

Effect of audit on critically ill pregnant women

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R.C. Pattinson conceived the project and wrote the protocol, analysed the data, ran the study at Kalafong Hospital and took a major role in writing the manuscript. APM helped draft the protocol and ran the study at Pretoria Academic Hospital. F. Backer and M. Kleynhans performed data entry and played a significant role in data analysis. A.P. McDonald, F. Backer and M. Kleynhans reviewed and substantially improved the manuscript. The authors would like to thank Dr Johan Coetzee for developing the Maternal Morbidity and Mortality Audit System software and the Medical Research Council of South Africa for funding the project.

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Purpose – The purpose of this research is to ascertain whether there has been a change in the outcome of critically ill pregnant women from the indigent South African population from a clearly defined region in Pretoria, after the introduction of new management protocols supported by regular audit and feedback.

Design/methodology/approach – A comparison of outcome of all women with severe acute maternal morbidity or maternal deaths was made between 1997/1998 (original protocol) and 2002/2004 (new protocol) was performed.

Findings – It was found that there was a significant increase in the prevalence of critically ill pregnant women between 1997/1998 (8.40/1,000 births) and 2002/2004 (10.22/1,000 births; $p < 0.014$), but a reduction in the MMR 133.2/100,000 births to 104.9/100,000 births (Odds Ratio 0.79, 95 Confidence Intervals 0.51 and 1.2) and in the

mortality index from 15.9 per cent to 10.3 per cent (Odds Ratio 0.61, 95 per cent Confidence intervals 0.39 and 0.96). The pattern of primary obstetric causes of critically ill pregnant women has remained unchanged during the study period, but the prevalence of each disease category increased. The average number of dysfunctional organ systems per patient declined from 1.41 in 1997/1998 to 1.19 in 2002/2004. There were significant reductions in the number of critically ill pregnant women with renal dysfunction, metabolic dysfunction and cerebral dysfunction. The number of patient related, administrative related and medical personnel avoidable factors all decreased.

Originality/value – The new protocols, audit and feedback have been associated with a reduction in the number of preventable and manageable complications experienced by critically ill pregnant women over the past five years.

Background

Since 1997 data on all critically ill pregnant women has been systematically collected and analyzed at daily audit meetings in the Pretoria Academic Complex using the definitions introduced by **Mantel *et al.* (1998)**. There were on average five times as many women with severe acute maternal morbidity (SAMM) compared to those who died (**Pattinson *et al.*, 2003**) and therefore by combining both data sets, information could be gathered sooner to assess the functioning of the health system (**Cochet *et al.*, 2003**). This allowed for more rapid detection of problems. Swift feedback to the relevant people makes earlier interventions possible. An analysis of trends can also be performed on a regular basis to evaluate if interventions have had the desired effect.

After the initial study was completed (**Pattinson *et al.*, 2003**) a detailed review of the protocols for managing critically ill pregnant women was undertaken and a new approach introduced for managing these women. This system was based on the systematic routine evaluation of each patient's organ systems and an abnormality to any system this served as a trigger to further investigate and support that organ system (**Pattinson and Mantel, 2001**). This policy was adopted for managing critically ill pregnant women with specific common conditions and as a group the guidelines became known as the “strict” protocols. These “strict” protocols were drawn up for the management of the main contributors to maternal morbidity and mortality namely hypertension, severe sepsis, post partum haemorrhage and HIV infection.

The change in policy was effected by regular reinforcement at daily audit meetings at the individual hospitals and weekly departmental meetings where the management of all SAMM and maternal deaths cases were a permanent agenda item. New trainees were introduced to the protocols immediately on starting, were given the relevant documents and where problems occurred face-to-face meetings were held. Special training sessions were introduced to stress specific points. Finally, a report was sent and presented to the provincial administration with specific recommendations for the region. There has been subsequent ongoing regular contact.

