Incidence of three conditions of acute severe maternal morbidity in a European population-based study: the MOMS-B survey

Wei-Hong Zhang M.D.*, Sophie Alexander M.D., PhD*, Marie-Hélène Bouvier-Colle†, Alison Macfarlane, BA, Dip Stat‡ and the MOMS-B Group§

AFFILIATIONS:

*Unité de recherche en Santé Reproductive et Epidémiologie Périnatale, Département des Politiques et Systèmes de Santé, Ecole de Santé Publique, Université Libre de Bruxelles, Brussels, Belgium

† Epidemiology Research Unit on Perinatal and Women's Health INSERM-U 149, 123 Boulevard de Port-Royal, 75014 Paris, France

‡ Department of Midwifery, St Bartholomew School of Nursing and Midwifery, City University, London EC1A 7QN

§ Members listed at end of paper

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CORRESPONDING AUTHOR:

Wei-Hong ZHANG, M.D., M.P.H.

Unité de recherche en Santé Reproductive et Epidémiologie Périnatale, Ecole de Santé Publique, Université Libre de Bruxelles, Route de Lennik 808, CP 597, B-1070 BRUXELLES, BELGIUM

Tel: ++ 32 2 555 40 46, Fax: ++ 32 2 555 40 49

Email: zhang.wei.hong@ulb.ac.be

ABSTRACT

Objective: To describe the incidence of three conditions of acute severe maternal morbidity in selected regions in nine European countries.

Design: A population based questionnaire survey.

Setting: 11 regions in nine countries of Europe.

Population: All the pregnant women in each region who had delivered during the time period covered by the study.

Methods: Standard definitions of three severe obstetric conditions, pre-eclampsia, postpartum haemorrhage and sepsis were established by a Steering Committee. A common questionnaire was used in each participating country. The incidence of the three obstetric conditions and characteristics of the study women were compared.

Results: The study identified 1734 women with at least one of the three conditions, with 847 experiencing severe haemorrhage, 793 experiencing severe pre-eclampsia and 142 experiencing severe sepsis. There were wide variations in incidence of three conditions combined, ranging from 14.7 per thousand in deliveries in Brussels, Belgium to 6.0 per thousand in Upper Austria.

Conclusions: It was possible to use standard definitions to identify and ascertain the incidence of three severe obstetric conditions at a regional level. The incidence of these severe obstetric conditions in general and severe haemorrhage varied significantly between countries. Overall, severe haemorrhage was the most common of the three conditions, followed closely by severe pre-eclampsia.

INTRODUCTION

Recent research has suggested that severe maternal morbidity may be a better indicator of the quality and effectiveness of obstetric care than mortality alone (1-4). Many earlier studies were small and restricted to a single country. Most were based on hospital populations and in many, cases of severe morbidity were defined as women admitted to an intensive care unit (ICU) with data being collected in the ICU only. Doing this invalidates international comparison as a European survey showed that countries differ in the ways they organised intensive care (5). As a consequence of this, comparisons based on ICU admissions are likely to be unreliable. In addition some of the studies were small and their definitions of the clinical conditions were inconsistent.

Severe haemorrhage, severe pre-eclampsia including HELLP syndrome and eclampsia and severe sepsis were the three complications most consistently reported in previous studies as causes of admission to intensive care (1,6-9). They were also with thromboembolic disease the leading causes of maternal mortality reported in national surveys (10-12) and are a significant public health problem, especially in developed countries.

The European concerted actions on 'MOthers Mortality and Severe morbidity' (MOMS) aimed to overcome these problems by using common definitions and collecting population-based data. The project had two parts, Survey A which collected and compared national data on maternal deaths (13) and Survey B which identified cases of severe morbidity in eleven regions within nine countries. This paper describes survey B.

METHODS

Defining the conditions

A steering committee of European clinicians and epidemiologists was set up in 1994. It met to establish the conditions to be studied and agreed on definitions for them. The criteria for these definitions, shown in Table 1, were that they should be mutually acceptable, applicable in practice and clinically based. The diagnosis of severe pre-eclampsia was purely clinical. It was taken from the US National High Blood Pressure Education Program Working Group report on High Blood Pressure in pregnancy (14). The only modification was to exclude the three blood criteria relating to platelets, creatinine and hepatic enzymes. The steering committee produced its own definition of severe haemorrhage. For sepsis, it adopted unchanged the definition produced by the American College of Chest Physicians / Society of Critical Care Medicine Consensus Conference (15).

