Registry and surveillance of rare complications in pregnancy

Belgian Obstetric Surveillance System
B.OSS

Approved and financially supported by the College Mother and Child
(F.P.S. Ministrie of Health, Food chain safety and Environment.)

Overview of the project 2013

General Introduction

In 2012 Larsson S, Lawyer P, Garellick G, Lindahl B and Lundström M. published in Health Affairs a study on the use of 13 disease registries for a preset diagnosis in 5 countries (Australia, Denmark, Sweden, the United Kingdom and the United States) in which they demonstrated that the use of the outcome data could improve the health care values. (Ref Larsson S et al Health Affairs 2012; 31:220-227); Indeed the information obtained through the study of diseases and the outcomes in a particular country, are shown to help to better understand the factors that lead to a better outcome and as a consequence can help on drawing recommendations on how the outcome can be improved.

This should be true even more so for medical conditions that are uncommon because it is even more difficult to have treated a large enough number of cases within a reasonable period of time to obtain the information required to formulate appropriate recommendations to improve the outcome of such rare conditions. Hence it is very important that the project on rare complications in pregnancy that was started under the impulse of the College of Mother and Child should continue for at least another year so that the denominators of the diseases/complications under investigation are sufficiently large to compare the outcome results with the outcomes and experiences in neighbouring countries. After having done so for a few such rare conditions, under impulse of the College Mother and Child other resources of financial support should be found to continue the project in accord with 'INOSS' (the International Network Obstetric Survey Systems).

Objective – Continuation of the project on rare complications in pregnancy, which started in July 2011.

The purpose of present study protocol "2013" is to continue with the registry and the surveillance of rare complications of pregnancy in Belgium. The purpose is to obtain enough data that allows a comparison with similar studies that have been carried out in other European countries.
Some complications in pregnancy are so rare that few midwives and obstetricians will ever in their whole careers come across them. The purpose of creating a registry and a surveillance for those rare complications in pregnancy is to bring together expertise on the knowledge and the management of those rare conditions so that in the future, pregnant women with a similar 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. Such an approach was started in the UK (UKOSS) and has meanwhile been followed by several other countries such as Australasion countries, Germany and Austria, the Netherlands, Italy, Catalonia, the Nordic countries, and Bratislava in Slovakia all assembled in INOSS

The Doctors of the college for 'the Mother and the Newborn' have, back in 2011, suggested a similar approach in Belgium and have decided to start by investigating the following three complications 1) eclampsia 2) uterine rupture 3) postpartum hysterectomy and/or embolization of the uterine arteries.

Definitions of the three selected topics were set as follows and will not change:

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

For Uterine rupture a larger definition is used 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.
Uterine rupture as defined by UKOSS (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),
Uterine rupture as defined by the LEMMoN study in the Netherlands (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
UKOSS and LEMMoN both excluded any asymptomatic palpable or visualized defect (for example dehiscence) noted incidentally at caesarean delivery.

Postpartum Hysterectomy and embolisation of the uterine arteries as defined in the same way it has been defined by UKOSS: being any woman giving birth to a fetus or infant and undergoing a **hysterectomy** in the same clinical episode. Yet, also "peripartum embolization of the uterine arteries" is being considered when occurring in the same clinical episode.

Methodology

The methodology used is based on UKOSS, and is meanwhile being applied by many other countries through INOSS (International Obstetric Surveillance System) which in turn is

similar to the methodology developed by the BPSU, British Paediatric Surveillance Unit, which was started in 1986 to undertake active surveillance of rare paediatric disorders.
It concerns anonymous descriptive cohort studies through a monthly case-collection scheme. In Belgium, each hospital with a maternity unit has been asked to participate through either an obstetrician or a midwive to report to B.OSS. Every month, every unit is sent a "rapporteringsformulier" with a list of the 3 conditions under surveillance (see the report of 2012). They are asked to tick the boxes indicating if any cases have occurred in the previous month, or if none, to return the card indicating a nil return. If there is no reply, consecutive reminders are being sent.
On receiving a case report (return of the monthly forms), the B.OSS team will dispatch a data collection form to receive more detailed information about the case. The data collection forms have been developed individually for each condition in a way that the information obtained allows comparison with the UKOSS, the LEMMoN data of the United Kingdom, and of the Netherlands respectively as well as with the data from the other 'INOSS' countries . Help with the completion of the form is being offered. A hospital case note number is requested in case further information is required. No personally identifiable information is kept in the analysis of the data. Patients concerned are all informed of the study and they can refuse participation by opting out (see the report of 2012)