This study reports on the complete cycle of audit, namely identification of problems, new strategies to solve those problems, implementation of those strategies and audit to evaluate the results of the new strategies. It further asks whether this intensive audit effort was worthwhile and if new problems have been identified requiring particular attention.

Methods

The Pretoria Academic Complex consists of two academic hospitals, (Pretoria Academic and Kalafong) and two district hospitals (Mamelodi Day and Pretoria West). The area receives referrals from other areas within Gauteng Province and the surrounding provinces. For the purposes of the audit, only pregnant women from the Pretoria area were included and all those women referred from areas outside Pretoria and births in the private sector of Pretoria were excluded in the analysis. The women in this cohort were representative of an indigent general South African urban population.

The criteria for women with SAMM have been defined by **Mantel *et al.* (1998)** and are based on clinical evaluation and specific investigations that are available at all regional, secondary and higher level hospitals. A woman fulfilling the SAMM criteria with organ system dysfunction or failure, without appropriate treatment or incredible good fortune, would usually die.

Data on women with SAMM and maternal deaths was collected every morning at the respective hospitals and a “near miss” form was completed for each woman with SAMM and the maternal death notification form used for all maternal deaths. The data were entered on the Maternal Morbidity and Mortality Audit System (MaMMAS) database. The initial two years of the audit 1997/1998 were entered retrospectively on the database, although it was collected prospectively. The initial project (**Pattinson, 2003**) served as the platform for developing the database, and there was no missing data. The second time sample, 2002/2004, was chosen as the strict protocols had been implemented and established and this time period coincides with the confidential enquiries into maternal deaths in South Africa reporting period. The data, from 2000 onwards, was entered on the database as each datasheet was completed by the departmental administrator.

Standard statistical techniques were used to compare the two time periods. The Chi square test was used to compare categorical data. A *p*-value of less than 0.05 was regarded as significant. The outcome measures were the maternal mortality ratio (MMR), mortality index defined as the number of maternal deaths, divided by the sum of women with SAMM and maternal deaths and expressed as a percentage (**Vandecruis *et al.*, 2002**). The criteria for each organ system dysfunction/failure is specified in the definition of a woman with SAMM (**Pattinson and Mantel, 2001**) and the rates of each organ system dysfunction were compared between the two groups. Details of the strict protocols are available in **Pattinson and Mantel, 2001; Lombaard *et al.*, 2005; and Snyman. *et al.* (n.d.)**.

The definitions used for primary obstetric causes of severe morbidity and death, were the same as those used for the confidential inquiry into maternal deaths in South Africa (**National Committee for Confidential Enquiries into Maternal Deaths, 2003**). AIDS (as a primary obstetric cause) was recorded under the non-pregnancy related infections only if an AIDS defining condition were present, for example cryptococcal meningitis or when the CD4 count was less than 200 uL. Other causes of non-pregnancy related infections included tuberculosis, meningitis, malaria and pneumonia. Pregnancy related sepsis included chorioamnionitis and puerperal sepsis but excluded septic abortions. The definitions used for avoidable factors, missed opportunities and substandard care were the same as defined in the **National Confidential Enquiry into Maternal Deaths (2003)**.

The Ethics Committee of the Faculty of Health Sciences, University of Pretoria gave approval for the initial study and the programme remains registered. Both hospital administrations continue to support the audit. All information is entered on the database after removal of all patient identification.

Results

The total number of births (excluding births of women referred from areas outside Pretoria) in the Pretoria Academic Complex for the biennium was 27,025 for 1997 and 1998 and 51,469 for the triennium 2002 to 2004, a 27 per cent increase. There was a significant increase in the prevalence of critically ill pregnant women between 1997/1998 (8.40/1,000 births) and 2002/2004 (10.22/1,000 births) ($p < 0.014$). The MMR declined from 133.2/100,000 births to 104.9/100,000 births (Odds Ratio 0.79, 95 per cent Confidence Intervals 0.51-1.2).

Table I gives the ages and parities of the critically ill patients for 1997/1998 and 2002/2004. There were no differences in pattern.

