé au médecin de définir son attitude: expectative, césarienne, accouchement par les voies naturelles.

Un taux de réponses de 55 % a été obtenu, ce qui garantit la qualité de l'échantillonnage et la validité de l'enquête prospective réalisée. Cette étude est actuellement en cours de dépouillement.

4. Le Collège a prévu et organisé les bases d'une étude sur sites au cours de l'année 2008. Il apparait en effet, d'après l'étude du SPF (Aelvoet W. et al, in press 2008), que les maternités peuvent être réparties en trois catégories en fonction du taux de césarienne. Celles qui sont comprises dans la moyenne et les « outliers » qui se caractérisent par un taux de césarienne soit exagérément élevé (au-delà de 95% par rapport à la moyenne), soit particulièrement bas, soit inférieur à 95% des maternités. Des visites sur sites sont prévues afin de vérifier, en fonction de critères établis par Chaillet, les raisons qui pourraient expliquer les différences par rapport à la norme tant vers le haut que vers le bas.

Les recommandations du Collège en matière de politique de prévention des inflations de césarienne devraient ainsi pouvoir être disponibles au cours de l'année 2008.

Propositions du thème en vue de l'établissement du contrat 2008

Analyse de l'étude prospective réalisée auprès des gynécologues belges

Comme écrit ci-dessus, cette étude prospective réalisée en 2007 porte sur 15 items et une fiche démographique reprenant le lieu d'activité, les caractéristiques de la pratique, l'âge des praticiens ... Cet ensemble de données collige au total 30 items par dossier avec un total enregistré à ce jour supérieur à 700 dossiers.

L'encodage est réalisé en collaboration avec l'UZ Gand (Mesdames Inge Tency et Evelyne Martens) et nécessitera 6 mois de travail à mi-temps.

D'autre part, l'étude prospective destinée à évaluer les critères de fonctionnement des maternités se situant dans la moyenne du taux de césarienne belge ainsi qu'auprès des « outliers » déviant vers le haut ou vers le bas nécessite des visites sur place par des experts non obstétriciens. Ces visites seront réalisées dans 5 maternités francophones et néerlandophones à taux élevé, moyen et faible de césarienne, soit un total de 30 maternités sur les 105 maternités du pays.

Elles seront réalisées sous la supervision de deux experts associés au Collège et probablement conduites par une unité de l'école de Santé Publique et de Sociologie de la VUB (pour la Communauté flamande) et de l'école de Santé Publique de l'Université de Liège (Unité APES pour la Communauté française).

Le but de ce travail est d'évaluer les stratégies mises en œuvre dans les trois types de maternité afin de contrôler le taux de césarienne selon les critères définis par Chaillet (cf annexe).

Perinatal referral in Belgium

I. Tency, E. Martens, G. Martens, JM. Foidart, M. Temmerman

College of physicians for Mother and Newborn

Writing committee:

S. Alexander, A. Clercx, JL. Deville, JM. Foidart, M. Hanssens, D. Haumont, M. Temmerman, P. Vanhaesebrouck, H. Van Hauthem, P. Van Reempts, G. Page, A. Van Assche

During the last 3 decades many western countries have made efforts to regionalize and optimize perinatal care. In Belgium, a Royal Decree has outlined the concept of maternal and neonatal referral in 1996, yet specific guidelines and actions of implementation and monitoring of maternal referral are lacking.

Therefore, the College of physicians of Mother and Newborn decided to embark on this project in order to inform and advise the Ministry of Health on the organisation of perinatal transfer in Belgium. 1. National data on perinatal care are difficult to obtain in a standardized and systematic way. Since more than a decade, Flanders has developed a comprehensive regional database linked with the birth certificate, allowing monitoring of care, similar to the medical birth registers of the Nordic countries. This system ensures both the routine collection of vital statistics and ad hoc surveys on topics which are considered of interest by research committees. Currently neither of these mechanisms are available in Wallonia and birth certificates only are available for Brussels.

After comparing the data extracted from the retrospective study and the limited. figures of the prospective study with the SPE, MOSAIC and NIC-audit datasets, it is concluded that the practice of in utero transfer of high-risk pregnancies in Belgium is progressively increasing over the last decade (± 300-500 IUTs/year in the nineties) and ± 800-1.000 IUTs/year during the last 5 years)²⁰. One decade ago postnatal referral of VLBW-babies was still important (up to 40% of all VLBW-admissions in Belgian NICUs during the nineties). Since the last 2 years (2005-06) the postnatal referral rate of VLBW-babies has decreased to nearly 15% or less. Data from SPE and NIC-audit show that nowadays nearly 90% of VLBW-infants are cared for in one of the 19 NICUs, most frequently admitted as inborns after in utero transfer.

However there is still room for improvement as far as prenatal referral of high-risk pregnancies is concerned, especially during the highly vulnerable period of pregnancy between 26 and 28 weeks' gestation. At present, perinatal referrals consist approximately of one third of in utero transfers (± 800-1.000/year²¹ or 90/10.000²² deliveries) and of two thirds of neonatal transfers (± 1.500-1.800/year²¹ or 143/10.000²² deliveries). Optimal perinatal care is achievable in Belgium by a further inversion of this ratio in favour of maternal referral²³.

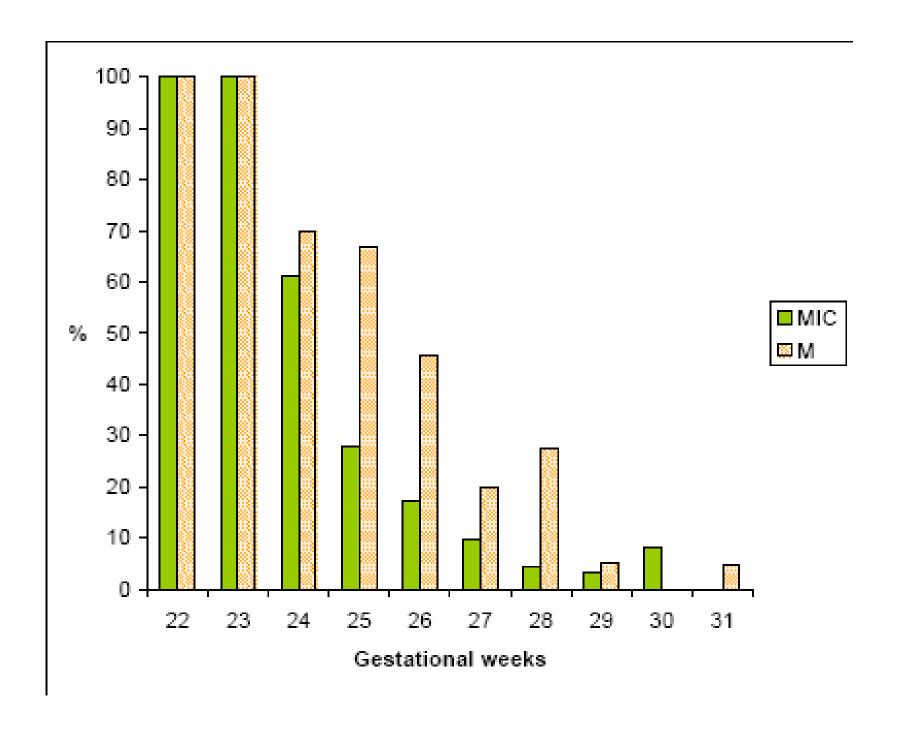
- 4. The importance of prenatal obstetrical care in high-risk pregnancies is stressed by the observation that nearly one third of all maternal referrals are retransferred to the original maternity hospital before delivery.
- Most obstetricians/gynaecologists and paediatricians support the concept of regionalized care and express the wish to be involved in the planning and organisation through their professional and scientific organisations.

- 6. Following <u>constraints and drawbacks</u> have been identified and need to be addressed in order to improve the quality of perinatal care:
 - Maternal transport modalities and responsibilities are not well elaborated
 - Communication tools between referring and referral hospital are not well established;
 - Financial compensations for referring institutions and physicians are not in place;
 - Tools for monitoring quality of maternal transfer are insufficiently developed;
 - Foetomaternal indications for prenatal transfer needs further elaboration;

6 Recommendations

Based on literature, various Belgian perinatal databases and our own observations and conclusions, we hereby recommend the national health authorities to develop strategies for prenatal transfer as part of a national perinatal program: Development of a national register on perinatal health linked with birth certificates, in collaboration with regional authorities, to allow monitoring, quality control and improvement of perinatal policies, as is already achieved in the northern part of the country. In addition, proper registration will allow assessing the needs for NIC/MIC beds in the country as well as their geographical spread. Organisation of maternal transport systems and defining reimbursement modalities for maternal transport and retransfer. Financial compensation will have to be addressed for the referring institutions and physicians. A mandatory on-line registration of perinatal transfer is a useful tool to improve quality control and set conditions for reimbursement or financial compensations. Development of operational strategies by the 1) Implementation of standardized agreements mentioning minimal criteria and modalities for prenatal, as well as for postnatal transfer and retransfer, allowing for local specificities; 2) Measures to encourage an active policy of in utero transfer, including operational definitions with indications and guidelines; 3) Organisation of structured communication between collaborating institutions; 4) Modalities for postgraduate training of the medical and nursing staff of the referring hospital to keep their clinical knowledge and experience in the management of high-risk pregnancies and neonates up to date 5) Measures to encourage fusion of small maternities (wherever possible) taken into account the critical mass needed for appropriate medical and nursing staff and expertise, have to be worked out.

- 4. <u>Creation of a consultative platform</u> with all stakeholders involved, including health authorities as well as scientific and professional societies, assess the national database and birth certificates and further elaborated guidelines of good practice as well as operational definitions for perinatal (re)transfer.
- Further health system research on perinatal transfer policy in Belgium should be carried out <u>by an expert team</u>, in particular indications for perinatal (re)transfer, the organisation of the MIC-service, evaluation of current transport systems, etc.



Problème de la prématurité extrême



Perinatal referral in Belgium

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However there is still room for improvement as far as prenatal referral of high-risk pregnancies is concerned, especially during the highly vulnerable period of pregnancy between 26 and 28 weeks' gestation. At present, perinatal referrals consist approximately of one third of in utero transfers (± 800-1.000/year²¹ or 90/10.000²² deliveries) and of two thirds of neonatal transfers (± 1.500-1.800/year²¹ or 140/10.000²² deliveries). Optimal perinatal care is achievable in Belgium by a further inversion of this ratio in favour of maternal referral.



Avis du groupe PERINAT du GGOLFB concernant

la politique de transfert intra-utérin formulée par le Collège Mère-Nouveau né

F. DEBIEVE, Y ENGLERT



Commentaar van de Vlaamse Werkgroep Verloskunde (VWV) van de VVOG op document:

"Avis du groupe PERINAT du GGOLFB concernant la politique de transfert intra-utérin formulée par le Collège Mère-Nouveau né »

door collegae F. Debieve en Y. Englert

R. Devlieger, voorzitter VWV

Le Collège des Médecins pour la Mère et le Nouveau-né a évalué en 2005 et 2006 l'efficacité de l'organisation des transferts intrautérins.

Ce travail d'analyse a fait l'objet d'un rapport récemment publié et intitulé «Perinatal referral in Belgium».

Nous tenons tout d'abord à saluer la qualité du travail accompli par le Collège.

- Wij sluiten ons aan bij de waardering voor het geleverde werk door het college.
- Ook willen we de groupe PERINAT van de GGOLFB en in het bijzonder de auteurs van het document, collegae Debieve en Englert, feliciteren met hun presentatie waarop we ons uitgebreid baseren om de eigen bemerkingen te formuleren.

Le Collège demande aux organisations scientifiques et professionnelles, sur base de ce rapport, des suggestions concernant la politique de transfert intra-utérin via 4 aspects:

- 1. Sur le contenu des accords génériques minimum applicables partout, tels que prévu dans l'Arrêté Royal de 1996 (mais permettant aussi des adaptations aux spécificités locales);
- 2. Sur les mesures destinées à encourager et à améliorer les transferts intra-utérins;
- 3. Sur le contenu des informations médicales à transférer avec la patiente;
- 4. Sur les indications et les règles de transfert intra-utérin, néonatal et de re-transfert.

 Beschrijving van de vraag gesteld door het college, geen commentaar.

Contenu des accords génériques minimum applicables partout tels que prévu dans l'Arrêté Royal de 1996.

- Conditions de transfert intra-utérin, en y précisant l'âge gestationnel et l'indication. Ces conditions pouvant être adaptées en fonction des capacités du centre M et N* référent.
- Notion que tout transfert implique obligatoirement la possibilité d'un retransfert lorsque les conditions médicales le permettent ; ces conditions devant être précisées dans l'accord.
- Liaison obligatoire entre les transferts intra-utérins et extra-utérins. Un service M ne pouvant donc décider de ne transférer que dans un NIC donné et pas dans un MIC de ce même hôpital, ceci afin de favoriser les transferts intra-utérins d'une part, et d'autre part d'éviter de créer un déséquilibre dans un NIC entre « in-born » et « out-born ».
- Interdiction de critères d'exclusivité stricts dans ces contrats afin de respecter la liberté du choix d'une institution pour la patiente, mais aussi pour le gynécologue ou néonatologue du centre M ou N* tout en favorisant une attitude de service
- Réunions d'évaluation de la politique de transfert entre fonction P et M-N*.

Geen commentaar

<u>2. Mesures destinées à encourager et à améliorer les</u> transferts intra-utérins.

➤ Le rapport souligne une relative surcharge des services NIC, illustré par l'enquête qui donne pour origine le NIC dans le refus de transfert intra-utérin dans 74% si on interroge les responsables de service MIC et 96% pour les responsables des services NIC.

Nous proposons donc:

- ✓ Effectivement d'améliorer le taux de transfert intra-utérin afin de diminuer le taux d'« out-born » dans les NIC.
- ✓ Le développement des unités N* associées aux NIC afin de pouvoir absorber les patientes « in born » de ces centres MIC de référence qui forcément auront un taux de grossesse à risque supérieur aux maternités M, et donc de patients NIC ne pouvant être re-transférés dans un N* extérieur.

 Akkoord, hoewel te verwachten is dat de globale NIC bezetting slechts marginaal zal verminderen door meer in-utero transfers (IUT). Daarom is deze stimulering niet los te zien van de uitbreiding van de N* centra. ✓ Une revalorisation et une réorganisation des services N* afin de pouvoir assurer réellement leurs compétences et charges et donc assumer les re-transferts de grossesses de plus de 32 semaines.

- ➤ Remboursement des transferts intra-utérins non médicalisés (les transferts médicalisés n'étant, selon nous, non-indiqués car faisant partie des contre-indications au transport).
- Création d'un code INAMI « transfert » afin de pouvoir assurer une juste rétribution au médecin prenant la décision de transférer la patiente et donc de « perdre » un acte d'accouchement éventuel.

Akkoord

- De terugbetaling van ZOWEL medisch begeleide als niet-begeleide IUTs lijkt ons cruciaal. Wij vinden niet dat medisch begeleide transporten een contra-indicatie zijn voor transport. De MIC pathologie, verder gedefinieerd, houdt juist in dat het om specifieke, acute pathologie gaat welke vaak best begeleid wordt door gespecialiseerd personeel. Wie het transport begeleid (vroedvrouw, assistent, ambulancier, gynaecoloog) kan best in overleg tussen verwijzer en M centrum worden bepaald. Indien enkel niet-begeleide transporten worden gestimuleerd vrezen wij dat dit vaak als alibi zal worden gebruikt om niet te moeten verwijzen, en dat het beoogde doel (verhogen van % IUTs) niet zal worden gestimuleerd. Transport voor terugverwijzing dient volgens ons onder dezelfde terugbetalingsvoorwaarden te vallen.
- Hieraan gelinkt vinden wij het noodzakelijk om een RIZIV nomenclatuurscode voor transfer te voorzien voor de verwijzer, MAAR eveneens terugverwijzing te stimuleren door een vergelijkbare code.

- Assurer une meilleure indication des transferts intra-utérins. La majorité des transferts sont effectués dans le cadre d'une menace d'accouchement prématuré avec ou sans rupture de poche. Or, le diagnostic de la menace d'accouchement prématuré et surtout la prédiction du risque d'accouchement dans les 48 heures n'est pas aisée. Les deux outils que sont l'échographie endovaginal pour la mesure de la longueur cervicale et la présence de fibronectine cervicale peuvent, selon la littérature internationale, améliorer la spécificité du diagnostic. Nous proposons que ces deux outils soient remboursés par la sécurité sociale.
- ➤ Une évaluation des politiques de transfert est essentielle. Ces données sont partiellement intégrées dans les statistiques du « S.P.E. » en région flamande. La création d'un centre analogue en Communauté Française avec un volet épidémiologique concernant les transferts intra-utérins devrait répondre à ce point.

- Wij zijn akkoord dat (naast de voorgeschiedenis), het effectieve risico op preterme partus bij preterme arbeid momenteel het best wordt ingeschat door middel van de combinatie echografische cervixlengtemeting en fFN-test. Wij menen echter niet dat er een afzonderlijke echografische code noodzakelijk is voor de cervixmeting. Deze kan volgens de werkgroep beter ingepast worden in een functionele echografie welke best wordt uitgevoerd om foetale oorzaken van preterme contracties (polyhydramnion, hematoom,...) uit te sluiten. Terugbetaling van de fFN-test lijkt ons gezien de relatief lage kost ervan (20-30 Euro) gerust door de patiënten te kunnen gebeuren of in een forfaitaire vergoeding te kunnen passen, maar terugbetaling zou het relatief beperkte gebruik ervan kunnen stimuleren.
- Akkoord. In deze tijden van internationalisering lijkt het op termijn cruciaal om over kwalitatieve nationale cijfers te beschikken vooral om zo de indicatoren van de Belgische Perinatale Zorgen in internationaal perspectief te kunnen evalueren.

<u>3. Contenu des informations médicales à transférer</u> avec la patiente.

- Àge gestationnel précis selon les dernières règles et selon le terme échographique avec date de détermination de ce terme.
- Antécédents médico-chirurgicaux.
- > Antécédents gynéco-obstétricaux.
- État du col de l'utérus déterminé par toucher vaginal et échographie du col au départ de la patiente.
- > Traitement en cours.
- Administration de corticoïdes à quelle dose et quand.
- Dernière prise de sang, selon le type de pathologie.
- > Pathologie foetale connue.
- > Toute remarque jugée importante.

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 Akkoord met de verstrekte lijst. Alleen vinden we niet dat vaginaal toucher dient uitgevoerd te worden indien reeds een cervixlengte werd uitgevoerd en omgekeerd.

4. Indications et les règles de transfert intra-utérin, néonatal et de re-transfert.

- > Dans la menace d'accouchement prématuré :
 - Col < 25mm mesuré par échographie endovaginale ou
 - Fibronectine présente au niveau vaginal ou
 - · Col effacé dilaté à 2 cm au toucher vaginal ou
 - Notion d'évolutivité sous tocolyse appropriée
 - Avant 32 ou 34 semaines selon les capacités du centre N* associé au centre M
- > Retard de croissance intra-utérin avec poids < 1500g.
- Pré-éclampsie, éclampsie ou Hellp syndrome avant 32 ou 34 semaines.
- > Pathologie foetale nécessitant des soins néonataux spécifiques :
 - · Cardiopathie congénitale suivant l'avis d'un cardiopédiatre
 - Hernie diaphragmatique
 - · Laparoschisis, omphalocèle
 - Autres , ...
- Complication maternelle sévère
- > Thérapeutique particulière, indépendamment de l'âge gestationnel

- De voorgestelde indicaties vinden wij erg gedetailleerd. De vrees van de werkgroep is dat hoe gedetailleerder, hoe meer gevallen die niet binnen deze definities zouden vallen als niet-tranfereerbaar zullen worden beschouwd. Details over de diagnostische criteria (cut off CX<15 of 25mm) kunnen met de stand van de wetenschap snel evolueren en kunnen derhalve beter in lokale of regionale richtlijnen opgenomen worden, eerder dan in een (aangepast) KB.
- Wij zijn grotendeels akkoord met de lijst maar stellen voor te beperken tot:
 - Dreigende vroeggeboorte voor 32 of 34 weken.
 - Groeiretardatie <P5 met argumenten voor verminderde uteroplacentaire functie op functionele echografie, zeker zo geschat gewicht<1500g.
 - Ernstige hypertensieve verwikkelingen voor 32 of 34 weken.
 - Foetale pathologie welke aangepaste neonatale opvang vereist onafhankelijk van de zwangerschapsduur..
 - Ernstige maternale ziekte, behandeling of verwikkeling, onafhankelijk van de zwangerschapsduur.

Les indications de re-transfert sont logiquement celles où la patiente ne se trouve plus dans une des situations reprises ci-dessus. Quant aux indications de transfert néonatal, elles nous semblent être du ressort du néonatologue.

Par contre, il nous semble important de préciser également les <u>contre-indications au transport</u>:

- > Contre-indications maternelles:
 - Instabilité cardiovasculaire
 - Risque d'accouchement per transport
 - Non-stabilisation d'une pathologie coexistante (p.ex éclampsie)
- Contre-indications fœtales :
 - Hématome rétro placentaire
 - Souffrance fœtale aiguë
 - Placenta hémorragique avec choc
 - Présentation transverse (siège) avec rupture de poche et col ouvert

VWV

- Akkoord met de formulering van de indicatie voor in utero retransfer en neonatale retransfer.
- Akoord met de meeste contra-indicaties voor transfer (en retransfer). Hier en daar kleine aanpassingen:
 - Maternale contra-indicaties: Dreiging van geboorte tijdens de transfer is aanwezig in zekere mate bij elk transport en kan niet gezien worden als contraindicatie voor transport. We stellen voor te herformuleren tot: "Belangrijke dreiging van geboorte tijdens de (re)transfer". Verder stellen we voor hier het voorbeeld van preëclampsie weg te laten.
 - Foetale contra-indicaties: Retroplacentair hematomen en randsinusbloedingen kunnen volgens de bestuursleden van de werkgroep niet als contra-indicatie voor transport gezien worden in de afwezigheid van actieve bloeding of tekens van foetaal lijden. Daarnaast lijkt het voorbeeld van de transverse ligging met ontsluiting en opening niet relevant door de zeldzaamheid. We stellen daarom voor de lijst van foetale contra-indicaties te beperken tot door:
 - Actieve bloedingen.
 - Acuut foetaal lijden.
 - Andere, in onderling overleg tussen de verwijzer en de MIC-verantwoordelijke.

