AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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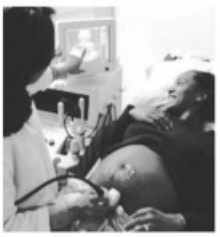


Safety+Quality COUNCIL

July 2002

Lessons From The Inquiry Into Obstetrics And Gynaecological Services At King Edward Memorial Hospital 1990 - 2000

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The Australian Council for Safety and Quality in Health Care was established in January 2000 by all Australian Health Ministers to lead national efforts to improve the safety and quality of health care, with a particular focus on minimising the likelihood and effects of error. Council reports annually to Health Ministers.

This document is an attachment to Council's third report to Health Ministers - *Safety Through Action — Improving Patient Safety in Australia, Third Report to the Australian Health Ministers' Conference 19 July 2002.*

Further information on the work of the Council can be found at www.safetyandquality.org or from the Council Management Group tel 02 6289 4244, fax 02 6289 8470 or email safetyandquality@health.gov.au

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Foreword

Learning from experience is essential in any health care system that places patient safety at the heart of its agenda. With this in mind, the Council commissioned this summary of the key findings and wider lessons from the Inquiry into the King Edward Memorial Hospital.

The Report shows that safe, high quality patient care not only requires skilled health care professionals, but also well-designed systems of care. System failures led to adverse events occurring at King Edward Memorial Hospital, despite there being many examples of exemplary care and significant effort on the part of individuals to overcome long-standing clinical and management problems. Of particular concern were ineffective systems to report and respond to performance problems, errors and adverse events, and poor communication with patients and families, particularly when things went wrong.

Australia is not alone in recognising that we need to do more to build safer health care systems. The summary notes that there are a number of common findings with the Bristol case in the United Kingdom involving heart surgery on babies. Both Inquiries call for change to establish a culture of inquiry and open disclosure and build better systems to improve the safety and quality of patient care. This is a challenge at all levels of health care, for health care professionals, managers, boards and governments alike.

The Council hopes that this summary will be widely read by health care leaders, managers and professionals who may in practical ways contribute to improvements in their own workplace.

Together we can make a difference.

Bruce Barraclough
Chair
Australian Council for Safety and Quality in Health Care

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Executive summary

The Australian Council for Safety and Quality in Health Care has summarised the key findings and lessons arising from the Inquiry into the King Edward Memorial Hospital Obstetrics and Gynaecological Services (Douglas et al 2001). The Council produced this report to support health care leaders, managers and staff in their efforts to improve the safety and quality of Australian health care. The report summarises the Inquiry's context, processes and outcomes, focusing on systems issues and improvement opportunities.

Background to the Inquiry

Kind Edward Memorial Hospital is Western Australia's only tertiary referral service for obstetrics and gynaecology, providing inpatient and outpatient services, neonatal intensive care and specialist emergency services. The years 1990–2000 saw a significant increase in the number of complex obstetric and gynaecological cases treated at the Hospital, as well as significant organisational restructure and upheaval in the Hospital's management.

The appropriateness of King Edward's obstetrics and gynaecological services was questioned during this period, resulting in the Child and Glover review being established by the Western Australia Metropolitan Health Service Board in 2000. This two-week review preceded the establishment of the Inquiry which over 18 months investigated clinical, and management practices at the Hospital from 1990–2000 and made recommendations to address service deficiencies.

Key findings

The lack of safety and quality systems at state, board and hospital level was evidenced by ineffective accreditation and credentialling systems, inadequate incident reporting systems, poorly performing statutory mortality reporting and investigation systems and non-existent inter-hospital comparative data analysis.

