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HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Collège de Médecins "pour la Mère et le Nouveau-Né"
College van Geneesheren "voor de moeder en pasgeborene"

2 Rapport- Section maternité

Le programme de recherche développé a comporté 2 volets :

1. Définition de critères d'admission et de référence, choix de critères objectifs permettant d'évaluer l'activité au sein des Maternal Intensive Care
2. Registry and surveillance of rare complications in pregnancy
3. National register for epidemiological record, concerted management related to rare gestational trophoblastic diseases.

Définition de critères d'admission et de référence, choix de critères objectifs permettant d'évaluer l'activité au sein des Maternal Intensive Care

Faisant suite au rapport publié en 2008 par le KCE, le Collège Mère Nouveau-Né a initié la sélection d'indicateurs de qualité de soins en obstétrique intensive, sur la base d'enquête menée auprès d'experts obstétriciens et des chefs de service des maternités belges.
L'objectif était de définir des critères objectifs d'admission, de transfert et de re-transfert, ainsi que des critères de référence de l'activité MIC. Les outils manquent également afin de déterminer quel est le niveau d'activité et la qualité de cette activité. **Le but final poursuivi par le collège Mère-Nouveau-Né section maternité est de fournir à l'autorité des outils d'appréciation de l'activité des soins intensifs maternels.**

Le rapport 2011 mentionne l'état d'avancement du projet.

La méthodologie prévoit la sélection d'indicateurs pertinents par enquête Delphi dont la caractéristique est de procéder par votes successifs pour collecter l'avis médian d'un groupe d'experts.

L'enquête DELPHI est actuellement en cours avec le support de l'Université du Québec à Montréal qui assure :

- le libellé de quelques 100 propositions qui constitue la matière de la délibération Delphi adressée avec codes de validation (login) à un maximum de 140 personnes
- l'informatisation et la maintenance complète de l'enquête.
- l'accès protégé aux résultats

- l’assistance lors de la « thématisation manuelle de qualité » par les experts du domaine.

Préalablement, les membres du collège et les experts ont sélectionné et validé un ensemble de questions relatives :

- à la structure,
- à la fonction MIC,
- à la fréquentation de ces unités,
- au profil des pathologies,
- à l’encadrement général des hôpitaux disposant d’un MIC
- à la compétence des équipes et à leur disponibilité en permanence pour assurer la continuité des soins,
- au taux d’activité au sein des MIC.

Ces questionnaires validés ont ensuite été analysés par l’équipe spécialisée de l’Université de Montréal pour en améliorer la présentation et faciliter leur scoring par 139 experts obstétriciens belges.
Ceux-ci ont été sélectionnés parmi les obstétriciens experts-chevronnés dans les universités, les maternités privées disposant ou non d’une unité MIC et les représentants des organisations scientifiques et professionnelles (VVOG et GGOLFB).

THEME 2

Registry and surveillance of rare complications in pregnancy

Introduction

Following a recent initiative by the European Commission and the European Medicines Agencies (EMEA) to encourage the research, the development and the marketing of "orphan" medicines to treat, prevent or diagnose rare diseases. In November 2008, the European Commision sent a note to the European Parliament, to the Council and to European economic and social committee as well as the committee of the regions on the problem of "rare diseases".

Rare diseases are defined by the European Union as diseases with a prevalence of 5 or less per 10 000 persons. The European Commission considers that *"The lack of specific health policies for rare diseases and the scarcity of the expertise, translate into delayed diagnosis and difficult access to care. This results in additional physical, psychological and intellectual impairments, inadequate or even harmful treatments and loss of confidence in the health care system, despite the fact that some rare diseases are compatible with a normal life if diagnosed on time and properly managed. Misdiagnosis and non-diagnosis are the main hurdles to improving life quality for thousands of rare disease patients."*

What is being said on rare diseases in general is also true for pregnancies of the mother to be with a rare disease or a rare complication of pregnancy, which not only is risking the life of the mother herself but also that of the child to be born

Registries and databases constitute key instruments to increase knowledge on rare diseases. Indeed, the use of registries and databases are excellent means for pooling information in order to achieve a sufficient sample size for epidemiological as well as clinical research.

Objective

The purpose of present study protocol is to achieve a registry and surveillance of rare complications of pregnancy in Belgium.

Indeed some conditions are so rare that few midwives and obstetricians will ever come across them in their whole careers. The purpose of creating a registry and surveillance for those conditions in pregnancy is to bring together expertise on the knowledge and the management of those uncommon conditions so that in future pregnant women with a rare complication of pregnancy could benefit through better information on the condition and the outcome of the condition. By pooling those rare cases together it becomes possible to study the best possible management because at present the clinical practice is rarely based on robust evidence.

A similar initiative was taken in the U.K. already in 2005 under the impulse of Dr Marion Knight and is called the "UKOSS, United Kingdom Obstetrics Surveillance System, project". She and a team of experts is working together with the RCOG, the Royal College of Obstetricians and Gynaecologists, in London and with the NPEU, the National Perinatal Epidemiology Unit, in Oxford.

The methodology used by UKOSS is similar to the one developed by the BPSU, British Paediatric Surveillance Unit, which was established by the Royal College of Paediatrics and Child Health, the Health Protection Agency and the Institute of Child Health, London in 1986 to undertake active surveillance of rare paediatric disorders. At present 14 different countries (Australia, Canada, Ireland, Malaysia, New Zealand, The Netherlands, Germany, Greece and Cyprus, Latvian, Papua New Guinea, Portugal, Switserland, Trinidad) outside the U.K. have joint this initiative using the same study protocols. In so doing a total of 10,000 clinicians covering a child population of 50 million have investigated over 150 rare conditions.