Standardization of the agreements

- Standardised agreements should be implemented with minimal criteria
- Conditions <u>IUT</u>: GA, indications
- A transfer implies necessarily the possibility of a retransfer → conditions <u>retransfer</u>
- A peripheral hospital should be encourage to organise their IUT as well as their neonatal transfer to the same P-function

Measures to encourage and improve an active policy of IUT

- Development of N*-unit associated with NIC in order to admit the inborns of their MIC-unit + revalorization, reorganisation and extension of the N*-service in peripheral hospitals
- Reimbursement of <u>IUT</u> and <u>retransfer</u>
- Creation of a RIZIV/INAMI nomenclature code for both <u>IUT</u> and <u>retransfer</u>

Medical assisted IUT or not?

- = an important but delicate issue
- A medical assisted transfer could be seen as a contraindication, but mostly it concerns a specific, critical which urges for specialised care in a MIC-service
- Situation of the referral hospital may influence the decision to assist a transfer

Medical assisted IUT or not?

Suggestions for modalities concerning medical assisted transfer should be incorporated in the agreement between peripheral hospital and P*function

Content of medical information in case of transfer

- A minimum of medical information in case of transfer should be provided such as:
 - □ GA
 - Medical history
 - Evaluation of the cervix
 - Current medical treatment
 - Administration of corticoids
 - Last blood test
 - □ Known foetal pathology
 - Other information considered as important

Indications of IUT, neonatal transfer and retransfer

- We have to avoid
 - □ a detailed list with indications → detailed definitions can have a counterproductive effect
 - (When patients don't comply with the mentioned criteria, the referring physician can conclude that IUT is not necessary or feasible)
 - □ diagnostic criteria, because of rapid evolution of the medical science → incorporate in local procedures and guidelines

Indications for IUT

- Threatened preterm delivery before 32-34 weeks' gestation
- IUGR (with arguments for decreased uteroplacental function and with an expected birth weight <1500 g)</p>
- Severe hypertensive complications before 32-34 weeks
- Foetal pathology which requires intensive neonatal care (independent of GA)
- Seriously maternal disorder, treatment or complication (independent of GA)

Note: Indications for neonatal transfer are rather the field of neonatologists/paediatricians. Therefore no neonatal indications were formulated by the professional organisations of gynaecologists/obstetricians

Indications for retransfer

When the above mentioned situations do no longer apply to the transferred patient, retransfer should be planned

Contraindications for IUT

- Maternal
 - □ Cardiovascular instability
 - Important threat of delivery during transfer
 - No stabilization of a coexistent pathology
- Foetal
 - Acute bleeding
 - □ Acute foetal distress
 - Other, by mutual agreement between referral hospital and MIC-service



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College of physicians for Mother and Newborn

Writing committee:

S. Alexander, A. Clercx, JL. Deville, JM. Foidart, M. Hanssens, D. Haumont, M. Temmerman, P. Vanhaesebrouck, H. Van Hauthem, P. Van Reempts, G. Page, A. Van Assche

Project participants

Project «Perinatal referral in Belgium»

Chair: Marleen Temmerman

Steering committee

Inge Tency, Evelyne Martens, Guy Martens, Jean-Michel Foidart

Writing committee

Sophie Alexander, Anne Clercx, Jean-Luc Deville, Myriam Hanssens, Dominique Haumont, Piet Vanhaesebrouck, Hilde Van Hauthem, Patrick Van Reempts, Geert Page, André Van Assche

Members of the college of physicians for Mother and Newborn

Neonatology section

Chair: Piet Vanhaesebrouck

Anne Charon, Hugo Devlieger, Dominique Haumont, Jean-Paul Langhendries, Patrick Van Reempts, Marianne Michel, Hilde Van Hauthem

Maternity section

Chair: Jean-Michel Foidart

Luc De Catte, Corinne Hubinont, Christine Kirckpatrick, Marleen Temmerman, Dominique Leleux, André Van Assche, Johan Van Wiemeersch

Workgroup «In utero transfer» (Maternity section)

Chair: Marleen Temmerman

Jean-Luc Deville, Roland De Vlieger, Corinne Hubinont, Yves Jaquemyn, Christine Kirckpatrick, Geert Page, Ann Verougstraete

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Executive Summary

In 1996, levels of perinatal care were outlined by the Belgian Government. The Royal Decree of 1996 has delineated the concept of maternal and neonatal referral. Yet specific guidelines and actions of implementation and monitoring have to be elaborated. Therefore, the *College of physicians of Mother and Newborn*, an advisory committee to the Federal Ministry of Health decided to give priority to the assessment of in utero transfer (IUT) in Belgium in order to inform and advice the Ministry of Health on the organisation of perinatal care in Belgium (IUT project).

The study aims at mapping the rates of perinatal (re)transfer in Belgium and assessing the determinants of perinatal transfer, as well as constraints and drawbacks.

A <u>literature review</u> was carried out showing that regionalisation of perinatal care and referral of high-risk pregnant women and high-risk neonates to specialised intensive care units substantially lowers perinatal mortality and morbidity.

In the <u>retrospective part</u> of the IUT study quantitative data were collected on perinatal transfer and retransfer of the index year of 2004 as well as qualitative data about knowledge, attitudes and practices in relation to IUT and retransfer of mothers and neonates. The <u>prospective part</u> of the IUT project collected on-line individual baseline information for every pregnant women transferred and for every neonate born between 22 and 32 weeks and/or with an expected birth weight of <1500 g. Data were collected during 1 year (from the first of September 2005 until 31 of August 2006).

The <u>quantitative data of the retrospective study</u> show that the IUT rate in Belgium can be estimated at 90/10.000 deliveries. One third (32.7%) of the IUT mothers were retransferred to the original M-service. No information was available about the remaining IUTs. Most hospitals have formal agreements with P*-functions, but these agreements are not standardized. There is a significant diversity in number of agreements per hospital and per P*-function and also a large variation in content of

agreements. Indications for transfer or retransfer for mother and neonate are missing in most documents. The costs for IUT and maternal retransfer are largely unknown by the M-service and maternal referral procedures are not well documented.

The <u>qualitative part of the retrospective study</u> shows that most obstetricians/gynaecologists and paediatricians are convinced that neonates <32 weeks gestation and/or <1500 gram should be transferred in utero. However, only 50% of the participants believe that national guidelines and criteria will improve perinatal transfer policies. They also agree that when stabilisation of the obstetrical patient occurs and/or gestational age of 34 weeks is reached, retransfer to the referring hospital should be organised by the P*-function.

The response rate (54.4% from M-service, 37.1% from N*-function, 61.1% from MIC-service) in the <u>prospective study</u> was too low to allow analyses. Therefore, only the information from the MIC centres was further analysed and compared to existing databases such as the data of Studiecentrum of Perinatale Epidemiologie (SPE) and the Flanders data of a European database (MOSAIC). The main reasons for IUT were preterm labour, PPROM, multiple birth and pre-eclampsia. In approximately 75% of in utero transfers, the mother remained in the MIC-unit until she gave birth. The findings of the prospective study correlate with the SPE data and the Flanders data in MOSAIC. Over 90% of the very preterm deliveries (<32 weeks and/or <1500g) take place in a referral centre, most frequently admitted as inborns after in utero transfer. However, it has to be noticed that specific improvement is still possible in a highly vulnerable period of pregnancy (26-28 weeks) where optimal obstetrical and neonatal care can undoubtedly recede neonatal mortality and morbidity.

Overall conclusions of this project are: 1) national data on perinatal care are difficult to obtain in a standardized and systematic way 2) the current practice of perinatal transfer of high-risk pregnancies and high-risk neonates in Belgium is good 3) there is all lack of transport modalities, clear guidelines and supporting mechanism and 4) there is an urgent need for directives guidelines and transparant financial aggreements to organise IUT (similar to neonatal transport) with compensations for referral.

The College of physicians of Mother and Newborn recommends to the Ministry of Health to develop a national perinatal program with following priorities: 1) development of a national register 2) organisation of better transport system with a financing based on online registration 3) development of operational strategies to improve the implementation of the Royal Decree of 1996 (e.g. standardization of agreements with minimal criteria, operational definitions of perinatal transfer, active referral policy, structured communication) 4) creation of a consultative platform with involvement of all stakeholders and 5) organisation of further health system research on perinatal transfer policy.

1 Introduction

During the last decades, neonatal survival has improved greatly in Belgium, in Europe and in the USA (Fig 1). Reductions in perinatal mortality are due in part to the development of neonatal intensive care (NIC) services (Paneth et al., 1982). Already in 1944, Sir Dugald Baird of Aberdeen showed that concentration of perinatal care is the key to better perinatal health (Baird, 1944). During the late 1960s and early 1970s, it became apparent that improved neonatal salvage was possible because of new care techniques in both obstetrics and paediatric practice. Numerous changes involving better metabolic and nutritional care for neonates, prenatal corticosteroids and prenatal surfactant, refined neonatal ventilator capabilities, and more aggressive treatment of infections became available for compromised neonates, especially very low birth weight babies (Pollack, 1996).

While these improved neonatal care techniques became apparent, obstetricians/gynaecologists recognised already in the seventies that certain pregnant women could benefit from delivering in a hospital where the newer care practices benefit potentially compromised newborns.

Thus, the stage was set for the beginning of a new era in perinatal health care—the regionalisation of care (Baird, 1944; Campbell, 1999; Committee on Perinatal Health, 1976; Gagnon, Allisoncooke, & Schwartz, 1988; Gerber, Dobrez, & Budetti, 2001; Gessner & Muth, 2001; Paneth et al., 1982)

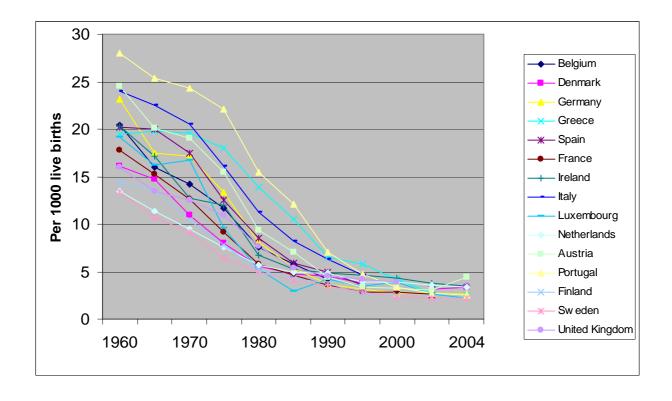


Figure 1: Neonatal mortality in Europe 1960-2004 (EUROSTAT¹)

In 1996, levels of perinatal care were outlined by the Belgian Government. The Royal Decree specifies general provisions and architectonic, functional and organisational standards of M-service², N*-function³ and P*-function⁴ (MIC⁵ and NIC⁶).

The heads of N*-functions and M-services were requested to develop procedures for collaboration between the two disciplines. One of these procedures was related to in utero transfer (IUT). The Royal Decree specifies consultation procedures before every in utero transfer, and invited interested parties to develop criteria for in utero and neonatal transfer and retransfer. These criteria were to be laid down in formal and written agreements with one of the NIC-services. Concerning maternal transfer and retransfer no provisions are mentioned in this Royal Decree of 1996. Criteria are provided by the federal Ministry of Health, while implementation fall under Community authorities.

³ Function of neonatal care

¹ EUROpean STATistics

² Maternity

⁴ Function of regional perinatal care

⁵ Maternal Intensive Care

⁶ Neonatal Intensive Care

The same Royal Decree includes criteria for the P*-functions. Each P*-function ought to make agreements of collaboration with hospitals with an M/N*-function, in order to cover a catchment area of at least 5000 deliveries per P*- function per year. The heads of departments of both services should meet twice a year in a structured consultation organised by the P*-function. A transport team should stand by in case of a neonatal transfer, and consultation is required with the referral hospitals with regard to conditions for maternal and neonatal transfer. However, neither written policies nor specific guidelines have been provided by National or Regional Authorities or by scientific and/or professional societies for the implementation of the directives of the Royal Decree of 1996.

Ensuring adequate access to intensive care for high-risk babies is a priority in Belgium as in other European countries. In many other Western countries, detailed strategies and financing mechanisms have been elaborated, implemented and assessed since the 1970's. In Belgium, a spontaneous shift in referring high-risk babies has been observed as shown by the fact that in 1983, over 80% of the very low birth weight (VLBW, <1500g) neonates were born outside a referral centre (outborn babies) whereas in 2005, more than 80% of the VLBWs were inborns (personal communication P Vanhaesebrouck, chair of the Neonatology section of the college of physicians of the Mother and Newborn). In Flanders, between 89-90 to 92 a steady increase in IUTs for births <32 weeks was seen from 27 to 66% (Studiecentrum voor Perinatale Epidemiologie, 1992).

However, the absence of specific guidelines and lack of documented best practices for the small proportion of pregnant women and babies that need intensive care may be detrimental and may cause significant loss of chances for those mothers and children. Therefore, in 2004 the *College of physicians for Mother and Newborn*⁷, an advisory committee to the Federal Ministry of Health decided to give priority to the assessment of the situation of in utero transfer in Belgium.

Ξ

⁷ College van geneesheren voor de Moeder en Pasgeborene/ Collège de médecins pour la Mère et le Nouveau-né

2 Objectives

- To study perinatal transfer rates (in utero transfer, neonatal transfer and maternal retransfer rates) in Belgium
- To assess determinants of perinatal transfer (implementation of the Royal Decree of 1996), as well as constraints and drawbacks
- To propose recommendations for health policy makers to improve perinatal transfers

3 Methodology

The study was carried out by the *College of physicians of Mother and Newborn*, an advisory committee of the *Federal Public Service (FPS) 'Health, Food Chain Safety and Environment'*. The College was established by a Royal decree of 15th of February 1999 with the goal to formulate recommendations in the area of Perinatal Medicine and Care to the Ministry of Health, health policy makers and stakeholders. The College consists of two sections: 1) the Neonatology section with paediatricians of N*-function and NIC-service and 2) the Maternity section with obstetricians/gynaecologists of M-service and MIC-service.

A study group of members of the *College of physicians of the Mother and Newborn* was formed; a research assistant was employed (30%) and supervised by Prof M Temmerman and Prof P Vanhaesebrouck, Ghent University, and Prof JM Foidart, University of Liège. A Steering committee was set up, consisting of paediatricians and obstetricians/gynaecologists.

The group decided to use the following methods:

- 1) A literature review, carried out by the team of JM Foidart
- 2) A retrospective study consisting of a quantitative part aiming at collecting data on IUT in 2004, as well as a qualitative part interviewing health care providers in the field about knowledge, attitude and practices in relation to IUT and retransfer of mothers and neonates (M Temmerman, P Vanhaesebrouck)

3) A *prospective study* to find out on an individual case basis the number of high-risk pregnant women and neonates referred and non-referred, determinants of referral, and in case of deviation of the Royal Decree to describe the reasons why some women and neonates had not been referred (deviation of 'optimal medical practice) (M Temmerman, P Vanhaesebrouck)

The results of the different parts of the project were regularly discussed with the Steering Committee. The draft report was presented to the Writing Committee by the end of 2006.

4 Results

4.1 Literature review

4.1.1 Methodology

The following electronic databases were searched to identify relevant publications:

- 1. Ovid MEDLINE(R) 1950 to January Week 2 2007
- 2. Ovid EBM Reviews-ACP Journal Club 1991 to January/February 2007
- 3. Ovid EBM Reviews-Cochrane Central Register of Controlled Trials 4th Quarter 2006
- 4. Ovid EBM Reviews-Cochrane Database of Systematic Reviews 4th Quarter 2006
- 5. Ovid EBM Review-Database of Abstracts of Reviews of Effects 4th Quarter 2006

The search strategy was used for MEDLINE and adapted to suit the other databases. MEDLINE search was limited to publications in the years 1980-2007. Unless otherwise stated, search terms are MeSH terms (Medline medical index terms). The exp. prefix indicates exploded MeSH terms. MeSH terms are combined with free text terms (.tw) searched in all of the fields in the databases which contain text words and which are appropriate for the subject. Textword index in Ovid MEDLINE (R) includes titles and abstracts. The dollar sign (\$) stands for any character(s).

The P.I.C.O. model for clinical questions was used to isolate three concepts to be searched separately: 1) Transportation or referral of patients (mothers, newborns, in utero transfers); 2) High-risk pregnancies, preterm labours and prematures; 3) neonatal (intensive) care. The criteria were combined two by two (#1 AND #2; #1 AND #3) in order to retrieve relevant publications.

Search strategies were developed as follows:

- 1. exp obstetric labour, premature/ (10775)
- 2. premature birth/ (779)
- 3. fetal membranes, premature rupture/ (3094)
- 4. premature labor.tw. (1755)
- 5. preterm labor.tw. (2853)
- 6. preterm birth\$.tw. (3070)
- 7. premature rupture.tw. (2802)
- 8. premature delivery.tw. (1405)

- 9. exp Infant, low birth weight/ (17599)
- 10. infant, premature/ (29170)
- 11.low\$ birth weight.tw. (11547)
- 12. preterm newborn\$.tw. (825)
- 13. preterm neonate\$.tw. (1493)
- 14. preterm infant\$.tw. (9037)
- 15. prematures.tw. (727)
- 16. or/1-15 (62939)
- 17. transportation of patients/ (6403)
- 18. patient transfer/ (3400)
- 19. medical transportation.tw. (30)
- 20. ambulance \$.tw. (4026)
- 21. transported patient\$.tw. (85)
- 22. patient transfer\$.tw. (448)
- 23. nontransported patient\$.tw. (2)
- 24. patient\$ transported.tw. (301)
- 25. transfer agreement/ (222)
- 26. or/17-25 (13398)
- 27.16 and 26 (271)
- 28. limit 27 to yr="1980 2007" (231)
- 29. from 28 keep 176 references
- 30. perinatal care/ (1261)
- 31. intensive care units, neonatal/ (5753)
- 32. neonatal care.tw. (1247)
- 33. neonatal intensive care.tw. (6248)
- 34. perinatal care.tw. (1121)
- 35. perinatal setting\$.tw. (25)
- 36. or/30-35 (12323)
- 37.26 and 36 (357)
- 38. limit 37 to yr="1980 2007" (328)
- 39. from 38 keep 124 references
- 40. exp pregnancy complications/ (250603)
- 41. pregnancy, high-risk/ (3184)
- 42. pregnancy complication \$.tw. (1557)

- 43. complicated pregnanc\$.tw. (698)
- 44. high-risk pregnanc\$.tw. (1831)
- 45. life threatening pregnanc\$.tw. (10)
- 46. or/42-47 (252970)
- 47.26 and 48 (230)
- 48. limit 49 to yr="1980 2007" (205)
- 49. from 48 keep 29 references
- 50.28 or 38 or 48 (554)
- 51.29 or 39 or 49 (329)

Selection of studies

After removal of duplicates, 554 references were retained from the different MEDLINE searches (1980-2007) and scanned for relevance. Articles were rejected on initial screen when neither titles, abstracts nor MeSH terms met the inclusion criteria. The remaining 329 articles were thus evaluated for inclusion in the current review.

The EBM Reviews databases did not contain any relevant publication.

From these extracted list and draft analysis, we finally integrated the data of 60 relevant publications.

4.1.2 Results

1. Regionalisation of care

Already in 1944, Sir Dugald Baird of Aberdeen showed that concentration of perinatal care is key to better perinatal health (Baird, 1944). One of the first efforts to put forth the philosophy of regionalized perinatal care was by the Department of National Health and Welfare in Canada, when it published 'Recommended Standards for Maternity and Newborn Care' in 1968 (Committee on Perinatal Health, 1976). It made the following statement: "It is recognised that certain mothers and infants, because of past pregnancy experience or present complications, are at high-risk for development of difficulties and require for their optimum care facilities and services

which may not be found in all hospitals providing maternity care. When these mothers and babies can be recognised and their problems anticipated there is a growing appreciation of the value of ensuring that they be cared for in hospitals with the best facilities even though this may require referral to another institution."

In 1970, a landmark paper 'The regional organisation of special care for the neonate', also from Canada, was published in *Pediatric Clinics of North America* (Swyer, 1970). In the following year, national bodies in both Canada (Graven, 1971) and the USA (AMA House of Delegates, 1971) published statements to urge that attention should be directed to the development and operation of centralized perinatal intensive care facilities in every geographic region. Two goals of regionalisation were described in the American Medical Association (AMA) document: (1) 'Programs to identify the high-risk pregnancy in sufficient time to allow for delivery at those hospitals which are staffed, equipped, and organised for optimal perinatal care'; and (2) 'Programs for the early recognition of high-risk infants not identified during the prenatal period, which provide for the prompt transfer of a distressed infant to a more appropriately equipped facility when indicated. Arrangements for transport should be an integral part of the planning for community centred programs'

The USA introduced the concept of regionalisation of perinatal care in the 1970s (Berger, Gillings, & Siegel, 1976). Programmes were designed to organize health services for high-risk babies to ensure that they were born in hospitals equipped with the optimal expertise and technology. They emphasized three parameters:

- 1. Maternity units were classified into three levels of care in relation to the services they could provide for high-risk mothers and babies,
- 2. Transport systems were organized to these centres,
- Links were organized between health structures to maintain expertise in lower level centres that were encouraged to transfer out their high-risk cases (Committee on Perinatal Health, 1976).

These programmes encouraged in utero transfer, considered to be the safest way to transfer a very preterm baby. Some Canadian provinces also implemented and evaluated these regionalisation programmes in the late seventies (Campbell, 1999).

