Near misses: a useful adjunct to maternal death enquiries

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In developed countries where maternal death is rare, the factors surrounding the death are often peculiar to the event and are not generalizable, making analysis of maternal deaths less useful. Near misses are defined as pregnant women with severe life-threatening conditions who nearly die but, with good luck or good care, survive. Incorporation of near misses into maternal death enquiries would strengthen these audits by allowing for more rapid reporting, more robust conclusions, comparisons to be made with maternal deaths, reinforcing lessons learnt, establishing requirements for intensive care and calculating comparative indices. The survival of a pregnant woman is dependent on the disease, her basic health, the health care facilities and personnel of the health care system. The criteria currently used to identify a near miss vary greatly. However, areas with similar health care facilities, medical records and personnel should be able to agree on suitable criteria, making their incorporation into maternal death enquiries feasible.

Introduction

An outcome-audit is a retrospective analysis of events that were associated with the particular outcome. To be of use, the outcome must be important, clearly defined and occur frequently enough so that the information gained will be useful for the population studied.

Confidential enquiries into maternal deaths are a common and useful outcome-audit. Obviously death is a very clear end point, making identification and collection of cases simple provided that the death occurs in a health facility. In circumstances where maternal death is or has been fairly frequent, the common causes of maternal death and the modifiable factors associated with the death have been identified. This has served as a diagnostic tool for identifying problems within the health care system and allowed for modification of the system. Confidential enquiries into maternal deaths have been associated with a fall in maternal mortality ratios, clearly documented in the UK over 50 years. The exact causes of
the fall in death ratios are not of course known but the Enquiry Reports and their recommendations are thought to have contributed.

However, maternal deaths in developed countries are now rare, and the factors that surround the death are often peculiar to the event, complex and are not generalizable. This does not mean that pregnancy is a safe condition in developed countries. Waterstone et al² reported a severe obstetric morbidity rate of 12.0 per 1000 births, and a ‘severe morbidity to mortality’ ratio of 118:1 in the South East Thames region. Contrary to what would be expected, the common causes of maternal mortality are not the same as the common causes of maternal morbidity. The two most common causes of severe morbidity were severe haemorrhage at 6.7 per 1000 births and complications of hypertension in pregnancy at 4.6 per 1000 deliveries in the London area². However, in the confidential enquiry into maternal deaths in the UK for 1997–1999³, there were only seven deaths due to haemorrhage and 15 deaths due to complications of hypertension but 35 deaths due to thrombosis and thromboembolism and 35 due to cardiac disease. This is due to the success that modern medicine has had in treating some previously fatal conditions. The diseases causing death are often very rare and information gained from analysing the death is, although useful, limited to those very few people with the condition. For example, congenital heart disease is an important contributor to maternal death in the UK, but congenital heart disease is a rare condition⁴.

If an outcome-audit in a developed country is to be conducted as a method of assessing the quality of maternal care, a more appropriate outcome other than death needs to be defined. Prevention of maternal mortality is obviously the aim of obstetricians; hence an outcome-audit of severe acute maternal morbidity would be a useful adjunct to an assessment of maternal deaths, and would concentrate on the management of morbidity once it has occurred. Prevention of maternal morbidity would require data on the population incidence of conditions such as pre-eclampsia and criterion-based audit of the management of a sample of cases.

In the developed world, where very few births occur out of hospital, and can be included in the analysis as civil registration is comprehensive, it may be possible to study inter-regional and secular change in rates of severe morbidity either per maternity, or per case of a given complication. For example, the incidence of status epilepticus per case of epilepsy might be used as an index of how good was ante- and intrapartum care. The situation is more complex for pre-eclampsia, which, because it is a multisystem disorder, might result in eclampsia, a cerebrovascular event, renal failure, or pulmonary oedema. Rates of pulmonary oedema might be used as a measure of the quality of fluid management in acute cases.

It is however difficult to analyse data on prevention of severe maternal morbidity in developing countries because obstetric complications and
consequent severe morbidity may present in the community setting and may or may not be referred to seek care in hospitals. Improvements in the system of care that result in more such referrals should, provided that care is of high quality, prevent severe morbidity and indeed mortality, but may appear to increase severe morbidity if referrals are late in the course of disease. Information about events in the community is essential for sensible interpretation of changes.