About UKOSS

Dr Marian Knight, UKOSS clinical co-ordinator, told the BBC News website: "There are a number of disorders that are rarely related to maternal death. But clinicians don't know how many women survive them." "We are hoping to prevent maternal deaths." "There are questions about the best way to manage these conditions."

Professor Jim Dornan, Vice-President of the Royal College of Obstetricians and Gynaecologists, said: "When problems are detected in pregnancy, it inevitably leads to stress and anxiety for the woman and her family." "UKOSS will allow obstetricians to begin to develop a greater insight into rare pregnancy disorders by building 'the bigger picture'. The information UKOSS gathers will then benefit mothers, their babies and clinicians alike."

Dr Peter Brocklehurst, Director of the National Perinatal Epidemiology Unit, added: "UKOSS is an important new research initiative which will provide reliable information about rare disorders affecting women in pregnancy." "The information gained will help improve the quality and consistency of care for women with these uncommon conditions and their babies."

A similar approach in Belgium is being developed using the following outlines

1. A number of uncommon complications in pregnancy (other rare complications of pregnancy and rare diseases associated with pregnancy could be considered at a later date) for which no general agreement exist on how best to treat the condition, are selected. The condition should occur in less than 1 in 2000 pregnant women. We would start by investigating the following three complications 1) eclampsia 2) uterine rupture 3) postpartum hysterectomy or embolization of the uterine arteries.
2. After a contact person (a gynaecologist) has been named in the various hospitals with an obstetric unit in Belgium, that person will be sent each month a report card to be returned duly filled out within one week (preferably by e-mail), reporting any cases of

eclampsia, uterine rupture or postpartum hysterectomy/embolization of the uterine arteries or to state that no such case attended their unit. See the form designed for this purpose. – Return of the report card is expected within 1 week – otherwise a reminder is being send.

3. During the year 2011, the VVOG and GGOLFB supported the initiative and provided support to organize the collect and the sentinel of rare cases in individual maternities. In Flanders, it is the VVOG which organizes directly the collection of the information. In Wallonia-Brussels, this will be achieved through the CEPIP.
4. At the same time the contact persons/gynaecologists were asked whether they wish to fill out an extensive questionnaire on the case and/or if they agree that a panel member comes along to the unit for this purpose. In so doing the case notes never leave the hospital.
5. Three questionnaires are constructed for this purpose.
6. The Survey runs for a preset time-period i.e. one year – each of the complication is thought to occur once in every 2000/4000 deliveries. Over a one year period, some 25/50 cases should be collected.
7. The information obtained is coordinated by the College Mother and Child. Collaboration with SPE, CEpiP, VWV (VVOG) and the Obstetric Working Party (GGOLFB) is to be sought.

Topics that have been selected for the present study

- Eclampsia defined according to **UKOSS as**

Any woman with **convulsion(s**) during pregnancy or within the first 10 days after delivery, in combination with at least 2 of the following features within 24 hours of the convulsion(s) :

- **Hypertension** : a maximum diastolic Blood Pressure of >= 90 mmHg and a diastolic increment of >= 25 mmHg (having had a diastolic Blood Pressure <90 mmHg at the first antenatal visit)
- **Proteinuria** : at least + protein in a random urine sample or >= 0.3 g of proteins in a 24-hour collection
- **Thrombocytopenia** : platelet count < 100000/ml
- **Raised transaminase levels** : ALT of >= 42 IU/l or AST of >= 42 IU/l

Hypertensive disorders in pregnancy, and more in particular preeclampsia/eclampsia, still are a major cause of perinatal maternal and infant morbidity and mortality. In the Netherlands, per 100,000 live born children, 2.7 mothers died of a hypertension related complication of pregnancy. Over half of them had had eclampsia. It is in the Netherlands the most important cause of maternal death.

A nationwide observational study in the U.K. in 1992 revealed an incidence of 4.9 cases of eclampsia for every 10,000 maternities with a maternal fatality rate of 1.8% . In 2005 a

UKOSS held nationwide survey revealed an incidence of 2.7 cases of eclampsie for every 10,000 births; whereas no woman died.

As a result of the above named studies, a better awareness of the problem must have improved the outcome. The clinical diagnosis of "preeclampsia" has been revised by the ISSHP in the year 2000. The use of Magnesium sulphate to prevent eclampsia in severely preeclamptic women and to prevent recurrence in those that already had an eclamptic fit, is since been a widespread common practice.

▪ Uterine Rupture

UKOSS defined "uterine rupture" as a complete separation of the wall of the pregnant uterus, with or without expulsion of the fetus, involving rupture of the membranes at the site of the uterine rupture or extension into uterine muscle separate from any previous scar, and endangering the life of the mother or the fetus.
UKOSS excludes any asymptomatic palpable or visualized defect (for example dehiscence) noted incidentally at caesarean delivery.

The purpose in Belgium is to use a larger definition including all uterine rupture cases as defined by UKOSS, but also to consider all other forms of uterine rupture as defined by the LEMMoN study in the Netherlands.
LEMMoN defined "uterine rupture" as the occurrence of clinical symptoms (abdominal pain, abnormal fetal heart rate pattern, acute loss of contractions, vaginal blood loss), leading to an emergency caesarean delivery, at which the presumed diagnosis of uterine rupture was confirmed; or peripartum hysterectomy of laparotomy for uterine rupture after vaginal birth.
LEMMoN excluded cases of scar dehiscence found during elective caesarean section without preceding clinical symptoms.

The broader registry than the one suggested by UKOSS should enable us to calculate a risk of rupture of a scarred uterus and should enable us to estimate the consequences hereof.