Objective evaluations of this organisation of perinatal care provide:

- 1. the basis for much of the scientific knowledge on the effects of place of delivery on the survival of high-risk babies (Paneth et al., 1982)
- 2. Routinely validated indicators for monitoring regionalisation (Lindmark & Langhoff-Roos, 2004; Lupton & Pendray, 2004; Yu & Doyle, 2004)

Good results of regionalised perinatal care resulted in the continuation of the system in North America, even as it has come under attack by managed care systems (Gagnon et al., 1988; Gerber et al., 2001; Gessner & Muth, 2001). An ideal system for monitoring outcomes includes mortality, morbidity and care appropriate to the needs. Of the various perinatal mortality rates, the neonatal mortality rate is probably the most obvious to choose for monitoring perinatal health. This is because foetal deaths occur also in non-hospital setting and may go unreported, and post neonatal deaths are heavily influenced by social factors. *The neonatal mortality rate best reflects hospital care including obstetric service, neonatal care and transport service* (Hein, 2004).

In Europe, the organisation of perinatal care is currently under development in many European countries. Many of the initiatives to implement transfer policies, either through government action or the recommendations of scientific societies are recent. In this regard it is noteworthy that the Nordic European countries have developed validated tools and indicators of quality for the evaluation of the policies of in utero and neonatal transfers (Lindmark & Langhoff-Roos, 2004). The French policy was implemented in 1998, in Poland in 1995 (Lindmark & Langhoff-Roos, 2004; Minister of Health, 1999), and in Belgium in 1996. Both the Dutch (Health Council of the Netherlands, 2000) and Italian (Bollettiono Regionale del Lazio, 1997) recommendations were issued in 1999. Large differences occur in terms of health policies and in the size, supply and characteristics of maternity and neonatal units.

Table 1 summarizes the situation in 1999 in Europe. Belgium has indeed a policy to define the levels of care, based on a Royal Decree of 1987, but has not listed the indications for maternal or neonatal transfer, and has not structured the modalities of transport (Zeitlin, Papiernik, & Breart, 2004).

Table 1 Government policies and recommendations from scientific or professional societies concerning perinatal transports (EUROPET⁸ 1997-1999)

	Government policy	Recommendation from scientific or professional society	No written policy or recommendations
Levels of care *	Belgium Czech Republic France Italy (certain regions) The Netherlands (level III only) Poland Portugal Sweden	Denmark Finland Germany Ireland Italy Slovenia UK	Austria Greece Luxembourg Spain Switzerland
Indications for maternal or neonatal transfer	Italy (certain regions) Poland Portugal (neonatal transfer only)	Austria Czech Republic France (certain regions) Germany Italy The Netherlands	Belgium Denmark Finland France (certain regions) Greece Ireland Italy (certain regions) Luxembourg Slovenia Spain Sweden Switzerland UK
Organisation of neonatal transport	Czech Republic Denmark (certain regions) France Greece Italy (certain regions) The Netherlands (air transport) Poland Portugal Slovenia Spain (certain regions)	Germany Ireland UK (certain regions) Sweden (air transport)	Austria Belgium Denmark (certain regions) Finland Italy (certain regions) Luxembourg The Netherlands Spain (certain regions) Sweden (ground transport) Switzerland UK (certain regions)

^{*} Levels of care directly related to the care of pregnant women and newborns.

2. Levels of care

Levels of care are defined differently in different places. Countries with officially designated levels of care include Belgium (Ministère des affaires sociales de la santé publique et de l'environnement, 1996), the Czech Republic, France (Ministère de l'Emploi et de la Solidarité, 1998), some regions of Italy, The Netherlands, Poland, Portugal and Sweden. In the Netherlands, only level III units have an official definition (Ministerie Volksgezondheid, 1999).

⁸ The EUROpean network for PErinatal Transport (1996)

3. Indications for transfer

Official policies can be more or less comprehensive. Policy in the Netherlands designates the 10 NICUs that are allowed to provide neonatal intensive care to very preterm babies, but does not itemize indications for transfer to these centres or other guidelines. In Poland, the transfer programme includes specific health objectives, the classification of all maternity units, the establishment of conventions between units, and indications for transferring mothers and babies (Gadzinowski, Szymankiewicz, & Breborowicz, 1998). Some national scientific societies (Germany, Italy, Slovenia and Austria) issue recommendations and guidelines, which generally emphasize the importance of in utero transfer and birth in level III centres for very preterm babies (AWMF online, 1996). They provide detailed indications for in utero transfer to perinatal centres with criteria for perinatal centres and describe their organisational structure and other requirements.

In other European countries, both government and scientific societies play a role. In the Netherlands, as mentioned above, the government regulates the supply of neonatal intensive care. Guidelines for in utero transfer and criteria for using these services, however, have been issued by a scientific society (AWMF online, 1996; Nederlandse vereniging voor obstetrie en gynaecologie-Nederlandse vereniging voor kindergeneeskunde, 1999). In Denmark, a scientific committee drew up practice guidelines, which were subsequently endorsed by the National Board of Health (AWMF online, 1996; Truffert, Gadzinowski, & Peitersen, 1999). Some countries like Belgium have no guidelines, official or otherwise, for the place of delivery of very preterm babies. The UK recommendations define four levels of neonatal care: maximal intensive care, high-dependency care, special care and normal care (AWMF online, 1996; British Association of Perinatal Medicine, 1996). These do not, however, map clearly on to individual units. However, a recent government report has made recommendations about the importance of reorganizing neonatal care provision into managed networks and identifying level I, II and III units (AWMF online, 1996; Department of Health, 2003). Similarly, most regions in Spain do not have policies, and Switzerland has no official policies.

In summary, there is significant diversity among European countries and regions, in approaches to the provision of intensive care services for the small proportion of pregnant women and babies that need it.

Discrepancies between European countries make comparisons rather difficult as well as between "European" and US standards. It is difficult therefore to extract a definite picture of intra uterine transfer in Europe from them (AWMF online, 1996; Zeitlin et al., 2004).

4. Transport

Initiatives to improve care for preterm babies in some European countries have focused on the provision of better neonatal transport systems (Field, Milligan, Skeoch, & Stephenson, 1997). Some countries, including Belgium, have neither regionally organized maternal antenatal and neonatal transport systems nor guidelines governing in utero or neonatal transport.

The components that facilitate an effective neonatal emergency transport network, and the human resources required for safe transport are well known and described (AWMF online, 1996; Lupton & Pendray, 2004). Lupton and Pendray for Canada address in their review paper of 2004 all requirements related to equipment, communications, quality assurance; data management, family support and education in the context of a neonatal transport programme. In addition, elements involved in the organisation of neonatal transport and transport issues pertaining to networking of neonatal care are highlighted (Lupton & Pendray, 2004).

5. Quality of perinatal care in Europe

Evaluations of the care and outcome of very preterm babies are performed at a National level in many European countries, and by several studies sponsored by the European Commission (EUROPET⁹ and MOSAIC¹⁰ programmes) (Field & Draper, 1999; Finnstrom et al., 1997; Kollée, Verloovevanhorick, Verwey, Brand, & Ruys,

¹⁰ Models of Organising Access to Intensive Care for very preterm babies (2003)

⁹ The EUROpean network for PErinatal Transport (1996)

1988; Obladen et al., 1994; Papiernik & Keith, 1995; Truffert, Goujard, Dehan, Vodovar, & Breart, 1998; Viisainen, Gissler, & Hemminki, 1994; Zeitlin et al., 2004). The EUROPET (BMH4-CT96-1583) project (1996) surveyed policies and practices of perinatal transport and of maternal transfers in high-risk pregnancies and neonatal transfers for babies born before 32 weeks of gestation (Debauche, Van Reempts, Chabernaud, Kollée, & Zeitlin, 1999). The aim was to develop good practice guidelines for Europe (Kollée, Chabernaud, Van Reempts, Debauche, & Zeitlin, 1999; Papiernik, Breart, Di Renzo, & Sedin, 1999; Zeitlin et al., 2004).

The methodology used by the College of physicians for Mother and Newborn in the course of this project was derived from these European studies. In EUROPET (1996), a short questionnaire collected information on the total number of very preterm babies (age of less than 32 completed weeks of gestation) admitted to the unit, separated by whether they were inborn (born in the adjoining maternity unit) or outborn (transferred from another unit).

The MOSAIC (QLG4-CT-2001-01907) study examined from 2003, the care of very preterm babies in 10 regions in Europe. A similar protocol collected indicators of care and outcome for all births before 32 weeks of gestation in the participating regions.

Place of birth of very preterm babies in Europe (<32 weeks)

Information from the EUROPET study of large NICUs as well as data from the published literature make it possible to draw a rough picture of the place of birth of preterm babies in Europe.

Table 2 Inborn rates of the very preterm population (<32 weeks) hospitalized in large NICUs in Europe (Zeitlin et al., 2004)

	Number of NICUs admitting more than 40 babies <32 weeks GA	Average inborn rate for babies <32 weeks GA in these units
Finland	4	97.9
Ireland	3	97.8
Portugal	9	88.9
Spain	9	85.9
Germany	30	84.6
Denmark	6	86.4
Sweden	6	86.2
Northern Ireland	2	84.1
Italy	19	82.2
Northern region, UK	4	78.9
Switzerland	8	77.9
Belgium	12	77.4
Poland: 10 regions	10	72.3
The Netherlands	10	71.1
Austria	8	61.1
Hungary	16	56.3
Greece	9	56.2
France	25	50.8

NICU. Neonatal intensive care unit; GA. gestational age.

Countries in italics had a response rate of <75% of all NICUs surveyed.

Table 2 provides information on the average inborn rates in 1996 in the EUROPET study (Zeitlin et al., 2004). In most European countries, only few very preterm babies were born in level I units. Postnatal transports of very preterm babies to tertiary centres are infrequent but the survey included only reference NICUs. It thus did not include babies born and cared for in other units, or babies who died before admission to a level III neonatal unit. Data are available from Finland (Viisainen et al., 1994; Wildman, Blondel, Nijhuis, Defoort, & Bakoula, 2003), France (Chale et al., 1997; Fresson, Blondel, & Truffert, 2001; Papiernik, Bucourt, Zeitlin, Senanedj, & Topuz, 2001), Germany (Papiernik et al., 2001; Von Loewenich & Vonderheit, 1996), The Netherlands (Jonsson, KatzSalamon, Faxelius, Broberger, & Lagercrantz, 1997; Kollee, Verwey, Ouden, & et al, 1996), Sweden (Finnstrom et al., 1997; Jonsson et al., 1997) and the UK (Cole & Macfarlane, 1995; Field & Draper, 1999). In addition, very preterm babies were born in large center NICUs.

France implemented its regionalisation programme in 1998. In 1991, only 15% of very preterm babies were delivered in level III unit vs. 63% in 1997, and 82% in 2003. In the Netherlands, between 1983 and 1995, the percentage of births delivered in level III units rose from 34% to 68%.

Overall, between 50% and 70% of the very preterm babies in the countries represented in this table were born in large units (1990s, 51).

^{*} One NICU was at a distance from its reference maternity unit; this unit has since moved, giving an overall rate of 80%.

4.1.3 Conclusions

The variety of approaches in countries with similar levels of development and medical technology offers a unique opportunity to understand how different organisational characteristics affect access to care, health outcomes and resources use. Comparative analyses of the efficacy of these different policies in terms of health outcomes for preterm babies have not yet been undertaken. Studies have identified significant variations in perinatal mortality rates linked to these differences (De Leeuw et al., 2000; Graafmans et al., 2001).

Despite their differences, European countries are seeking answers to common problems. The multitude of recently issued policies and recommendations on these high-risk births suggest unresolved difficulties in many countries (Debauche et al., 1999). There is, for example, uncertainty over the appropriate size of units in which babies at risk should receive care. Some studies show that mortality is higher among infants who receive care in small neonatal units with a low volume of patients (Darlow & Horwood, 1992; Finnstrom et al., 1997; Harding & Morton, 1994; Phibbs, Bronstein, Buxton, & Phibbs, 1996). In other settings, however, equivalent outcomes result from delivery and hospitalization in smaller units for very preterm newborns and, in some cases, transport after birth does not increase the risks of mortality (Arad et al., 1999; Field & Draper, 1999; Meadow et al., 2002; Phibbs et al., 1996; UK Neonatal Staffing Study Group, 2002). A recent study of high-risk infants in Scotland and Australia conjectured that observed differences in mortality were due to differences in the characteristics of neonatal units (International Neonatal Network, Scottish Neonatal consultants, & Nurses Collaborative Study Group, 2000; Meadow et al., 2002).

Another common problem concerns space and management impeding maternal transfers. In the UK, for example, the number of transfers between level III units is increasing due to lack of space (Parmanum, Field, Rennie, & Steer, 2000). These problems also exist in The Netherlands: The authors of a recent governmental report concluded that 983 mothers whose babies needed intensive care were not admitted to a perinatal centre before delivery (Health Council of the Netherlands, 2000).

Further study of the advantages and the disadvantages of the diverse European models of care could provide insight for countries seeking to improve the organisation of care and health outcomes for this population of high-risk births (Zeitlin et al., 2004).

The experience in the USA, UK and Australia has indicated that, despite the great benefits of regional organisation, a number of common and inevitable problems will arise, which require careful attention and management.

The following problems have been summarized in the review by Yu & Dunn (2004):

- 1. The conflict of interest between the centralization of resources and local provision
- 2. The problem of transporting patients and relatives between hospitals;
- 3. The potential loss of skills in managing high-risk pregnancies and babies at the level of the peripheral hospital in case all high-risk patients are transferred to level III units.
- 4. A loss of status and prestige for the referring hospital;
- 5. A loss of income for the referring hospital and the referring physician;
- 6. The problem of inadequate staffing and facilities in the NICs and MIC's, and the need to place over-reliance on junior doctors and nurses in training even in many of the best regional perinatal centres."

4.2 Retrospective study

4.2.1 Methodology

1. Setting and population

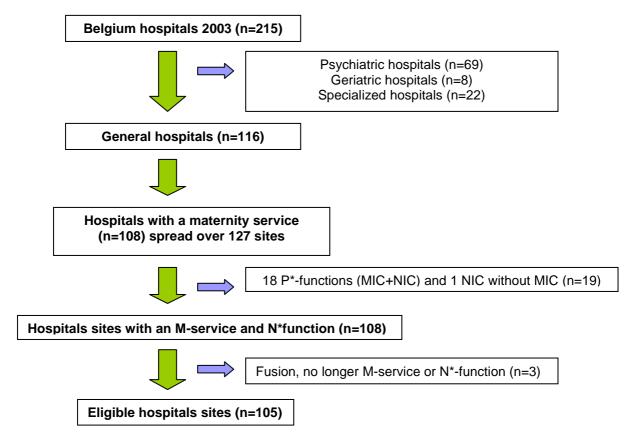
In 2003, Belgium counted 215 hospitals, 116 of them registered as general hospitals. Of these, 108 hospitals have a maternity service spread over 127 sites¹¹. In Belgium, hospitals with a maternity service are obliged to havean N*function. In this study only hospitals with an M-service and an N*-function (n= 108) were included. The 19 hospitals that were excluded, are 18 P*-functions (with a MIC and NIC-service) en one hospital with only a NIC-service. Patients from an M-service respectively N*-function are referred to the MIC/NIC hospitals in case they need specialized intensive care.

Three out of the 108 eligible hospitals with M/N*-service were excluded because they have been merged with another hospital or they reported not longer having an M-service or N*-function in their hospital. Thus, 105 hospitals with M/N*-function were invited to participate in the study.

¹¹ Source: Federal Public Service, Health, Food chain safety and Environment

Figure 2 provides an overview of the selection of the study population.

Figure 2 Flow chart selection of the study population



2. Design and data collection

A semi-quantitative questionnaire (Annex 4) was addressed to the heads of departments M-service and N*-function. In a first part the questionnaire asked for quantitative data (general numerical data) for the year 2004 (e.g. number of deliveries, number of obstetricians/gynaecologists/paediatricians in place, number of (re)transfer). Qualitative data were collected through a semi-structured questionnaire asking about current policies, as well as their opinion and suggestions on how to improve care. Because of the specificity of certain topics, two different types of questionnaires were developed: one for the M-service and one for the N*-function.

4.2.2 Results

A. QUANTITATIVE DATA

1. Response rate

A response was received of 87 of the 105 hospitals (82.9%). From 62 hospitals (71.3%) both M-service and N*-function filled the questionnaire. For 13 hospitals (14.9%) and 12 hospitals (13.8%) response was only available from respectively the N*-function and the M-service. <u>Further analyses are based on data obtained from the 62 hospitals where both sections have provided data.</u>

2. Number of deliveries

In 2004, 117.990¹² deliveries were registered in Belgium. Of these, 86.179 (=73.0%) occurred in a maternity service and 31.811 (27.0%) in a maternity with MIC-service.

The data available in this study are related to the total number of <u>50.577 deliveries</u> in the Belgian M-services (2004). Hence, our study represents <u>58.7%</u> (50,577 out of 86.179) of the deliveries registered. Table 3 illustrates the distribution of the number of deliveries in 7 categories according to the size of the maternity.

Table 3: Distribution of deliveries (retrospective study)

Number of deliveries (category)	Number of hospitals within category (n=62)	Number of deliveries (n=50.577)
0-399	5 (8.1%)	1.798 (<1%)
400-599	16(25.8%)	8.553 (16.9%)
600-799	19 (30.6%)	13.066 (25.8%)
800-999	8 (12.9%)	7.199 (14.2%)
1000-1199	7 (11.3%)	7.417 (14.7%)
1200-1399	3 (4.8%)	3.862 (<1%)
≥1400	4 (6.5%)	8.682 (17.2%)

Most of the deliveries are performed by an obstetrician/gynaecologist (98.8%). Only 0.8% of the deliveries were handled by a general practitioner.

¹² Source: Federal Public Service, Health, Food chain safety and Environment

3. In utero-transfers (IUT)

The number of IUTs in 2004 was provided by 57/62 (91.9%) M-services. They reported 421 IUT transfers out of a total of 46.747 deliveries (which is the total of deliveries performed in these 57 M-services). **The IUT rate in Belgium (2004) can be estimated at 0.9% or 90 transfers/10.000 deliveries.**

The range in number of IUTs is large between the different M-services. About half of the M-service reported 3 to 10 IUT in 2004.

Over half of the hospitals (56.1% or 32/57) have a number of deliveries ranging between 400 to 799 per annum and therefore account for the preponderance of IUTs (Table 4). However, it may also be noticed that the few relatively larger hospitals (≥ 1000 deliveries) still account for about one third of all IUTs (32.5% or 137/421).

Table 4: Distribution of IUTs in relation to the number of deliveries (category)

Number of deliveries (category)	Number of hospitals within category (n=57)	Number of in utero transfers within category	Number of deliveries (n=46.747)	IUT rate
0-399	5	10 (2.4%)	1.798 (<1%)	0.6%
400-599	15	88 (20.9%)	7.976 (17.1%)	1.1%
600-799	17	139 (33.0%)	11.709 (25%)	1.2%
800-999	7	47 (11.2%)	6.389 (13.7%)	0.7%
1000-1199	6	55 (13.1%)	6.331 (13.5%)	0.9%
1200-1399	3	33 (7.8%)	3.862 (<1%)	0.9%
≥ 1400	4	49 (11.6%)	8.682 (18.6%)	0.6%

4. Maternal transfers in the postnatal period

We tried to collect information on the number of transfers (2004) in the postnatal period for maternal indications. Most respondent have interpret this question incorrectly and included in their answers also or only postnatal neonatal transfers where the mother is admitted in the early postpartum to accompany her newborn baby who is admitted for intensive care. Therefore we decided not presenting these results in the report.

5. Maternal retransfers

We asked for the number of maternal retransfers in 2004. Maternal retransfer means the retransfer of a <u>pregnant woman</u> from the MIC-service to the referring M-service. Answer was obtained from 83.9% (52/62) M-services. They reported 113 maternal retransfers out of 41.010 deliveries (which is the total of deliveries performed in these 52 M-services). The rate of maternal retransfer in Belgium (2004) can be estimated at 0.28% or 28 retransfers/10.000 deliveries.

Most M-services (90.4% or 47/52) reported 0 to 5 retransfers. Of the participants who answered this question, 61.5% (30/52) mentioned no maternal retransfer in 2004.

In our study approximately 32.7% (113 maternal retransfers/ 346 IUTs) of the mothers, hospitalized in a MIC-service after IUT, were retransferred to the referring hospital. Answer on both questions was obtained from 80.6% (50/62) participants. Analysis of the relation between IUT and maternal retransfer per hospital was difficult because of the small sample size.

6. Neonatal transfers (Outborns)

By asking for the number of neonatal transfers (2004) we want to gain clear insight in the number of neonates, whom are born in the referring hospital and need transfer to a neonatal intensive care unit. Answer was obtained from 60/62 (96.8%) N*-functions. They reported 712 neonatal transfers out of 49.618 deliveries¹³ (which is the total of deliveries performed in these 60 M-services). The rate of neonatal transfer in Belgium (2004) can be estimated at 1.43% or 143 neonatal transfers/10.000 deliveries. About half of the N*-functions report 7 to 14 neonatal transfers in 2004

Over half of the hospitals (56.7% or 34/60) have a delivery rate of 400 to 799 deliveries per annum and therefore account for the preponderance of neonatal transfers (Table 5). However, it may also be noticed that the few larger hospitals (≥ 1000 deliveries) still account for about one third of all neonatal transfers (33.8% or

241/712). It seems that relatively smaller hospitals have a higher rate of neonatal transfers than the few larger ones.