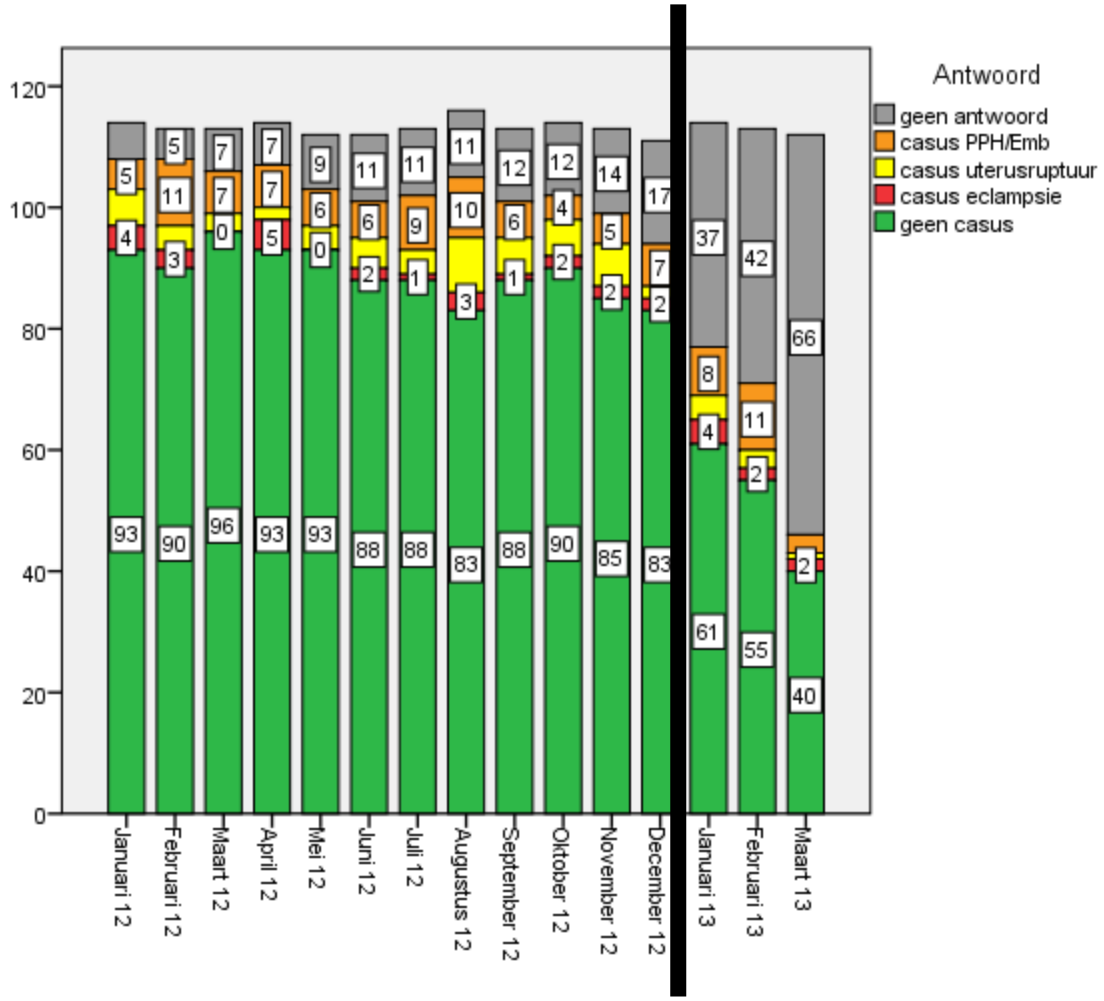
"B.OSS" **is conducted by two teams**: there is one team for the Dutch-speaking maternities in Flanders and the VUB in Brussels and one team for the French and German-speaking maternities in Wallonia and Brussels with the exception of the VUB in Jette. The team in the Northern part of country presently consists of Griet Vandenberghe and Marlies Deblaere of UGent, Myriam Hanssens, Ann Langedock, and Marine Guisset of KU Leuven and Joachim Van Keirsbilck of Brugge; the team in the Southern part of the country accords with the responsibles for CEPiP Yvon Englert of the ULB, Virginie Van Leeuw and Laura Guzy. The two teams cooperate and meet every three months to update on their progress, to discuss difficulties and help finding solutions, to propose ideas for further improvement. All the correspondence between the B.OSS team and the gynaecologists/midwives/maternities is done either *in the Dutch* or *in the French language*.
Data collection forms (one form for each complication under consideration) are *available* *in the English language.* As already mentioned in previous reports, the forms have been based on the UKOSS data collection forms, with adaptations and additions based on similar international studies on the topic, to enable comparison of the data with other countries including the LEMMoN study in the Netherlands. The data collection forms seek confirmation of the appropriate case definition and additional information on risk factors, management and outcomes.
The collection of patient information by B.OSS has been **formally approved by the Medical Ethics Committee** of the University Hospital Ghent (EC UZG 2012/734; B670201215359) and by the Medical Ethics Committee of the Free University of Brussels (EC ULB 2012/111; B406201213660) provided an information letter would be offered to the patient/or its closest relative, enabling an opt-out system. See the report of 2012 on this. The Medical Ethics Committees will be informed of the continuation of the study.
Besides the financial support from the College of Mother and Child, approval and endorsement for B.OSS has been requested and obtained from VWV (Vlaamse Werkgroep Verloskunde) of the VVOG, GGOLFB, SPE and CEpiP, the various universities and the perinatal Centres in the country.