The use of the LEMMoN definition allows the study of clinical symptoms preceeding uterine rupture.

According to the WHO, a uterine rupture occurs in 5 women for every 10,000 births. The incidence is lower in high income countries, the incidence being 3 for every 10,000 births. Moreover in Western countries the chance of the rupture to occur in an unscarred uterus is much lower being 0.6 for every 10,000 births (i.e. 1 in 6 cases of uterine rupture).

▪ Postpartum Hysterectomy and embolisation of the uterine arteries as defined by **UKOSS :**

Any woman giving birth to a fetus or infant and undergoing a **hysterectomy** in the same clinical episode.

Similarly **"peripartum embolization of the uterine arteries"** will be considered when occurring in the same clinical episode.

Peripartum hysterectomy and/or embolization of the uterine arteries are usually carried out in the context of a life-threatening obstetric haemorrhage. From the UKOSS report on the the subject of peripartum hysterectomy it is observed that to control hemorrhage was the reason for performing a hystectomy in 315 of 318 cases. It is clear from the CEMCD report 2003-2005 that, at least in the United Kingdom, maternal deaths due to hemorrhage had increased. Study of the 'near-miss' events is not only useful in defining risk factors but also helps to study appropriate management and preventative measures.
A nationwide observational study in the U.K. in 2005 revealed that for each woman that died of hemorrhage 150 women survived. Two women died (case fatality rate of 0.6%) following peripartum hysterectomy, whereas many more had bladder damage (7-23% depending on the cause of post partum hemorrhage) and some 20% required further surgery either to control hemorrhage or to repair damage to other organs. There also was a strong correlation with the presence of a uterine scar from caesarean section(s) in previous pregnancies.

The same nationwide observational study in the U.K. in 2005 revealed that there were only 87 attempts to solve the hemorrhage with a more conservative approach such as embolization of the uterine arteries. We do not know how many of the uterine arterial embolization procedures are successful and how many are deemed to be followed by hysterectomy.
Since embolization of the uterine arteries is becoming more and more common for that purpose, we decided we could not omit the evaluation of that tool in controlling hemorrhage. There will be overlap in some cases.

Methodology

In every maternity unit in the country, a contact person has been sought – for that purpose a letter has been sent to all the 'heads of departments/units' with the question who should be contacted monthly to get a list of complications that occurred in the previous month.

A detailed report card specific to each of the 3 considered rare diseases has be sent to the contact person of every hospital in the country with an obstetric unit.

Due to their close interaction with Belgian maternities in perinatal epidemiology, the supports of the CEpiP and SPE are mandatory to collect all available data.

National register for epidemiological record, concerted management related to rare gestational trophoblastic diseases.

INTRODUCTION

Following the recent initiative by the European Commission and the European Medicines Agencies (EMEA) mentioned above, to encourage the research, the development and the marketing of "orphan" medicines to treat, prevent or diagnose rare diseases, the College of Mother and New Born whishes to consider the case of Gestational trophoblastic diseases (GTD).

GTD are including a wide spectrum of diseases going from benign precancerous lesions, partial and complete hydatidiform mole (MP and MC, respectively), to malignant lesions, invasive moles, choriocarcinoma and tumours on the implantation site.

The most common forms are:

1. The complete mole characterized by diffuse hyperplasia of the cytotrophoblast and syncytiotrophoblast and by the absence of embryonic tissue;
2. The partial mole is characterized by hyperplasia focused and discrete cytotrophoblast and syncytiotrophoblast and the presence of embryonic tissues.

The risk of progression to persistent trophoblastic tumour occurs in 20% of women who present with a complete molar pregnancy and 5% of women who experience a partial molar pregnancy. These malignant tumours are globally named gestational trophoblastic tumours.

During pregnancy, the normal trophoblast invades endometrium and uterine vessels and becomes a zone of exchange between maternal and fetal bloods: it is the placenta. In gestational trophoblastic tumours, mechanisms regulating the proliferation and the invasion of the trophoblast are impaired and the resulting tumours are usually highly vascularised and, in the case of choriocarcinoma, quickly metastasise throughout the body. This can quickly lead to death by major tumour extension or massive haemorrhage. Thus, early recognition of malignant transformation is essential to administrate effecient chemotherapy for almost all patients.

Given that the chorionic gonadotropin hormone (hCG) is produced by all forms of mole, regular assessment of this hormone allows to identify abnormal evolution after partial or complete mole.

Trophoblastic diseases are rare diseases in Europe. In Britain and France, the incidence is estimated as 1 molar pregnancy for 1000 reported births. In Belgium, there is no incidence data but it is presumably similar to this of these two countries, annually between 90 and 100 molar pregnancies and 10 to 15 trophoblastic tumours. Only 16% of complete moles and 0.5% of partial moles will present with malignant transformation justifying chemotherapy.

Furthermore, the histological diagnosis of GTD is difficult and requires a true expertise in pathology to allow to define the type of follow up. For example, a complete molar pregnancy

usually requires 1 year follow up, while for a partial molar pregnancy, a follow-up of 6 months is sufficient. On the other hand, banal miscarriage doesn't require special monitoring.

Trophoblastic diseases are rare and complex diseases, which explain that the diagnosis of the type of mole may be wrong, that surveillance may be incomplete or excessive or that the treatments are not suitable. Thus, the inadequate management of such diseases can impair the vital prognosis of patients, either by underestimating tumour aggressiveness, or conversely, by prescribing inappropriate heavy chemotherapy.

So far in Belgium, there is no referral centre. Trophoblastic diseases are usually managed by gynaecologists and referred to medical oncologists in case of persistent gestational disease. This practically means that today, a gynaecologist will face the management of one single mole every 10 years, a pathologist will diagnosed a mole every 4 years and a persistent disease will be referred to medical oncologist every 12 years.