Table II gives the primary obstetric cases of the women with SAMM and the maternal deaths for each time period. The pattern of disease has remained basically the same with the top five causes being complications of abortion, postpartum haemorrhage, hypertension, antepartum haemorrhage and pre-existing medical conditions. The individual rates have also all increased, with significant increase in postpartum haemorrhage. The overall rate increased significantly.

The overall mortality index declined during the same period (15.9 per cent in 1997/1998 to 10.3 per cent in 2002/2004, $p < 0.041$, Odds Ratio 0.67, 95 per cent Confidence Intervals 0.39 and 0.96). (The morbidity to mortality ratio was 5.3:1 in 1997/1998 and 8.7:1 in 2002/2004). The mortality index for the individual conditions mostly declined. The decline was significant in the case of women with complications of abortion ($p = 0.02$, Odds Ratio 0.28, 95 per cent Confidence Intervals 0.1 and 0.79).

There was a reduction in the proportion of critically ill women who developed renal failure ($p = 0.07$), cerebral compromise ($p = 0.056$) and metabolic dysfunction (0.006) in

2002/2004 when compared with 1997/1998 (**Table III**). The category immune system failure was divided into septic shock and immune system failure due to HIV infection. There was a significant reduction septic shock from 16.7 per cent 1997/1998 to 3.9 per cent 2002/2004 ($p=0.0001$) and a rise in immune system failure due to HIV infection from 0 per cent to 10.3 per cent ($p=0.0001$). (Testing for HIV infection was performed in 17.6 per cent of cases in 1997/1998 and 32.2 per cent in 2002/2004). Although a similar number of women developed respiratory failure in both groups, significantly less women died with respiratory failure in 2002/2004 than 1997/1998 ($p=0.04$). The average number of organ systems dysfunctional per patient declined from 1.41 in 1997/1998 to 1.19 in 2002/2004. However, as expected the number of organ systems that failed in women who subsequently died did not differ significantly (1.53 in 1997/1998 and 1.36 in 2002/2004).

Table IV lists the common avoidable factors missed opportunities and substandard care recorded in the patients. During 2002/2004 significantly less patient related, administrative related and medical personnel related factors were recorded. Significantly fewer problems were reported with health facilities mainly related to availability of intensive care beds. Fewer cases in which the standard protocol was not followed resulted in the major reduction in the medical personnel factors.

Discussion

Previous studies (**Mantel *et al.*, 1998; Cochet *et al.*, 2003; Pattinson *et al.*, 2003; Brace *et al.*, 2004**) have shown that audit of SAMMs and maternal deaths are feasible, and by using both SAMMs and maternal death cases more frequent meaningful audits of maternal care can be performed. This allows for earlier recognition of problems and possibly to an earlier improvement in maternal care. This study reports on the complete audit cycle, namely identification of problems, new strategies to solve those problems, implementation of those strategies and audit to evaluate the results of the new strategies.

The data showed an increase of 27 per cent in births from 1997/1998 to 2002/2004 and an increase of 21.7 per cent in the prevalence of critically ill pregnant women. This increase in the prevalence of critically ill pregnant women is not easy to explain. There has been a rapid in-migration of people from poor rural areas into the more prosperous Gauteng Province (**Statistics South Africa, 2003**). This increase of the lowest socioeconomic group of people will bring more illness but would probably also enable patients to access medical care and most likely contributes significantly to the increase. The increase is also probably due to better detection of critically ill women by use of the structured approach. Thus the numerator is automatically increased and hence prevalence. This would clearly have happened as checklists have been consistently found to improve uptake of tests (**Hulsscher *et al.*, 2004**). The main effect of the intervention thus might be due to more accurately identifying morbidity rather than actually improving outcome. However the MMR decreased from 133.2/100,000 births in 1997/2008 to 104.9/100,000 births for the triennium 2002-2004 so care did improve to at least some extent. Further, if better detection of cases alone were the reason, a sudden increase in the prevalence and then a

levelling off would have been expected. The prevalence initially dropped to 6.42/1,000 births in 2000 and then increased to 8.71/1,000 births in 2001 (**Cochet *et al.*, 2003**). The final option is that the primary health care system might be failing to detect problems and refer early enough. This again appears unlikely given that the avoidable factors, missed opportunities and substandard care have not risen but declined. In assessing a case the quality of care from first contact with the health service is evaluated and if the primary health care system was malfunctioning an increase in avoidable factors would be expected.

