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Under-reporting of maternal and perinatal adverse events in New Zealand

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Title page

Title: Under-reporting of maternal and perinatal adverse events in New Zealand

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Abstract

Aim To determine the proportion of maternal and perinatal mortality and morbidity cases identified by the Perinatal and Maternal Mortality Review Committee (PMMRC) that are also reported within the annual Serious Adverse Events (SAE) reports published by the Health Quality and Safety Commission (HQSC) since 2009.

Method Every SAE report published by the HQSC from 2009 to 2012 was scrutinised for maternal and perinatal cases using the short case history provided by individual District Health Boards (DHB). Further detail of each case was requested from each DHB to establish whether they had been identified as maternal or perinatal mortalities or morbidities by the PMMRC.

Results Fifty eight maternal and perinatal serious adverse events were identified from the SAE reports 2009-2012. Of these, 50 fit under the PMMRC reporting definitions, all of whom were also reported by the PMMRC. In the same time frame, the PMMRC captured 536 maternal and perinatal mortalities and morbidities that fitted the HQSC SAE case definition. Fewer than 9% of maternal and perinatal SAEs are captured by the HQSC SAE reporting process.

Conclusion The rate of maternal and perinatal adverse event reporting to the HQSC is low and not improving annually, compared to PMMRC reporting of eligible events. This is of concern as these events may not be adequately reviewed locally and because the SAE report is considered a measure of quality by the DHBs and the HQSC. Currently, the reporting of serious adverse events to the HQSC cannot be considered a reliable way to monitor or improve the quality of maternity services provided in New Zealand.

Article Summary

Strengths and limitations of this study

The strengths of this study include its use of robust and accurate data on maternal and perinatal serious adverse events captured by the PMMRC and the careful matching of cases with those reported by the HQSC SAE reports with the help of data from individual DHBs. This means the data presented is reliable.

The main limitation of the study is the analysis of data between two reporting bodies who claim to have different purposes and aims. However, the HQSC SAE report purpose is to provide transparency and improve the quality and safety of health and disability services, which may be compromised if only a fraction of cases are being reported.

1 to 5 bullet points related to the study

- Maternal and perinatal serious adverse events (SAE) are significantly under-reported by the Health Quality and Safety Commission (HQSC) annual report when compared to those reported to the Perinatal and Maternal Mortality Review Committee (PMMRC).
- Under reporting of SAE to the HQSC suggests that cases are not undergoing adequate local review and that the report is not a useful way to monitor the quality, safety and experience of maternity services in New Zealand.

- This paper highlights the need for the HQSC and PMMRC to work towards improving the recognition, reporting and review of SAE and prevent the duplication of reporting by health care staff.

Introduction

Since 2008 the Health Quality and Safety Commission (HQSC) has published an annual report on serious adverse events (SAE) (formerly known as serious and sentinel events).⁽¹⁾ According to the HQSC, a SAE is defined as 'one which has led to significant additional treatment, is life threatening or has led to an unexpected death or major loss of function'.⁽²⁾ It is recommended that DHBs review these events and report them to the HQSC, which publishes rates and case summaries on an annual basis.⁽²⁾ However, unlike the Perinatal and Maternal Mortality Review Committee (PMMRC), which is a statutory committee of the HQSC, where reporting is mandatory, reporting SAEs is voluntary and relies upon local systems.

From 2006 and 2007 respectively, the PMMRC has reported on maternal and perinatal mortalities, and from 2010, the PMMRC also reported on maternal morbidities, as defined by the Australasian Maternity Outcomes Surveillance System (AMOSS), and on cases of neonatal encephalopathy (survivors and deaths).

The HQSC New Zealand was established to lead and coordinate work across the health and disability sector for the purposes of monitoring and improving the quality and safety of health and disability services. The Commission works towards the New Zealand Triple Aim which is improving the quality, safety and experience of care, improving health and equity for all populations and providing better value for public health system resources.⁽³⁾

Since the inception of SAE reporting, the PMMRC has noted that maternal mortalities are infrequently reported, and more recently, that neonatal encephalopathy cases are also rarely reported. The purpose of this study was to establish if all relevant maternal and perinatal serious adverse events reported to the HQSC were also captured and reported by the PMMRC and vice versa. This information will help the PMMRC to establish whether it is achieving full case ascertainment, and what proportion of PMMRC cases fitting the SAE definition are being reported as SAEs.

Methods

The PMMRC reports both perinatal and maternal mortality and morbidity data. These data are the result of the collaborative efforts of the PMMRC, lead maternity carers, local coordinators and clinicians in each DHB, supported by a national coordination service, the Mortality Review Data Group of the University of Otago and the HQSC. The data are collected under section 59e of the New Zealand Public Health and Disability Act 2000.

Maternal death is defined as the death of a woman while pregnant or within 42 days of the termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.⁽⁴⁾

Perinatal related deaths are deaths of babies from 20 weeks gestation (or if gestation is unknown a birth weight from 400g) to 28 completed days of life.

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3 The PMMRC has developed a system of reporting contributory factors and potentially
4 avoidable maternal and perinatal mortality. There are three domains of contributory
5 factors: organisational and management factors, personnel factors and factors related to
6 barriers to access and/or engagement with care. Each domain includes a check list of
7 items to be considered. A death is categorised as potentially avoidable if the absence of
8 the contributory factor/s could have prevented the death.⁽⁵⁾
9