OBJECTIVES

The purpose of the creation of a register of GTD in Belgium is:

1. to improve the management of patients with complete or partial molar pregnancy and their complications;
2. to enable the conduct of parallel cohort or case-control as well as descriptive epidemiological studies.
3. to prepare and implement Belgian guidelines support for the different gestational trophoblastic diseases;

PATIENT MANAGEMENT – OPERATIONAL PATHWAY

National Organization

The register will be made unique and contain information on patients in two centres:
- Centre in French region (Doctor F. GOFFIN, CHU Liège, Liège)
- Centre in Flanders (Professor I. VERGOTE, KUL, Gasthuisberg, Leuven).

Operationnal pathway (algorithm adapted from Reference Centre for Disease trophoblastic Lyon)

1. A practitioner is discovering a molar pregnancy, most often on a product of curettage. He calls the centre, once patient consent is obtained, for a management assistance, a direct advice, or simply to report the case.
2. The referral centre gynecologist gives advises on how to conduct the treatment according to the stage of disease (watching over the evolution of hCG, extension assessment in case of abnormal development, OMS classification and chemotherapy protocol for possible trophoblastic tumours ...).
3. The Centre faxes the practitioner a registration form, a leaflet for the patient.
4. The Center contacts the patient local biological laboratory.

5. A letter is sent to the pathology laboratory that originally carried the diagnosis of molar pregnancy. The histological slides are sent to the referral centre pathologist who will perform a proof-reading to confirm or refute the diagnosis.
6. As soon as the Center receives consecutive hCG assessments from the local lab, the clinical nurse establishes the hCG rate evolution curve and transmits it to the referral center gynecologist who analyses the hCG results and informs the practitioner.
7. As soon as they receive the review of pathological proof-reading, a letter is sent to the patient's practitioner in order to specify the duration of follow up. This observation takes 6 to 12 months after hCG negativity depending on the type of mole.
8. In case of abnormal development, the practitioner is immediately contacted by phone so that a concerted approach is decided. The practitioner contacts himself his patient.
9. The patient receives a mail at the time of her registration in the centre, of the negativation of her hCG and every 3 months until the end of her follow up. The booklet gives detailed coordonates of the centre so that she can call whenever she wants to get a result of hCG or any other information.
10. The encoding of clinical data will be performed in a computerized database for the 2 centres with secured access limited to members of the Centres and, by delegation to data managers.

EXPECTED BENEFITS

Improving diagnosis

It is now commonly admitted that protocols based on scientific evidence and multidisciplinary management are usually better implemented in a specialized environment and their better application ensures better monitoring. The experience of referral centres clearly shows a benefit for patients.

It has been shown that when a partial mole is diagnosed by a "non-expert centre", the diagnosis is confirmed only in 50% of cases after proof-reading by a "expert centre". A study in England showed that, in 23% of cases, the result of the second reading of histology didn't confirm a mole pathology (false positive diagnosis). Those false-positive diagnosis led to non required treatment and follow up. Another example comes from the Disease Trophoblastic Centre of Lyon, with 583 cases in whom the initially carried diagnosis was confirmed by the pathologist of the centre in 451 cases (77.3% of cases), meaning that in 22.7% of cases, initial diagnosis had to be corrected [http://www.mole-chorio.com].

Improving monitoring and follow up

Monitoring is based on hCG assessment to be repeated every month for 6 to 12 months depending on the type of disease, (6 months for partial moles and 12 months for typically complete moles). Both situations justify systematic follow up of all patients who presented a molar pregnancy. For patients registered at the centre, a nurse will be responsible to monitor the levels of hCG and to transmit the results to the referral center gynecologist. Supervision by a referral centre can earlier detect the cases that progress to persistent disease and quicker propose an effective treatment.

Evaluation's harmonization
A secondary evolution toward a persistent gestational disease (or choriocarcinoma) requires the implementation of an extended evaluation. The evaluation must be perform by using some pertinent tests and avoiding unnecessary evaluations (clinical or radiological). In general, experience shows that the application of additional tests (imaging, biology) is inversely proportional to the practitioner's experience.

Evaluation by a multidisciplinary team
In case of persistent gestational disease, the results of the assessments will be discussed to optimize care at a multidisciplinary meeting involving gynaecologists, medical oncologists, pathologists, radiotherapist and radiologists.

Improvement of information to patients
A detailed booklet will be sent to patients in order that they find practical answers to the most frequently asked questions (duration of contraception, risk of recurrence, obstetrical future ...).

ETHICAL AND LEGAL CONSIDERATIONS

The study protocol and informed consent form will be submitted to the Hospital and Medicine Faculty at the University of Liege (Leading Committee) and to any local Committees where a gynaecologist is willing to obtain support in his GTD management.

The registry will be created according to good clinical practice guidelines implemented since July 1991 in the European Community and according to the rules of the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for human use" (ICH / GCP Steering Committee of 1 May 1996, Helsinki declaration drafted in order to protect people who participate in clinical trials). It will also meet the requirements of Belgian law on experimentation on human beings of May 7, 2004 implemented in December 2007.

Patients will only be included, provided they have given their free and informed consent in writing.

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HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

Section Mère du Collège Mère – Nouveau-Né -

Definition of eligibility and referral criteria, choice of objective criteria to assess the activity within the Maternal Intensive Care Units

The MIC (Maternal Intensive Care) beds are designed to allow intensive observation and care of patients whose pregnancy is at high risk, women who require highly specialized care after birth, or whose babies require intensive care after birth.