At Hospital level, the Inquiry found many examples of exemplary care and significant effort on the part of individuals to overcome long-standing clinical and management problems. However, the Inquiry also found significant leadership, management and clinical performance problems including:

- a culture of blame, unsupportive of open disclosure of errors and adverse events;
- lack of clarification of senior staff responsibilities and accountability;
- non-existent "safety nets" or systems to effectively monitor performance and respond to performance issues;
- ineffective or non-existent systems to ensure staff had the right credentials, training, support and performance management to meet the demands and skill requirements of their roles and responsibilities;
- failure to meet the emotional needs of many women and their families, excluding them from decisions about care or failing to give them honest, complete and timely information when things went wrong; and
- failure to address serious and ongoing management and clinical problems that resulted in serious adverse events and poor outcomes for women and their families.

Comparison with the Bristol Case

The Bristol Case involved heart surgery on babies in Britain's Bristol Royal Infirmary from 1988 to 1994. Both the Bristol and King Edward Memorial Hospital cases arose from "whistle-blowers" reporting serious problems rather than the problems being identified and

addressed or prevented through rigorous and routine safety and quality monitoring systems. Both cases called for changes at government, board and management level to establish a culture of inquiry and open disclosure, and to introduce systems to monitor and improve the safety and quality of health care.

Lessons

The Inquiry's key findings raise important issues about leadership and culture, accountability and responsibility, systems for safety and quality, support and development of staff, and concern and compassion for patients and their families.

- To assure safe, quality care, governments, boards, health care leaders and managers must create an open and transparent culture, where people willingly discuss and address errors and systems problems.
- Effective organisations have people at all levels doing the right thing. Organisational structures, regardless of their intent or design, can only be effective if people know and aim to meet their responsibilities and are held accountable for their actions.
- Effective leaders and managers ensure that their organisation has systems that effectively monitor the key aspects of its performance, and ensure timely and appropriate responses to performance issues.
- To do a good job, people need the right credentials, training, support, performance management and development consistent, with the demands and skills requirements of their roles and responsibilities.
- A caring, concerned health care service recognises the importance of involving patients and their families in care, provides information about care options, involves them in decisions about care and advises them openly and honestly when things go wrong.

Improvement opportunities

Health care leaders, managers and staff have the opportunity to consider the findings and the lessons arising from the Inquiry as the basis for identifying and responding to improvement opportunities in their own workplaces.

1 The Inquiry

This section includes discussion of the background to the Inquiry, its methods and limitations.

1.1 Background to the Inquiry

The Hospital's role

As the state's only tertiary referral service for obstetrics and gynaecology, the Hospital receives and treats the most difficult and complex obstetric cases in Western Australia twenty-four hours per day, seven days per week. The Hospital is the state's only major teaching hospital in obstetrics and gynaecology, is a centre for midwifery training and for post-graduate medical training in obstetrics and gynaecology.

The Hospital has 250 inpatient beds, 60 neonatal cots and intensive care services, and a range of outpatient services. Each year 5,000 gynaecological operations are performed at the Hospital, approximately 5,000 babies are born there, and the Hospital's Emergency Centre has 8,000–10,000 women presenting for gynaecological or obstetric treatment.

Patient profile

From 1999–2000, the Hospital treated significantly fewer privately insured low-risk women and many more high-risk patients including those:

- from poorer socioeconomic backgrounds;
- who were un-booked and presented late in pregnancy;
- with morbid obesity and/or substance abuse problems; and
- subject to domestic violence and other severe societal problems.

Structural changes

The Hospital experienced considerable management restructure and significant upheaval from 1990–2000 including:

- merging with Princess Margaret Hospital for Children in 1993;
- appointing two new Chief Executives during this period;
- establishing a devolved management structure in 1996; and
- having its board of management replaced by the Metropolitan Health Service Board in 1997.

These factors created uncertainty about the future of the Hospital, and it might reasonably be assumed that this had a significant impact on the Hospital's staff and patients.

Lead-up to the Inquiry

In 1990 the Health Department of Western Australia commissioned the University of Western Australia's Professor of Obstetrics and Gynaecology to report on the state's future obstetric, gynaecological and neonatal service requirements. The report recommended changes at King Edward Memorial Hospital, including revision of obstetric staffing levels. However these recommendations were not implemented despite the Hospital medical and nursing clinicians repeatedly raising concerns about staffing levels with Hospital management throughout the 1990s. Nor was there any evidence that the Hospital management conveyed this information to the Health Department of Western Australia.