10 The PMMRC's reporting remit includes all perinatal and maternal mortalities, which the
11 SAE reports would not be expected to capture. Therefore, we limited the mapping of
12 PMMRC cases to those which had been identified by the PMMRC as potentially avoidable
13 as they would fulfil the definition of a SAE as unexpected deaths. We excluded cases that
14 the PMMRC identified as potentially avoidable secondary to barriers to accessing care as
15 the only contributory factor.
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17 NE is defined as 'a clinically defined syndrome of disturbed neurological function within
18 the first week of life in the term (≥ 37 weeks) infant, manifested by difficulty in initiating
19 and maintaining respiration, depression of tone and reflexes, subnormal level of
20 consciousness and often seizures'.⁽⁶⁾ NE is associated with brain injury including cerebral
21 palsy. Of those infants affected by NE, approximately one quarter will die and an
22 unknown proportion of the survivors will have long term neurological complications
23 (brain damage) resulting in chronic disability.^(5, 7) Data are not currently available on
24 whether surviving cases of NE were potentially avoidable, however SAE reports record
25 cases of NE therefore all cases of NE have been included in our searches.
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29 Maternal morbidity data collection also commenced in 2010 and has been conducted in
30 collaboration with AMOSS. AMOSS is a national surveillance mechanism designed to
31 study a variety of rare or serious conditions in pregnancy, childbirth and the post natal
32 period. The following are AMOSS notifiable conditions reported between 2009 and 2012:
33 amniotic fluid embolism, antenatal pulmonary embolism, eclampsia (reported until
34 September 2010), morbid obesity in pregnancy (reported until December 2010),
35 placenta accreta, influenza in pregnancy requiring intensive care admission and
36 peripartum hysterectomy (reported until December 2012).^(5, 7, 8) Of these conditions,
37 only peripartum hysterectomy definitively fulfils the criteria for a SAE and has been
38 included in searches.
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41 The HQSC has several descriptions of a SAE. The National Reportable Events Policy
42 describes an adverse event as an incident which results in harm to a consumer, which
43 may include events defined as incidents, near misses and reportable events.⁽⁹⁾ The HQSC
44 website describes a SAE as one which has led to significant additional treatment, is life
45 threatening or has led to an unexpected death or major loss of function.⁽²⁾ The SAE
46 report states that 'the precise definition of a SAE has often been difficult to pinpoint, as
47 every case is different. However, some DHBs are reviewing their own threshold for
48 reporting SAEs resulting in more incidents being classified as SAE'.⁽¹⁰⁾ Health and
49 disability service providers are required to establish each event's Severity Assessment
50 Code (SAC) which is a numerical rating which defines the severity of an adverse event
51 and as a consequence, the expected level of reporting and investigation to be
52 undertaken for the event.⁽⁹⁾ All health and disability service providers are expected to
53 report adverse events that meet the criteria of SAC 1 and 2 within 15 working days from
54 the date an event is reported to the provider using Part A of the Reportable Event Brief
55 (REB).⁽⁹⁾ SAC 1 and 2 events are defined as those that have incurred either severe or
56 major consequences to the patient with any likelihood of recurrence, or an event that
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3 has incurred moderate consequences with at least a moderate likelihood of
4 recurrence.⁽¹¹⁾ Part B of the REB is required within 70 working days of the event being
5 initially reported to the provider and includes a summary of the findings and
6 recommendations related to the reportable event.
7

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9 The reportable events are summarised and published annually as the SAE report. Each
10 published report between 2009 and 2012 was searched for perinatal and maternal cases
11 using the short case summary provided by the DHB. The PMMRC requested the NHI
12 number and date of event for each case from the notifying DHB. Using this information,
13 the PMMRC databases (Perinatal, Maternal, NE, AMOSS) were searched to establish
14 whether these cases were also reported to PMMRC and, if they were perinatal or
15 maternal deaths, whether they were potentially avoidable (Figure 1).
16

17 Results

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19 From 2009 to 2012, a total of 58 perinatal and maternal SAE were reported. There were
20 8 cases of maternal morbidity secondary to conditions that are not AMOSS reportable
21 conditions (four women with postpartum haemorrhage, one woman with fulminating
22 HELLP, one woman who suffered a medication error at caesarean section, one woman
23 who suffered respiratory arrest, and one woman with retained products of conception).
24

25 The remaining 50 SAE were reported by one of the PMMRC processes.
26

27 Maternal deaths: There were three maternal deaths identified as having been reported
28 as SAE: one by searching the SAE reports between 2009 and 2012 and two further
29 maternal deaths were identified as having been reported as SAE from PMMRC data. We
30 surmise that these two deaths were reported within the SAE report, but that it was not
31 clearly stated that these were maternal deaths. In this time-frame, the PMMRC identified
32 7 maternal deaths that occurred in hospital and were considered to be potentially
33 avoidable with contributory organisation, management and/or personnel factors.
34

35 Maternal morbidity: There were 4 women with severe maternal morbidity (peripartum
36 hysterectomy) that met the AMOSS notifiable conditions definition who were also
37 reported in the SAE reports between 2009 and 2012. AMOSS started its collection of
38 data on severe and rare disorders of pregnancy in 2010. Since then 86 women who had
39 a peripartum hysterectomy were reported by AMOSS.
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42 Perinatal Deaths: There were 28 perinatal deaths reported in the SAE reports between
43 2009 and 2012. Within the same time-frame, the PMMRC reported 216 deaths that were
44 considered potentially avoidable with organisational, management and/or personnel
45 contributory factors. Lack of protocols and guidelines were the major organisational
46 factors and failure to follow best practice was the most common personnel-related
47 factor. The most common antecedent cause of death among potentially avoidable
48 perinatal deaths reported by the PMMRC and perinatal deaths reported in the SAE
49 reports, was hypoxic peripartum death, which occurred in 40 of the 216 (18.5%) PMMRC
50 reported cases and 11 of the 28 (39%) perinatal SAE reported cases. Of the 28
51 perinatal deaths reported as SAE, 21 were reported in the PMMRC data as potentially
52 avoidable perinatal deaths. The remaining 7 were identified as deaths by the PMMRC but
53 not determined to be potentially avoidable. Among the 216 perinatal deaths reported as
54 potentially avoidable by the PMMRC, but not reported by the SAE reports, the majority
55 were classified as secondary to 'hypoxic peripartum death' (18.5%), followed by 'fetal
56 growth restriction' (15.7%), and 'specific perinatal conditions' (14.8%).
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3 Neonatal encephalopathy: There were 15 infants with NE reported within the SAE reports
4 from 2009 to 2012, all of whom survived the perinatal period. The PMMRC reported 227
5 infants with NE in the same time period, of whom 179 survived (Table 1).
6