Since 1996, 18 of the 106 Belgian maternity wards are equipped with MIC beds and are equipped with a neonatal intensive care service. The number of beds MIC is independent of the size of the maternity and varies between 8 and 20 by maternity. In practice, MIC beds do not constitute a separate setting but are eligible for additional funding that strengthens the team of midwives specialized in the care of high risk pregnancy.

The legislator has not detailed the indications for admission to a MIC bed. There are therefore large variations between hospitals in terms of admission policy and reference. In general, according to the 2008 report of KCE, only 40% of patients with high-risk pregnancy are actually admitted to a MIC.

Tools to determine what level of activity and quality of this MIC activity lack as well as tools to evaluation the operational functioning of the MIC centers in terms of meeting criteria for MIC admission, transfer and re-transfer.

That's why the College Mother Newborn wishes to select with your help the indicators of quality of care in intensive obstetrics.

The following questionnaire is the first round of a series of rounds of a Delphi survey. During the first round, we ask you to rate the importance of a set of potential quality indicators in obstetrics intensive care, which can be followed routinely to identify the quality of a MIC setting. Two dimensions of each potential indicator should be considered: its validity and its feasibility.

Definition of validity
A valid quality indicator has suitable characteristics for the intended use and is considered as a good measure of the quality of care in a MIC setting. It seems you that there is a need to follow it in each MIC daily practice and monitor its progress.
1= the potential indicator doesn't seem important to you to measure the quality of MIC care
9= the potential indicator seems very important to you to measure the quality of MIC care.

Definition of the feasibility

A quality indicator is defined as feasible if the collection of information necessary for its construction is easy with respect to staff workload.
1= it is not possible to find the requested information to design such a indicator
9= Requested information to design such an indicator is easy to obtain in daily practice

You can, if you wish, comment on the quality indicators in the dedicated area.
You can also add quality indicators that you consider necessary to follow for a better MIC care in case they are not suggested.
You can now begin to answer questions. To maximize the reliability and consistency of judgment, it is best to complete the questionnaire in one sitting.

STRUCTURE

Neonatal Intensive Care Unit in same hospital
Intensive Care Unit in same hospital
Operating Room in labor ward
Interventional radiology in same hospital
Blood bank in same hospital
Clinical and molecular Genetics service in hospital
Fetal pathology service in hospital

24h/24h availability of trained midwives in MIC
24h/24h availability of competent MIC OB/GYN (on call)
24h/24h availability of competent MIC OB/GYN (in hospital)
24h/24h availability of anesthesiologists in hospital
24h/24h availability of anesthesiologists trained in high risk obstetrics
24h/24h availability of surgical team to handle all major obstetrical complications
24h/24h availability of neonatologists

Capacity to perform 3th level Ultrasound
Capacity to do Invasive Prenatal Diagnostics
Possibility of fellowship in maternal-fetal medicine in hospital

PROCEDURE

Multidisciplinary staff meeting daily
Multidisciplinary staff meeting weekly
Multidisciplinary staff meeting monthly

Availability of locally adapted guidelines
Availability of locally adapted guidelines to the referring centers

Regular contact between referring and referral center by phone
Regular contact between referring and referral center by mail
Regular contact between referring and referral center by letter

Level of doctors in MIC referral center responding to phone calls from referring center
Level of doctors in MIC referral center who first see the transferred patients

Presence of clear admission criteria for MIC

OUTCOME

Scientific output: number of national publications per year
Scientific output: number of international publications per year
Permanent education of medical staff
Permanent education of midwifery staff

Number of intrauterine transfers per year
Number of postpartum transfers per year maternal or neonatal

Number of refused transfers per year (= number of demands for transfer to MIC unit that could not be accepted due to practical reasons (eg no place in NIC unit)
Number of retransfers per year
Percentage of retransfers per year
Number of patients transferred from Intensive Care Unit to MIC or from MIC to Intensive Care Unit per year
Number of prenatal outpatient referrals per year

Mean Occupancy rate (= % of MIC beds with MIC pathology = number of MIC patients/number of MIC beds/day)
Number of admissions of MIC patients per year
Number of MIC patients per year

Number of births < 28 weeks per year
Number of births < 32 weeks per year
Number of births < 34 weeks per year
Number of babies with birth weight < 1000 g per year
Number of babies with birth weight < 1500 g per year
Number of babies > 22 weeks with congenital abnormalities per year
Number of babies > 22 weeks with congenital abnormalities who need Neonatal Intensive Care and/or surgery per year
Number of invasive prenatal procedures (intra-uterine transfusions, laser coagulation, foetal surgery) per year
Number of Preeclampsia/HELLP/acute fatty liver of pregnancy < 34 weeks per year

Number of deliveries of HIV positive mothers per year
Number of deliveries of mothers using hard drugs per year
Number of deliveries of mothers with severe psychopathology requiring hospitalisation per year
Number of deliveries of severely ill mothers (severe astma, liver failure, renal failure, severe heart disease, sickle cell anemia …) per year

Number of severe Obstetrical Complications or 'near-miss' events (eclampsia, uterine rupture, peripartum hysterectomie or embolisation of uterine vessels) per year

Determinants of high and low rates of Caesarean deliveries in Belgium. Recommendations to avoid unnecessary Caesarean sections.

A REPORT OF THE COLLEGE MOTHER AND NEW BORN

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I. Introduction

Epidemiology

The caesarean section (Cs) rate continues to rise in many countries with good access to medical services, yet this increase is not associated with improvement in perinatal mortality or morbidity. The World Health Organization states that no region in the world is justified in having a caesarean section rate greater than 15 percent [1,2] which is the median percentage observed worldwide. USA, Mexico, Brazil, and Italy have the highest rate (over 35 percent) and Africa has the lowest (under 5 percent). The mean caesarean delivery rate in developed countries is 21.1 percent, but is only 2 percent in the

least developed countries. The caesarean delivery rate in China ranges from 20 to 60 percent, depending on whether the hospital is rural or urban [4-6] and was 25 percent in teaching hospitals in India [7].