Table 5: Distribution of neonatal transfers in relation to the number of deliveries (category)

Number of deliveries (category)	Number of hospitals within category (n=60)	Number of neonatal transfers within category	Number of deliveries (n=49.618)	Neonatal transfer rate
0-399	4	51 (7.2%)	1.497 (<1%)	3.4%
400-599	16	122 (17.1%)	8.553 (17.2%)	1.4%
600-799	18	199 (27.9%)	12.408 (25%)	1.6%
800-999	8	99 (13.9%)	7.199 (14.5%)	1.4%
1000-1199	7	138 (19.4%)	7.417 (14.9%)	1.8%
1200-1399	3	34 (1.8%)	3.862 (<1%)	0.8%
≥1400	4	69 (9.7%)	8.682 (17.5%)	0.8%

7. In utero transfer versus neonatal transfer

To get further insight in the transfer policy of a hospital, we explored the potential relationship between the number of in utero transfers and the number of neonatal transfers for the referring hospitals. A high IUT rate may be expected with a low neonatal rate and vice versa. A slight negative, but non significant correlation was found between in utero transfer and neonatal transfer (r= -0.195, P=0.149) (Fig 3). Also a ratio IUT-neonatal transfer was calculated and correlated with the total number of deliveries. This correlation was also weak (r= 0.141) and not significant (P=0.304) (Fig 4). Analysis per hospital was not done due to the small sample size.

 $^{^{13}}$ A more appropriate denominator should be live births, but these data are not available. In 2004, Foetal death in Flanders was 0.42% (SPE)

Figure 3: Correlation between number of in utero transfers and number of neonatal transfers (2004)

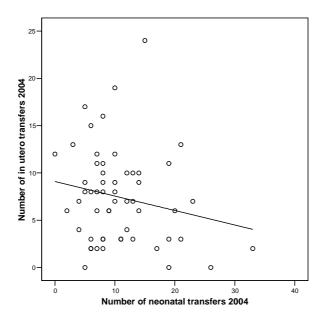
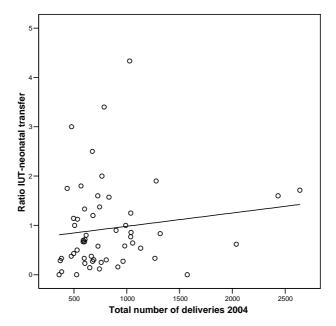


Figure 4: Correlation between ratio "IUT-neonatal transfer" and number of deliveries



8. Neonatal retransfers (In/outborns)

A question about the total number of neonatal retransfers in 2004 was included in the questionnaire. For these, no distinction was made between the retransfer of inborn (after IUT) and outborn neonates. Answer was obtained from 59/62 (95.2%) N*-functions. They reported 566 neonatal retransfers.

In our study approximately 54.2% of the neonates, hospitalized in a NIC-service after IUT or neonatal transfer, were retransferred to the referring hospital. This retransfer rate might be slightly underestimated, because approximately one third of the IUTs were retransferred and thus these neonates are not inborns. Only the hospitals (87.1% of 54/62) from whom an answer was obtained on these three questions (number of IUTs, neonatal transfer and retransfer) were included in the analysis.

9. Refusal rate of transfers by P*-function

We asked the participants if the P*-function ever refused their request for maternal or neonatal transfer. Approximately <u>one third of the participants mentioned a non acceptance of transfer by the P*-function (M-service: 30.6% or 19/62, N*-function: 40.3% or 25/62).</u>

Further we examined the reason for refusal. In most cases the transfer was refused because the maximal hospital bed occupancy of the NIC-service was reached. The M-service and N*-function reported a problem of the NIC-service in 73.7% (14/19) respectively 96% (24/25) of the refusals. A non acceptance of transfer occurred in 42.1% (8/19) by the MIC-service. Two responders mentioned another reason for refusal: a gestational age <24 weeks and transfer refused by obstetricians/gynaecologists, paediatrician and family.

10. Costs of maternal transfer and retransfer

One of the questions refers to the costs related to maternal (re)transfer. The heads of department M-service were asked if they had an idea of the financial contribution to (or reimbursement for) these costs by their institution. Only a few participants are

aware of the costs of maternal transfer (24.6% or 15/61) and retransfer (13.1% or 8/61). One of the questions was related to the awareness of the costs or reimbursement of these costs. Answer on this question was obtained from 79.4% (43¹⁴/62) of the participants. Only 18.6% (8/43) mentioned having an idea of the amount of costs.

11. Determinants of perinatal referral patterns

In the questionnaire we had included a list of reasons/determinants why an M-service and N*-function refer to a particular P*-function. The participants were asked to number these reasons in sequence according to their preference (1= first choice and 7=last choice). We asked the participants to classify following determinants: distance, preference patient, organisation and policy P*-function, language purpose, agreement with P*-function, specificity P*-function and institution of academic education. Also the possibility "other" was provided as an answer option.

For analysis we included only the three main motivations for choice of referral hospital. Incomplete answers were excluded. Because of the small sample size, no separate analysis was made for M-service and N*-function only. There seemed no significant difference in the answers of the M-service and N*-function, except for the determinant distance (two-side P-value = 0.04).

A total response rate (M-service and N*-function) for this question was obtained by 89.5% (111/124) of the participants. Approximately a same response rate was received from both services. For the M-services 88.7% (55/62) and N*-functions 89.5% (56/62) of the participants answered this question.

Of all determinants of perinatal transfer, distance was mentioned by the M-service and N*-function in 22.5% of the cases as the most important or second important reason. Institutional or academic links (4.1%) and language (5.0%) were not reported as determinants for perinatal transfer. The other determinants seemed to be of the same importance: preference patient (17.1%), organisation and policy P*-function (17.1%), agreement with P*-function (18.0%) and specificity P*-function (16.7%).

¹⁴ From 19 participants we did not obtained an answer on this question

12. Written agreement between M/N*-function and P*-function

In this study 90.3% (56/62) of the M-services and 93.5% (58/62) of the N*-functions report having an agreement with a MIC/NIC unit (P function). According to the heads of departments of M-service and N*-function, most of the obstetricians/gynaecologists (83.9% or 47/56) and paediatricians (94.8% or 55/58) in service comply with this written agreement.

When asked if the agreement contains criteria for maternal or neonatal transfer, only 50% (28/56) mention criteria for IUT, 32.1% (18/56) criteria for maternal transfer in postpartum and 56.9% (33/58) criteria for neonatal transfer.

A copy of the agreement between M/N*-function and a P*-function was received from 59 out of the 105 hospitals (56.2%). In all, 131 agreements were sent in, but only 123 agreements were considered, corresponding with a response of 51.4% (54/105) of the hospitals. Eight agreements were excluded of analysis because they contain no elements of collaboration between M/N*-functions and P*-functions. Of these 8 agreements, 2 agreements were an intern order, 2 a collaboration between departments, 3 a protocol concerning SIDS (sudden infant death syndrome) and one was under negotiation.

The analysis of the agreements received shows a great difference in number of agreements per hospital. As illustrated in the following figure, most hospitals have 1, 2 or 3 agreements with a given P^* -function. A few hospitals mention \geq 4 agreements with a P^* -function.

Number of hospitals **Number of agreements**

Figure 5: Number of agreements per hospital

The same trend can be seen for the number of agreements per P*-function. Some P*-functions have an agreement with one hospital. Others have an agreement with more than 1 up to 18 hospitals (Fig 6)

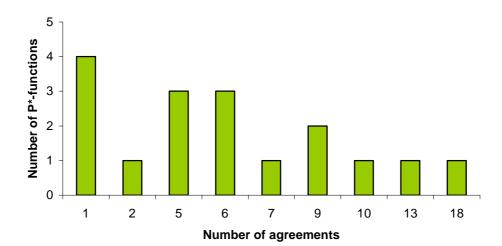


Figure 6: Number of agreements per P*-function

The type of agreement is not specified in 61.8% (76/123) of the agreements. Only 0.8% (1/123) was exclusive, the others (37.4% or 46/123) were defined as non-exclusive.

B. QUALITATIVE DATA

In the qualitative part of this study, nine statements (table 6) concerning perinatal referral policy were formulated. The participants had to evaluate these statements on a 5 point Likert scale (1= strongly agree to 5= strongly disagree).

Table 6: Nine statements concerning perinatal referral policy

- 1. National guidelines and criteria are necessary for an optimal policy of transfer and retransfer
- 2. Standardization of perinatal policy will bring benefits from a medical point of view
- 3. Standardization of perinatal policy will bring benefits from a social point of view (mother and family)
- 4. Standardization of perinatal policy will bring benefits from a financial point of view
- Neonates <32 weeks gestation and/or <1500 grams should be transferred in utero to a P*function
- 6. An elimination of the high-risk situation of mother or foetus and/or a gestational age of 34 weeks are good criteria for retransfer
- 7. The transfer of a high-risk pregnancy is a multidisciplinary decision of paediatricians and obstetricians/gynaecologists of both referring hospital and the P*-function
- 8. In utero transfer is preferred over neonatal transfer, except in case of an imminent threatened delivery
- 9. The structured organisation of perinatal care has an important influence on neonatal morbidity and mortality

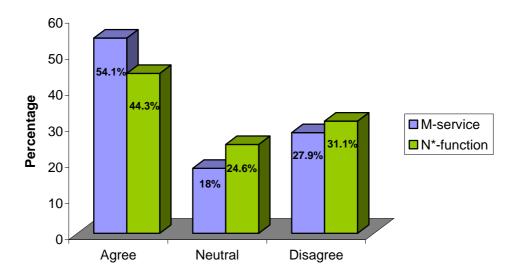
To enhance the interpretations of the results, statistical analyses were performed on a 3 point Likert scale (1 = strongly agree to agree, 2 = neutral, 3 = disagree to strongly disagree). Table 7 presents the opinions of both M-service and N*-function on the different statements on the 3 point Likert scale. No significant difference were found between the answer of the heads of M-service and N*-function.

Table 7: Opinions of the M-service and N*-function regarding perinatal referral policy (N=123)

		Agree	Neutral	Disagree
1.	National guidelines and criteria	60 (49.2%)	26 (21.3%)	36 (29.5%°
2.	Standardization medical point of view	76 (61.8%)	20 (16.3%)	27 (22.0%)
3.	Standardization social point of view	32 (26.0%)	47 (38.2%)	44 (35.8%)
4.	Standardization financial point of view	38 (30.9%)	53 (43.1%)	32 (26.0%)
5.	<32 weeks an/or <1500 grams→ IUT	100 (82.0%)	10 (8.2%)	12 (9.8%)
6.	Resolution high-risk situation and/or 34 weeks → retransfer	112 (91.1%)	0 (0%)	11 (8.9%)
7.	Transfer of high-risk pregnancy = multidisciplinary decision	113 (91.9%)	1 (0.8%)	9 (7.3%)
8.	In utero transfer is preferred above neonatal transfer	112 (92.6%)	2 (1.7%)	7 (5.8%)
9.	Organisation perinatal care \rightarrow influence neonatal mortality/morbidity	110 (89.4%)	9 (7.3%)	4 (3.3%)

Figure 7 shows that only 50% of the participants (54.1% M-service, 44.3% N*-function) are convinced of the usefulness of national guidelines and criteria concerning transfer policy.

Figure 7: National guidelines and criteria are necessary for an optimal policy of transfer and retransfer



As illustrated in figures 8-10, the participants consider standardization of perinatal referral policy to be beneficial from a health point of view, not at social and financial levels.

Figure 8: Standardization of perinatal policy will bring benefits from a medical point of view

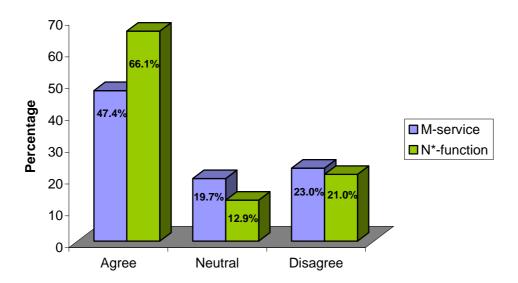


Figure 9: Standardization of perinatal policy will bring benefits from a social point of view (mother and family)

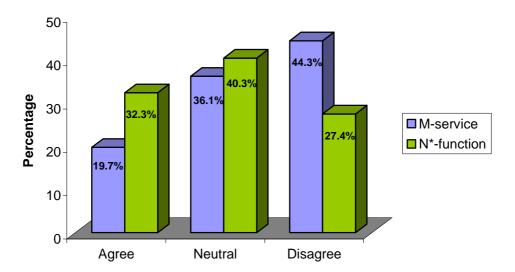
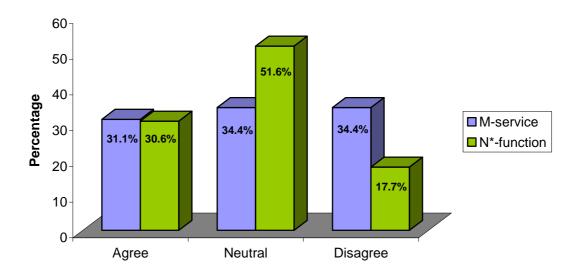


Figure 10: Standardization of perinatal policy will bring benefits from a financial point of view



Over 80% of the respondents endorse in utero transfer for neonates <32 weeks gestation and/or <1500 gram (Fig 11).

Figure 11: Neonates <32 weeks gestation and/or <1500 grams should be transferred in utero to a P*-function

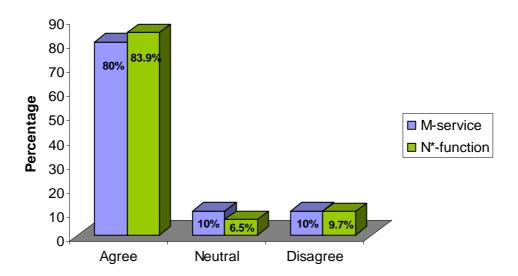
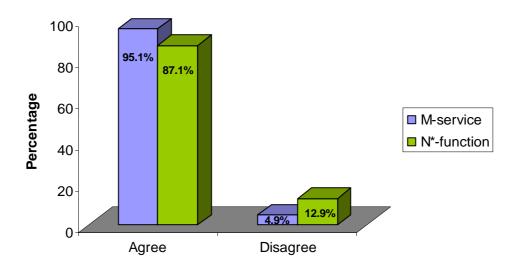


Figure 12 illustrates that stabilisation of the obstetrical problem and/or a gestational age of 34 weeks can be seen as good criteria for retransfer.

Figure 12: Stabilisation of the obstetrical problem and/or a gestational age of 34 weeks are good criteria for retransfer



Most participants agree that the transfer of a high-risk pregnancy has to take place after multidisciplinary decision of paediatricians and obstetricians/gynaecologists (Fig 13) and that in utero transfer is preferred above neonatal transfer (Fig 14).

Figure 13: The transfer of a high-risk pregnancy is a multidisciplinary decision of paediatricians and obstetricians/gynaecologists of both referring hospital and the P*-function

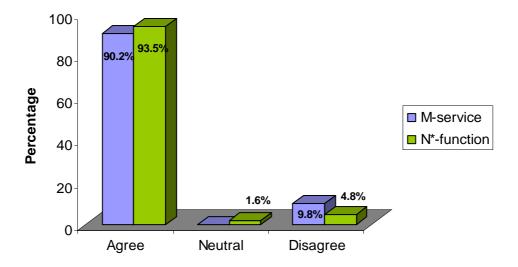


Figure 14: In utero transfer is preferred over neonatal transfer, except in case of an imminent threatened delivery

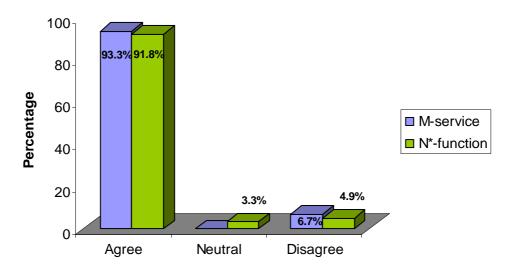
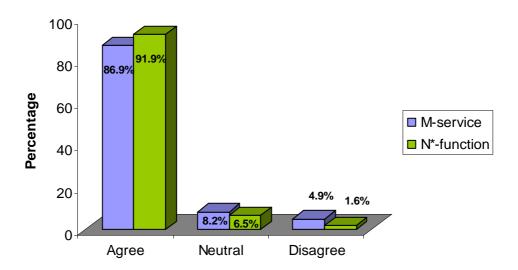


Figure 15 illustrates that the participants believe that neonatal morbidity and mortality can be influenced by the way perinatal care is organised.

Figure 15: The structured organisation of perinatal care has an important influence on neonatal morbidity and mortality



At the end of the questionnaire, participants were invited to formulate recommendations to improve perinatal referral patterns. Although few responders provided an answer to this question, some interesting findings emerged.

In particular, the heads of departments M-service (25.8% or 16/62) and N*-function (41.9% or 26/62) emphasized following obstacles and recommendations:

- P*-functions should organize practical and theoretical training (e.g. literature review, discussion forums on patient cases) and consultation for physicians and paramedical personnel of the M-services and N*-functions
- Communication between referral and referring hospitals should be optimized
 (e.g. spontaneously daily briefing by telephone, e-mail)
- Clearly defined criteria for transfer and re-transfer have to be established, and should be discussed with societies of paediatricians and obstetricians/gynaecologists before implementation
- Guidelines should be not undermining the autonomy of the physicians in regional hospitals. It should be possible to make decisions in function of available means and professional competence (fear of overregulation).
- More uniformity and consensus concerning perinatal transfer policy between
 P*-functions is necessary

- A better financing system for physicians in referring hospitals is needed (e.g. a code of RIZIV/INAMI for multidisciplinary communication, a number of admission for the neonate)
- P*-functions should have a clear and active policy of retransfer
- Perinatal care in Belgium should be more regionalised
- Clear policies are needed in the area of perinatal transfer and re-transfer on the organisational, financial and legal level.

It has to be emphasized that these statements are individual comments of obstetricians/gynaecologists and paediatricians who participated in the retrospective study.

4.2.3 Conclusions

Based on the results of this retrospective study, following rates of maternal and neonatal (re)transfer were calculated for the year 2004

In utero transfer	90 transfers/10.000 deliveries
Maternal retransfer	28 transfers/10.000 deliveries
Neonatal transfer (outborns)	143 transfers/10.000 deliveries

The <u>in utero transfer rate</u> in Belgium can be estimated at 90/10.000 deliveries. The proportional transfer was higher for small hospitals. Out of 10.000 deliveries 143 neonatal transfers were reported. No correlation was found between the number of neonatal transfers and the number of in utero transfers.

Retransfers of pregnant women from the MIC-service to the referring M-service can be estimated at 28/10.000 deliveries. In relation to the number of IUT, it means that one third (32.7%) of the IUTs were retransferred to the original M-service. No information was available about the other IUTs: the mother can be delivered in the P*-function after IUT or she can be discharged directly home.

The Royal Decree of 20th August 1996 provides no recommendations and modalities concerning transport systems. It is only mentioned that a transfer team should be

available for neonatal transfer. (Art 5. § 2 point 4). Further, the organisation of a maternal transfer is not specified. The retrospective study did not allow conclusions about how the maternal transfer occurred in Belgium. In the field, heads of maternal and neonatal departments did not seem to be knowledgeable about the costs and reimbursement modalities of transport. Our study shows that costs for IUT and maternal retransfer are largely unknown by the M-services and that maternal referral procedures are not well documented.

In Belgium, P*-functions have established agreements of collaboration with an M/N*-function, in order to cover for a joint total of at least 5000 deliveries per year. Also the N*-function should develop criteria for neonatal transfer and retransfer which should be concretized in an agreement with a NIC-service. Our results show that most of hospitals have indeed written agreements, but these agreements are heterogeneous, not standardized. Although we received copies of the agreements from 51.4% (54/105) hospitals with a P*-function only, we found a significant diversity in number of agreements per hospital and per P*-function. In fact, this may indicate that the concept of regionalisation of perinatal care has not been realised all over the country. There is also large variation in content of the agreements. Indications for transfer or retransfer for mother and neonate are missing in most documents

The qualitative part of the study shows that most participants are convinced that neonates <32 weeks gestation and/or <1500 gram should be transferred in utero, however, only 50% of the participants believes that national guidelines and criteria will improve perinatal transfer policies. They also agree that when stabilisation of the obstetrical patient occur and/or gestational age of 34 weeks retransfer to the referring hospital should be organised by the P*-function.

Limitations of the study

Despite the actual analysable response rate of 82.9%, the results of this retrospective study should be interpreted with caution. In Belgium there is no standard registered data system available concerning perinatal referral patterns.

Because of the difference in health systems, thus in organisation of perinatal care between (European) countries, it was not possible to translate data from other countries to the Belgium situation. Therefore the study has to be seen as a unique nationwide experiment or pilot study. To study the perinatal referral patterns in Belgium, data collection occurred using of a semi-structured questionnaire leading to some incomplete response rate and missing data. Furthermore data analysis is based on self reported data from the heads of departments of M-service and N*-function which can be threaten the validity of the study. The sample size was rather small to perform statistical analysis, because of the relative small number of hospitals in Belgium. A longer registration period may be increase the validity of data.

In summary, out of the data of the retrospective study and taking the limits of the study into account, we can conclude that 1) most surveyed health care providers in the field are knowledgeable about the transfer policies laid down in the Royal Decree in 1996, 2) that they are convinced that pregnant women at risk for very preterm labour (<32 weeks gestation and/or with an expected birth weight of <1500 g) should be referred to a perinatal centre, 3) that the referral rates in Belgium appear to be good, and that most hospitals adhere to the Decree, 4) that there is a lack of clear guidelines about implementation of IUT and retransfer, including clinical agreements, financial regulations for referrals and costs of transport, 5) that there is a need for better support, evaluation and monitoring of regionalized perinatal care.

4.3 Prospective study

4.3.1 Methodology

1. Setting and population

In the prospective study, hospitals with an M-service and N*-function (n= 105) or MIC-service (n=18) were included. One hospital with only a NIC-service (NIC without MIC) was excluded. Three out of the 108 eligible hospitals with M/N*-service were excluded because they have been merged with another hospital or they reported not longer having an M-service or N*-function in their hospital.

2. Design and data collection

The objective of this study was to collect on-line individual baseline information for every pregnant woman transferred and for every neonate born between 22 and 32 weeks and/or with an expected birth weight of <1500 g. In order to have precise data on transfer and re-transfer information was to be collected prospectively for a period of 1 year.