The prevalence of critically ill pregnant women in Pretoria (10.22/1,000 births) is more than twice that reported from Scotland (**Brace *et al.*, 2004**) (3.8/1,000 births) and Canada (**Health Canada, 2004**) (4.62/1,000 births), but considerably lower than that reported in a teaching hospital in Uganda (**Kaye *et al.*, 2003**) (110.2/1,000 births). All these studies used similar definitions of severe morbidity to the current study. The morbidity to mortality ratio was also much higher in Scotland (49:1) but similar to that found in Uganda (6:1) (**Kaye *et al.*, 2003**).

The pattern of primary obstetric causes of severe acute morbidity and mortality has stayed the same but the rates of all causes have increased. The pattern of disease has remained basically the same with the top five causes being complications of abortion, postpartum haemorrhage, hypertension, antepartum haemorrhage and pre-existing medical conditions. If early pregnancy complications are excluded (data not collected in Canada) the major direct causes of morbidity in Pretoria are the same as in Canada (**Health Canada, 2004**) and Scotland (**Brace *et al.*, 2004**) namely haemorrhage and hypertension.

The prevalence of HIV in antenatal clinics has increased from 17 per cent in 1997 to 27 per cent in 2002 (**South African Department of Health, 2002**). Along with complications of hypertension, AIDS was the most common cause of maternal death in the Pretoria area in the triennium 2002/2004, and immune system failure is playing an increasingly common role in critically ill pregnant women. The use of antiretroviral therapy will hopefully help combat this trend. The shift from the sub-category septic shock to immune system failure due to HIV infection probably reflects more an increased awareness and ability to diagnose HIV infection than a reduction in septic shock. Testing for HIV has become much easier during the period of the study as seen by the 83 per cent increase in critically ill women tested in 2002/2004 compared with 1997/2008.

The mortality index overall has declined by a third. Despite the increase in the number of critically ill pregnant women, fewer women were dying. This reduction is due to significantly fewer women developing or dying from preventable or manageable conditions like septic shock, renal failure, cerebral complications and metabolic disorders than before. The average number of organ systems with dysfunction per critically ill pregnant woman declined from 1.41 in 1997/1998 to 1.19 in 2002/2004. The number of organ systems with dysfunction in women who subsequently died did not differ significantly, with a value of 1.53 in 1997/1998 and 1.36 in 2002/2004. As expected, more organ systems were affected in patients that died. The reduction in average number

of dysfunctional or failing organ systems can indicate earlier identification, intervention and better support of organ systems. The earlier identification is probably the result of the checklist type of approach that was used in the systematic routine evaluation of each patient's organ systems. Reminders to physicians have been shown to be effective in improving practice (**Hulscher *et al.*, 2004**).

A significant decline in mortality index was seen in the complications due to abortions. This follows the introduction of the Choice of Termination of Pregnancy Act in South Africa in 1996. Although there were still a considerable number of unsafe abortions (**Table IV**), it appears women are presenting earlier than before. This is possibly responsible for the shift away from the number of cases with septic shock.

The rate of cardiac and respiratory failure however, showed no improvement. Respiratory and cardiac failure is commonly recorded in severe maternal morbidity reports. In Pretoria they ranked second and third; the Scottish report (**Brace *et al.*, 2004**) ranked them fourth and fifth; and the Canadian report (**Health Canada, 2004**) demonstrated a significant increase in the rates of adult respiratory distress syndrome and pulmonary oedema when comparing severe maternal morbidity in 1991-1993 and 1998-2000. Protocol reviews needs to be focused in this area to determine better ways of preventing and treating pulmonary oedema and respiratory failure.