Concerned about important process and performance issues at the Hospital, the recently appointed Chief Executive wrote to the Metropolitan Health Service Board Chief Executive Officer in 1999 about the:

- lack of an overall clinical quality management system;
- problems identifying and rectifying clinical issues by senior management;
- inadequate systems to monitor and report adverse clinical incidents;
- absence of a proper and transparent system to deal with patient complaints and claims;
- shortage of qualified clinical specialists particularly after hours;
- inadequate supervision of junior medical staff; and
- possibility of sub-standard patient care.

The Hospital's Chief Executive also outlined changes he had established to address these issues and recommended additional changes. After consultation with the Health Department's Chief Medical Officer, the Hospital's Chief Executive provided evidence of poor practice at the Hospital. As a result, the Metropolitan Health Service Board commissioned a review by an independent senior clinician to examine the issues. This review also raised concerns about significant clinical issues and recommended a more detailed investigation into the Hospital's obstetric and gynaecological services.

In consultation with the Commissioner of Health and the Minister, the Chief Medical Officer and the Metropolitan Health Service Board Chief Executive Officer commissioned the Child and Glover Review (Child & Glover 2000). This two-week review identified significant system and performance issues. As a result, the Minister in consultation with the Premier agreed to establish the Douglas Inquiry under the Hospitals Act and the Public Sector Management Act.

Strong public debate arose from the high public profile given to the Hospital during this time and the issues raised about its future. Individual doctors and the Western Australian branch of the Australian Medical Association actively debated the issues, resulting in public criticism of the Child and Glover findings. The Douglas Inquiry's findings are consistent with those of the Child and Glover Review. Refer to Appendix 5 for a summary of the Child and Glover findings.

1.2 Overview of the Inquiry

Purpose

The Inquiry's brief was "to inquire into the provision of obstetric and gynaecological services at King Edward Memorial Hospital" over the period 1990 to 2000. The Inquiry focused on systemic and organisational deficiencies and considered management and clinical practices, policies and processes. The Inquiry recommended changes to address these deficiencies. Refer to Appendix 1 for a summary of the Inquiry's recommendations.

Method

Over 18 months the Inquiry accessed information from more than 1,600 patient clinical files from the Hospital as well as:

- analysing 605 patient clinical files qualitatively and quantitatively;
- analysing 293 written submissions;
- interviewing 70 former Hospital patients;
- reviewing various consultants' reports;
- comparing the Hospital's clinical performance data with data from similar Australian services;
- reading 106 transcripts from current and former Hospital staff; and
- reviewing other documents from the Hospital and elsewhere.

Case review focused on the management of selected high-risk obstetric and gynaecological cases requiring complex care, as these were the cases the Hospital was expected to manage well. Refer to Appendix 2 for a summary of the framework used for the Clinical File Review.

1.3 Limitations of the Inquiry

Detailed analysis and opinion on the strengths and weakness of the Inquiry's methods and conclusions is beyond the brief of this report. However, readers should consider the contextual issues affecting the Hospital, as well as the intentional bias in the Inquiry's structure.

The Inquiry's brief was to examine management and clinical practices and recommend changes to improve the safety and quality of the care provided. Rather than identify a representative sample of all Hospital cases (a costly and resource-intensive exercise beyond the brief of the Inquiry), the Inquiry reviewed a sample of high-risk cases requiring complex care in detail, as these were cases the Hospital was expected to manage. It was also beyond the Inquiry's brief to determine the overall incidence of good or poor outcomes for the review period.