7 Discussion

8
9 This report has compared maternal and perinatal SAE reported to the HQSC with those
10 reported to the PMMRC over the time period 2009-2012. The purposes of the PMMRC
11 and HQSC SAE reporting differ. They are bodies with different aims and processes.
12 However, despite their differences, they both hold the common goal of improving
13 care.⁽¹²⁾ With this in mind, it is reassuring that the PMMRC has identified and reported all
14 the maternal and perinatal cases within the serious adverse event reports that fall under
15 PMMRC and AMOSS reporting definitions.
16

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18 There are, however, significant numbers of cases of maternal and perinatal mortality and
19 morbidity which appear to fulfil the definition of SAE that have not been reported to the
20 HQSC (figure 2).
21

22 The purpose of the SAE reports is 'to provide transparency and improve the quality and
23 safety of our health and disability services'.^(1, 14) The Commission's national reportable
24 events policy sets out a process for ensuring that serious adverse events are reviewed
25 appropriately by the provider organisation, and subsequently reported to the
26 Commission.⁽⁹⁾ The latest report notes that comparing data between years is problematic
27 because more events are being reported and reviewed each year. It also recommends
28 that the data should not be used to measure safety because there is considerable
29 variation in the rates of reporting as well as the provision of services and the size of the
30 community that each DHB serves. The clinical lead for the commission has stated that
31 'accurate information and analysis helps the health sector understand the extent and
32 type of patient harm occurring'.⁽¹⁵⁾
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35 The World Health Organisation has published guidelines for implementing effective
36 reporting systems, outlining its core concepts: to enhance patient safety by learning
37 from failures, ensuring reports are handled in a non-punitive manner, that reporting is
38 followed by a constructive response with feedback, and that there is a meaningful
39 analysis and dissemination of lessons learnt with recommendations for changes.⁽¹⁶⁾
40 Despite this transparent approach, there remains a recognised problem with local and
41 national incident reporting systems.⁽¹⁷⁾ These problems include fear of punitive action,
42 poor safety culture in an organisation, lack of understanding among clinicians about
43 what should be reported, and how the reports will ultimately impact on patient safety.⁽¹⁷⁾
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46 It has been identified by a similar patient safety organisation in England and Wales, the
47 National Reporting and Learning System (NRLS), that organisations that report low
48 numbers of patient safety incidents, are often reporting these events locally, but not
49 nationally.⁽¹⁸⁾ Therefore, to overcome the same problem encountered by the process in
50 NZ, the HQSC could work with the mortality review committees and the DHBs to
51 consider how these organisations might share data submitted on severe adverse events
52 to prevent duplication of reporting and utilise data reported to the HQSC for different
53 purposes. Some statutory changes to the legislation would be necessary to allow the
54 mortality committees to report their data to the HQSC Central Repository Group.
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57 Whilst local investigation and reflection on SAEs is to be commended, there may be
58 perceived barriers to submitting reports, for example, time pressure, lack of perceived
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3 benefit, damage to the reputation of the organisation, and duplication of reporting, all of
4 which have been cited as strong disincentives to reporting adverse events in
5 healthcare.⁽²⁰⁾ Additionally, there may be a concern by healthcare workers about the
6 potentially identifiable nature of case histories which are published in the report for each
7 SAE. This is in contrast to the mandatory nature of reporting to the PMMRC, with
8 corresponding statutory protection of information. The mandatory nature of reporting to
9 the PMMRC may account for the differences in the two reports.
10

11 We recognise that the purpose of SAE reporting and PMMRC reporting differ. It is also
12 important to recognise that low reporting of SAE does not necessarily mean that lessons
13 are not being learnt and that positive changes are not being made locally. However, we
14 have identified underreporting of maternal and perinatal SAEs to the HQSC which
15 suggests that a significant number of these cases are not undergoing adequate local
16 review and that the report is not a useful way to monitor the quality, safety and
17 experience of maternity services in New Zealand.
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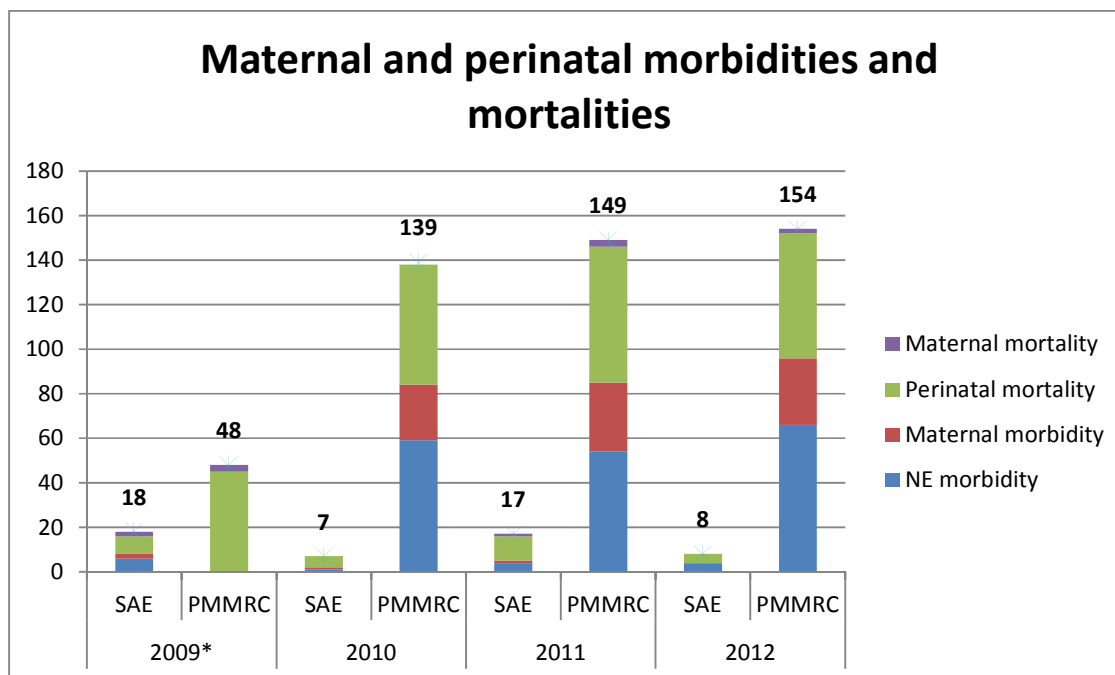
20 **Ethics, funding and data sharing**

