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Incidence of severe pre-eclampsia, postpartum haemorrhage and sepsis as a surrogate marker for severe maternal morbidity in a European population-based study: the MOMS-B survey

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The members of MOMS-B Group are listed on page 94

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 Eleven regions in nine countries of Europe.

Population All the pregnant women in each region who had delivered during the 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.

Main outcome measures Incidence of three severe obstetric conditions: pre-eclampsia, postpartum haemorrhage and sepsis.

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 deliveries in Brussels, Belgium to 6.0 per thousand deliveries in Upper Austria.

Conclusions This study sets a simple and straightforward approach to the definition of three severe obstetric conditions and allows population-based comparisons between developed countries in Europe, even though difficulties may have been present with applying the definition across countries. The reported incidence of these severe obstetric conditions in general and severe haemorrhage varied significantly between countries. Overall, severe haemorrhage in particular 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. The validity of such comparisons is poor as a European survey showed that countries differ in the way in which they organise their intensive care.[5] 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.[3,6–9] Together with thromboembolic disease, these conditions are the leading causes of maternal mortality reported in national surveys[10–12] and are a significant public health problem, especially in developed countries.

MOthers Mortality and Severe morbidity (MOMS) is a European initiative aimed to overcome these problems by using common definitions and collecting population-based data. The project had two parts, Survey A, which collected

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Table 1. Definition of selected conditions of acute severe maternal morbidity.

	Definition
Severe pre-eclampsia[14]	Hypertension greater than 140/90 mmHg or blood pressure increases of 30 mmHg systolic or 15 mmHg diastolic and proteinuria greater than 0.3 g complicated by one or more of the following: Hypertension greater than 160/110 mmHg Proteinuria greater than 2 g/24 h or +++ on dipstick Oliguria <60 mL for 2 successive hours or <500 mL/24 h Epigastric or liver pain Headache and blurred vision Pulmonary oedema
Eclampsia	Any fitting in pregnancy that is unrelated to epilepsia.
HELLP (Haemolysis, Elevated Liver, Enzymes and Low Platelet Count)	Hemolytic anaemia, hepatic cytolysis and thrombocytopenia: bilirubin $\geq$1.0 mg/dL or 17.1 μmol/L (haptoglobin $\leq$50 mg or schizocytes + (if available)) and elevated aspartate aminotransferase $\geq$70 U/L or elevated γ-glutamyltransferase $\geq$70 U/L and platelets count below 100×10^9/L
Severe haemorrhage	Measured blood loss $\geq$1500 mL at the time of pregnancy outcome, including birth, abortion, caesarean, ectopic pregnancy or blood loss requiring plasma expanders and/or blood 2500 mL in 24 hours or blood loss resulting in maternal death
Sepsis[15]	Sepsis is a systemic inflammatory response to infection limited to the time of pregnancy outcome such as birth or abortion and so forth. There must be coexisting: A. Infection such as bacteraemia, endometritis B: Two or more of the following: Temperature >38°C or <36°C Heart rate >90 beats/minute Respiratory rate >20/min or $Paco_2$ <32 mmHg White cell count 12×10^9/L or $<4 \times 10^9$/L or >10% immature forms

and compared national data on maternal deaths,[13] and Survey B, which identified cases of severe morbidity in 11 regions within nine countries. This article describes Survey B.

METHODS

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 (Table 1). 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 the definition produced by the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference.[15]

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

Table 2. The participating regions, the study period, the methods of ascertainment for cases identification and the number of deliveries according to the participating country.

Country	Region	Study period (month/year)	Methods of ascertainment	No. of deliveries
Austria	Upper Austria	9/1996–8/1997	Prospective	6022
Belgium	Brussels	1/1996–12/1996	Prospective	17,042
Finland	65% of all deliveries	5/1996–9/1996	Prospective	17,249
France	Champagne-Ardenne, Lorraine and Centre	1/1995–12/1995	Retrospective	71,909
Hungary	Upper Danube	1/1995–12/1995	Prospective	13,667
Ireland	Cork	1/1996–12/1996	Prospective	1800
Italy	Puglia	3/1996–2/1997	Prospective	3170
Norway	Oslo	1/1995–12/1995	Prospective	3010
UK	South East Thames	1/1997–2/1998	Prospective	48,865

Table 3. The number of women and incidence rate for all cases and for each specific condition according to the participating country.