Three standard forms were developed to be filled out in the prospective study (Annex 5)

- for every mother transferred from an M-service to a MIC-unit, or if there was no maternal transfer, the reason of non-transfer. The form was filled out by the obstetrician/gynaecologist.
- for every neonate transferred from an N*-function to a NIC-unit, or if there was no maternal transfer, the reason of non-transfer. The form was filled out by the paediatrician.
- for each transferred mother from an M-service to a MIC-unit, the form was filled out by the obstetrician/gynaecologist of the MIC-unit.

For every mother transferred from an M-service to a MIC-unit two forms were to be filled out, one by the obstetrician/gynaecologist of the referring hospital (1) and one by the obstetrician/gynaecologist of the MIC-unit (3) (data control).

The prospective study started the first of September 2005 and ended the 31st of August 2006.

Inclusion criteria: all in utero transfers with a gestational age between 22 weeks and less than 32 weeks, and/or an expected birth weight less than 1500 gram. Pregnancies lower than 22 weeks or higher than 32 weeks were excluded, as well as third trimester interruptions of pregnancy (for severe fetal malformations).

Due to poor quality of the data and low response rate, the results were related to data of SPE¹⁵ and MOSAIC¹⁶.

4.3.2 Results

1. Response rate

After a first evaluation at 6 months, the response rate was low and the data were of poor quality. The study team decided to call upon the hospitals and to send reminders. Finally, we managed to get a response rate of 51.4% (54/105) of the M-services, 37.1% (39/105) of the N*-functions and 61.1% (11/18) of the MIC-services (Fig. 16).

¹⁵ Studiecentrum voor Perinatale Epidemiologie

¹⁶ Models for Organising Access to Intensive Care for very preterm babies

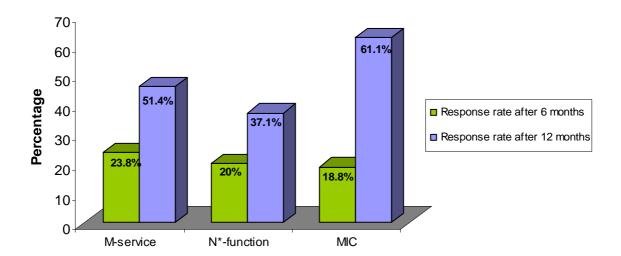


Figure 16: Response rate on the prospective study after 6 and 12 months

2. Number of deliveries

In 2004, 117.990¹⁷ deliveries were registered in Belgium. Of these, 86.179 (=73.0%) occurred in a maternity service and 31.811 (27.0%) in a maternity with MIC-service.

The data available in this prospective study is related to a total number of <u>45.634</u> <u>deliveries</u> in the <u>Belgian M-services</u> and <u>16.858 deliveries</u> in the <u>MIC-services</u> (2004). Hence, our study represents <u>58.7%</u> (45.634 out of 86.179) of the deliveries registered in the <u>M-services</u> and <u>53.0%</u> (16.858 out of 31.811) in the <u>MIC-services</u>.

Tables 8 to 10 illustrate the distribution of the number of deliveries in 7 categories according to the size of the maternity.

¹⁷ Source: Federal Public Service, Health, Food chain safety and Environment

Table 8: Distribution of deliveries (prospective study, responses from M-service)

Number of deliveries (category)	Number of hospitals within category M-service (n=54)	Number of deliveries (n=45,634)
0-399	5	1.709 (3.7%)
400-599	14	7.384 (16.2%)
600-799	15	10.465 (22.9%)
800-999	8	6.949 (15.2%)
1000-1199	4	4.323 (9.5%)
1200-1399	3	3.814 (8.4%)
≥1400	5	10.880 (23.8%)

Table 9: Distribution of deliveries (prospective study, responses from N*-function)

Number of deliveries (category)	Number of hospitals within category N*-function (n=39)	Number of deliveries (n=32,304))
0-399	2	678 (2.1%)
400-599	11	5.876 (18.2%)
600-799	14	9.827 (30.4%)
800-999	4	3.644 (11.3%)
1000-1199	2	2.169 (6.7%)
1200-1399	3	3.861 (12.0%)
≥1400	3	6.249 (19.3%)

Table 10: Distribution of deliveries (prospective study, responses from P*-function)

Number of deliveries (category)	Number of hospitals within category MIC (n=11)	Number of deliveries (n=31811)
0-399	0	0
400-599	0	0
600-799	0	0
800-999	2	1.768 (5.6%)
1000-1199	1	1.078 (3.4%)
1200-1399	2	2.506 (7.9%)
≥1400	6	11.506 (36.2%)

3. Validation of the findings

Because of the low response rates and because of the concern of inaccuracies in the files received from the hospitals, we decided to contact the principal investigators of 2 other datasets, (1) in Flanders (SPE) and (2) in Europe (the MOSAIC project) and in Belgium (NIC-audit project), with the objective to validate the broad range of our findings.

In order to provide a better understanding of the 2 projects, we hereby summarize them:

A. The MOSAIC project

The MOSAIC studies the organisation of health care for very preterm births and its impact on access to care and severity-adjusted health outcomes for all births occurring before 32 weeks gestation in 10 regions with diverse perinatal health system in 9 European countries.

In each region, two parallel studies gather information on very preterm births and health services: (1) a prospective population-based cohort study of very preterm births in 2003 and (2) a survey of maternity and neonatal units, based on the year 2002.

The population-based cohort study of very preterm births includes all very preterm live-births and still-births occurring between 22 and 31 completed weeks' gestation in maternity units in each participation region¹⁸. Each region, of which Flanders is one, collects information on a population of between 40.000 and 60.000 births a year.

B. The SPE data

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¹⁸ One of the participation regions is Flanders. The region of Flanders (Northern Belgium) covers 13524 km² and has 6 millions inhabitants. During the study period (1 January 2003-31 December 2003) 60406 births took place, of which 793 cases between 22 and 31 completed weeks (1.3%)

The SPE registration is a regional registration, covering the whole of Flanders. Particularly important is the fact that all Flemish hospitals collaborate on a voluntary basis to the registration, so that it encompasses all deliveries occurring in Flanders, except for the very small number of home deliveries. All data refer to stillbirths or live births of infants with a weight of 500 gram or more. The definitions are in agreement with the WHO-rules.

During the first 4 months of the prospective study (September-December 2005) we received forms from 32 M-services (50%) in Flanders. Only 4 pregnant women meeting the referral criteria were reported as not being transferred to a tertiary centre. However, in the same time period the SPE database revealed a total of 42 very premature babies born in an M-unit, hence born to mothers who should have been transferred while pregnant indicating that our prospective study captured only 4 out of 42 true cases (9.5%), resulting in an unacceptable low coverage rate despite multiple efforts to contact the participating units.

The prospective study about the neonatal transfer from an N*-function to a NIC-unit had a response rate of only 37.1% (39/105), also too low to draw valid conclusions. Also, the data control function between the forms received from maternity hospitals with M-service and those from the MIC-units was too low.

After discussing the results in the plenary meeting of the College of physicians of the Mother and Newborn the 23rd of October 2006, the writing committee found the response rate for both groups (M-services and N*-functions) unacceptable low, not allowing the study to continue. Therefore, we decided to stop the prospective part of the study in the general maternities and to concentrate on the forms filled in the MIC-units only, where a higher response rate was obtained. The response rate of the forms from the MIC-units was 61.1% (11/18 of the MIC-units).

C. NIC-audit

The NIC-audit is a federal registration on newborn infants admitted in one of the 19 NICU's in Belgium. Data on the origin of the admitted infants are in accordance with the findings of the present study (www.colnic.be).

4. In utero transfer (IUT) in the regions

Of the 18 MIC-units in Belgium, only 9 recorded the required data during a whole year. Two of the MIC-units provided a six month registration and another 7 declined registration (table 11).

Table 11: Number of MIC-units who participated in the prospective study

MIC-units	n=11
one year registration	9/18 (50.0%)
six month registration	2/18 (11.1%)
no registration	7/18 (38.9%)

Both Flanders and Wallonia had 4 MIC-units who participated in the recording. There are 458 cases with in utero transfer, from one hospital to another hospital or from an M-service to a MIC-unit. In Flanders there were 251 cases (54.8%) and Wallonia had 27.5% with 126 cases. Also 2 MIC-units from Brussels registered, they had 81 cases (17.7%).

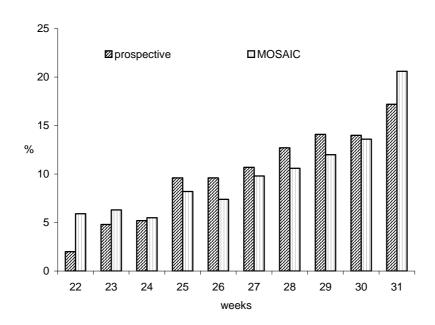
Table 12: The different regions and their cases (prospective study)

Regions	MIC-units	MIC-units		cases
	with	total	%	
	registration			
Brussels	2	6	33.3	81
Flanders	5	7	71.4	251
Wallonia	4	5	80.0	126
Total	11	18	61.1	458

5. Distribution of gestational age

Figure 17 provides gestational age at the time of IUT for the prospective study and the MOSAIC study (Flanders) (Fig 17)

Figure 17: Distribution of gestational age from intra-uterine transfers to a MIC-unit: prospective study (n=458) and MOSAIC-study (Flanders) (n=793)



6. Indications for in utero transfer

In 45.2% (207/458) of the cases in utero transfers took place because of very preterm labour. Another frequent indication is PPROM (preterm premature rupture of membranes) (24.7% or 113/458). In 14.2% (65/458) of the cases the reason to transfer is a multiple birth. Pre-eclampsia and eclampsia together count for 11.8% (54/458). Many cases (22.5% or 103/458) mention also other reasons for in utero transfer. These were recoded in following 3 categories: maternal disease, HELLP, and foetal disease. The largest indication is maternal diseases with 12.4% (57/458) (Table 13)

Comparing the prospective data and the MOSAIC study (Flanders) we find that both studies have nearly the same percentage for the most common indications for in

utero referral: 45.2% for preterm labour, 24.7% PPROM, 11.8% for pre-eclampsia, 8.5% IUGR (Table 14)

Table 13: Reasons for in utero transfer (prospective study)

Reasons for in utero transfer			
(3 possible reasons allowed)	n	%	
pre-eclampsia/eclampsia	54	11.8	
PPROM	113	24.7	
chorioamnionitis	16	3.5	
preterm labour	207	45.2	
diabetes	4	0.9	
birth weight < 1500 g	4	0.9	
IUGR	39	8.5	
low inserted placenta	26	5.7	
other placental anomaly	17	3.7	
multiple birth	65	14.2	
other			
maternal disease	57	12.4	
HELLP	14	3.1	
Foetal disease	32	7.0	

Table 14: Summary of the most frequent reasons for in utero transfer (prospective study versus MOSAIC-Flanders)

Reasons for in utero transfer	Prospective study (%)	MOSAIC-study (Flanders) (%)
preterm labour	45.2	47.2
PPROM	24.7	26.6
Pre-eclampsia/eclampsia	11.8	11.3
IUGR	8.5	13.0
HELLP	3.1	5.7

7. Retransfer of the mother

Of the 458 in utero transfers, 112 (24.5%) were retransferred before delivery (Table 15). In approximately 74.0% of the in utero transfers, the mother remained in the MIC-units until she gave birth. Some data were missing (1.5% or 7/458).

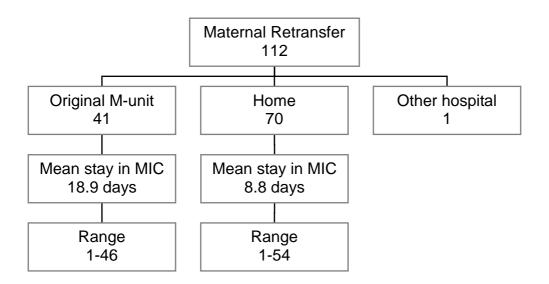
Table 15: Number of retransfers (prospective study)

Retransfer	n	%
yes	112	24.5
no	339	74.0
missing	7	1.5

As already mentioned, 112 mothers were retransferred; 41 (36.6%) of them went to their original M-service, but the majority went home (62.5% or 70/112). In 1 case the mother was retransferred to another hospital on demand (Fig 18).

Of the 41 mothers who went to their original M-service, the mean stay in the MIC-unit was 18.9 ± 12.7 days with a range of 1 to 46 days. The mean reason for transfer was preterm labour in 68% of the cases. In contrast, the mothers who were retransferred at home stayed on average 8.8 ± 10.9 days in the MIC-units. Here the main reasons for in utero transfer were preterm labour (51%) and maternal diseases (32%).

Figure 18: Maternal retransfers (prospective study)



8. No retransfer

Of the 339 women (74.0%) who stayed in a MIC-unit, 334 gave birth in the MIC-unit. There are 4 missing values and one case was still on the MIC-unit waiting for the delivery. The mean stay between arrival in MIC-unit and delivery was 7.4 ± 11.1 days (range 0-79). The reasons for transfer, without retransfer, were 41% for preterm labour, 31% for PPROM, 16% for multiple birth and 15% for pre-eclampsia. Finally 50% of the deliveries were Caesarean sections.

9. Comparison with the MOSAIC project (Flanders)

In the MOSAIC study (Flanders) 44.5% of the cases has a maternal transfer during the pregnancy. Most of them (30.8%) are transferred from an M-service, after a hospitalisation of at least 24 hours, to a MIC-unit. This definition is used by the MOSAIC project. The other 13.7% are called 'ambulatory transfers' (Table 16).

Table 16: Maternal transfers (MOSAIC-Flanders)

	n	%
Yes	353	44.5
IUT with previous hospitalisation	244	30.8
IUT without hospitalisation	109	13.7
No .	440	55.5

IUT from MIC -> to MIC = 10

From the 793 babies born between 22 weeks and 31 weeks gestational age, 31% died before or just after the delivery. The other 69% were transferred to a NIC-unit. From those 547 babies transferred, 463 (84.6%) are survivors and have left the NIC-unit or the N*-function. 84 (15.4%) died during the neonatal period.

Table17: Outcome of delivery (MOSAIC-Flanders)

	n	%
Termination of pregnancy	50	6.3
fetal death before labour	140	17.7
Intrapartum death	22	2.8
death in delivery room	34	4.3
NICU admissions	547	69.0
neonatal death	84	15.4
NICU survivors	463	84.6

10. Comparison with SPE

The database of the SPE included all births (still- and live births) from 500 gram or more in the Community of Flanders in 2004. A selection was made for all births between 22 and 31 weeks completed weeks' gestation. Out of the 100% hospital registration, 778 children were born: 614 of them were liveborns and 164 stillbirths.

From the 614 live births 583 (95.0%) were transferred, 97% to a NIC-unit and 3% to the local N*-function adjacent to the M-service.

Figure 19: Very preterm babies (SPE)

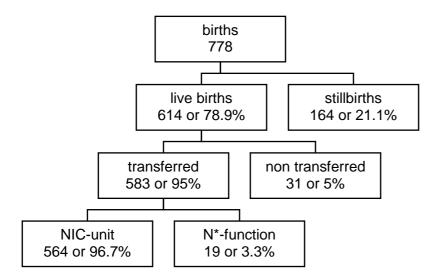


Table 18 describes the gestational age, the birth weight and the time between birth and death, for the 31 non transferred cases. Twenty of them died in less than 20 minutes, all of them within two hours.

Table 18: Not transferred babies after delivery (SPE)

Gest. age	weight	Early neonatal death	Gest.	weight	Early neonatal
22	550	0:16	24	840	0:11
22	535	0:20	24	620	1:20
22	550	0:01	24	600	0:05
22	440	0:01	24	920	0:05
22	508	0:06	24	430	0:01
23	510	0:01	24	600	0:02
23	670	1:00	24	600	0:30
23	700	0:25	24	800	0:15
23	610	0:20	25	350	0:01
23	480	0:01	25	580	0:10
23	560	0:01	26	800	0:17
23	540	0:01	26	800	1:46
23	570	0:02	27	1040	1:50
23	530	0:46	27	1030	1:30
23	620	1:01	30	1420	0:24
23	500	1:20			

Nineteen (3%) babies stayed in the same hospital of the M-service and were transferred to the local N*-function. In table 19, gestational age, birth weight and time of early neonatal death were listed for these 19 infants. Two children born at a gestational age less than 30 weeks die shortly after the delivery. The other 17 of whom 14 have a birth weight higher than 1500 gram, stay in the N*-function. One of the 3 babies with a birth weight lower than 1500 gram die after 55 minutes, the 2 others 1275 gram and 1355 gram survived.

Table 19: Babies transferred to N*-function (SPE)

weeks	n	birth weight (g)	neonatal death	
26	1	670	yes (2:30, anencephaly)	
27	0			
28	1	870	yes (0:50, low birth weight)	
29	0			
30	3	1275 , 1505 , 1985		
31	14	710	yes (0:55, trisomie 18)	
		1355		
		1560, 1630, 1770, 1920, 1950		
		2010	yes (after 8 days)	
		2050, 2050, 2070, 2145, 2215, 2240		

Of the 564 live births transferred to a NIC-unit, 76% are born in a MIC-unit (inborns) and 24% in an M-service (outborns).

In table 20 and figure 20 the numbers of early neonatal death¹⁹ born in the MIC-units (inborns) and born in M-service (outborns) are illustrated.

Table 20: Early neonatal death of babies born in a MIC-unit and M-service (SPE)

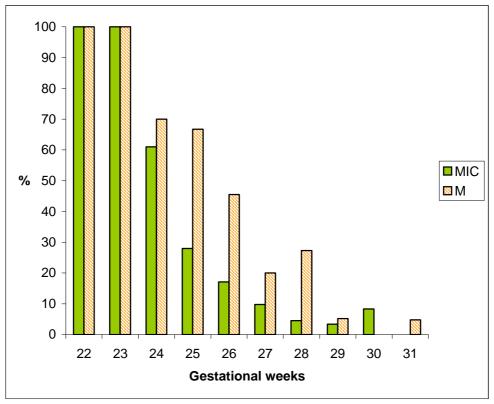
		MIC-unit (Inborns)		M-servi (Outbor	
Live births (n=614)	Gestational age at birth	Number of early neonatal death (n-51)	Number of live births (n=469)	Number of early neonatal death (n=33)	Number of live births (n=145)
5	22	1	1	4	4
12	23	7	7	5	5
28	24	11	18	7	10
31	25	7	25	4	6
46	26	6	35	5	11
71	27	6	61	2	10
77	28	3	66	3	11
77	29	2	58	1	19
123	30	8	96	0	27
144	31	0	102	2	42

¹⁹ Live borns who died within 7 days after birth

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From the 614 liveborn babies with a gestational age lower than 32 weeks 76.4% (469/614) are inborns and 23.6% are outborns (145/614). It has to be noticed that in utero transfer has not necessary occurred at the same gestational age at birth, but sometimes at a former gestational age (see supra p56/point 8) Early neonatal death occurred by 11% of the inborns and 23% of the outborns. Early neonatal death is nearly the same if the place of birth is a MIC-unit or an M-service if the gestational age is lower than 25 weeks. However between 26 and 28 weeks' gestation (counting for 31.6% or 194/614 of the very preterm babies) there are 22% less early neonatal deaths in MIC-units (15/162 or 9.3%) than in M-services (10/32 or 31.3%).

Figure 20: Early neonatal death from babies born in a MIC-unit and M-service (SPE study)



4.3.3 Conclusions

The challenge of conducting a large prospective on-line study has been underestimated. Because of the low response the data were compared with data from other studies (SPE, MOSAIC-Flanders). One of the reasons might have been the extra administrative burden for the maternity and neonatal units where staff has

to fill out many questionnaires from regional, federal and European authorities. They have the feeling that the same information is requested over and over again without much coordination between datacollectors.

The data of the participating MIC-units were acceptable and allowed data comparison with other perinatal datasets.

The findings of the prospective study are based on 423 cases between 22 and 32 weeks' gestation. The main reasons for transfer were preterm labour (45%), PPROM (25%), multiple birth (14%) and pre-eclampsia (12%). Of the 423 in utero transfers, 26% were retransferred before delivery. In 74% of the in utero transfers, the mother remained in the MIC-units until she gave birth.

There is little evidence for substantial gain in case of IUT before 25 weeks' gestation, as early neonatal death is nearly the same irrespective of the place of birth (MIC or M-service). A significant reduction of neonatal mortality and morbidity can be obtained in the vulnerable period of pregnancy (26-28 weeks) when delivery takes place in a referral unit (table 20 and figure 20). In some cases, IUT can be indicated at 23-24 weeks' gestation to prolong the time in utero to offer specific care in the MIC-unit and to provide intensive neonatal care if delivery take place between 26-28 week's gestation or after this period of very preterm deliveries

5 Overall Conclusions

From a thorough review of the literature, it is concluded that regionalisation of perinatal care and referral of high-risk pregnant women to a perinatal care centre can substantially reduce perinatal mortality and neonatal morbidity.

During the last 3 decades many western countries have made efforts to regionalize and optimize perinatal care. In Belgium, a Royal Decree has outlined the concept of maternal and neonatal referral in 1996, yet specific guidelines and actions of implementation and monitoring of maternal referral are lacking.

Therefore, the *College of physicians of Mother and Newborn* decided to embark on this project in order to inform and advise the Ministry of Health on the organisation of perinatal transfer in Belgium.

Overall conclusions emanating not only from this project, but also from existing databases in Belgium or Flanders on perinatal epidemiology:

- 1. National data on perinatal care are difficult to obtain in a standardized and systematic way. Since more than a decade, Flanders has developed a comprehensive regional database linked with the birth certificate, allowing monitoring of care, similar to the medical birth registers of the Nordic countries. This system ensures both the routine collection of vital statistics and ad hoc surveys on topics which are considered of interest by research committees. Currently neither of these mechanisms are available in Wallonia and birth certificates only are available for Brussels.
- 2. Executing the project was more difficult than anticipated, especially the prospective study where participation was low, probably due to administrative overlap and clinical overload. It is important that hospital managers and planners include time for surveys, audits and evaluation of practice, within the time schedule of the medical staff.