Definition of maternal morbidity

The definition of severe maternal morbidity is crucial to establishing an audit of maternal morbidity. It must comply with the previously mentioned prerequisites, namely be easily definable, important and occur frequently enough. The World Health Organization (WHO) defines direct obstetric morbidity as resulting from obstetric complications of the pregnancy states (pregnancy, labour and puerperium) from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above. The definition is clearly linked to the health care system and implies that all morbidity is preventable, which is obviously not true. Developing an audit system based on this definition is not advisable, though the analysis of the management of cases could follow this pattern.

All health care workers must intuitively understand the definition used, even if the criteria by which such a case is identified are not. A high threshold for defining morbidity would be useful; otherwise the number of cases generated will overwhelm the system. A high threshold would make a comparison with maternal deaths more relevant. For this reason, the term near miss has been borrowed from the airline industry. It should be noted that its use in the context of maternity care is quite different to its use in air traffic control where a process has occurred and two aircraft pass too closely to each other but an accident is avoided. This would be analogous to identification by routine audit of prescription errors in the labour ward that may or may not cause a clinical problem. Here we are discussing an outcome audit. There are various definitions of near miss, all of which express the same thing:

1. A severe life-threatening obstetric complication necessitating an urgent medical intervention in order to prevent likely death of the mother.
2. Any pregnant or recently delivered woman, in whom immediate survival is threatened and who survives by chance or because of the hospital care she received.
3. A very ill woman who would have died had it not been that luck and good care was on her side.
Having a clear understanding of what a near miss is, however, does not lead to uniformity in defining the criteria by which a case is identified. How much blood must be lost before a pregnant woman is nearly dead, 1.5 or 2.5 litres? The criteria that have been used to define this life-threatening event have been very different. This is partly due to the context in which the near miss occurred. The general state of health of the woman and the health facilities available to her determine the chance of her dying. A woman with prior anaemia may die with a relatively small loss. The facilities available will also determine what care can be given, for example if no blood is available then a blood transfusion cannot be given. The definition used in an environment where intensive care facilities are not available will obviously not include admission to intensive care as a criterion. For this area of morbidity, the near miss rate, and the mortality index, will be determined by the threshold chosen.

The search for a universally acceptable set of criteria is not attainable, although the conceptual definition of a near miss is. The criteria selected must be locally usable and relevant\(^\text{10}\). They need to be locally generated and consensus attained in their choice. For example it should be possible for developed countries to develop criteria that would be universally acceptable to the whole country because the level of the facilities available is more or less the same. They have intensive care monitoring and treatment facilities on which criteria can be based. The larger the area that uses the criteria, the more valuable the audit will be in comparing different sites and gaining relevant information for that area. Developing countries have a much larger problem in attaining consensus, because of the lack of intensive care monitoring and treatment facilities. If death rates are high, maternal death audits would be a priority but in a feasibility study carried out in four countries, some harmonization of near miss audits was possible\(^\text{10}\).

There are essentially three methods of identifying severe maternal morbidity: by defining clinical criteria related to a specific disease entity such as pre-eclampsia; a specific intervention such as admission to an intensive care unit or procedure such as a hysterectomy or massive blood transfusion; or a method whereby organ system dysfunction is defined.

**Clinical criteria related to a specific disease entity**

This was the route taken by Waterstone et al\(^\text{2}\). They carefully defined disease-specific morbidities, namely severe pre-eclampsia, eclampsia, HELLP syndrome, severe haemorrhage, severe sepsis and uterine rupture. Using this system, they recorded an incidence of severe maternal morbidity
of 12 per 1000 births. The criteria used, while clearly indicating maternal morbidity, have too low a threshold of morbidity to be called near misses. Furthermore, the most common direct cause of maternal mortality was omitted, namely pulmonary embolus, because of the difficulty of diagnosing pulmonary emboli accurately when they are not fatal. This illustrates part of the problem of a system based on a specific disease entity. The system also left out early pregnancy complications such as ectopic pregnancies and abortions.