In Belgium, the Cs rate was in 2004 18.5%.

The present situation in Belgium

The perinatal epidemiology (SPE* and CEPIP) reports in 2009 a global Caesarean section rate of 18.5 % in Flanders (range : 12%-29%) and 19.2% of total singleton deliveries in Wallonia+ Brussels (range: 7.9% - 32.1%),**
or respectively 19.8 % or 20.5% of all newborn babies.
These data are identical to the 2008 figures.

*** :** H. Cammu, G. Martens, E.Martens, C. Van Mol, P. Defoort : Perinatale activiteiten in Vlaanderen 2009 (http://www zorg-en-gezondheid.be).
** : Minsart AF, Van Leeuw V, Wilen G, Van de Putte S, Verdoot C, Englert Y : Données périnatales en Région wallonne – année 2009. Centre d'Epidémiologie Périnatale, 2011.

91.4% of breech presentation were delivered in 2009, by Cs in Flanders and 90.1% in Wallonia and Brussels. The induction rate was 24.2% (range 13.1-38.3) in Flanders and 33.3% in Wallonia + Brussels (range 22.6% - 59.3%). Among induced labours, the Caesarean section rate was 19.3% in Wallonia + Brussels and this figure was 13.1% in spontaneous deliveries. This confirms our previous demonstration that elective labor induction for non medical reasons is associated with an increased risk of Cs.

Consequences

The **short-term risk for the mother** is postpartum morbidity and reduced fertility. The major nonanesthesia-related complications related to caesarean delivery are infection, hemorrhage, injury to pelvic organs, and thromboembolic disorders.

The **long term risks** are an increased risk of abnormal placentation in future pregnancies A meta-analysis (n = 3.7 million women) reported the baseline frequency of placenta previa was 1 in 200 deliveries. However, in women with at least one prior caesarean, the risk of development of placenta previa in a subsequent pregnancy was two to three times higher than at baseline, and the risk increased with the number of prior caesarean births [34]. The higher rate of placenta previa is of concern, due to the inherent risks of this disorder and because of the increased frequency of placenta accreta in women with placenta previa and a prior hysterotomy. There is an increased risk of placenta accreta with increasing numbers of prior caesarean deliveries even in the absence of placenta previa.

For **the child**, Cs is associated with postpartum respiratory morbidity, less breast-feeding and possibly more atopic disease. The fetal risks include iatrogenic prematurity and birth trauma; the latter occurs in 0.4 to 3 percent of caesareans and consists mostly of mild lacerations related to emergency delivery

[27-31]. Transient tachypnea of the newborn (TTN) is more common after scheduled or planned caesarean birth. In a review of 29,669 deliveries, the incidence of TTN was about three times higher after planned caesarean than after vaginal delivery [32]. Caesarean delivery has also been reported to be a modest risk factor for respiratory distress syndrome (RDS), particularly if the caesarean was performed in a nonlaboring patient [33].

For **society**, the cost of a caesarean section is not dramatically different from that of a vaginal delivery, taking into account delivery with oxytocin or epidural anesthesia. The average cost for all women who attempt vaginal delivery was only 0.2% less than the per-patient cost of elective cesarean delivery (Bost BW. Cesarean delivery on demand: what will it cost? Am J Obstet Gynecol 2003; 188:1418).

In summary

The major short-term complications related to caesarean delivery are infection, hemorrhage, injury to pelvic organs, and thromboembolic disorders. The major long-term risks are abnormal placentation and issues relating to route of delivery in future pregnancies.There is thus every reason to attempt prevention of a further increase in caesarean section rates.

Causes: a mix of medical and non medical indications

The rise in prevalence of caesarean deliveries in developed countries has been attributed to multiple factors, including changes in physician/patient expectations and attitudes about risk, changes in clinical practice (e.g., fewer trials of labor after previous caesarean delivery, vaginal breech births, and instrumental deliveries; more inductions of labor and caesarean deliveries by maternal request), medico legal concerns, and financial issues [**10-13**]. Increasing maternal age at delivery, an increase in the proportion of births among primi gravidae > 30y, and the increased prevalence of multiple gestation and maternal obesity are also factors. In summary, medical factors but also non medical factors contribute to the enhancement of the Cs rate.

The CEPIP and SPE 2009 data for Belgium confirm that the three most frequent causes of caesarean section in Belgium in 2009 are:

1. **fetal malpresentations** (mainly breech), (36.3% of all Cs in Flanders, 17.8% in Wallonia & Brussels)
2. **repeat Caesarean section** (24.7% in Flanders and 21% of all C/S in Wallonia & Brussels) and,

3. **dystocia** (24.5% in Flanders, 24.7% in Wallonia + Brussels)

It may therefore be concluded that
it is essential to avoid the first unnecessary Caesarean section,
since subsequently most obstetricians will repeat a second Caesarean section.