21
22 Ethics application wasn't necessary for this work and all data were freely available
23 through the published PMMRC and HQSC SAE reports.
24

25 No funding was obtained for this study.
26

27 Data were shared between the DHBs and the PMMRC in order to accurately identify
28 potential maternal and perinatal SAEs from the HQSC report. There are no unpublished
29 data.
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Figure 1: Maternal and perinatal morbidities and mortalities recorded by the PMMRC and SAE per annum.



*The PMMRC commenced data collection on NE and maternal morbidity in 2010

Table 1: A summary of maternal and perinatal morbidities and mortalities reported as Serious Adverse Events to the HQSC and to the PMMRC

	Reported by HQSC SAE report (and meets PMMRC/AMOSS reporting definitions) N=50	Reported by PMMRC (and meets definition of SAE) N= 536
Maternal mortality	3	7
Perinatal mortality	28	216
Maternal morbidity*	4	86
Neonatal encephalopathy - morbidity	15	179

*AMOSS = Australasian Maternity Outcomes Surveillance System.

Contributor statement:

Prof Cindy Farquhar conceived the idea for the paper. The data gathering and extraction was undertaken by Ms Boa Kim, Ms Vicki Masson and Dr Sarah Armstrong. Dr Sarah Armstrong wrote the initial draft which was edited by Dr Lynn Sadler, Prof Cindy Farquhar and Ms Vicki Masson.

Competing interests:

Prof Cindy Farquhar is the past Chair of the PMMRC

Ms Vicki Masson is the National Coordinator of the PMMRC

Dr Lynn Sadler is the epidemiologist for the PMMRC

Funding:

No funding was received for this work

Data sharing statement:

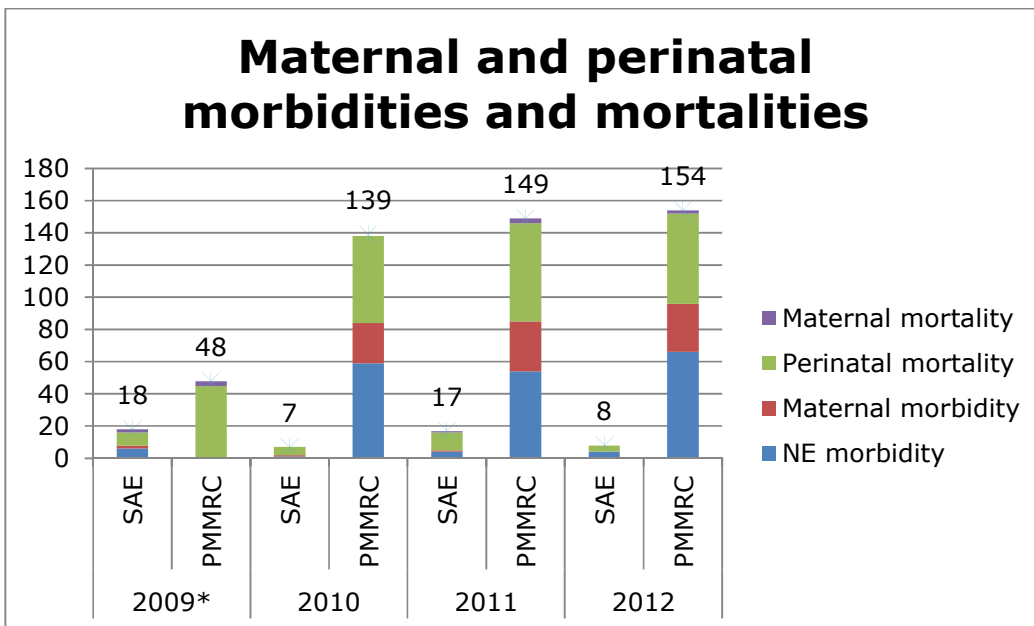
All unidentifiable data from this project are freely available from PMMRC and HQSC SAE reports which are published in the public domain.

References:

1. Making health & safety disability services safer: Serious adverse events reported to the Health Quality & Safety Commission 1 July 2012 to 30 June 2013. Wellington: Health Quality & Safety Commission, 2013.
2. Serious Adverse Events Reports [26/6/2014]. Available from: <http://www.hqsc.govt.nz/our-programmes/reportable-events/serious-adverse-events-reports/>.
3. About the Commission: Health Quality & Safety Commission; [27/6/14]. Available from: <http://www.hqsc.govt.nz/about-the-commission/>.
4. International Statistical Classification of Diseases and Related Health Problems. Geneva: World Health Organization, 1992 Tenth Revision.
5. PMMRC. 2011. Fifth Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting mortality 2009. Wellington: Health Quality & Safety Commission, 2011.
6. PMMRC. 2014. Eight Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting mortality 2012. Wellington: Health Quality & Safety Commission, 2014.
7. PMMRC. 2010. Information about the Neonatal Encephalopathy Working Group. Wellington: Ministry of Health; 2010.
8. Studies: AMOSS; 2014 [27/6/2014]. Available from: <http://www.amoss.com.au>.
9. HQSC. Health Quality & Safety Commission (2012) New Zealand Health and Disability Services – National Reportable Events Policy 2012. Wellington: Health Quality & Safety Commission, 2012.
10. HQSC. Making health and disability services safer: Serious adverse events reported to the Health Quality & Safety Commission 1 July 2012 to 30 June 2013. Wellington: HQSC, 2013.
11. HQSC. SAC Matrix Consequence Table 2012 [21/07/2014]. Available from: <http://www.hqsc.govt.nz/our-programmes/reportable-events/publications-and-resources/publication/636/>.
12. PMMRC. Eighth Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting mortality 2012. Wellington: Health Quality and Safety Commission, 2014.