The percent of events with avoidable factors, missed opportunities and substandard care declined in the triennium 2002/2004. Assessing these factors tends to be subjective despite criteria to assess cases. The adherence to the protocols was gratifying and possibly is a direct result of the audit and feedback mechanism. The audit process of identifying cases, discussing each one in detail against a set protocol and having specific teaching sessions on the identified problems, has been associated with a reduction in preventable morbidity. This is supported by the findings of **Grimshaw *et al.* (2001)** in their overview of systematic reviews of interventions that physician reminders, face-to-face feedback, multimedia teaching and development of the protocols “in-house” can be effective in changing practice.

This method of audit and feedback used in this report is labour intensive, but there appears to have been some positive results. **Brace *et al.* (2004)** have shown in Scotland that by using the local risk management systems a sustainable system of detecting and evaluating severe morbidity can be introduced nationwide. Any woman developing an organ dysfunction or failure during pregnancy would be regarded as an adverse event and should be detected by the local risk managers and the case examined by the risk management committees. Hence there is a system already in place, and in hospitals with risk management systems, it would not add extra work for clinicians.

Finally, if the data from 1997-1998 is extrapolated to 2002-2004 and compared with the actual data, then the deaths of 30 pregnant women have been prevented. The introduction of the “strict” protocols and the maternal morbidity and mortality audit and feedback system has been associated with this change.

Table I Comparison of age and parity of critically ill pregnant women between 1997/1998 and 2002/2004

	Age								Parity							
	<20 %	20-24 %	25-29 %	30-34 %	35-39 %	40-44 %	45 + %	Unknown %	0 %	1 %	2 %	3 %	4 %	5 %	6 + %	Unknown %
1997/1998	6.6	20.3	18.9	24.7	20.3	7.0	1.8	0.4	23.3	25.1	19.8	13.7	7.5	4.8	3.5	2.2
2002/2004	6.7	18.1	24.5	23.7	18.1	6.1	0.8	1.9	27.6	25.1	22.0	8.9	4.5	4.5	0.8	6.7

Table II Comparison of the indices of severe acute morbidity and mortality rates between 1997/1998 and 2002/2004

	1997-1998						2002-2004					
	SAMM	MD	SAMM + MD	%	Rate	MI	SAMM	MD	SAMM + MD	%	Rate	MI
Pre-existing medical disease	18	3	21	9.3	0.78	14.3	36	6	42	8.0	0.82	14.3
Non-pregnancy-related infections	3	6	9	4.0	0.33	66.7	11	10	21	4.0	0.41	47.6
Ectopic pregnancy	17	0	17	7.5	0.63	0.0	48	3	51	9.7	0.99	5.9
Abortion	43	10	53	23.3	1.96	18.9	107	7	114	21.7	2.22	6.1
Pregnancy-related sepsis	8	2	10	4.4	0.37	20.0	25	3	28	5.3	0.54	10.7
Antepartum haemorrhage	28	0	28	12.3	1.04	0.0	46	1	47	8.9	0.91	2.1
Postpartum haemorrhage	36	2	38	16.7	1.41	5.3	98	8	106	20.2	2.06	7.5
Hypertension	31	9	40	17.6	1.48	22.5	71	10	81	15.4	1.57	12.3
Anaesthetic accidents	6	2	8	3.5	0.30	25.0	19	0	19	3.6	0.37	0
Embolism	0	1	1	0.4	0.04	100.0	4	3	7	1.3	0.14	42.9
Acute collapse (cause unknown)	1	1	2	0.9	0.07	50.0	6	2	8	1.5	0.16	25.0
Unknown	0	0	0	0.0	0.0	0.0	1	1	2	0.4	0.03	50.0
Total	191	36	227	100.0	8.40	15.9	472	54	526	100	10.22	10.3