II Medical indication

The four most common medical indications for caesarean delivery according to the international literature account for approximately 80 percent of these deliveries [16]:

1. Failure to progress during labor (30 percent)
2. Previous hysterotomy (usually related to caesarean delivery, but also related to myomectomy or other uterine surgery) (30 percent)
3. Nonreassuring fetal status (10 percent)
4. Fetal malpresentation (11 percent)

Additional, less common indications for caesarean delivery include, but are not limited to:

- Abnormal placentation (eg, placenta previa, vasa previa, placenta accreta), maternal infection (eg, herpes simplex or human immunodeficiency virus), multiple gestation, fetal bleeding diathesis, mechanical obstruction to vaginal birth (eg, large leiomyoma or condyloma acuminata, severely displaced pelvic fracture, macrosomia, fetal anomalies such as severe hydrocephalus;
- increased risk of complications from tissue trauma related to cervical dilation, the descent and expulsion of the fetus, or episiotomy (invasive cervical cancer or active perianal inflammatory bowel disease, or past repair of a rectovaginal fistula or pelvic organ prolapse);
- (not routinely indicated) for fetal issues :extremely or very low birth weight (<1000 g and ≤1500 g, respectively) [17], or certain congenital anomalies (some skeletal dysplasias, and gastroschisis with herniated liver) [18,19]

III The non medical factors:identification of factors that influence the CS decision.

Since there is no correlation between Cs rate and improved fetal or maternal outcome, it is important to better understand the non-medical parameters resulting in enhanced number of unnecessary Caesarean sections. It is hoped that the elucidation of such factors and use of non-clinical interventions, applied independently on patient care will reduce the unnecessary Cs rate in low risk

pregnancies (Low risk pregnancy is defined as: singleton, vertex, full-term, live born, <4500g,>2499g)).

A recent Cochrane study (Non-clinical interventions for reducing unnecessary caesarean section. Cochrane Database Syst Rev. 2011 Jun 15) concluded that:

1. Implementation of guidelines with mandatory second opinion can lead to a small reduction in caesarean section rates, predominately in intrapartum sections.
2. Peer review, including pre-caesarean consultation, mandatory secondary opinion and postcaesarean surveillance can lead to a reduction in repeat caesarean section rates.
3. Guidelines disseminated with endorsement and support from local opinion leaders may increase the proportion of women with previous caesarean sections being offered a trial of labor in certain settings.
4. Nurse-led relaxation classes and birth preparation classes may reduce caesarean section rates in low-risk pregnancies.

The College identified:

- Factors other than medical reasons, that are associated with differential Cs rate;
- Differential organizations already in place in some hospitals (and absent in others), that contribute to prevent (or reduce) unnecessary Cs;
    1. Whether or not validated tools to decrease the unnecessary Cs rate are also operational in Belgium in maternities with low Cs rate and absent from maternities with high Cs rate.

Population

Twelve maternities were chosen following the criterion of language and Cs rate (3 high, 1 low & 2 median in Dutch speaking Community, 3 high and 3 low in French speaking Community). The maternities were characterized following a high, an average or a low Cs rate by independent expert of the SPF. In each maternity, the researchers have interviewed: 1 gynecologist head of the department, 2 gynecologists, 1 head midwife, 1 midwife.

Until the interpretation of the results, the study was double blinded. The researchers and the experts did not have access to the real Cs rates of the visited maternities.

The information gathered through interviewing the professionals was analyzed by means of a thematic analysis and a reduction methodology process. In other words, the information was successively analyzed by different methods in order to produce a structured, condensed and thick set of results. The reduction was helped by the use of the program Nvivo (A well-known Qualitative data analysis software, qualitative research).

What are the differences between maternities with low and high rates Cs ?

Common factors

The study demonstrates common factors found in all maternities, independently of the Cs rate. In all maternities, professionals speak about the difficulty of interpreting the Electronic foetal heart rate monitoring (EFHRM). They discuss its low specificity, excessive sensitivity and its high false positive rate. This seems to be a major factor contributing to recognize the advantages of the STAN and to recommend its use.

Young obs/gyn are stigmatized by their older colleagues for their lack of working experience and therefore would prefer to perform a Cs since they perceive it as a 'safer' option. Moreover, all professionals recognize a loss of confidence in instrumental obstetric or in their capacity to practice it. They are also all concerned about the legal pressure perceived as a powerful pressure that does not allow professionals to take any risk.

Besides, some professionals say that they try to preserve their quality of life by means of induction or Cs. Convenience induction becomes a tool to manage the *alea* of their agenda.

Finally, the obstetric practice is embedded within a technological paradigm: the technological improvement (e.f. STAN) puts the professionals under additional pressure: accountability and responsibility towards the parents.

Factors discriminating between low and high Cs rates

In all maternities with low CS rates, managing the parental pressure is seen as a part of the duty of guiding patients throughout pregnancy.

Low Cs rate maternities are characterized by a "working culture" favoring physiological delivery and avoiding unnecessary preterm induction for convenience. This policy is supported by staff meetings and/or staff training. This culture resists the idea that a Cs would be a better/safer option for the newborn.

The low Cs rate maternities are organized to avoid a stressing context. The working organization avoids professional isolation, and ensures a second opinion before performing a Cs. Management of the stress is well illustrated by the way the medico-legal pressures is not a pretext to use with uncertainty "the grey zone of a non reassuring monitoring ", or to misuse the interpretation of monitoring to legitimate a Cs decision.

In maternities with high Cs rates, ob/gyn indicate often that they feel alone facing a decision of which they carry the legal responsibility. When they face a doubt, professional isolation often leads to the "no short term risk" decision. Taking no risks implies preferably performing a caesarean section. This procedure is perceived as more controllable than guiding women through physiological labor.

In practice in high Cs rate maternities, we note factors that contribute to construct a social representation predisposing to Cs. The ob/gyn develops a true relativism about the evidence based guidelines and other recommendations. Following such a social representation, the "*alleged*

exception" allows the professional to deviate from a good practice. As such clinicians say "*each pregnancy is unique and I am therefore allowed not to take into account the guidelines or recommendations*". Such excuses allow to avoid strict adherence to the established guidelines.