13. Alpha Scientists in Reproductive M, Embryology ESIG. Istanbul consensus workshop on embryo assessment: proceedings of an expert meeting. Reproductive BioMedicine Online. 2011;22(6):632-46.
14. Health Quality & Safety Commission (2012) New Zealand Health and Disability Services – National Reportable Events Policy 2012. Wellington: Health Quality & Safety Commission 2012.
15. HQSC. Media Release: Serious Adverse Events Report 2012–13 Wellington: Health Quality & Safety Commission; 2014 [28/07/2014]. Available from: <http://www.hqsc.govt.nz/our-programmes/reportable-events/news-and-events/news/1239/%22%20class=%22title:%20%7B'Serious%20Adverse%20Events%20Report%202012-13.%20%20itemLink>.
16. WHO. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. Geneva: World Health Organisation, World Alliance for Patient Safety; 2005.
17. Mahajan RP. Critical incident reporting and learning. Brit J Anaesth. 2010 Jul;105(1):69-75.
18. Patient Safety - About the Patient Safety division [6/5/14]. Available from: <http://www.nrls.npsa.nhs.uk/about-us/>.
19. New Zealand Incident Management System -Severity Assessment Code 2014 [6/5/14]. Available from: <http://www.hqsc.govt.nz/assets/Reportable-Events/Resources/severity-assessment-code-poster-v1-1.pdf>.
20. Leape LL. Reporting of Adverse Events. New Engl J Med. 2002;347(20):1633-8.
21. Springford V. Patient's bowel punctured by enema. NZ Herald. 2013.

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Abstract

Objectives To determine the proportion of maternal and perinatal mortality and morbidity cases identified by the Perinatal and Maternal Mortality Review Committee (PMMRC) that are also reported within the annual Serious Adverse Events (SAE) reports published by the Health Quality and Safety Commission (HQSC).

Setting Nationally collated data from the PMMRC and HQSC, New Zealand.

Participants Retrospective analysis of maternal and perinatal mortality and morbidity data 2009-2012.

Interventions Every SAE report published by the HQSC from 2009 to 2012 was scrutinised for maternal and perinatal cases using the short case history provided by individual District Health Boards (DHB). Further detail of each case was requested from each DHB to establish whether they had been identified as maternal or perinatal mortalities or morbidities by the PMMRC.

Primary outcome measure The proportion of maternal and perinatal mortality and morbidity cases identified by HQSC SAE reports, compared to PMMRC reporting.

Results Fifty eight maternal and perinatal serious adverse events were identified from the SAE reports 2009-2012. Of these, 50 fit under the PMMRC reporting definitions, all of whom were also reported by the PMMRC. In the same time frame, the PMMRC captured 536 potentially avoidable maternal and perinatal mortalities and morbidities that fitted the HQSC SAE case definition. Fewer than 9% of maternal and perinatal SAEs are captured by the HQSC SAE reporting process.

Conclusions The rate of maternal and perinatal adverse event reporting to the HQSC is low and not improving annually, compared to PMMRC reporting of eligible events. This is of concern as these events may not be adequately reviewed locally and because the SAE report is considered a measure of quality by the DHBs and the HQSC. Currently, the reporting of serious adverse events to the HQSC cannot be considered a reliable way to monitor or improve the quality of maternity services provided in New Zealand.

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Strengths and limitations of this study

The strengths of this study include its use of robust and accurate data on maternal and perinatal serious adverse events captured by the PMMRC and the careful matching of cases with those reported by the HQSC SAE reports with the help of data from individual DHBs. This means the data presented is reliable.

The main limitation of the study is the analysis of data between two reporting bodies who claim to have different purposes and aims. However, the HQSC SAE report purpose is to provide transparency and improve the quality and safety of health and disability services, which may be compromised if only a fraction of cases are being reported.

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- Under reporting of SAE to the HQSC suggests that cases are not undergoing adequate local review and that the report is not a useful way to monitor the quality, safety and experience of maternity services in New Zealand.
- This paper highlights the need for the HQSC and PMMRC to work towards improving the recognition, reporting and review of SAE and prevent the duplication of reporting by health care staff.

Introduction

Since 2008 the Health Quality and Safety Commission (HQSC) has published an annual report on serious adverse events (SAE) (formerly known as serious and sentinel events).(1) According to the HQSC, a SAE is defined as 'one which has led to significant additional treatment, is life threatening or has led to an unexpected death or major loss of function'.(2) It is recommended that DHBs review these events and report them to the HQSC, which publishes rates and case summaries on an annual basis.(2) However, unlike the Perinatal and Maternal Mortality Review Committee (PMMRC), which is a statutory committee of the HQSC, where reporting is mandatory, reporting SAEs is voluntary and relies upon local systems.

From 2006 and 2007 respectively, the PMMRC has reported on maternal and perinatal mortalities, and from 2010, the PMMRC also reported on maternal morbidities, as defined by the Australasian Maternity Outcomes Surveillance System (AMOSS), and on cases of neonatal encephalopathy (survivors and deaths).