Populations covered

Nine countries of the European Union and two countries outside the European Union, Hungary and Norway, participated. In most of the countries, data collection took place in just one region, but in France three regions were included and in Finland the whole country was covered. Data for Denmark and Spain were excluded from the analysis, because of incompleteness. The regions are listed in Table 2

Inclusion criteria and data collection

Data were collected about women who delivered after 24 completed weeks of gestation and experienced one or more of the three conditions being studied.

A data collection form was designed by the steering group. The data items included were the woman's demographic details, her medical and obstetric history, her antenatal care during the index pregnancy, the stage of pregnancy at which one of the conditions first arose and the care given. Data were collected by specially trained researchers who visited each hospital in each region at two weekly intervals. The exception was in France where data were collected retrospectively from case notes.

The women's post codes were recorded to exclude those who lived outside the region, Data were collected over the years, 1995 to 1998, but the time periods covered varied from country to country, as Table 2 shows. To ensure that no deaths associated with the conditions studied were excluded, data were also collected about all maternal deaths in each region. The numbers of deliveries in the region during the study period was ascertained from identical sources.

Statistical analyses

Incidence rates were calculated for each condition separately as well as in terms of the numbers of women with one or more of the conditions. A woman with several conditions is counted separately within each condition. Therefore the numbers with each condition cannot be added to derive the total number of women. Ninety five per cent confidence intervals were constructed for the rates. Countries' rates were compared using the chi-squared test. The Kruskal-Wallis H test was used to compare the distributions of women's ages.

The analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 10.0 (16).

RESULTS

The methods of ascertainment, the study period and the number of deliveries in each participating region are summarised in Table 2 and the incidence rates and 95 per cent incidences intervals are shown in Table 3. Overall 1,734 women with one or more of the specified conditions were identified in all the study regions combined.

Severe haemorrhage was the most common of the three conditions with an incidence of 4.6 per thousand, followed by severe pre-eclampsia with an incidence of 4.3 per thousand while severe sepsis was much less common with an incidence of 0.8 per thousand. Among the 793 women with severe pre-eclampsia there were 660 with diagnoses of pre-eclampsia, 53 with diagnoses of eclampsia and 123 with diagnoses of HELLP.

There were wide variations in the incidence rate of the three conditions combined, ranging from 14.7 in Belgium, 14.3 in Finland and 11.8 in the United Kingdom to 6.0 in Austria and 6.1 in Ireland.

Among the 1734 women there were 84 fetal deaths. There were four maternal deaths, three amongst women with a diagnosis of haemorrhage including two from France and one from Italy, One death among the women with a diagnosis of severe pre-eclampsia was reported from France. A further five deaths were recorded in the former South East Region of the United Kingdom during the study period, but because of the constraints under which the Confidential Enquiry into Maternal Deaths in the United Kingdom operates, details about them were not made available to our study (17). Nevertheless, they were included in calculations, which gave a case fatality of 5.2 per thousand among 1739 women.

Data about the women's age and parity and whether they were admitted to an intensive care unit are shown in Table 4. On average, the women in Hungary were younger than those in other countries and the percentages of women aged fewer than 35 were lowest in Norway and Hungary. There was also a significant difference between the percentages of primaparae.

Marked differences were seen in the percentages of women admitted to an intensive care unit. About half the Austrian women and around a quarter of women in Belgium, France, Italy and the United Kingdom were admitted.

DISCUSSION

In its use of common definitions and methods of data collection on a population basis, this study was an advance on studies that used admission to an intensive care unit as a proxy measure of acute severe maternal morbidity. This is not a valid basis for an international study as the availability and definition of intensive care units varies between countries and from place to place within countries as do the admission criteria. For example, in some Dutch hospitals, some intensive care, such as applying capillary wedge pressure with the Swanz-Cranz catheter is undertaken within obstetric units. In addition, pilot studies in Brussels suggested that the threshold for transfer to intensive care units might vary according to the workload on the labour ward on the day concerned.