- 3. After comparing the data extracted from the retrospective study and the limited figures of the prospective study with the SPE, MOSAIC and NIC-audit datasets, it is concluded that the practice of in utero transfer of high-risk pregnancies in Belgium is progressively increasing over the last decade (± 300-500 IUTs/year in the nineties and ± 800-1.000 IUTs/year during the last 5 years)²⁰. One decade ago postnatal referral of VLBW-babies was still important (up to 40% of all VLBW-admissions in Belgian NICUs during the nineties). Since the last 2 years (2005-06) the postnatal referral rate of VLBW-babies has decreased to nearly 15% or less. Data from SPE and NIC-audit show that nowadays nearly 90% of VLBW-infants are cared for in one of the 19 NICUs, most frequently admitted as inborns after in utero transfer. However there is still room for improvement as far as prenatal referral of high-risk pregnancies is concerned, especially during the highly vulnerable period of pregnancy between 26 and 28 weeks' gestation. At present, perinatal referrals consist approximately of one third of in utero transfers (± 800-1.000/year²¹ or 90/10.000²² deliveries) and of two thirds of neonatal transfers (± 1.500-1.800/year²¹or 143/10.000²² deliveries). Optimal perinatal care is achievable in Belgium by a further inversion of this ratio in favour of maternal referral²³.
- 4. The importance of prenatal obstetrical care in high-risk pregnancies is stressed by the observation that nearly one third of all maternal referrals are retransferred to the original maternity hospital before delivery.
- 5. Most obstetricians/gynaecologists and paediatricians support the concept of regionalized care and express the wish to be involved in the planning and organisation through their professional and scientific organisations.

²² Retrospective part of the study

 $^{^{20}}$ IUT = intrauterine transfer *stricto sensu* i.e. resulting in the admission of the newborn infant(s) in the NICU; data collected by the Belgian NICUs from 1990 until now (Prof. dr. Gaston Verellen).

²¹ NIC-audit

²³ Obviously, the need for intensive care of newborns can not always be predicted. Therefore neonatal transfer is unavoidable e.g. imminent threatened delivery, neonatal sepsis, foetal distress,

- 6. Following <u>constraints and drawbacks</u> have been identified and need to be addressed in order to improve the quality of perinatal care:
 - Maternal transport modalities and responsibilities are not well elaborated
 - Communication tools between referring and referral hospital are not well established;
 - Financial compensations for referring institutions and physicians are not in place;
 - Tools for monitoring quality of maternal transfer are insufficiently developed;
 - Foetomaternal indications for prenatal transfer needs further elaboration;

6 Recommendations

Based on literature, various Belgian perinatal databases and our own observations and conclusions, we hereby recommend the national health authorities to develop strategies for prenatal transfer as part of a national perinatal program:

- Development of a national register on perinatal health linked with birth certificates, in collaboration with regional authorities, to allow monitoring, quality control and improvement of perinatal policies, as is already achieved in the northern part of the country. In addition, proper registration will allow assessing the needs for NIC/MIC beds in the country as well as their geographical spread.
- Organisation of maternal transport systems and defining reimbursement modalities for maternal transport and retransfer. Financial compensation will have to be addressed for the referring institutions and physicians. A mandatory on-line registration of perinatal transfer is a useful tool to improve quality control and set conditions for reimbursement or financial compensations.
- 3. Development of operational strategies by the 1) Implementation of standardized agreements mentioning minimal criteria and modalities for prenatal, as well as for postnatal transfer and retransfer, allowing for local specificities; 2) Measures to encourage an active policy of in utero transfer, including operational definitions with indications and guidelines; 3) Organisation of structured communication between collaborating institutions; 4) Modalities for postgraduate training of the medical and nursing staff of the referring hospital to keep their clinical knowledge and experience in the management of high-risk pregnancies and neonates up to date 5) Measures to encourage fusion of small maternities (wherever possible) taken into account the critical mass needed for appropriate medical and nursing staff and expertise, have to be worked out.

- 4. <u>Creation of a consultative platform</u> with all stakeholders involved, including health authorities as well as scientific and professional societies, assess the national database and birth certificates and further elaborated guidelines of good practice as well as operational definitions for perinatal (re)transfer.
- 5. <u>Further health system research on perinatal transfer policy</u> in Belgium should be carried out <u>by an expert team</u>, in particular indications for perinatal (re)transfer, the organisation of the MIC-service, evaluation of current transport systems, etc.

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8.3 List of abbreviations

AMA = American Medical Association

EBM = Evidence Based Medicine

EUROPET = EUROpean network for PErinatal Transport

EUROSTAT = EUROpean STATistics

FSP = Federal Public Service

HELLP = Haemolysis Elevated Liver enzymes and Low Platelets

IUGR = Intra Uterine Growth Restriction

IUT = In Utero Transfer

MIC = Maternal Intensive Care

MOSAIC = Models of Organising Access to Intensive Care for very preterm babies

NIC = Neonatal Intensive Care

NICU = Neonatal Intensive Care Unit

PPROM = Preterm Premature Rupture Of Membranes

PROM = Prelabour Rupture Of Membranes

SIDS = Suddenly Infant Death Syndrome

SPE = Studiecentrum voor Perinatale Epidemiologie

VLBW = Very Low Birth Weight

8.4 Retrospective study questionnaire

ENQUÊTE COLLEGE MOEDER/PASGEBORENE

Materniteit & neonatologie Deel voor gynaecologen

LUIK 1. Algemene vragen (kwantitatief luik)

IN TE VULLEN DOOR GYNAECOLOOG

Hoeveel bevallingen hadden plaats in uw dienst in de loop van 2004 ? • Aantal bevallingen verricht door de gynaecoloog? • Aantal bevallingen verricht door de huisarts?	
Hoeveel gynaecologen zijn obstetrisch actief in uw dienst?	
Aantal <u>intra-uteriene</u> doorverwijzingen in 2004 ? Aantal <u>postnatale</u> doorverwijzingen in 2004 ?	
Aantal maternele terugverwijzingen in 2004?	

LUIK 2. Uw beleid, mening en suggesties (kwalitatief luik)

IN TE VULLEN DOOR GYNAECOLOOG

۱.		schikt orverwijzir	uw ngsovere	dienst enkomst na	over ar een MIC-	een centrum?	<u>schriftelij</u>	<u>k</u> Ja □ Neen □ ? □
		en ja:	•					
	a. b.	Gelieve or	bestaand	n een kopie te de beleid mee		efd door de	gynaecologe	en
		Indien nee	'n.					Ja □ Neen □ ? □
				nen hiervoor	aangehaald	worden?:		
				Te	•		e gynaecoloo an de pediate	•
				Te	erughouden	dheid van c	de patiënte ze	lf Ja □ Neen □ ? □
		Vanuit Andere hir		el oogpunt (vo Terugh	or patiënte,	gynaecoloc	van de patiër og, ziekenhuis kenhuisdirecti	s) Ja 🗆 Neen 🗆 ? 🗆
		7 tridere riii		ı. 				
2.	Be	vat deze o	vereenko	omst ook ter	ugverwijscr	riteria?		Niet van toepassing □ Ja □ Neen □ ? □
	Ind	<u>ien ja</u> :						
	a. b.			n een kopie te en geformule	•			
		1. Teru	ugverwijzi	ing van de pa 2. Terugv			vangerschap nte na partus	Ja □ Neen □ ? □ Ja □ Neen □ ? □
	C.	Worden de	eze afspr	aken meestal	l nageleefd d	door het MI	C-centrum?	Ja □ Neen □ ? □
		Indien nee Welke red		inen hiervoor	aangehaald	worden?		

IN TE VULLEN DOOR GYNAECOLOOG

1.	Voorziet uw instelling een tussenkomst in de kosten voor het transport?
	a. Kosten voor doorverwijzing Ja □ Neen □ ? □
	b. Kosten voor terugverwijzing Ja □ Neen □? □
	c. Heeft u een idee van de grootte-orde van dit bedrag? Ja □ Neen □ ? □
	<u>Indien ja</u> , hoeveel bedraagt dit bedrag? □ Bedrag: □ ?
2.	Werden er ooit aanvragen tot doorverwijzing geweigerd door de MIC Ja - Neen - ? - waarmee u samenwerkt?
	a. Zo ja, hoeveel doorverwijzingen werden geweigerd? Aantal:
	Indien ja: 1. Was dit wegens een "probleem" in de MIC-dienst? Ja □ Neen □ ? □ 2. Was dit wegens een "probleem" in de NIC-dienst? Ja □ Neen □ ? □
	Indien ja, gelieve toe te lichten:
3.	Welke redenen bepalen de keuze van de P*-functie (MIC en NIC). Gelieve te nummeren van 1 tot 7 of van 1 tot 8 (Indien optie "Andere" wordt ingevuld).
	afstand voorkeur patiënt beleid en organisatie van de P*-functie
	samenwerkingsovereenkomst met P*functie specifieke faciliteiten en capaciteiten van de P*-functie plaats waar uzelf bent opgeleid andere, specifeer:

IN TE VULLEN DOOR GYNAECOLOOG

4. We willen graag uw mening kennen over volgende uitspraken over perinataal doorverwijs- en terugverwijsbeleid.

Beoordeel volgende uitspraken volgens een 5-puntenschaal: 1=helemaal akkoord, 2=akkoord, 3=neutraal, geen mening, 4=niet akkoord, 5=helemaal niet akkoord. Omcirkel uw antwoord.

1.	Nationale richtlijnen en criteria zijn noodzakelijk voor een optimaal perinataal doorverwijs- en terugverwijsbeleid	1	2	3	4	5
2. 3. 4. 5.	Standaardisatie in het perinataal beleid zal op <u>medisch gebied</u> voordelen opleveren Standaardisatie in het perinataal beleid zal op <u>sociaal gebied</u> voordelen opleveren	1 1 1 1	2 2 2 2	3 3 3	4 4 4 4	5 5 5 5
6.	Het wegvallen van de hoogrisicotoestand van de moeder/foetus en/of een zwangerschapsduur ≥ 34 weken, zijn goede criteria voor terugverwijzing naar het verwijzend ziekenhuis	1	2	3	4	5
7.	Het doorverwijzen van een hoogrisico zwangere is een multidisciplinaire aangelegenheid waarbij pediater en gynaecoloog van het perifeer ziekenhuis èn P*-functie betrokken zijn	1	2	3	4	5
8.	Intra-uterien transport is te verkiezen boven postnataal transport tenzij een bevalling	1	2	3	4	5
9.	niet kan uitgesteld worden De wijze waarop perinatale voorzieningen en diensten georganiseerd zijn, beïnvloeden in belangrijke mate de neonatale morbiditeit en mortaliteit	1	2	3	4	5
5.	Welke suggesties heeft u voor een optimaal perinataal doorve terugverwijzingsbeleid in België?	rwi	jzir	ngs	; -	en

ENQUÊTE COLLEGE MOEDER/PASGEBORENE Materniteit & neonatologie Deel voor pediaters

LUIK 1. Algemene vragen (kwantitatief luik)

IN TE VULLEN DOOR PEDIATER

 Hoeveel bevallingen hadden plaats in uw dienst in de loop van 2004? Aantal bevallingen verricht door de gynaecoloog? Aantal bevallingen verricht door de huisarts? 	
Hoeveel pediaters zijn actief in uw dienst?	
Aantal <u>intra-uteriene</u> doorverwijzingen in 2004 ? Aantal <u>postnatale</u> doorverwijzingen in 2004 ?	
Aantal neonatale terugverwijzingen in 2004?	

LUIK 2. Uw huidig beleid, mening en suggesties (kwalitatief luik)

IN TE VULLEN DOOR PEDIATER

1.		schikt orverwiizir	uw nasovere	dienst enkomst na	over	een -centrum?	<u>schrifteli</u>	<u>ijke</u>	Ja □ Neen □ ? □
			<u>igoovere.</u>	<u>mitornot</u> na	ar con mo	oona ann.			od i Noon i . i
	Indi	<u>ien ja</u> :							
	a. b.			n een kopie t nkomst mee		efd door de p	ediaters van	uw	Ja □ Neen □ ? □
		Indien nee Welke red		nen hiervoor	r aangehaal	d worden?:			
					•	noudendheid endheid van	•		Ja - Neen - ? - Ja - Neen - ? -
					Terughoud	lendheid van	de patiënte :	zelf	Ja □ Neen □ ? □
			Vanuit fina	ancieel oogp	ount (voor pa	van de familie atiënte, pedia eid van de zie	ater, ziekenhu	uis)	Ja :: Neen :: ? :: Ja :: Neen :: ? :: Ja :: Neen :: ? ::
		Andere hi	nderpalen		griodaeriari	sia vaii de zie	SKCI II IdiSdil C	Otio	od i Nocii i i i
2.	Bev	vat deze o	vereenko	mst ook ter	[.] ugverwijsc	riteria?			van toepassing □ Neen □ ? □
	<u>Ind</u>	lien ja:							
				n een kopie t en geformule		-			
						1. Intra-uteri ataal transpo			a 🗆 Neen 🗆 ? 🗆 a 🗆 Neen 🗆 ? 🗆
	C.	Worden d	leze afspra	aken meesta	al nageleefd	door het NIC	C-centrum?	J	a □ Neen □ ? □
		Indien nee Welke rec		nen hiervoor	r aangehaal	d worden?			

IN TE VULLEN DOOR PEDIATER

3.		oorverwijzing geweigerd? erwijzingen werden geweigerd?	Ja 🗆 Neen 🗆 ? 🗅 Aantal:
	<u>Indien ja</u> : 1. Wa <u>Indien ja,</u> gelieve	s dit wegens een overbezetting in de NIC-dienst? 2. Door een ander probleem? toe te lichten:	
	<u>, g</u> g		
4.		n de keuze van de P*-functie (MIC en NIC). van 1 tot 7 of van 1 tot 8 (Indien optie "Andere"	' wordt ingevuld).
		afstand	
		voorkeur patiënt beleid en organisatie van de P*-functie taal	
		menwerkingsovereenkomst met de P*-functie e faciliteiten en capaciteiten van de P*-functie plaats waar uzelf bent opgeleid	
		andere:	

IN TE VULLEN DOOR PEDIATER

5.	We	willen	graag	uw	mening	kennen	over	betreffende	volgende	uitspraken	over
	peri	inataal d	doorver	wijs.	en terug	verwijsb	eleid.				

Beoordeel volgende uitspraken volgens een 5-puntenschaal: 1=helemaal akkoord, 2=akkoord, 3=neutraal, geen mening, 4=niet akkoord, 5=helemaal niet akkoord. Omcirkel uw antwoord.

1.	Nationale richtlijnen en criteria zijn noodzakelijk voor een optimaal perinataal doorverwijs- en terugverwijsbeleid	1	2	3	4	5		
2.		1 1	2	3	4	5 5		
 Standaardisatie in het perinataal beleid zal op <u>sociaal gebied</u> voordelen opleveren 1 Standaardisatie in het perinataal beleid zal op <u>financieel gebied</u> voordelen opleveren 1 Neonati <32 weken en/of <1500 g worden best intra-uterien getransfereerd naar een 1 								
	P*-centrum Het wegvallen van de hoogrisicotoestand van de moeder/foetus en/of een		2	3		5 5		
0.	zwangerschapsduur ≥ 34 weken, zijn goede criteria voor terugverwijzing naar het verwijzend ziekenhuis	•	_	J	7	Ü		
7.	Het doorverwijzen van een hoogrisico zwangere is een multidisciplinaire aangelegenheid waarbij pediater en gynaecoloog van het perifeer ziekenhuis èn P*-functie betrokken zijn	1	2	3	4	5		
8.	Intra-uterien transport is te verkiezen boven postnataal transport tenzij een bevalling onvermijdelijk is of wanneer een neonaat niet te voorziene intensieve zorgen nodig heeft	1	2	3	4	5		
9.	De wijze waarop perinatale voorzieningen en diensten georganiseerd zijn, beïnvloeden in belangrijke mate de neonatale morbiditeit en mortaliteit	1	2	3	4	5		
6.	Welke suggesties heeft u voor een optimaal perinataal d terugverwijsbeleid in België?	001	rvei	wij	s-	en		
	terugverwijobeleid in beigie:							
	terugverwijsbeield in Beigie:							
	teragverwijsbeleid in Belgie.							
	teragretingsbeleid in Belgie.							
	teragretingsbeleid in Belgie.							
	teragretingsbeleid in Belgie.							
	teragretingsbeleid in Belgie.							

ENQÛETE COLLEGE MERE/NOUVEAU-NE Maternité & néonatologie Questionnaire destiné aux gynécologues

VOLET 1. Questions d'ordre général (volet quantitatif)

A REMPLIR PAR LE GYNECOLOGUE

Combien d'accouchements ont-ils été réalisés dans votre service au cours de l'année 2004 ?	
 Nombre d'accouchements réalisés par un gynécologue? 	
 Nombre d'accouchements réalisés par un médecin généraliste? 	
Combien de gynécologues (actifs sur le plan obstétrical) travaillent-ils dans votre service?	
Nombre de transferts intra-utérins au cours de l'année 2004?	
Nombre de transferts maternels après accouchement au cours de l'année 2004 ?	
Nombre de retransferts maternels au cours de l'année 2004 ?	

VOLET 2. Votre politique, vos opinions et vos suggestions (volet qualitatif)

A REMPLIR PAR LE GYNECOLOGUE

1.		re service dispose-t-il d'une (ou plusieurs) <u>convention(s) ecrite(s)</u> ncernant la politique de transfert en MIC?	Oui 🗆 Non 🗆 ? 🗆		
	Si c	<u>oui</u> :			
		Veuillez-nous en adresser une copie Ces conventions sont-elles généralement respectées par les gynécologues de votre service?	Oui - Non - ? -		
		Si non:			
		Quelles en sont les raisons?			
		Réticences du gynécologue Réticences du pédiatre Réticences de la patiente Réticences de la famille de la patiente Raisons financières (pour la patiente, le gynécologue, l'hôpital)	Oui		
		Réticences de la direction hospitalière Autres obstacles:	Oui 🗆 Non 🗆 ? 🗆		
		Author distance.			
2.	Cet Si o	te convention contient-elle également des critères de retransfert	Pas d'application □ Oui □ Non □ ? □		
	a.	Veuillez-nous en adresser une copie Ces recommandations sont-elles formulées pour:			
		 Le retransfert (ou le réadressage) de la patiente au cours de la grossesse Le retransfert (ou le réadressage) de la patiente après l'accouchement 			
	C.	Ces accords sont-ils généralement respectés par la section MIC?	Oui □ Non □ ? □		
		Si non: Quelles en sont les raisons?			

A REMPLIR PAR LE GYNECOLOGUE

3.	Votre institution intervient-elle au niveau des frais de transfert et de retransfert?	
	a. Frais de transfert	Oui Non ?
	b. Frais de retransfert	Oui 🗆 Non 🗆 ? 🗆
	c. Avez-vous une idée de l'ordre de grandeur de ce remboursement?	
	Si oui, quel est-il?	□ Somme: □ ?
4	Voc demandes de transfert ent elles nerfeis été refusées?	Oui – Non – 2 –
4.	Vos demandes de transfert ont-elles parfois été refusées? a. Si oui, combien de demandes de transfert ont-elles été refusées?	Oui Non ? Nombre:
	Si oui: 1. A cause d'un problème au niveau du MIC? 2. A cause d'un problème au niveau du NIC?	Oui - Non - ? - Oui - Non - ? -
	Si oui, merci de nous éclairer sur ce problème:	
5.	Quelles raisons déterminent-elles le choix de la fonction P* (MIC et NIVeuillez les énumérer, par ordre d'importance croissante, de 1 à 7 ou l'option « autre » est choisie)?	
	Distance Préférence du patient Organisation et gestion de la fonction P* Langue Convention de collaboration avec fonction P* Spécificité(s) de la fonction P* Endroit où vous avez reçu votre formation Autres, spécifier:	

A REMPLIR PAR LE GYNECOLOGUE

6. Nous souhaitons connaître votre opinion concernant les affirmations suivantes :

Donnez votre appréciation des affirmations suivantes, en utilisant une échelle graduée de 1 à 5 : 1=tout-à-fait d'accord, 2=d'accord, 3=neutre, pas d'opinion 4=pas d'accord, 5=pas du tout d'accord. Veuillez entourer votre réponse.

1.	Des directives et des critères nationaux sont indispensables pour une	1	2	3	4	5	
2.	organisation optimale des transferts et retransferts périnatals La standardisation de la politique de transfert périnatal apportera des avantages	1	2	3	4	5	
3.	sur le <u>plan médical</u> La standardisation de la politique de transfert périnatal apportera des avantages	1	2	3	4	5	
4.	sur le <u>plan social</u> La standardisation de la politique de transfert périnatal apportera des avantages	1	2	3	4	5	
5.	sur le <u>plan financier</u> Les nouveau-nés de <32 semaines et/ou d'un poids estimé de <1500 g	1	2	3	4	5	
6.	devraient de préférence être transférés en ante-natal vers une fonction P* La disparition de la situation à haut risque ayant induit le transfert de la mère /du fœtus et/ou une durée de grossesse ≥ 34 semaines sont de bons critères de	1	2	3	4	5	
7.	retransfert vers l'institution référente. Le transfert d'une grossesse à haut risque est une problématique multidisciplinaire où le pédiatre et le gynécologue de l'hôpital référant et de la	1	2	3	4	5	
8.	fonction P* sont concernés. Le transport fœtal est préférable au transport postnatal, sauf en cas d'accouchement imminent ou lorsque l'on prévoit que le nouveau-né ne nécessitera pas de soins intensifs.	1	2	3	4	5	
9.	L'organisation des soins périnatals a une influence importante sur la mortalité et la morbidité périnatales.	1	2	3	4	5	

ENQUÊTE COLLEGE MERE/NOUVEAU-NE Maternité & néonatologie Questionnaire destiné aux pédiatres

VOLET 1. Questions d'ordre général (volet quantitatif)

A REMPLIR PAR LE PEDIATRE

Combien d'accouchements ont-ils été réalisés dans votre service au cours de l'année 2004 ? Nombre d'accouchements réalisés par un gynécologue? Nombre d'accouchements réalisés par un médecin généraliste?						
Combien de pédiatres sont-ils actifs dans votre service (M + N*)?						
Nombre de transferts intra-utérins au cours de l'année 2004 ? Nombre de transferts postnatals (nouveau-nés) au cours de l'année 2004 ?						
Nombre de retransferts néonatals au cours de l'année 2004?						