Most often, the ob/gyn finds the excuse to deviate from the recommendations in the social context of the parents. More professionals in maternities with high Cs rates also exploit in a subjective way the « grey zone » of borderline anomalies. In other words, they are ready to interpret any deviation of the fetal heart rate pattern as a pathology and perform a Cs as a form of "defensive medicine" that protects them from a legal suit, or to turn a normal pregnancy into sickness in order to transform it into a high risk pregnancy and to legitimate the CS decision.

From the visits and qualitative assessment of the non medical parameters that influence the Cs rates, some discriminating factors were evidenced between maternities with high and low rates of Cs:

1) Differences in the organization: isolated management or team work / (systematic second advice) with staff meetings, training sessions, permanent education;
2) Differences in the promotion of physiological births : Maternities with high rates of Caesarean section do not promote the physiological births, but often, justify the "well-being" of the child to justify a Caesarean decision, that is not based on objective criteria;
3) Differences in the handling of the parental psychological pressure;
4) Differences in legitimating induction;
5) Different attitudes toward litigation;
6) In maternities with low rates of Cs the parental pressure is tempered and not taken into account by the team beyond reasonable limits because it is considered as a somewhat normal and usual parameter in the relationship with the parents. Planned Cs decisions are being taken by the team, and Cs in labor, as much as possible with a second opinion. Guidelines are available and regularly discussed and updated by the staff. Finally the physiological delivery is promoted by most obstetricians in such maternities. Meetings, staffs, evaluations of individual practices are reviewed at regular intervals.
7) In maternities with high Cs rates isolated obstetricians take their decisions alone. They tend to "manipulate" and adjust the limits of the various scoring systems, tests in order to justify their decision of performing a Cs (gray zone of subjective assessment of a medical parameter). They perceive themselves the Cs as less risky than the normal vaginal delivery, even in low risk pregnancies. The parameters of the partograms are more often used to justify a posteriori a Cs decision. Their rate of induction for personal reasons is also significantly higher.
8) A few other factors that can potentially affect the Cs rates although we could not firmly conclude from this limited study are the fact that the obstetricians are mainly isolated independents without a team spirit and no leader, and the several tools used for the surveillance of the parturient (monitoring, STAN, pH, partogram…) are more often considered as a possible threat rather than reassuring instruments documenting the safety of the vaginal route. Finally, the freedom of deciding alone is considered in the high Cs rate maternities as the sovereignty of the medical decision.

Several factors may play a significant role in reducing or preventing the unnecessary Cs rates. However the study could not demonstrate their role in all visited maternities, for example: duty organization, team building politics, head of the department politics, fetal monitoring, medical

sovereign opinion. The medical sovereign opinion does not seem to differentiate low and high maternities. For example, in the low Cs rate maternities, the "medical sovereign opinion" is framed by the existence of staff meetings, respecting guidelines and pro-physiological culture.

On the contrary, medical sovereign opinion plays another role in maternities with a high Cs rate. There, the professionals are prone to assume their liberty of decision. This liberty is no more framed as in low Cs rate maternities, but more often linked with the opportunities of interpreting « grey zone » or to justify a decision by their legally recognized expertise.

IV Recommendations to reduce the Caesarean Section rates

a. Medical factors

The causes of Cs inflation are multiple. Among them, our previous report (2009) has evidenced several medical factors. The most prevalent is the inappropriate induction of primigravidae with unfavorable cervix (a Bishop score ≤ 6). The second medical factor is the automatic repeat Cs delivery after a first Cs performed for non mechanical dystocia reasons.

It appears therefore wise to recommend for the delivery of low risk unifetal pregnancies:

1. Enforcement of a policy prohibiting induction of labor before a term of 40 weeks;
2. Induction restricted to women with a Bishop score of at least 6;
3. Post term induction should be considered from 41.5 weeks, only;
4. Discussion with the parents to evaluate the benefits/risks of a trial of labor in women with a previous Cs. (TOLAC) Several guidelines have been edited that allow in safe conditions a vaginal birth after caesarean delivery (VBAC);
5. To implement in case of induction a policy of informed consent that allows the mother to be fully informed of the possible consequences and benefits of an induction for non medical reasons;
6. When the Bishop score is not modified after local application of prostaglandins for convenience induction, the procedure should be stopped and the lady should be sent home with the message that her uterus is not ripe to enter in labor.

b Recommendations pertaining to the health care organization

Multifaceted strategies, based on audit and detailed feedback, are advised to improve clinical practice and effectively reduce caesarean section rates. Moreover, our findings indicate that identification of barriers to change is a major key to success.

1. A team-work approach with a better organization to prevent the isolation of practitioners;

2. A policy of mandatory second opinion for all Cs (planned or not);

3. Written Guidelines available for all physicians at the hospital;

4. Regular discussion and updating of the guidelines to implement their daily use;

5. Individual feedback provided to the obstetricians about their practice including Cs rates with possible face to face interviews;

6. Monthly medical audits of the Obstetrical practice;

7. Discussion at Seminars, peer-review meetings (GLEMs) of the Cs rates and circumstances;

8. Organization of pre-caesarean section consultations.

Finally, these recommandations were implemented among the trainees, hospital staff members, private practitioners having an obstetrical activity in an academic center during the year 2010. The rate of Cs delivery decreased from 26,0 to 20,2 %. The Cs rate associated with the MIC unit was not modified. The decrease resulted almost exclusively from a significant reduction in the number of Ceasarian deliveries performed in women presented with a low risk pregnancy, demonstrating the efficacy of such measures when collectively implemented.

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