The HQSC New Zealand was established to lead and coordinate work across the health and disability sector for the purposes of monitoring and improving the quality and safety of health and disability services. The Commission works towards the New Zealand Triple Aim which is improving the quality, safety and experience of care, improving health and equity for all populations and providing better value for public health system resources.(3)

Since the inception of SAE reporting, the PMMRC has noted that maternal mortalities are infrequently reported to the HQSC, and more recently, that neonatal encephalopathy cases are also rarely reported. The purpose of this study was to establish if all relevant maternal and perinatal serious adverse events reported to the HQSC were also captured and reported by the PMMRC and vice versa. This information will help the PMMRC to establish whether it is achieving full case ascertainment, and what proportion of PMMRC cases fitting the SAE definition are being reported as SAEs.

Methods

The PMMRC reports both perinatal and maternal mortality and morbidity data. These data are the result of the collaborative efforts of the PMMRC, lead maternity carers, local coordinators and clinicians in each DHB, supported by a national coordination service, the Mortality Review Data Group of the University of Otago and the HQSC. The data are collected under section 59e of the New Zealand Public Health and Disability Act 2000.

Maternal death is defined as the death of a woman while pregnant or within 42 days of the termination of pregnancy, irrespective of the duration and the site of the pregnancy,

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3 from any cause related to or aggravated by the pregnancy or its management, but not
4 from accidental or incidental causes.(4)

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6 Perinatal related deaths are deaths of babies from 20 weeks gestation (or if gestation is
7 unknown a birth weight from 400g) to 28 completed days of life.

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9 The PMMRC has developed a system of reporting contributory factors and potentially
10 avoidable maternal and perinatal mortality. There are three domains of contributory
11 factors: organisational and management factors, personnel factors and factors related to
12 barriers to access and/or engagement with care. Each domain includes a check list of
13 items to be considered. A death is categorised as potentially avoidable if the absence of
14 the contributory factor/s could have prevented the death.(5)

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17 The PMMRC's reporting remit includes all perinatal and maternal mortalities, which the
18 SAE reports would not be expected to capture. Therefore, we limited the mapping of
19 PMMRC cases to those which had been identified by the PMMRC as potentially avoidable
20 as they would fulfil the definition of a SAE as unexpected deaths. We excluded cases that
21 the PMMRC identified as potentially avoidable secondary to barriers to accessing care as
22 the only contributory factor.

23
24 Neonatal encephalopathy (NE) is defined as 'a clinically defined syndrome of disturbed
25 neurological function within the first week of life in the term (≥ 37 weeks) infant,
26 manifested by difficulty in initiating and maintaining respiration, depression of tone and
27 reflexes, subnormal level of consciousness and often seizures'.(6) NE is associated with
28 brain injury including cerebral palsy. Of those infants affected by NE, approximately one
29 quarter will die and an unknown proportion of the survivors will have long term
30 neurological complications (brain damage) resulting in chronic disability.(5, 7) Data are
31 not currently available on whether surviving cases of NE were potentially avoidable,
32 however SAE reports record cases of NE therefore all cases of NE have been included in
33 our searches.

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36 Maternal morbidity data collection also commenced in 2010 and has been conducted in
37 collaboration with AMOSS. AMOSS is a national surveillance mechanism designed to
38 study a variety of rare or serious conditions in pregnancy, childbirth and the post natal
39 period. The following are AMOSS notifiable conditions reported between 2009 and 2012:
40 amniotic fluid embolism, antenatal pulmonary embolism, eclampsia (reported until
41 September 2010), morbid obesity in pregnancy (reported until December 2010),
42 placenta accreta, influenza in pregnancy requiring intensive care admission and
43 peripartum hysterectomy (reported until December 2012).(5, 7, 8) Of these conditions,
44 only peripartum hysterectomy definitively fulfils the criteria for a SAE and has been
45 included in searches.

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48 The HQSC has several descriptions of a SAE. The National Reportable Events Policy
49 describes an adverse event as an incident which results in harm to a consumer, which
50 may include events defined as incidents, near misses and reportable events.(9) The
51 HQSC website describes a SAE as one which has led to significant additional treatment,
52 is life threatening or has led to an unexpected death or major loss of function.(2) The
53 SAE report states that 'the precise definition of a SAE has often been difficult to pinpoint,
54 as every case is different. However, some DHBs are reviewing their own threshold for
55 reporting SAEs resulting in more incidents being classified as SAE'.(10) Health and
56 disability service providers are required to establish each event's Severity Assessment
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Code (SAC) which is a numerical rating which defines the severity of an adverse event and as a consequence, the expected level of reporting and investigation to be undertaken for the event.(9) All health and disability service providers are expected to report adverse events that meet the criteria of SAC 1 and 2 within 15 working days from the date an event is reported to the provider using Part A of the Reportable Event Brief (REB).(9) SAC 1 and 2 events are defined as those that have incurred either severe or major consequences to the patient with any likelihood of recurrence, or an event that has incurred moderate consequences with at least a moderate likelihood of recurrence.(11) Part B of the REB is required within 70 working days of the event being initially reported to the provider and includes a summary of the findings and recommendations related to the reportable event.

The reportable events are summarised and published annually as the SAE report. Each published report between 2009 and 2012 was searched for perinatal and maternal cases using the short case summary provided by the DHB. The PMMRC requested the NHI number and date of event for each case from the notifying DHB. Using this information, the PMMRC databases (Perinatal, Maternal, NE, AMOSS) were searched to establish whether these cases were also reported to PMMRC and, if they were perinatal or maternal deaths, whether they were potentially avoidable.

Results

From 2009 to 2012, a total of 58 perinatal and maternal SAE were reported. There were 8 cases of maternal morbidity secondary to conditions that are not AMOSS reportable conditions (four women with postpartum haemorrhage, one woman with fulminating HELLP, one woman who suffered a medication error at caesarean section, one woman who suffered respiratory arrest, and one woman with retained products of conception).

The remaining 50 SAE were reported by one of the PMMRC processes (Figure 1).

Maternal deaths: There were three maternal deaths identified as having been reported as SAE: one by searching the SAE reports between 2009 and 2012 and two further maternal deaths were identified as having been reported as SAE from PMMRC data. We surmise that these two deaths were reported within the SAE report, but that it was not clearly stated that these were maternal deaths. In this time-frame, the PMMRC identified 8 maternal deaths that occurred while the woman was an inpatient and were considered to be potentially avoidable with contributory organisation, management and/or personnel factors.