VOLET 2. Votre politique, vos opinions et vos suggestions (volet qualitatif)

A REMPLIR PAR LE PEDIATRE

1.		re service dispose-t-il d'une (ou de plusieurs) <u>convention(s)</u> <u>ite(s</u>) concernant la <u>politique de transfert en NIC</u> ?	Oui 🗆 Non 🗆 ? 🗆
	Si c	<u>oui</u> :	
	a. b.	Veuillez-nous adresser une copie de ces conventions Ces conventions sont-elles généralement respectées par les pédiatres de votre service?	Oui - Non - ? -
		<u>Si non</u> :	
		Quelles en sont les raisons?: Réticences du pédiatre Réticences du gynécologue Réticences de la patiente Réticences de la patiente	Oui
		Reticences de la familie de la patiente Raisons financières (pour le patient, le pédiatre, l'hôpital) Réticences de la direction hospitalière Autres obstacles:	Oui = Non = ? = Oui = Non = ? =
2.			d'application □ □ Non □ ?□
	Si d a. b.	oui: Veuillez-nous en adresser une copie Ces recommandations sont-elles formulées pour:	
			Oui □ Non □ ? □ Oui □ Non □ ? □
	c.	Ces accords sont-ils généralement respectés par le service NIC?	Oui □ Non □ ? □
		Si non: Quelles en sont les raisons?	

A REMPLIR PAR LE PEDIATRE

3.	Vos demandes a. Si oui, comb	s de transfert ont-elles parfois été refusées ? bien de fois?	Oui Non ? Nombre:
	<u>Si</u>	oui: 1. A cause d'une surpopulation au niveau du NIC? 2. A cause d'un autre problème?	
	<u>Si</u>	oui, merci de nous éclairer sur ce problème	
4.	référence? Veuillez les én	s déterminent-elles le choix de la fonction P* (MIC et umérer, par ordre d'importance croissante de 1 à 7 c n «autres» est choisie)?	•
		Distance Préférence du patient Organisation et gestion de la fonction P* Langue Convention de collaboration avec la fonction P* Spécificité de la fonction P* Service où vous avez fait votre formation Autres:	

A REMPLIR PAR LE PEDIATRE

5. Nous souhaitons connaître votre opinion concernant les affirmations suivantes :

Donnez votre appréciation des affirmations suivantes, en utilisant une échelle graduée de 1 à 5 : 1=tout-à-fait d'accord, 2=d'accord, 3=neutre, pas d'opinion 4=pas d'accord, 5=pas du tout d'accord. Veuillez entourer votre réponse.

1.	Des directives et des critères nationaux sont indispensables pour une	1	2	3	4	5
	organisation optimale des transferts et retransferts périnatals					
2.	, , , , , , , , , , , , , , , , , , , ,	1	2	3	4	5
	sur le <u>plan médical</u>					
3.	La standardisation de la politique de transfert périnatal apportera des avantages	1	2	3	4	5
	sur le <u>plan social</u>		_	_		_
4.	La standardisation de la politique de transfert périnatal apportera des avantages	1	2	3	4	5
_	sur le <u>plan financier</u>		_	0	4	_
5.	ı	1	2	3	4	5
6.	devraient de préférence être transférés en ante-natal vers une fonction P* La disparition de la situation à haut risque ayant induit le transfert de la mère	1	2	3	1	_
0.	/du fœtus et/ou une durée de grossesse > 34 semaines sont de bons critères	•	_	3	4	5
	de retransfert vers l'institution référente.					
7.	Le transfert d'une grossesse à haut risque est une problématique	1	2	3	4	5
•	multidisciplinaire où le pédiatre et le gynécologue de l'hôpital référant et de la	•	_	Ū	•	Ū
	fonction P* sont concernés.					
8.	Le transport fœtal est préférable au transport postnatal, sauf en cas	1	2	3	4	5
	d'accouchement imminent ou lorsque l'on prévoit que le nouveau-né ne					
	nécessitera pas de soins intensifs.					
9.	L'organisation des soins périnatals a une influence importante sur la mortalité et	1	2	3	4	5
	la morbidité périnatales.					
6.	Quelles mesures suggérez-vous pour optimaliser la stratégie de tr	ans	sfer	t pe	érin	atal en

6.	Quelles mesures Belgique?	suggérez-vous	pour	optimaliser	la	stratégie	de	transfert	périna

8.5 Prospective study questionnaire

Volgnummer:

LUIK 3: Prospectief onderzoek naar het verwijspatroon in België

IN TE VULLEN DOOR GYNAECOLOOG

Inclusiecriteria:

- Zwangerschapsduur tussen 22-32 weken
- Geschat geboortegewicht <1500 gram

Exclusiecriteria:

- Zwangerschapsduur <22 weken
- Zwangerschapsinterruptie in het derde trimester

Maternele transfer							
Ja □ Neen □							
Patiëntnummer							
Zwangerschapsleeftijd (wk-d)							
Datum van transfer (dd-mm-yyyy)							
Naar welke instelling?							
Reden van transfer	☐ Pre-eclampsie						
	☐ Eclampsie						
	□ PROM						
	☐ Chorio-amnionitis						
	☐ Premature arbeid						
	☐ Diabetes						
	☐ geboortegewicht < 1500g						
	□ IUGR						
	☐ Placentaire anomalieën						
	☐ Laag geïnsereerde placenta						
	☐ Placenta accreta						
	☐ Andere, specifieer :						

Maternele Non-transfer									
Ja □ Neen □									
Patiëntnummer									
Partusnummer									
Zwangerschapsleeftijd (wk-d)									
Datum van bevalling (dd-mm-yyyy)									
Geboortegewicht (gram)									
Overlijden neonaat in verloskamer	Ja □ Neen □								
Indien ja, specifieer:	☐ Mors in utero☐ Perpartum☐ Postpartum								
Reden van non-transfer	•								

Numéro d'ordre:

VOLET 3: Etude prospective des stratégies de transfert périnatal utilisées en Belgique

A REMPLIR PAR LE GYNECOLOGUE

Critères d'inclusion:

- Age gestationnel ≥ 22 et < 32 semaines
- Poids de naissance estimé <1500 grammes

Critères d'exclusion:

- Age gestationnel <22 semaines
- Interruption volontaire de grossesse au cours du troisième trimestre.

Transfert Maternel							
Oui □ Non □							
Patiente numéro							
Durée de la grossesse (semaines-jours)							
Date du transfert (dd-mm-yyyy)							
Vers quelle institution?							
Motif(s) du transfert	 □ Prééclampsie □ Eclampsie □ PROM □ Chorioamnionite □ Mise en travail prématurée 						
	 □ Diabète □ PN < 1500g □ RCIU □ Anomalie placentaire □ Placenta bas inséré □ Placenta accreta □ Autre spécifier: 						

	4	
Non-transfert maternel		
Oui □ Non □		
Patiente numéro		
Accouchement numéro		
Durée de la grossesse (semaines-jours)		
Date de l'accouchement (dd-mm-yyyy)		
Poids de naissance		
(grammes)		
Nouveau-né décédé en	Oui □ Non □	
salle d'accouchement		
Si oui, spécifier:	☐ Mort in utéro	
	□ Perpartum	
	□ Postpartum	
Raison(s) du non-transfert		

Volgnummer:

LUIK 3: Prospectief onderzoek naar het verwijspatroon in België

IN TE VULLEN DOOR PEDIATER

Inclusiecriteria:

- Zwangerschapsduur tussen 22-32 weken
- Geschat geboortegewicht <1500 gram

Exclusiecriteria:

- Zwangerschapsduur <22 weken
- Zwangerschapsinterruptie in het derde trimester

Neonataal transfer		
Ja □ Neen □		
Patiëntnummer (neonaat)		
Partusnummer		
Zwangerschapsleeftijd (wk-d)		
Datum van bevalling (dd-mm-yyyy)		
Geboortegewicht (gram)		
Datum van transfer (dd-mm-jjjj)		
Naar welke instelling?		
Reden van transfer		

Neonataal Non-transfer		
Ja □ Neen □		
Patiëntnummer		
Partusnummer		
Zwangerschapsleeftijd (wk-d)		
Datum van bevalling (dd-mm-yyyy)		
Geboortegewicht (gram)		
Overlijden neonaat	Ja □ Neen □	
Reden van non-transfer		

Numéro d'ordre:

VOLET 3: Etude prospective des stratégies de transfert périnatal utilisées en Belgique

A REMPLIR PAR LE PEDIATRE

Critères d'inclusion:

- Age gestationnel ≥ 22 et < 32 semaines
- Poids de naissance estimé <1500 grammes

Critères d'exclusion:

Age gestationnel <22 semaines

Interruption volontaire de grossesse au cours du troisième trimestre.

Transfert néonatal						
Oui □ Non □						
Patient numéro (nouveau-né)						
Accouchement numéro						
Age gestationnel (semaines-jours)						
Date de l'accouchemet (dd-mm-jjjj)						
Poids de naissance (grammes)						
Date du transfert (dd-mm-jjjj)						
Vers quelle institution?						
Motifs du transfert						

Non-transfert néonatal							
Oui □ Non □							
Patient numéro							
Accouchement numéro							
Age gestationnel (semaines-jours)							
Date de l'accouchement (dd-mm-jjjj)							
Poids de naissance (grammes)							
Décès	Oui □ Non □						
Motifs du non-transfert							

Volgnummer:

Prospectief onderzoek naar het verwijspatroon in België Deel MIC

Inclusiecriteria:

- Zwangerschapsduur tussen 22-32 weken
- Geschat geboortegewicht <1500 gram

Exclusiecriteria:

- Zwangerschapsduur <22 weken
- Zwangerschapsinterruptie in het derde trimester

Maternele do	orverwijzing
Patiëntnummer	
Zwangerschapsleeftijd (wk-d)	
Datum van doorverwijzing (dd-mm-yyyy)	
Van welke instelling?	
Reden van doorverwijzing	 □ Pre-eclampsie □ Eclampsie □ PROM □ Chorioamnionitis □ Premature arbeid □ Diabetes □ PN < 1500g □ IUGR □ Laag geïnsereerde placenta □ Placenta accreta □ Andere placentaire anomalieën □ Andere, specifieer :

Maternele terugverwijzing						
Ja □ Ne	een □					
Patiëntnummer						
Zwangerschapsleeftijd (wk-d)						
Datum van terugverwijzing (dd-mm-yyyy)						
Terugverwijzing naar:						
	☐ oorspronkelijke instelling					
	□ huis					
	☐ Andere, specifieer					
Reden indien er geen terugverwijzing plaatsvond						

Numéro d'ordre:

Etude prospective des stratégies de transfert périnatal utilisées en Belgique Partie MIC

Critères d'inclusion:

- Age gestationnel ≥ 22 et < 32 semaines
- Poids de naissance estimé <1500 grammes

Critères d'exclusion:

- Age gestationnel <22 semaines
- Interruption volontaire de grossesse au cours du troisième trimestre.

Transfer	t Maternel
Patiente numéro	
Durée de la grossesse (semaines-jours)	
Date du transfert (dd-mm-yyyy)	
En provenance de quelle institution?	
Motif(s) du transfert	☐ Prééclampsie
	☐ Eclampsie
	□ PROM
	☐ Chorioamnionite
	☐ Mise en travail prématurée
	☐ Diabète
	☐ PN < 1500g
	□ RCIU □ Placenta bas inséré
	☐ Placenta bas insere
	☐ Autre anomalie placentaire
	☐ Autre spécifier:
	☐ Autre specifier.

Retransfert	maternel						
Oui □ Non □							
Patiente numéro							
D'. In In							
Durée de la grossesse (semaines-jours)							
Date du retransfert (dd-mm-yyyy)							
Retransfert vers:	E Lorde Com Badalan						
	☐ Institution d'origine☐ Domicile☐						
	☐ Autre spécifier						
En cas d'absence de retransfert, motif(s) :							

Evidence-Based Strategies for Reducing Cesarean Section Rates: A Meta-Analysis

Nils Chaillet, PhD, and Alexandre Dumont, MD, PhD

ABSTRACT: Background: Canada's cesarean section rate reached an all-time high of 22.5 percent of in-hospital deliveries in 2002 and was associated with potential maternal and neonatal complications. Clinical practice guidelines represent an appropriate mean for reducing cesarean section rates. The challenge now lies in implementing these guidelines. Objectives of this metaanalysis were to assess the effectiveness of interventions for reducing the cesarean section rate and to assess the impact of this reduction on maternal and perinatal mortality and morbidity. Methods: The Cochrane Library, EMBASE, and MEDLINE were consulted from January 1990 to June 2005. Additional studies were identified by screening reference lists from identified studies and expert suggestions. Studies involving rigorous evaluation of a strategy for reducing overall cesarean section rates were identified. Randomized controlled trials, controlled before-and-after studies, and interrupted time series studies were evaluated according to Effective Practice and Organisation of Care Group criteria. Results: Among the 10 included studies, a significant reduction of cesarean section rate was found by random meta-analysis (pooled RR = 0.81 [0.75, 0.87]). No evidence of publication bias was identified. Audit and feedback (pooled RR = 0.87 [0.81, 0.93]), quality improvement (pooled RR = 0.74 [0.70, 0.77]), and multifaceted strategies (pooled RR = 0.73 [0.68, 0.79]) were effective for reducing the cesarean section rate. However, quality improvement based on active management of labor showed mixed effects. Design of studies showed a higher effect for noncontrolled studies than for controlled studies (pooled RR = 0.76 [0.72, 0.81] vs 0.92 [0.88, 0.96]). Studies including an identification of barriers to change were more effective than other interventions for reducing the cesarean section rate (pooled RR = 0.74 [0.71, 0.78] vs 0.88 [0.82, 0.94]). Among included studies, no significant differences were found for perinatal and neonatal mortality and perinatal and maternal morbidity with respect to the mode of delivery. Only 1 study showed a significant reduction of neonatal and perinatal mortality (p<0.001). Conclusions: The cesarean section rate can be safely reduced by interventions that involve health workers in analyzing and modifying their practice. Our results suggest that multifaceted strategies, based on audit and detailed feedback, are advised to improve clinical practice and effectively reduce cesarean section rates. Moreover, these findings support the assumption that identification of barriers to change is a major key to success. (BIRTH 34:1 March 2007)

Key words: meta-analysis, cesarean section, clinical practice guidelines, behavioral change, health service research

Nils Chaillet and Alexandre Dumont are at the Research Centre of Sainte-Justine Hospital and in the Department of Obstetrics and Gynaecology, University of Montréal, Montréal, Quebec, Canada.

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Address correspondence to Nils Chaillet, PhD, Centre de recherche de l'hôpital Sainte-Justine, Département Obstétrique et Gynécologie, Université de Montréal, 3175 chemin de la Côte Ste-Catherine, Local 4986-B, Montréal, Québec, Canada H3T 1C5.

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The World Health Organization states that no region in the world is justified in having a cesarean section rate greater than 10–15 percent (1). The cesarean section rate in Canada increased steadily from 17.5 percent of deliveries in 1994–1995 to 21.2 percent in 2000–2001 (2). Canada's cesarean section rate reached an all-time high of 22.5 percent of in-hospital deliveries in 2001–2002, according to a recent report by the Canadian Institute for Health Information (3). Moreover, cesarean delivery was associated with a high maternal and neonatal complication rate and increased health costs (4–8).

Clinical practice guidelines implement the best evidence into practice and represent an appropriate means for reducing cesarean section rates. The development of guidelines for obstetric care has increased in recent years in developed countries because of the leadership of nongovernmental, professional, and expert organizations and national and international agencies. The challenge now lies in implementing these guidelines (9–13).

Strategies for implementing guidelines produce different results and are classified into 3 levels of effectiveness (9,14): generally ineffective, mixed effects, and generally effective (9–13). With respect to general medical practice, ineffective interventions are mailing (i.e., using postal services) (15–17) and didactic, traditional continuing medical education (18–20). Mixed-effects interventions are opinion leader (21–23), audit and feedback (23–25), and continuous quality improvement (26). Interventions that are generally effective are manual or computerized reminders (27,28), academic detailing (29,30), and multifaceted interventions (31–33).

The premise of this study is that effective strategies for reducing cesarean section rates differ from those of other medical specialties because of different forces and variables that influence professional behavior in obstetrics. Moreover, each clinical environment presents specific challenges in the implementation of an intervention. The identification of specific barriers to change represents a new challenge in developing specific interventions adapted to specific clinical environments (4,8,13,33–35).

The objectives of this meta-analysis are, first, to assess the effectiveness of interventions for reducing the cesarean section rate, second, to determine if an identification of barriers to change can improve the effect of interventions, and, third, to assess the impact of cesarean section rate reduction on maternal and perinatal mortality and morbidity.

Methods

Data Source and Identification of Studies

Together with a medical librarian, 1 investigator (N.C.) conducted multiple searches of the Cochrane Library, in the Registry of Controlled Trials, EMBASE, and MEDLINE databases in publication type category from January 1990 to June 2005, using the following MeSH terms: "cesarean section," "trial of labor," and "vaginal birth after cesarean." These terms were then combined with text words: "mailing," "education," "continuous education," "continuing education," "audit," "peer review," "second opinion," "opinion leader," "academic detailing," "educational outreach," "continuous quality improvement," "management of labor," "community-based model," "quality improvement," "computer reminder," "paper reminder," "reminder," "multifaceted strategy," "multiple strategy," "tailored intervention," "multifaceted intervention," or "multiple intervention." Additional studies were identified by screening reference lists from identified studies and from expert suggestions.

Inclusion Criteria

Studies involving rigorous evaluation of a strategy for reducing overall cesarean section rates were identified. Randomized controlled trials, quasi-randomized controlled clinical trials, controlled before-and-after studies, and interrupted time series studies were evaluated. Usually, the best source of evidence is considered to be controlled trials; however, the rigorous, interrupted time series studies design may be a reliable source of information (36).

The standard Cochrane and Effective Practice and Organisation of Care criteria were used to assess inclusion and quality of studies with respect to design and to enhance internal validity of the analysis (9,14,37). The minimum inclusion criteria included objective measurement of performance and relevant and interpretable data presented or obtainable. Two additional minimum criteria for controlled beforeand-after studies (contemporaneous data collection and appropriate choice of control site) and for interrupted time series studies (intervention time clearly defined and at least 3 data points before and 3 after the intervention) are included.

Quality Assessment

Eight quality criteria were assessed for controlled studies: protection against selection bias (randomized

controlled trials and quasi-randomized controlled clinical trials), characteristics of study and control practitioners (controlled before-and-after studies). exclusion bias, follow-up of patients, detection bias, baseline performance, reliability of first outcome, and protection against contamination. Specific quality criteria were assessed for interrupted time series studies: protection against secular changes, appropriate data analysis, reason for the number of point preintervention and postintervention, specification of the shape of the intervention effect, protection against detection bias, completeness of data set, and reliable first outcome. Each criterion is noted "done," "not clear," or "not done." Studies classified as "fair" and "good" quality, according to the Cochrane and Effective Practice and Organisation of Care quality scale (14,37), were included in this study.

Data Extraction and Analysis

After the first screening, 2 reviewers (N.C. and A.D.) independently abstracted specific information from full-text studies according to standardized data extraction checklist items derived from the Cochrane and Effective Practice and Organisation of Care checklist (14). Discordances between the 2 reviewers were resolved by consensus. When information about individual observations over time was reported only graphically in the original paper, the data set was derived by computer scanning the figures (14,38).

Dichotomous data were meta-analyzed with relative risk as measures of effect size. Interstudy variation was incorporated with the assumption of a random effects model for the treatment effect using the DerSimonian and Laird method to address potential heterogeneity (37,39). For randomized controlled trials, cesarean section rate was directly compared between the control and the intervention groups. For cluster randomized design, potential baseline imbalance between control and intervention groups was controlled using adjusted risk ratio (14,40). Adjusted risk ratio for baseline imbalance was given by the relation (mean postrate intervention/mean postrate control)/(mean baseline rate intervention/mean baseline rate control). Moreover, for a cluster randomized trial, sample size needed to be reduced by a factor based on intracluster correlation for assuming a same degree of statistical power than for a patient randomized trial (41,42). Intracluster correlation was determined by ACluster-design 2.0 ©WHO 2000, when data were available, or estimated from similar studies (14,43,44). Further statistical details are available from the authors on request.

For interrupted time series, effect size was estimated reporting prerate and postrate interventions (14,37). Inclusion of interrupted time series in meta-analysis is a statistical challenge because the change might be just due to the trend and not due to the intervention. To control this bias and validate the intervention effect, data were analyzed using an autoregressive integrated moving average (ARIMA) model to isolate the effect of the intervention from existing time trends (14.38.45).

Begg's statistics and funnel plot were computed for assessed publication bias according to Cochrane procedures (14,37). Q and I^2 tests, meta-regression models, and subgroups analysis were selected for addressing heterogeneity from adjusted risk ratios (14,37). An ARIMA model was computed using SPSS version 11.0, and meta-analysis and meta-regression were computed using Stata version 7.0 (46,47).

Results

A total of 831 studies corresponding to our search strategy were identified for the period 1990-2005 (Fig. 1). Of these, 810 were excluded based on eligibility criteria outlined in the Methods section and Fig. 1. The full-text articles for the remaining 21 citations were retrieved. Four additional articles were obtained from reference lists and expert suggestions, bringing the total number of identified studies to 25. After review of the full-text articles using the eligibility criteria, 11 studies remained and were evaluated further for quality. One interrupted time series (48) was excluded for "poor" quality based on Cochrane and Effective Practice and Organisation of Care quality criteria (assessment of reduction of cesarean section rate by regional statistics). The reasons for exclusion of the 14 studies were data not obtainable for overall cesarean section rates (23,49) (2 controlled studies), data not presented or study comprising fewer than 500 women (24,50–52) (3 studies), and lack of 3 data points before and after the intervention for interrupted time series (53–60) (9 studies). In all, 10 studies met all the inclusion and quality criteria.