Results as from 01/01/2013

We count 104 Belgian maternity hospitals, some of them existing of two or more campuses or associations that register separately making a total of 115 Belgian centres that are 'registring

centres'. **97,3 %** (112/115) of the Belgian centres agreed with the principles. Two centres declined participation and one centre has never replied on several attempts to contact.
All participating centres except 4, so far, have responded at least once at the monthly call for cases: hence **93,9 %** (108/115) of the Belgian centres is actually particating .
The response rate from January 2013 appears to have declined as compared to the response rates seen in 2012 – However not all the answers have yet been included and reminders have been sent by e-mail or reporting gynaecologists have been contacted by telephone.

Short overview of the course of the project



Although the response rates we obtained appear to correspond well with the rates seen in other countries. We do encounter reluctance to report cases for fear of recognition (in a small country) and subsequent litigation.

In the first 3 months of 2013 so far of the number of **cases for each of the three topics reported** were as follows:

- **8** cases of Eclampsia: incidence of 2.4 / 10 000 deliveries
  (using an estimated 32 250deliveries in Belgium over that period of time as denominator)
- **6** cases of Uterine Rupture: incidence of 1.9 / 10 000 deliveries
- **21** cases of Postpartum hysterectomie and/or embolization: incidence of 6.5 / 10 000 deliveries

All reporting contact-persons and maternity hospitals are regularly informed of the current state of affairs through newsletters being sent in the language of origine. (**a second**

newsletter was sent in February 2013 in the Dutch and in the French language as appropriate)

Specific Objectives for 2013 :

1- To improve the completeness of the collection of cases and to improve on the quality of the information received on the case, whereas an even better anonymity should be guaranteed (see comments made earlier in this document)
These should be achieved :
by **going (as has been implemented in other INOSS countries) for a « web-based data- collection »**
and
by **improving the forms conform an internet based format**. The questions have already been scrutinized and made clearer so that the difference can be made between whether or not an item was either « not performed », « not asked » or « wether the result was negative ».

2- Belgian data should continue, as planned for the three topics already started, until December 31st, 2013 hereby resulting in a reasonable number of cases for comparaison with the data obtained in the neighboughing countries (see data from INOSS) . Inter-countries (the countries involved are: United Kingdom, Germany, the Netherlands, Austria – with together at least 1.5 miljon mothers involved) analyses have been suggested. It should be possible to compare e.g. related to uterine ruptures **1) rare conditions of uterine rupture** a) rupture of the previously unscarred uterus b) spontaneous (pre-labour) ruptures c) ruptures in the first and the second trimester of pregnancy **2) common determinants of uterine rupture** a) gestational age at which previous caesarean section was done b) history of a surgically treated corneal pregnancy c) previous pregnancy complications d) previous medical complications e) the presence of myomata f) history of the usage of any new conservative treatment g) the use of an epidural analgesia **3) management and oucome**. Advise on how to reduce the complication rates should result from the data.

3- Statistical analysis is planned the **SPSS statistical program** which includes descriptive statistics and confidence interval analyses

4- As the financiel support from the College for Mother and Newborn is limited, we would like to use the results of this project as an example for the future grant-applications which should enable us to extend the project to other rare complications of pregnancy.