Maternal morbidity: There were 4 women with severe maternal morbidity (peripartum hysterectomy) that met the AMOSS notifiable conditions definition who were also reported in the SAE reports between 2009 and 2012. AMOSS started its collection of data on severe and rare disorders of pregnancy in 2010. Since then 86 women who had a peripartum hysterectomy were reported by AMOSS.

Perinatal Deaths: There were 28 perinatal deaths reported in the SAE reports between 2009 and 2012. Within the same time-frame, the PMMRC reported 216 deaths that were considered potentially avoidable with organisational, management and/or personnel contributory factors. Lack of protocols and guidelines were the major organisational factors and failure to follow best practice was the most common personnel-related factor. Of the 28 perinatal deaths reported as SAE, 21 were reported in the PMMRC data as potentially avoidable perinatal deaths. The remaining 7 were identified as deaths by

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3 the PMMRC but not determined to be potentially avoidable. The most common
4 antecedent cause of death among potentially avoidable perinatal deaths reported by the
5 PMMRC and perinatal deaths reported in the SAE reports, was hypoxic peripartum death,
6 which occurred in 40 of the 216 (18.5%) PMMRC reported cases and 11 of the 28 (39%)
7 perinatal SAE reported cases. This was followed by 'fetal growth restriction' (15.7%),
8 and 'specific perinatal conditions' (14.8%).
9

10 Neonatal encephalopathy: There were 15 infants with NE reported within the SAE reports
11 from 2009 to 2012, all of whom survived the perinatal period. The PMMRC reported 227
12 infants with NE in the same time period, of whom 179 survived (Table 1).
13

14 Discussion

15 This report has compared maternal and perinatal SAE reported to the HQSC with those
16 reported to the PMMRC over the time period 2009-2012. The purposes of the PMMRC
17 and HQSC SAE reporting differ. They are bodies with different aims and processes.
18 However, despite their differences, they both hold the common goal of improving
19 care.(12) With this in mind, it is reassuring that the PMMRC has identified and reported
20 all the maternal and perinatal cases within the serious adverse event reports that fall
21 under PMMRC and AMOSS reporting definitions.
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24 There are, however, significant numbers of cases of maternal and perinatal mortality and
25 morbidity which appear to fulfil the definition of SAE that have not been reported to the
26 HQSC.
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29 The purpose of the SAE reports is 'to provide transparency and improve the quality and
30 safety of our health and disability services'.(1, 13) The Commission's national reportable
31 events policy sets out a process for ensuring that serious adverse events are reviewed
32 appropriately by the provider organisation, and subsequently reported to the
33 Commission.(9) The latest report notes that comparing data between years is
34 problematic because more events are being reported and reviewed each year. It also
35 recommends that the data should not be used to measure safety because there is
36 considerable variation in the rates of reporting as well as the provision of services and
37 the size of the community that each DHB serves. The clinical lead for the commission
38 has stated that 'accurate information and analysis helps the health sector understand the
39 extent and type of patient harm occurring'.(14)
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42 The World Health Organisation has published guidelines for implementing effective
43 reporting systems, outlining its core concepts: to enhance patient safety by learning
44 from failures, ensuring reports are handled in a non-punitive manner, that reporting is
45 followed by a constructive response with feedback, and that there is a meaningful
46 analysis and dissemination of lessons learnt with recommendations for changes.(15)
47 Despite this transparent approach, there remains a recognised problem with local and
48 national incident reporting systems.(16) These problems include fear of punitive action,
49 poor safety culture in an organisation, lack of understanding among clinicians about
50 what should be reported, and how the reports will ultimately impact on patient
51 safety.(16)
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54 It has been identified by a similar patient safety organisation in England and Wales, the
55 National Reporting and Learning System (NRLS), that organisations that report low
56 numbers of patient safety incidents, are often reporting these events locally, but not
57 nationally.(17) Therefore, to overcome the same problem encountered by the process in
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NZ, the HQSC could work with the mortality review committees and the DHBs to consider how these organisations might share data submitted on severe adverse events to prevent duplication of reporting and utilise data reported to the HQSC for different purposes. Some statutory changes to the legislation would be necessary to allow the mortality committees to report their data to the HQSC Central Repository Group.

Whilst local investigation and reflection on SAEs is to be commended, there may be perceived barriers to submitting reports, for example, time pressure, lack of perceived benefit, lack of recognition of an event as being a significant maternal morbidity, damage to the reputation of the organisation, and duplication of reporting, all of which have been cited as strong disincentives to reporting adverse events in healthcare.⁽¹⁸⁾ Additionally, there may be a concern by healthcare workers about the potentially identifiable nature of case histories which are published in the report for each SAE. This is in contrast to the mandatory nature of reporting to the PMMRC, with corresponding statutory protection of information. The mandatory nature of reporting to the PMMRC may account for the differences in the two reports.

We recognise that the purpose of SAE reporting and PMMRC reporting differ. It is also important to recognise that low reporting of SAE does not necessarily mean that lessons are not being learnt and that positive changes are not being made locally. However, we have identified underreporting of maternal and perinatal SAEs to the HQSC which suggests that a significant number of these cases are not undergoing adequate local review and that the report is not a useful way to monitor the quality, safety and experience of maternity services in New Zealand.

Ethics, funding and data sharing

The PMMRC is appointed under section 59E of the New Zealand Public Health and Disability Act (NZPHD Act 2000) to report on perinatal and maternal mortality and morbidity. All data collection is covered by this legislation; this data was requested as part of the PMMRC process to ensure full case ascertainment. As such ethics approval was not required for this work.

No funding was obtained for this study.

Details of possible cases from published HQSC SAE reports were sent to the relevant DHB with a request that they provide National Health Index number and date of event. No other data were shared.