The system has various advantages in that it is straightforward to interpret, data can be obtained retrospectively from case notes or registers and the quality of care of that particular disease can be assessed. However, the London study was a research study and could not be carried out routinely without major expenditure.

The ability to examine the quality of care of a specific disease entity had been well illustrated by Bouvier-Colle et al. Cases of severe obstetric haemorrhage were analysed to determine what factors related to health services in France might explain substandard care. Severe obstetric haemorrhage was defined as a haemorrhage occurring at the time of pregnancy outcome if blood loss equalled 1.5 litres, required plasma expanders, equalled 2.5 litres over 24 h or the equivalent expressed in packed cells, or resulted in transfusion, hysterectomy or maternal death. The cases were retrospectively identified and data collected by trained investigators. Criteria for quality of care were selected based on the international literature or because the expert group considered them to be essential. Importantly, 23% of the cases could not be assessed due to poor documentation. However the group found that lack of a 24-h on-site anaesthetist at the hospital and low volume of deliveries were the factors associated with substandard care. This study identified the need for the reorganization of obstetric services in the three French regions, and clearly illustrates the value of this type of audit.

**Intervention-based criteria**

In most developed countries, admission to an intensive care unit or the requirement of critical care have been used as the criteria to identify near misses. This system has the advantage that it is simple to identify the cases. However, there are major disadvantages. The most obvious problem is the accessibility of intensive care beds for patients requiring them. In the UK, only 31% of the maternal deaths were recorded as having intensive care possibly because most maternity units have high dependency care available. The major reasons for lack of admission to intensive care were that the death occurred before admission, the lack of availability of beds or because of the distance between the maternity unit and...
intensive care facilities. In France, however, most maternal deaths had been seen in intensive care\textsuperscript{12}. Obviously, admission criteria to intensive care units vary, as does what constitutes intensive care. Data based on this have to be interpreted with caution, and this is not suitable as the only criterion on which to identify near misses.

Other interventions like the performance of intrapartum hysterectomy\textsuperscript{16}, blood transfusion or caesarean section\textsuperscript{8} have been used to identify near misses. The advantage of these criteria again is the ease of identification of cases. Most would be recorded in a register in the hospital, allowing for a retrospective analysis of the cases. This is particularly useful in developing countries. However, it is prone to the same disadvantages of using intensive care as a criterion and is biased by resources available. A condition that is life threatening in a country where no appropriate response can be given may not be classified as a near miss and interventions such as caesarean section may often be carried out on women who are not suffering from severe acute maternal morbidity—though this may be less common in the developing than in the developed world.

**Organ system dysfunction-based criteria**

This system is based on the concept that there is a sequence of events leading from good health to death. The sequence is clinical insult, followed by a systemic inflammatory response syndrome, organ dysfunction, organ failure and finally death. Near misses would be those women with organ dysfunction and organ failure who survive. The criteria for defining a near miss are generic and are defined per organ system. Markers for organ system dysfunction or failure are specified, but have avoided highly technical laboratory or haemodynamic investigations. For example, renal dysfunction is defined as oliguria (<400 ml/24 h) that does not respond to fluids or diuretics, or a serum urea ≥15 mmol/l, or a creatinine ≥400 mmol/l, or the need for dialysis. Respiratory dysfunction or failure is defined as intubation and ventilation for ≥60 min for a patient not related to anaesthesia, or where the oxygen saturation is <90% for ≥60 min. The presence of any one of the markers in a pregnancy from conception to 42 days post delivery constitutes a near miss. Having identified the case, the primary obstetric cause can then be identified and classified. This method is the same as that of a maternal death where the death is identified then the cause allocated, but is opposite to the clinical criterion-based systems where the disease is the starting point. This system allows for identification of all critically ill women and allows for the identification of new and emerging disease priorities. It mimics the confidential enquiries into maternal death systems that a number of countries have instituted. Potentially the same system could be used to
complement maternal death enquiries, as is currently occurring in Scotland\textsuperscript{17}. The system has the advantage of being a method that a large number of developed countries can use, if agreement can be reached on the markers for organ system dysfunction and failure.