Country	No. of women with conditions				Incidence rate, per 1000 deliveries (95% CI)*			
	All	Severe PET**	Haemorrhage	Sepsis	All	Severe PET**	Haemorrhage	Sepsis
Austria	36	32	4	0	6.0 (4.1–8.3)	5.3 (3.6–7.5)	0.7 (0.2–1.8)	0.0 (0.0–0.6)†
Belgium	250	115	103	54	14.7 (12.9–16.6)	6.4 (5.6–8.1)	6.0 (5.0–7.4)	3.1 (2.4– 4.1)
Finland	246	86	152	18	14.3 (12.5–16.1)	5.0 (4.0–6.2)	8.8 (7.5–10.4)	1.0 (0.6–1.6)
France	459	214	221	36	6.4 (5.8–7.0)	3.0 (2.6–3.4)	3.1 (2.7–3.5)	0.5 (0.4–0.7)
Hungary	107	81	22	6	7.8 (6.4–9.5)	6.4 (5.1–7.9)	1.6 (1.0–2.5)	0.4 (0.2–1.0)
Ireland	11	9	2	0	6.1 (3.1–10.9)	5.0 (2.4–9.8)	1.1 (0.2–4.5)	0.0 (0.0–2.0)†
Italy	22	19	4	1	6.9 (4.4–10.5)	6.0 (3.7–9.5)	1.3 (0.4–3.5)	0.3 (0.0–1.8)
Norway	26	6	8	12	8.6 (5.7–12.6)	2.0 (0.8–4.6)	2.7 (1.2–5.2)	4.0 (2.1–7.0)
UK	577	231	331	15	11.8 (10.9–12.8)	4.7 (4.1–5.4)	6.8 (6.1–7.5)	0.3 (0.2–0.5)
Total	1734‡	793	847	142	9.5 (9.1–9.9)	4.3 (4.0–4.7)	4.6 (4.3–5.0)	0.8 (0.7–0.9)
P§					<0.001	<0.001	<0.001	<0.001

* Confidence interval.
** PET = pre-eclampsia including HELLP syndrome and eclampsia.
† Exact limit.
‡ Numbers do not add to total as some women had more than one condition.
§ P values for the differences of incidence rates between countries are based on the χ^2 tests.

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.

Data were collected on 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 periods covered varied from country to country (Table 2). To ensure that no deaths associated with the conditions studied were excluded, data were also collected about all maternal deaths in each region. The number of deliveries in the region during the study period was ascertained from identical sources.

Incidence rates were calculated for each condition separately as well as in terms of the number of women with one or more of the conditions. A woman with several conditions is counted separately within each condition. Ninety-five percent confidence intervals were constructed for the rates. The incidence of each condition for each country was compared using the χ^2 test. The Kruskal–Wallis H test was used to compare the distributions of the study population.

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% confidence intervals are shown in Table 3. Overall, 1734 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 deliveries, followed by severe pre-eclampsia with an incidence of 4.3 per thousand deliveries, while severe sepsis was much less common with an incidence of 0.8 per thousand deliveries. 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. Forty-two fetal deaths were in the women with a diagnosis of severe pre-eclampsia, 32 fetal deaths were in the women with a diagnosis of haemorrhage, 5 deaths were in the women with a diagnosis of sepsis and the remaining 5 fetal deaths were in the women with a diagnosis of more then one condition. There were four maternal deaths, three among women with a diagnosis of haemorrhage including two from France and one from Italy. One death from France occurred from severe pre-eclampsia. A further five deaths were recorded in the former southeast 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

Table 4. The baseline characteristics of women with acute severe morbidity and organisation of care according to the participating country.