Notes: Rate – per 1,000 births; MI – Mortality Index

Table II. Comparison of the indices of severe acute morbidity and mortality rates between 1997/1998 and 2002/2004

Table III Comparison of the percentage organ system dysfunction or failure in critically ill pregnant women between 1997/1998 and 2002/2004

	1997-1998				2002-2004				p
	SAMM n = 191	MD n = 36	SAMM + MD n = 227	%	SAMM n = 472	MD n = 54	SAMM + MD n = 526	%	
Hypovolaemia	97	3	100	44.1	220	11	231	43.9	1.0
Respiratory failure*	29	17	46	20.3	75	18	93	17.7	0.46
Cardiac failure	36	12	48	21.1	73	12	85	16.2	0.12
Renal failure	19	5	24	10.6	32	2	34	6.5	0.07
Liver failure	2	0	2	0.9	10	1	11	2.1	0.39
Cerebral compromise	9	6	15	6.6	8	9	17	3.2	0.056
Metabolic dysfunction	5	2	7	3.1	1	1	2	0.4	0.006
DIC	36	4	40	17.6	79	5	84	16.0	0.65
Immune system failure	32	6	38	16.7	51	17	68	12.9	0.20

Notes: *Significant reduction in deaths with respiratory failure in 2002-2004 group; DIC – Disseminated intravascular coagulation; NS – not significant; a patient can have more than one organ system failure or dysfunctional

Table III. Comparison of the percentage organ system dysfunction or failure in critically ill pregnant women between 1997/1998 and 2002/2004

Table IV Comparison of avoidable factors, missed opportunities and substandard care in critically ill pregnant women between 1997/8 and 2002/4

Factor	1997-1998				2002-2004				p
	MD	SAMM	Total	%	MD	SAMM	Total	%	
<i>Patient-related</i>									
No information	6	8	14		9	25	34		
Denominator	30	183	214		45	454	499		
No avoidable factor	9	102	111	51.9	29	286	315	63.1	0.01
No/infrequent antenatal care	10	46	56	26.2	7	70	77	15.4	NS
Delay in seeking help	9	23	32	15.0	10	75	85	17.0	NS
Family problems	0	16	16	7.5	4	12	16	3.2	NS
Unsafe abortion	4	12	16	38.5*	3	32	35	30.7*	NS
<i>Administration</i>									
No information	1	0	1		4	9	13		
Denominator	35	191	226		50	470	520		
No avoidable factor	19	151	170	75.2	41	397	438	84.2	0.005
Transport	2	4	6	2.7	5	19	24	4.6	NS
Barriers	2	5	7	3.1	0	2	2	0.4	NS
Lack of facilities	20	30	50	22.1	4	33	37	7.1	0.0000
Lack of blood for transfusion	1	6	7	3.1	0	2	2	0.4	0.006
Lack of personnel	1	2	3	1.3	2	11	13	2.5	NS
Poor communication	4	6	10	4.4	2	8	10	1.9	NS
<i>Medical personnel</i>									
Poor initial assessment	4	7	11	4.8	6	26	32	6.1	NS
No/poor problem list/diagnosis	7	17	24	10.6	5	57	62	11.8	NS
Delay in referral	3	12	15	6.6	3	27	30	5.7	NS
Managed at inappropriate level	0	5	5	2.2	0	7	7	1.3	NS
Incorrect management	2	9	11	4.8	3	19	22	4.2	NS
Substandard management	16	43	59	26.0	7	44	51	9.7	0.0000
No/poor monitoring	6	22	28	12.3	8	14	22	4.2	NS
Poor resuscitation	15	33	48	21.1	8	84	92	17.5	NS
Total cases			227				526		

Notes: *Denominator is number of abortions; patient can have more than one avoidable factor

Table IV. Comparison of avoidable factors, missed opportunities and substandard care in critically ill pregnant women between 1997/8 and 2002/4

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