The original system included management-based markers as criteria, namely emergency hysterectomy or intensive care admission for any reason or anaesthetic accidents. This was to collect the potential near miss cases. For example, performing a timely hysterectomy for severe postpartum haemorrhage before losing 2.5 litres of blood or other organ failure occurred. These cases clearly represent severe morbidity but are they near misses? The value of including these cases has not been determined, and they might bias the sample. The indications for emergency hysterectomy might vary from site to site depending on how pro-active the consultants are. Perhaps these cases should be classified as near misses and the management-based criteria left out of a near miss definition. It could be argued that blood loss at delivery, or clinical hypovolaemia, would be more compatible with the organ system dysfunction system than criteria based on intervention, such as transfusion, or surgery.

The organ system dysfunction has several advantages, namely:

1. Establishing the patterns of diseases causing morbidity and their relative importance.
2. Comparisons can be made providing definitions can be standardized and used in many different settings.
3. The health system is not part of the definition, so problems within the health system can be studied.
4. Cases can be flagged when they occur as a function of an ongoing audit, making it a virtually prospective audit, avoiding the problem of poor recording as illustrated earlier\textsuperscript{11}.

There are also a few disadvantages. It is dependent on a minimum level of care in the country. There must be functioning laboratories for some specific blood tests and basic critical care monitoring must be available. Retrospective identification of cases is very difficult because of the inability to identify cases from registers.

All methods of identifying near misses suffer from the same problem of being dependent on diligent and enthusiastic people to collect cases. Good units might detect more cases than poor units, giving a false impression of the quality of care in various areas. In some developed countries, such as Scotland, staff (usually midwives and/or obstetricians) are already given responsibility for identifying certain cases as part of risk management. The threshold for cases is usually much lower, including third degree tears, etc., but should always include near misses. Exploration is required of whether hospital to hospital variation in near
near miss rates is simply due to small number fluctuations or whether there is differential ascertainment.

Near miss analysis as a method of assessing quality of care

The basic assumption of most outcome-audits is that by examining a few specified cases, solutions to the inadequacies found will improve not only the quality of care of similar cases but also the care of other patients in the service. The assumption is that substandard care in the patient reflects the general care of patients and is not specific to that patient. The only evidence to support this assumption is from Pandy et al\textsuperscript{18}. Their group collected all maternal deaths and near misses due to hypertension in pregnancy from a clearly defined area in KwaZulu-Natal (South Africa). They also collected a control group of two pregnant women with hypertension per near miss or maternal death from the same area, delivered on the same day and matched for age and parity. The case notes were blinded and the quality of care assessed by an independent person. Substandard care was similar for the near miss cases and maternal deaths and uncomplicated pregnant women with hypertension.

The usefulness of analysing a few important, easily identifiable, clearly defined cases as a method of assessing the quality of care is clearly established in the case of maternal deaths. If near misses are added the first immediate advantage is the potential for more rapid reporting and more robust conclusions if done per disease entity. Any system of identifying near misses will automatically expand the database of cases for assessing maternal care.

An example of this is in Pretoria where an organ system dysfunction and failure criteria are used to identify near misses. During 2000–2001, a pattern shift occurred in the primary obstetric causes of near misses. Complications of abortions and obstetric haemorrhage became the largest cause of near misses, yet only two deaths per year resulting from abortion and one in 2000 and three in 2001 from obstetric haemorrhage were recorded. The number of near misses more than doubled from 12 to 27 cases for abortion and from 25 to 58 cases for obstetric haemorrhage. If maternal deaths alone were used to detect problems in maternal care in Pretoria, these problems would have been overlooked and remedial action considerably delayed\textsuperscript{19}.

The second advantage is the ability to compare maternal deaths with near misses, bringing into focus areas in the health system where there are challenges and establishing priority for action. De Bernis et al\textsuperscript{20} reported on the comparison of maternal morbidity and mortality in two different populations in Senegal. In one site (Kaolack area), the women
gave birth mainly in district health care centres usually assisted by traditional birth attendants, whereas in the other site (Saint-Louis), women gave birth mainly in the regional hospital and were usually assisted by midwives. The morbidity rate was lowest in the Kaolack area, but they had a significantly higher maternal mortality. Univariate and multivariate analyses showed morbidity was mainly associated with the level of training of the birth attendant in the facility deliveries. It appears that midwives in the health facilities detect more obstetric complications than traditional birth attendants. Immediate detection leads to immediate care and low fatality rates.