Country	Age of women, years			Parity			Admitted to ICU	
	Mean (SD)	≥35 years (%)	n^*	0 (%)	≥1 (%)	n^*	%	n^*
Austria	28.2 (5.8)	17.1	35	44.4	55.6	36	50.0	36
Belgium	29.4 (5.6)	19.6	250	39.0	61.0	246	24.7	243
Finland	30.4 (5.4)	22.0	246	34.6	65.4	246	8.7	230
France	28.5 (5.2)	12.9	459	45.3	54.7	459	29.5	457
Hungary	26.0 (5.8)	8.5	106	48.6	51.4	107	6.5	107
Ireland	29.9 (7.2)	36.4	11	63.6	36.4	11	0.0	11
Italy	29.2 (6.7)	18.2	22	31.8	68.2	22	22.7	22
Norway	28.2 (4.6)	7.7	26	53.8	46.2	26	3.8	26
UK	29.7 (5.8)	21.0	577	40.4	59.6	577	22.7	573
P^{**}	<0.001	0.001		0.048			<0.001	

ICU = Intensive care unit; SD = standard deviation.

* Number of women with information available for analysis.

** P value for age difference between countries is based on Kruskal–Wallis H non-parametric test; P values for percentage differences between countries of 35 year old women, parity and admitted to ICU are based on the χ^2 tests.

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 percentage of women aged younger than 35 years was lowest in Norway and Hungary. There was also a significant difference between the percentages of primaparae among the different countries in the study.

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

The use of common definitions and methods of data collection on a population basis is an advantage over those studies that used admission to an intensive care unit as a proxy measure of acute severe maternal morbidity. The availability, definition and admission criteria of intensive care units vary between countries and from one region to another within the same country. For example, in some Dutch hospitals, the measurement of capillary wedge pressure with the Swanz–Ganz catheter is undertaken within obstetric units, whereas it is conducted in intensive care units in other hospitals. In addition, pilot studies in Brussels suggested that the threshold for transfer to intensive care units might vary according to the clinical workload of the labour ward on the day concerned.

Table 5. Comparison of the incidence rate of three conditions of acute severe maternal morbidity between MOMS-B survey and other published data.

Author, place	Study year	No. of deliveries	Incidence per 1000 deliveries (n)**		
			Pre-eclampsia*	Haemorrhage	Sepsis
Graham and Luxton,[6] UK	1982–1986	21,983	0.6 (13)	0.05 (1)	
Baskett and Sternadel,[8] Canada	1980–1993	76,119	0.2 (14)	0.2 (12)	0.1 (8)
Monaco *et al.*,[41] USA	1983–1990	15,323	1.0 (12)	0.2 (2)	
Kilpatrick and Matthay,[42] USA	1985–1990	8000	0.9 (7)	0.5 (4)	0.6 (5)
Mabie and Sibai,[43] USA	1986–1989	22,651	4.1 (92)	0.9 (21)	0.4 (9)
Lapinsky *et al.*,[44] Canada	1990–1994	25,000	0.9 (23)	0.4 (11)	0.1 (2)
Mahutte *et al.*,[45] Canada	1991–1997	44,340	0.6 (28)	0.8 (34)	0.3 (13)
Tang *et al.*,[46] Hong Kong	1988–1995	39,354	0.2 (7)	0.7 (26)	
Bouvier-Colle *et al.*,[47] France	–	140,323	0.8 (114)	0.6 (87)	0.1 (19)
Hazelgrove *et al.*,[48] UK	1994–1996	122,850	0.7 (83)	0.6 (70)	
Murphy and Charlett,[49] UK	1988–1999	51,567	0.3 (16)	0.2 (12)	0.05 (3)
Bewley and Creighton,[50] UK	1991–1992	6039	2.3 (14)	2.3 (14)	0.5 (3)
Stones *et al.*,[51] UK	1986–1986	2164	2.8 (6)	3.2 (7)	
MOMS-B, Europe	1995–1998	182,734	4.3 (793)	4.6 (847)	0.8 (142)

* Including HELLP syndrome and eclampsia.