Characteristics of Interventions

Tables 1–3 present information about the characteristics and effect size of each strategy. There were 2 cluster randomized controlled trials (40,61), 3 randomized controlled trials (64–66), and 5 interrupted time series studies (62,63,67–69). A prospective identification of the barriers to change in order to improve implementation of intervention was performed in 40

percent of studies. Among the 10 included studies, 4 involved audit and feedback, 4 involved quality improvement, and 2 involved multifaceted strategies. The strategy based on a mandatory second opinion (40) was considered as an audit and feedback. Quality improvement programs were based on active management of labor (64,65,67) and community-based continuity of care (66). Multifaceted programs included physician and public education, physician peer review, and physician, hospital payment, and malpractice reform (68); the other program included physician education and audit and feedback (69). The total number of included women was 776,909, with 686,334 from randomized controlled trials.

Four controlled trials and 1 interrupted time series study met all criteria and were rated as "good quality" (40,64–66,68). The remaining studies were rated as "fair." The main reasons for fair quality rating for randomized controlled trials were that baseline measures were not reported or unclear (61) and protection against contamination was not clear (61). Four interrupted time series studies were rated fair because no ARIMA model or time series regression models were used for data analysis (62,63,67,69).

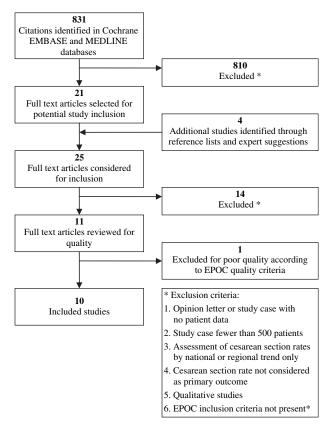


Fig. 1. Study eligibility flow chart.

*Effective Practice and Organisation of Care Group (EPOC) exclusion criteria.

Meta-Analysis

Adjusted from an existing time trend, ARIMA model analysis showed a significant difference between baseline and intervention for the 5 included interrupted time series (p < 0.05; Table 3). Thus, time trends did not explain the observed changes, and the interrupted time series studies were included in the random meta-analysis.

Among included studies, we found a significant reduction of cesarean section rates (pooled RR, 0.81; 95% CI, 0.75–0.87; p < 0.00001; Fig. 2). A formal test for heterogeneity gave a significant result ($I^2 = 87.6\%$, p < 0.00001), and a random effects model was used. We noted a relative diminution of cesarean section rate of 19 percent (relative risk reduction, 19%; 95% CI, 13–25%).

The Begg's funnel plot showed no striking evidence of publication bias. Neither Begg's adjusted rank correlation test (p=0.86, continuity corrected) nor Egger's regression asymmetry test (p=0.83) gave a statistically significant result.

Heterogeneity and Subgroups Analysis

A meta-regression was performed for exploring heterogeneity among studies. Various covariables, such as publication and study years, study design, strategy used, country, identification of barriers to change, type of providers, study quality, source of guidelines, total number of women, study and intervention duration, number of centers, and initial cesarean section rates were assessed. Three covariables were highly significant and explained 61–80 percent of the variation (strategy used, 61%, p = 0.003; study design, 72%, p < 0.001; and identification of barriers, 80%, p < 0.001). Most of the variation was explained by these 3 covariables (p < 0.001).

Subgroups analyses were performed for these 3 covariables (Table 4). Pooled risk ratios for audit and feedback, quality improvement, and multifaceted strategy were significant for reducing cesarean section rate. However, a significant heterogeneity, due to design, was found for audit and feedback ($I^2 = 81.7\%$, p < 0.01). Indeed, subgroups analysis for audit and feedback stratified by design showed a significant homogeneity (I^2 for audit and feedback [controlled] = 0%, p = 0.97; I^2 for audit and feedback [interrupted time series] = 0%, p = 0.32). Multifaceted strategy presented a highly significant reduction of cesarean section rates (pooled RR, 0.73; 95% CI, 0.68-0.79; p < 0.00001) with a relative risk reduction of 27 percent (95% CI, 21-32%).

Pooled risk ratio for controlled and noncontrolled studies was in favor of a reduction of cesarean section

Table 1. Nature and Description of Strategies Used for Reducing Cesarean Section Rate

Study	Nature of Strategies	Description of Programs for Reducing Cesarean Section Rate
Althabe, 2004 (40)	Audit and feedback	Policy of mandatory second opinion systematically before cesarean section. Both physicians discussed the case in relation to the guidelines. After this process, the attending physician made the final decision. The guidelines were made available for all physicians at intervention hospitals.
Bickell, 1996 (61)	Audit and feedback	External peer reviews were done by ACOG-trained teams of 4 physician and nurse reviewers, who visited the hospital, interviewed key staff members, and reviewed 100 labor and delivery records to assess the quality of care. Review teams provided feedback through an exit interview and a written
Liang, 2004 (62)	Audit and feedback	summary of findings and recommendations. The peer review included precesarean consultation and post- cesarean surveillance. A weekly departmental cesarean indica- tion conference was organized to present every cesarean case. A second opinion by a consultant was required for all cesarean sections. VBAC was encouraged. Feedback was provided by conferences.
Robson, 1996 (63)	Audit and feedback	The medical audit cycle takes the concept of medical audit a stage further. Clinical standards are established, current practice is compared, modification of management takes place, and medical audit is continued with emphasis on completing this "feedback loop." Monthly medical audit and meetings where all results were reviewed were held.
Frigoletto, 1995 (64)	Quality improvement	Active management of labor protocol had 3 components: one-to-one nursing care, standardized criteria for the diagnosis of labor, and management of labor based on ACOG guideline that encourages early amniotomy, cervical examination performed every 2 hr, and early diagnosis of inefficient uterine action treated with oxytocin.
Lopez-Zeno, 1992 (65)	Quality improvement	Program of active management of labor that encourages early amniotomy, early diagnosis of slow progress in labor, and the use of higher than usual doses of oxytocin. The fetal heart was monitored electronically. Use of intrauterine pressure catheters was encouraged. Umbilical cord arterial and venous blood was obtained routinely.
Homer, 2001 (66)	Quality improvement	Continuity of midwifery care was a focus of the community-based model. The emphasis was on continuity of care (a consistent team approach) rather than caregiver (the same midwife). An informal evening at which the women could meet the midwives was held every 2 mo. One midwife was always on call for women in labor.
Socol, 1992 (67)	Quality improvement	Three initiatives were undertaken. VBAC was more strongly encouraged, and EFM was routinely used. Quality management initiative was introduced because of suspected differences among physicians, and annual report was distributed. A program of active management of labor for term nulliparous women was undertaken.
Poma, 1998 (68)	Multifaceted strategy	Proposed strategies include physician and public education about maternal and fetal benefits of vaginal delivery; practice guidelines for management of labor, with physician peer review and feedback, and corrective measures when guidelines are not followed; and physician, hospital payment, and malpractice reform.
Lagrew, 1996 (69)	Multifaceted strategy	Clinical guidelines' changes were made to facilitate lowering the cesarean section rate. The nursing staff was given extensive education in the techniques of AML and EFM. Monthly summary statistics were generated by computer, analyzed, and reported to the medical and nursing staffs. A confidential report was delivered to physicians every 6 mo.

Fable 2. Study Settings

		Study	Study of				No. of	
Study and Country	Study Period	Design	Barriers	Strategy	Centers	Practitioners	Participants	Quality
Althabe, South America, 2004 (40)	1999–2000	C-RCT	N _o	AF	34	90	149,038	Good
Bickell, USA, 1996 (61)	1989–1993	C-RCT	No	AF	47	Mixed	534,239	Fair
Liang, Taiwan, 2004 (62)	1993–2000	SLI	Š	AF	1	90	17,801	Fair
Robson, UK, 1996 (63)	1984–1992	ITS	Yes	AF	-	Mixed	21,125	Fair
Frigoletto, USA, 1995 (64)	1991–1993	RCT	Š	QUAL	17	Mixed	1,263	Good
Lopez-Zeno, USA, 1992 (65)	1990 - 1991	RCT	Š	QUAL	1	Mixed	705	Good
Homer, Australia, 2001 (66)	1997–1998	RCT	Š	QUAL	-	Mixed	1,089	Good
Socol, USA, 1992 (67)	1986 - 1991	SLI	Yes	QUAL	1	90	26,619	Fair
Poma, USA, 1998 (68)	1991–1996	ITS	Yes	MULTI:	1	90	12,912	Good
Lagrew, USA, 1996 (69)	1988–1994	STI	Yes	AF EDUC/REF MULTI:EDUC/AF	-	90	12,118	Fair

AF = audit and feedback; C-RCT = cluster randomized controlled trial; EDUC = educational strategy; ITS = interrupted time series; mixed = medical and paramedical practitioners; MULTI = obstetricians and gynecologists; QUAL = quality improvement; RCT = randomized controlled trial; REF = physician, hospital payment, and malpractice reform. rates (Table 4). However, noncontrolled studies had a greater reduction in cesarean section compared with controlled studies (pooled RR = 0.92 [0.88, 0.96], p = 0.00037 for controlled studies and 0.76 [0.72, 0.81], p < 0.00001 for noncontrolled studies). A significant heterogeneity, explained by the study of barriers, was found for noncontrolled studies ($I^2 = 83.8\%$, p = 0.02). Indeed, subgroups analysis for noncontrolled studies stratified by study of barriers showed a significant homogeneity (I^2 for noncontrolled studies with identification of barriers = 46.3%, p = 0.13; only 1 noncontrolled study had no identification of barriers).

Pooled risk ratios were more significantly in favor of a reduction of cesarean section rate among the interventions including an identification of barriers to change, compared with other interventions (Table 4). Pooled risk ratio was 0.74 [0.71–0.78] (p <0.00001) for interventions with identification of barriers and 0.88 [0.82, 0.94] (p < 0.00042) for standard interventions. A test for heterogeneity did not give a significant result for interventions including an identification of barriers ($I^2 = 46.3\%$, p = 0.13). For interventions with no identification of barriers, a significant heterogeneity, due to 1 noncontrolled study, was detected ($I^2 = 64.0\%$, p = 0.02). Indeed, subgroup analysis for controlled studies with no identification of barriers showed a significant homogeneity $(I^2 = 0\%, p = 0.49).$

Morbidity Associated with Reduction of Cesarean Section Rates

In this study, the relative cesarean section rate was reduced by 19 percent (pooled RR = 0.81; 95% CI, 0.75–0.87). The major part of this reduction was explained by a significant reduction of cesarean section for the following indications: dystocia (40,62,63,67–69), repeat cesarean section (62,63,67,68), fetal distress (40,62,69), and maternal indications (40).

Among included studies, no significant differences were found for stillbirth rate (40), perinatal and neonatal mortality (40,68,69), neonatal and maternal admission to intensive care unit (40,63,66–68), and perinatal and maternal morbidity (66,68,69). Only 1 study showed a significant reduction of neonatal and perinatal mortality (p < 0.001) associated with a reduction of cesarean section rates (67). For this study, overall cesarean section rate was reduced by 7 percent, the neonatal mortality was reduced from 10.3 to 3.8 per 1,000 live births between 1986 and 1991 (RR = 0.37; 95% CI, 0.21–0.64), and the perinatal mortality was reduced from 19.5 to 10.3 per 1,000 in the same period (RR = 0.53; 95% CI, 0.37–0.75).

Table 3. Assessment of Studies' Effect Size

	(Cesarean Section Rates (%)			ARIMA		Effect Size	
	Intervention	n Group	Control (
Study	Baseline	Post	Baseline	Post	β (SD β)	p	$ARR (\%)^{b}$	RR^{c}
Althabe, 2004 (40) ^a	26.3	24.7	24.6	24.9	_	_	-1.9 [-3.8, -0.1]	0.93 [0.86, 1.00]
Bickell, 1996 (61) ^a	29.1	25.8	25.1	24.0	_	_	-2.2 [-4.0, -0.4]	0.93 [0.87, 0.99]
Liang, 2004 (62)	37.0	30.7	_	_	-0.81(0.03)	0.03	-6.3[-7.7, -4.9]	0.83 [0.80, 0.87]
Robson, 1996 (63)	12.0	9.5	_	_	-0.04(0.01)	0.02	-2.5 [-3.3, -1.6]	0.79 [0.73, 0.86]
Frigoletto, 1995 (64)	_	10.9	_	11.5			-0.5[-4.0, 2.9]	0.95 [0.70, 1.30]
Lopez-Zeno, 1992 (65)	_	10.5	_	14.1	_	_	-3.6 [-8.4 , 1.3]	0.75 [0.50, 1.11]
Homer, 2001 (66)	_	13.3	_	17.8	_	_	-4.5 [-8.8 , -0.2]	0.75 [0.56, 0.99]
Socol, 1992 (67)	25.9	19.0	_	_	-2.53(0.48)	0.01	-7.0[-8.0, -5.9]	0.73 [0.70, 0.77]
Poma, 1998 (68)	22.8	17.3	_	_	-0.07(0.01)	0.00	-5.4[-6.8, -4.0]	0.76 [0.71, 0.82]
Lagrew, 1996 (69)	27.6	19.5	_	_	-0.04(0.02)	0.05	-8.1[-9.6, -6.6]	0.71 [0.66, 0.75]
Pooled effect size					,		- · · · ·	$0.81 [0.75, 0.87]^{d}$

^aNumber of cesarean sections and deliveries of cluster trials were determined taking into account the cluster effect (event/design effect). $IF = 1 + (m-1) \times ICC$. IF is the design effect, m is the average cluster size in the trial, and ICC is the intracluster correlation coefficient.

^bFor cluster trials: ARR (absolute risk reduction) = (rate change in intervention group) – (rate change in control). ARR for randomized controlled trials (RCTs) = (rate change in intervention group) – (rate change in control group).

^cFor cluster randomized controlled trials, risk ratio was adjusted for baseline imbalance. Adjusted risk ratio = (mean postrate intervention/mean postrate control)/(mean baseline rate intervention/mean rate control). For RCTs, risk ratio = (mean rate intervention/mean rate control).

^dPooled risk ratio (see Fig. 2).

ARIMA = auto regressive integrated moving average; post = postintervention; RR = risk ratio.

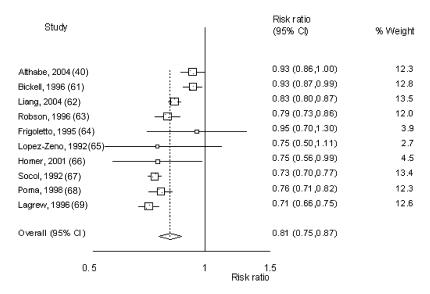
Discussion

The findings of this meta-analysis showed that audit and feedback, quality improvement, and multifaceted strategies were effective in changing clinical practice and reducing cesarean section rates. Pooled risk ratio was more effective to reduce the cesarean section rate for multifaceted strategies than for audit and feedback. However, both multifaceted interventions included audit and feedback as an essential part of their program.

Audit and feedback seeks to improve patient care and outcomes by systematic review of care against explicit criteria and the implementation of change with feedback (13). Audit and feedback is an effective strategy to reduce the cesarean section rate, but this diminution is limited when it is used alone. Cesarean section rate was only reduced by 13 percent when audit and feedback was used alone but reduced by 27 percent when audit and feedback was used in a multifaceted strategy. This difference can be partially explained by a contamination bias for 1 cluster randomized controlled trial (61) and by the lack of identification of barriers to change for 3 out of 4 studies.

Quality improvement meta-analysis presented a significant pooled risk ratio. However, this effect was due only to a noncontrolled study based on active management of labor (67). Although the 3 randomized controlled trials were in favor of a reduction of cesarean section rate, the 2 randomized controlled trials based on active management of labor were nonsignificant (64,65). One study based on a continuityof-care program showed a significant reduction of overall cesarean section rates but no significant differences in subgroups analysis because the study was potentially underpowered (66). Despite significant results in the meta-analysis, quality improvement based on active management of labor seems to present mixed effects, but these results could be explained by a potential lack of statistical power for the randomized controlled trials. In a systematic review, quality improvement based on nonrandomized studies can improve outcomes of care; but the few randomized studies suggest no impact on clinical outcomes and no evidence of organization-wide improvement in clinical performance (26). Quality improvement interventions have highly variable effectiveness and are extremely dependent on the context in which they are used and the way they are implemented (26).

Multifaceted strategies were effective and showed the strongest reduction of cesarean section rate. No significant heterogeneity was found. A multifaceted intervention has been defined as one that involves 2 or more interventions targeting different barriers to change (13). Included multifaceted interventions were based on guideline education, audit and feedback, hospital payment and malpractice reform, and identification of barriers to change. Detailed feedback has



Total intervention (95% CI): 145,571 (baseline), 143,751 (posinterventiont); total control (95% CI): 242,823 (baseline), 244,764 (postintervention).

. Total intervention events: 39,000 (baseline), 33,707 (postintervention); total control events: 60,779 (baseline), 58,976

Test for heterogeneity: $Chi^2 = 72.78$, df = 10, $I^2 = 87.6\%$ (P < 0.01)

Test for random overall effect: Z = 5.83 (P < 0.00001)

Fig. 2. Meta-analysis of included studies (left: favor cesarean section rate reduction; right: favor cesarean section rate augmentation).

been identified as a major part of the tailored programs for changing clinical practice and reducing cesarean section rates (68,69). The findings of this study confirmed that audit and feedback strategy must be included in a change program, targeting different barriers and promoting a detailed feedback, to be fully effective.

The relative reduction of the cesarean section rate was higher for noncontrolled studies than for controlled studies. However, of the 5 controlled trials, 1 presented a contamination bias (61) and 3 based on quality improvement presented a lack of statistical power (64-66). When controlled for potential confounding variables, the effect size of 1 randomized controlled trial became significant (OR = 0.57; 95% CI, 0.36-0.95) (65). Moreover, the 2 cluster randomized controlled trials were based on audit and feedback, and no controlled trial was based on multifaceted strategies. These biases could explain the smaller reduction of cesarean section rate for controlled trials in this meta-analysis. Additional cluster randomized studies are necessary to validate the significant effect of multifaceted strategies.

The identification of facilitators and barriers is a necessary stage to improve local definition and adaptation of the final structure and processes of the intervention. These barriers and facilitators are related to, first, external changes influencing the practice environment; second, the practice environment, including unit leadership, policy, and availability of equipment; third, the potential adopters; and, fourth, strategies used to promote uptake of the guideline recommendations (35). In this meta-analysis, studies including identification of barriers improved the implementation of interventions, and a higher reduction of cesarean section rate was noted. These findings demonstrated that those wishing to reduce the cesarean section rate should consider using such influences.

Finally, 2 robust controlled studies, based on opinion leader and computerized audit and feedback,

were not included because data were not obtainable (23,49). These studies showed a significant reduction of overall cesarean section rates. Lomas et al noted no significant changes for maternal death, stillbirth rate, and Apgar scores less than 7 at 1 minute between the control and the opinion leader groups and an Apgar score at 5 minutes that was significantly better (p < 0.001) in the opinion leader group (23). One case of ruptured uterus occurred in the opinion leader group but not in the planned cesarean group (23). These results seem to confirm that cesarean section rates can be safely reduced.

Study Limitations

Many included studies were published from the middle 1990s. During recent years, obstetric practices may have changed. Today, obstetric practitioners seem more risk averse about policies concerning induction or vaginal birth after cesarean, and the efficiency of interventions could be different. However, 2 recent included studies (40,62) showed that cesarean section rates could be safely decreased with interventions based on audit and feedback. Nevertheless, the type of interventions should be adapted considering the current trends in obstetrics practice.

Moreover, in this review, perinatal morbidity was assessed by 3 noncontrolled studies and measured by birth trauma, low Apgar scores and thick meconium (68,69), and Apgar scores and birthweight (66). Maternal morbidity was assessed by 1 study (66). However, several authors showed a significant increase in uterine ruptures for women undergoing a trial of labor after cesarean delivery (6,70). In the literature, the risk of urinary incontinence is higher among women who have had vaginal deliveries than among women who have had cesarean sections (71,72), but the risk of complications in a future pregnancy is higher among women who have had cesarean

Table 4. Pooled Risk Ratios (RR) Stratified by Strategy, Design, and Identification of Barriers, Random Effect Model

Subgroups Meta-Analysis	No. of Studies	Pooled RR (95% CI)	Test for Overall Effect (p)	I ² (%)	p (Heterogeneity)
Audit and feedback (40,61,62,63)	4	0.87 [0.81, 0.93]	0.00014	81.7	<0.01 [†]
Quality improvement (64–66,67)	4	0.74 [0.70, 0.77]	< 0.00001	0.0	0.44
Multifaceted strategy (68,69)	2	0.73 [0.68, 0.79]	< 0.00001	54.8	0.14
Controlled studies (40,61,64–66)	5	0.92 [0.88, 0.96]	0.00037	0.0	0.49
Noncontrolled studies (62,63,67–69)	5	0.76 [0.72, 0.81]	< 0.00001	83.8	<0.01 [†]
No identification of barriers (40,61,62,64–66)	6	0.88 [0.82, 0.94]	0.00042	64.0	0.02^{*}
Identification of barriers (63,67–69)	4	0.74 [0.71, 0.78]	< 0.00001	46.3	0.13

I²: heterogeneity scale in percentage.

^{*}Significant heterogeneity.

[†]Highly significant heterogeneity.

sections (6). Thus, the findings in this review about maternal morbidity must be considered with caution. Further studies are necessary to assess the evolution of perinatal and maternal morbidity with respect to the mode of delivery.

Conclusions

The cesarean section rate can be safely reduced by complex interventions that involve health workers in analyzing and modifying their practice. Our results suggest that multifaceted strategies, based on audit and detailed feedback, are advised to improve clinical practice and effectively reduce the cesarean section rate. Moreover, these findings support the assumption that identification of barriers to change is a major key to success.

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