Another example is from Mantel et al. who showed that delays in transport and lack of intensive care facilities occurred significantly more in maternal deaths than women who had near misses in the Pretoria area. The delays were due in part to the lack of a decentralized obstetric service with the majority of maternal deaths coming from provinces outside of Pretoria. The upgrading of a hospital in one of the provinces led to a significant reduction in deaths.

A further advantage is the ability to examine the quality of care of a specific disease entity and identify specific problem areas such as obstetric haemorrhage as has been described above. Risk factors for maternal morbidity can also be identified as shown by Waterstone et al. and these were remarkably similar to those of maternal death in the UK. Bewley et al. divided the risk factors into three categories:

1. Those not amenable to change (e.g. race, spontaneous twinning).
2. Those that might be amenable to social change (e.g. maternal age, social equity).
3. Those that are within the control of health care professions (e.g. the care of complicated women and intervention rates).

While acknowledging the interaction between medical, political and social conditions, they suggested that the risk factors most amenable to change are obstetric interventions. They illustrate the case by giving the example of emergency caesarean section. The adjusted odds ratio of developing severe sepsis after an emergency caesarean section is particularly high. Efforts to reduce the rapidly rising caesarean section rate might be justified by the consequent reduction in severe maternal morbidity. Although it could alternatively be argued that earlier caesarean section might have avoided or reduced sepsis, the benefits or otherwise of interventions can be securely established only by randomized controlled trials.

When considering whether substandard care has occurred, informal discussion may be of some value, but prior establishment of evidence-based criteria, for what would be adequate care would be preferable, and can be achieved for most common types of morbidity. That this
approach is feasible even in small district hospitals in developing countries is encouraging but it can only succeed in improving care (a) if the records are adequate, (b) if the staff feel ‘ownership’ of the audit (‘holding up a mirror’) and (c) if supplies and facilities exist to improve care. It remains to be seen whether maternal mortality will benefit. It should be noted also that as this study was focused on improving the care of women with severe acute morbidity who had actually reached hospital, it is not informative about events in the community.

In determining substandard care, those factors related to the patients’ behaviour and their environment are the least accessible to analysis in women who die. Yet this is a major area where gaps in the system can be targeted and corrected. Interviews with the relatives of the dead women are fraught with difficulties and the data obtained not reliable. Inclusion of near misses provides an opportunity of obtaining this information on behaviour and environmental factors. For example, in interviews of all the near misses that occurred in the Pretoria region, some clear barriers to access of services were identified. Seventy-nine percent of women did not have a telephone at home or a private car. The majority of women (58%) did not know that the clinic closest to them was closed after hours. On average, the nearest local 24-h services was 45 min away and 82% had to use a taxi to get to that service. Patients bypassed local services and went directly to the tertiary hospitals because they apparently did not know of their existence or did not trust their quality of care, thereby delaying treatment that could have prevented the near miss.

A number of authors have suggested establishing an index of sorts so that the changes can be identified. Bewley et al suggested the Morbidity to Mortality Ratio. Bouvier-Colle et al described the Lethality Rate, which is the ratio of maternal deaths to all obstetric patients admitted for treatment or surveillance to an intensive care unit or the closest equivalent surgical or medical resuscitation or critical care unit in the region. Vandecruys et al described the Mortality Index, which was defined as the number of maternal deaths divided by the sum of maternal deaths and near misses. All these indices have the advantage of comparing units and of plotting changes in a particular unit over time. For this to be achieved, consensus on the criteria used to identify near misses must be agreed and there must be constancy in their use. The advantages for this can be illustrated by the following example. Sites in Bloemfontein, Pretoria and Soweto in South Africa achieved agreement on the criteria. This allowed comparison of Mortality Indices for various conditions at the three sites. Surprisingly large differences occurred in the three sites with generally two sites (not consistently the same sites) being similar and one site significantly higher. Investigation into the differences showed variations in management protocols and the way the health system functioned. The Pretoria region has used the same definitions of near miss for the past 5 years. Changes in rates of near misses and maternal deaths and
Near misses