The conditions were chosen firstly because they are leading causes of maternal mortality and secondly because they can be diagnosed without sophisticated equipment. Pulmonary embolism was excluded for the second reason, despite the fact that it is the leading cause of maternal death in the United Kingdom (18)

For the same reason, the definition of pre-eclampsia was restricted to clinical criteria, on the assumption that there might be differences in the availability of and accessibility to laboratory and imaging techniques. Despite its precise definition, sepsis may not have been fully ascertained. There is evidence that some cases occurred after the woman had been discharged from hospital. If these cases were managed by primary care services, or in a hospital without a maternity unit, they may have been missed by the project researchers.

Differences in incidence

Overall differences between countries were dominated by differences in the incidence of haemorrhage. This ranged from 8.8 per thousand deliveries in Finland to 0.7 in Austria.

Possible explanations include differences in ascertainment, differences in the age distribution after women giving birth (17,19-21) and differences in the ways in which care is provided and in its quality (22-24).

Observed differences should be interpreted with caution, however, given the small numbers of cases in some countries. Differences in ascertainment may also play a part. In France, the people who collected the data were qualified midwives and doctors but they collected data retrospectively from case notes and had not been involved in care for the women. This means that ascertainment was dependent on the completeness of the information in the notes. In other countries, data were collected on an ongoing basis, with the clinicians who had given care to the woman being asked to complete the study form at the same time as the case notes. Nevertheless the incidence rate of the three conditions combined was also low in Austria and Ireland, so differences in methodology do not necessary account for all the differences observed.

Incidence rates may also reflect differences in clinical management. Haemorrhage is reported to be the leading cause of maternal death in Japan and Europe as a whole and the third most common cause in the United States (25-29). Active management of the third stage may decrease the incidence of haemorrhage (30-31). This approach is commonly advocated in the United Kingdom, but a survey of maternity units conducted in 2000-2001 showed considerable differences in practice between units (32).

In our study, the countries with the highest incidence of morbidity were not necessarily those with the highest maternal mortality. Nor was there any obvious ecological association between morbidity and some other factor on the lines of the well-recognised association between infant mortality and per capita income (33). The three countries with the highest reported incidence of morbidity associated with the three selected conditions were Belgium,

Finland and the United Kingdom. This could be because these countries had the most complete ascertainment. It could also be that maternal mortality is more closely associated with the quality of care provided than with the prevalence of morbidity (34-35).

It would have been useful to have calculated age and parity specific rates or standardised incidence rates for age and parity. Unfortunately, the data required were not available for all women delivering in the study areas for the time periods when the studies were under way. The wide differences apparent in Table 4 in the percentages of older women and or primparous women among the cases of severe morbidity identified in the study, suggest that these could reflect differences in the childbearing populations in the regions studied.

It is also likely that the choice of regions within countries may have contributed to the differences observed. For example Brussels and the former South East Thames region of England both include substantial inner city areas with high proportions of women from migrant and minority ethnic groups, while France chose three regions without major cities.

Comparisons with other studies of maternal morbidity and the incidence of the conditions ascertained in our study are summarised in Table 5. As can be seen, some were undertaken in the countries of Europe which took part in our collaboration and some in other developed countries (36-46).

Is 'near miss' maternal morbidity a useful concept?

A number of recent articles have explored the concept of 'near miss' maternal morbidity and proposed it as a useful tool for monitoring maternal health. (47). It is however a concept, which requires further calcification and definition before it can be used widely in comparative studies. In our study, it is likely that despite concerted unequivocal definitions, the differences

in rates observed between regions are partly related to ascertainment differences. This is most likely to be true for haemorrhage, where diagnosis is always difficult (48), but more detailed exanimation showed it can apply elsewhere (49). Difficulties with the concept of "near-miss" exist on many levels. On a purely semantic level, authors have yet to agree on a unique expression which would encompass these cases of severe morbidity. Attempting to identify them in a Medline search, each of the expressions: "critical", "catastrophic", "life-threatening", "near-miss", "severe" "emergency" and "intensive care" identified articles, which were not retrieved by any of the others. There may be further keywords that we have not identified. This semantic problem is only the tip of the iceberg. Even if we could agree on a unique term to be used in all cases where the clinician believes life to be in danger, how reproducible would this concept be? Is there a need for a comprehensive list? By definition it is bound to exclude fatal condition. In addition to the subjectivity inherent in the formulation of such a list, identification cases would still be dependent on the nature and organisation of health care systems. In the same way as assessment of maternal deaths in the developing world is hampered by lack of good information systems, it might be difficult to assess a' near miss', even in the developed world if vital information is not recorded in clinical notes or if the notes were lost.