Figure 1: Maternal and perinatal morbidities and mortalities recorded by the PMMRC and SAE per annum.

*The PMMRC commenced data collection on NE and maternal morbidity in 2010

Table 1: A summary of maternal and perinatal morbidities and mortalities reported as Serious Adverse Events to the HQSC and to the PMMRC

	Reported by HQSC SAE report (and meets PMMRC/AMOSS reporting definitions) N=50	%	Reported by PMMRC (and meets definition of SAE) N= 489	%
Maternal mortality	3	6	8	2
Perinatal mortality	28	56	216	44
Maternal morbidity*	4	8	86	18
Neonatal encephalopathy - morbidity	15	30	179	37

*AMOSS = Australasian Maternity Outcomes Surveillance System.

Contributor statement:

Prof Cindy Farquhar conceived the idea for the paper. The data gathering and extraction was undertaken by Ms Boa Kim, Ms Vicki Masson and Dr Sarah Armstrong. Dr Sarah Armstrong wrote the initial draft which was edited by Dr Lynn Sadler, Prof Cindy Farquhar and Ms Vicki Masson.

Competing interests:

Prof Cindy Farquhar is the past Chair of the PMMRC

Ms Vicki Masson is the National Coordinator of the PMMRC

Dr Lynn Sadler is the epidemiologist for the PMMRC

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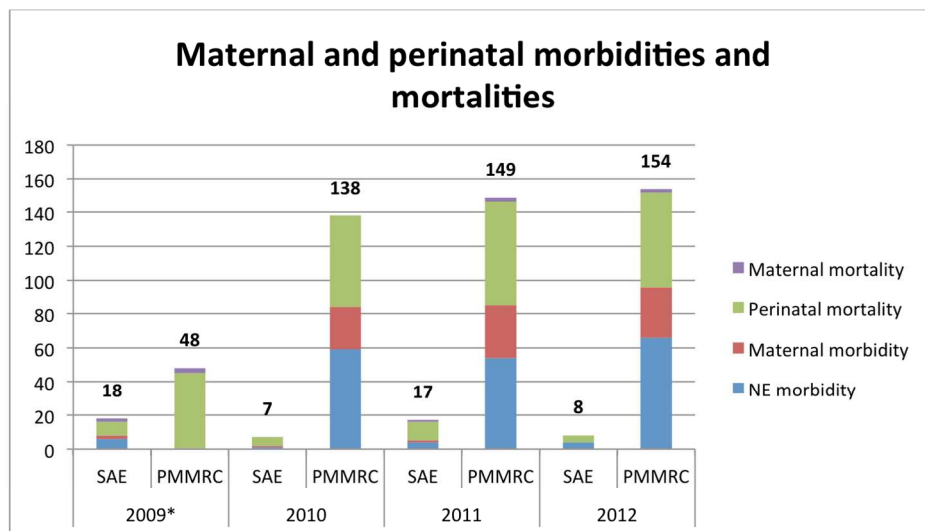
Data sharing statement:

All unidentifiable data from this project are freely available from PMMRC and HQSC SAE reports which are published in the public domain.

References:

1. Making health & safety disability services safer: Serious adverse events reported to the Health Quality & Safety Commission 1 July 2012 to 30 June 2013. Wellington: Health Quality & Safety Commission, 2013.
2. Serious Adverse Events Reports [26/6/2014]. Available from: <http://www.hqsc.govt.nz/our-programmes/reportable-events/serious-adverse-events-reports/>.
3. About the Commission: Health Quality & Safety Commission; [27/6/14]. Available from: <http://www.hqsc.govt.nz/about-the-commission/>.
4. International Statistical Classification of Diseases and Related Health Problems. Geneva: World Health Organization, 1992 Tenth Revision.
5. PMMRC. 2011. Fifth Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting mortality 2009. Wellington: Health Quality & Safety Commission, 2011.
6. PMMRC. 2014. Eight Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting mortality 2012. Wellington: Health Quality & Safety Commission, 2014.
7. PMMRC. 2010. Information about the Neonatal Encephalopathy Working Group. Wellington: Ministry of Health; 2010.
8. Studies: AMOSS; 2014 [27/6/2014]. Available from: <http://www.amoss.com.au>.
9. HQSC. Health Quality & Safety Commission (2012) New Zealand Health and Disability Services – National Reportable Events Policy 2012. Wellington: Health Quality & Safety Commission, 2012.
10. HQSC. Making health and disability services safer: Serious adverse events reported to the Health Quality & Safety Commission 1 July 2012 to 30 June 2013. Wellington: HQSC, 2013.
11. HQSC. SAC Matrix Consequence Table 2012 [21/07/2014]. Available from: <http://www.hqsc.govt.nz/our-programmes/reportable-events/publications-and-resources/publication/636/>.
12. PMMRC. Eighth Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting mortality 2012. Wellington: Health Quality and Safety Commission, 2014.
13. Health Quality & Safety Commission (2012) New Zealand Health and Disability Services – National Reportable Events Policy 2012. Wellington: Health Quality & Safety Commission 2012.
14. HQSC. Media Release: Serious Adverse Events Report 2012–13 Wellington: Health Quality & Safety Commission; 2014 [28/07/2014]. Available from: [BMJ Open 12 5 15 \(3\) vm sa edits 2.docx](#).
15. WHO. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. Geneva: World Health Organisation, World Alliance for Patient Safety; 2005.
16. Mahajan RP. Critical incident reporting and learning. *Brit J Anaesth.* 2010;105(1):69-75.
17. Patient Safety - About the Patient Safety division [6/5/14]. Available from: <http://www.nrls.npsa.nhs.uk/about-us/>.
18. Leape LL. Reporting of Adverse Events. *New Engl J Med.* 2002;347(20):1633-8.

Figure 1: Maternal and perinatal morbidities and mortalities recorded by the PMMRC and SAE per annum.



*The PMMRC commenced data collection on NE and maternal morbidity in 2010

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