** Number of cases.

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

For the same reason, a clinical diagnosis of pre-eclampsia was employed 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 be missed by the project researchers.

The differences in rates of pre-eclampsia between countries with a very low rate in Norway are, at this point, difficult to explain. Hypotheses may be generated, such as, differences in population susceptibility (genetic component), differences in management of mild pre-eclampsia or differences in diet. The same questions apply to sepsis with zero value in Austria and in Ireland. A future study of fuller understanding of the aetiology and the effect of area characteristics on risk of maternal morbidity is needed.

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 number of cases in some countries. Differences in ascertainment may also play a part. In France, qualified midwives and doctors collected the 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 prospectively. Nevertheless, the incidence rate of three conditions combined together was low in Austria and Ireland, and hence, differences in method of data collection do not account for all variation observed in these results.

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 in UK 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 factors similar to 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]

On average, the women with severe morbidity identified in our study had higher mean age, 29.1 years and higher proportion of women aged 35 years and older, 17.8% (not shown in the results). Although maternal deaths are rare in the United States and in Europe, women aged 35 years and older have a higher risk for pregnancy-related death than younger women.[36,37] Morbidity related to older age has public health implications, because there is trend toward delayed childbearing in better-educated women.[38] The childbirth-related morbidity increases with maternal age.[39,40]

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 that took part in our collaboration and some in other developed countries.[6,8,41–51] The incidence rates of severe pre-eclampsia, postpartum haemorrhage and sepsis in our study are far higher than those studies which used a definition based on intensive care admission,[8,41,42,44–50] and are also higher to that which used a definition based on specific pathology[51] or to that reported in centre which have developed obstetric ICUs as part of the labour and delivery area; however, even 0.4 per thousand women in this centres need further transfer to a medical or surgical intensive care unit.[43] The higher incidence in our study may be in part due to improved data assessment identifying more (nearly all) cases by using standardised definition in a large population.

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.[52,53] It is however a concept, which requires further clarification and definition before it can be used more widely in comparative studies. In our study, it is likely that despite concerted unequivocal definitions, differences in rates observed between regions are partly related to ascertainment bias. This is most likely to be true for haemorrhage, where diagnosis is always difficult,[54] but this has been successfully used elsewhere.[55] Difficulties with the concept of 'near-miss' exist on many levels. On a purely semantic level, authors have yet to agree on a unique definition that would encompass most of the cases of severe maternal morbidity. We have conducted a Medline search using the following keywords: 'critical', 'catastrophic', 'life-threatening', 'near-miss', 'severe' 'emergency' and 'intensive care' and have identified articles which have not been previously retrieved. There may be further keywords that we have not managed to identify. 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 maternal 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 conditions. In addition to the subjectivity inherent in the formulation of such a list, identification of such 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 these notes were lost.

As maternal mortality is a rare event in developed countries, initiatives towards measuring maternal morbidity may be more desirable. Potential indicators cover a wide spectrum of subjective measures ranging from normal well-being,[56] long term disability, mental ill health, to severe physical morbidity. It has been suggested by Geller *et al.*[52] that a conceptual framework for 'near-miss' maternal morbidity should include a complex set of three categories of items: clinically defined *conditions* such as severe pre-eclampsia, *events* such as seizures, and medical *procedures* such as ventilation. This approach was, in effect, the one the steering committee had developed intuitively early on in the MOMS-B study, although it must be said that they had not formally acknowledged the three-component approach as it has since been established by Geller *et al.*[52] We therefore believe that the MOMS-B study is an exploratory study in this direction. Further work on a practical measure for severe maternal morbidity will be necessary. The validity of such a tool could be explored further using case–control studies. Meanwhile, population-based epidemiological descriptions of severe maternal morbidity are continuing to be reported.[17,57]

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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