As, maternal mortality is a rare event in developed countries, moves towards monitoring maternal morbidity may be desirable. Potential indicators cover a wide spectrum of subjective measures ranging from well being (50), long-term disability, mental ill health, to severe physical morbidity. Il has been suggested that a conceptual framework for 'near miss' maternal morbidity should include a complex set of items, including clinically defined conditions such as severe pre-eclampsia, events such as seizures, and procedures such as ventilation (47). This approach was, in effect, the one the steering committee had developed early on in the MOMS study, although it had not formally acknowledged the need for a mixed

set of outcome measures. We therefore believe that the MOMS study is an exploratory study in this direction. Further work will be necessary to agree on an operational indicator for severe disease in pregnancy. Further exploration of the validity of such a tool could include case control studies. Meanwhile population based epidemiological descriptions of severe maternal morbidity are appearing (17, 51).

CONCLUSIONS

By using standardised definitions and a population-based approach, we have demonstrated that conditions associated with acute severe maternal morbidity are not rare. Severe haemorrhage was the most common of the three conditions we studied, but its incidence varied widely between European countries.

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Project Leader: M.H Bouvier-Colle ; coordinator for MOMS-B subprojectSophie Alexander, Brussels, Belgium. Austria-M Klein, C Vutuc Vienna. Belgium-S Alexander, Brussels. Finland-R Erkkola, Turku; M Gissler, Helsinki. France-, G Breart, B Salanave, N Varnoux, Paris. Hungary-I Berbik, Esztergom; J Egyed, Budapest. Ireland-M Jenkins, Cork. Italy-L Chiechi, Bari. Norway-B Stray-Pedersen, Oslo. United Kingdom-A Macfarlane, C Wolfe, M Waterstone, London.

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Table 1. Definition of selected conditions of severe maternal morbidity

Severe pre eclampsia[14]	*is pre eclampsia, defined as hypertension* *greater than 140/90 mm Hg or blood pressure increases of 30mm Hg systolic or 15mm Hg diastolic and proteinuria greater than 0.3g* *complicated by one or more of the following:* Hypertension greater than 160/110 mm H Proteinuria greater than 2.0 g/24h or +++on dipstick Oliguria < 60 ml for 2 successive hours or < 500 ml/24h Spigastric or liver pain Headache and blurred vision Pulmonary oedema
Eclampsia	is defined as any fitting in pregnancy, excluding fitting clearly related to known epilepsia**.**
HELLP (Haemolysis, Elevated Liver, enzymes and Low Platelets).	is defined as thrombocytopenia and hemolysis and hepatic cytolysis Low platelets count below 100×10^9/l and bilirubin ≥ 1.0 mg/dl or 17.1 micromoles/l (haptoglobin ≤ 50 mg or schizocytes + (if available)) and Elevated aspartate aminotransferase ≥ 70 U/l or elevated γ-glutamyltransferase ≥ 70 U/l
Severe haemorrhage	*is limited to those occurring at the time of pregnancy outcome, including birth, abortion, caesarean, ectopic pregnancy.* *Severe haemorrhage is:* blood loss ≥ 1500 ml if measured or blood loss requiring plasma expanders and /or blood 2.500 ml in 24 hours or the same expressed in packed cells or blood loss resulting in death
Sepsis[15]	*is limited to sepsis at the time of pregnancy outcome such as birth or abortion etc. Sepsis is a systemic inflammatory response to infection. There must coexist:* A. Infection such as bacteraemia, endometritis B: Two or more of the following: Temperature greater than 38ºC or <36ºC Heart rate greater than 90 beats/minute

Respiratory rate greater than 20/min or PaCO2 <32 mmHg

White cell count greater than 17×10^9/l or < 4×10^9/l

or greater than 10% immature forms.