Table 1 Comparison of the pattern changes in rates of near misses plus maternal deaths in Pretoria over 5 years

<table>
<thead>
<tr>
<th>Primary obstetric causes</th>
<th>1997–9</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abortion</td>
<td>152</td>
<td>87</td>
<td>169</td>
<td>228</td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
<td>50</td>
<td>51</td>
<td>25</td>
<td>133</td>
</tr>
<tr>
<td>Antepartum haemorrhage</td>
<td>73</td>
<td>43</td>
<td>125</td>
<td>76</td>
</tr>
<tr>
<td>Postpartum haemorrhage</td>
<td>96</td>
<td>137</td>
<td>238</td>
<td>228</td>
</tr>
<tr>
<td>Hypertension</td>
<td>84</td>
<td>108</td>
<td>138</td>
<td>133</td>
</tr>
<tr>
<td>Pregnancy-related sepsis</td>
<td>15</td>
<td>43</td>
<td>75</td>
<td>57</td>
</tr>
<tr>
<td>Embolism</td>
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<td>7</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Anaesthetic complications</td>
<td>27</td>
<td>36</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Indirect</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-pregnancy-related infections</td>
<td>23</td>
<td>58</td>
<td>25</td>
<td>63</td>
</tr>
<tr>
<td>Pre-existing maternal disease</td>
<td>46</td>
<td>72</td>
<td>50</td>
<td>51</td>
</tr>
</tbody>
</table>

Rates expressed per 100,000 births.

Table 2 Comparison of the changes in Mortality Indices in Pretoria over 5 years

<table>
<thead>
<tr>
<th>Primary obstetric causes</th>
<th>1997–9</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
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<tbody>
<tr>
<td>Direct</td>
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<td>Ectopic pregnancy</td>
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<td>16</td>
<td>0</td>
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<tr>
<td>Antepartum haemorrhage</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
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<td>Postpartum haemorrhage</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>5.2</td>
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<tr>
<td>Hypertension</td>
<td>9.1</td>
<td>20</td>
<td>23</td>
<td>8.7</td>
</tr>
<tr>
<td>Pregnancy-related sepsis</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Embolism</td>
<td>100</td>
<td>100</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Anaesthetic complications</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Indirect</td>
<td></td>
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<td>Non-pregnancy-related infections</td>
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<td>37.5</td>
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<tr>
<td>Pre-existing maternal disease</td>
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<tr>
<td>Total</td>
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<td>19</td>
<td>11</td>
<td>10</td>
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</table>

the Mortality Indices are shown in Tables 1 and 2. In Pretoria, preventing complications for abortions, obstetric haemorrhage and hypertension are the priority concerns despite the fact that the highest Mortality Indices are for embolism, which is rare but commonly fatal.

Conclusion

Confidential enquiries into maternal deaths have been associated with decreases in maternal deaths, but in developed countries, maternal deaths are now rare and the relevance of the information gleaned from the occasional maternal death to the general population is becoming distant. The incorporation of near misses into the confidential enquiry
systems might allow for more relevant data on maternal care being made applicable. Hall\textsuperscript{17} listed several reasons for their inclusion.

1. Larger numbers lead to more robust conclusions.
2. More rapid reporting on maternal care issues (because of the larger number of cases).
3. Useful lessons learnt from near misses will reinforce the lessons learnt when these cases previously died.
4. Near misses will provide relevant controls for maternal deaths, since presumably most women who die pass through a phase of organ dysfunction before dying.
5. Provided an ethical solution can be found to the confidentiality problem, the near misses can be interviewed providing valuable information on the risk factors and substandard care.
6. Obstetric requirements for intensive care can be quantified.
7. Comparative ratios/indices can be calculated.

However, before such a system is introduced, consensus will need to be attained on the criteria used to identify a near miss.

References