The Inquiry commissioned a comparative analysis of perinatal, obstetric and gynaecological clinical indicator results between the Hospital and 13 other Australian hospitals. The reliability of these inter-hospital data comparisons was limited by demographic differences, reliance on routinely collected data and difficulties adjusting for variability. However, while the authors advised readers to consider the results in light of these limitations, they believed their findings were sufficiently valid to identify major differences between the hospitals and to recommend further investigation into several results.

With the exception of clinical indicator comparison, the Inquiry focused on one hospital's performance. In all other aspects of the Inquiry's work, it avoided making an assessment of the Hospital's strengths and weaknesses relative to other hospitals. There is no way of knowing how the Hospital's performance compares overall with other Australian hospitals. However, we can draw lessons from the Inquiry and its extensive case reviews of patient, families and staff, that may be applicable to other hospitals and may point to potential improvement opportunities.

2 Lessons

This section presents the lessons arising from the Inquiry's key findings for health care leaders, managers and staff to consider in the context of their own work environments. The Inquiry's report raises important issues about leadership and culture, accountability and responsibility, systems for safety and quality, support and development of staff, and concern and compassion for patients and their families.

2.1 Leadership and culture

There was a lack of active involvement in important safety and quality issues at board and hospital management levels over many years. The Hospital's leadership and management problems were evidenced by a negative work culture, non-existent effective support systems, inability to make important decisions affecting safety and quality and non-compliance by senior staff with Hospital policy.

To assure safe, quality care, governments, health care leaders and managers should create an open and transparent culture, where people willingly discuss and respond to errors and systems problems. Strong leaders ensure issues are responded to, and decisions are made and acted on to benefit and protect patients, and improve health care performance and outcomes.

2.2 Organisational structure and performance management

The Metropolitan Health Service Board and previous boards of management were responsible for the safety and quality of care the Hospital provided. The Hospital's devolved management structure was meant to improve clinical decision-making and responsiveness to clinical care needs. However, unclear lines of authority, responsibility and lack of accountability for clinical care and decision-making resulted in poor staff and patient outcomes.

Effective organisations have people at all levels doing the right thing. Organisational structures, regardless of their intent or design, can only be effective if people know and discharge their responsibilities, and are held accountable for their actions. For this to occur, organisations should have a strong and appropriate, robustly implemented performance management process.

2.3 Safety and quality systems

The Hospital needed "safety nets" to protect patients and support staff to do a good, safe job. Without these, junior staff faced difficult situations they were poorly equipped to handle, and women and babies bore the brunt of human and systems errors.

People are fallible, and systems, processes and policies become obsolete and outdated. Assuming and stating that an organisation gives good care is just not enough to meet legal, ethical and public demands and expectations.

Effective governments, leaders and managers ensure the organisations and services that they are responsible for, have good systems to monitor and manage the key aspects of patient safety, and ensure timely and appropriate responses to safety and quality concerns. These systems include effective third party accreditation systems, rigorous credentialling and performance management systems, reliable incident and adverse event reporting and response systems, data collection and comparison processes and tenable statutory mortality reporting and investigation systems.

2.4 Staff support and development

The Hospital gave inadequate support to its staff, particularly junior doctors who hesitated to call senior doctors. They feared being labelled as unable to cope, or when they did ask for help, a response was delayed or the request was ignored.

To do a good job, people need the right credentials, training, support, performance feedback and development to meet the demands and skills requirements of their roles and responsibilities.

2.5 Concern for consumers and families

The Hospital failed to respond to the emotional needs of many patients and families. People felt excluded from decisions about care, and that the hospital had failed to give them frank, honest and timely information when things went wrong.

A caring health service recognises the importance of involving patients and families and establishes sustainable systems to involve, support and inform them of their health care options and the associated risks. A caring health service gives a full explanation when things go wrong and actively involves patients and families in follow-up and improvement processes.

3 Major findings

This section presents the findings associated with:

- clinical practice;
- clinical policies and guidelines;
- incident reporting and management;
- reporting deaths to the Coroner;
- staff and staffing matters;
- involving women and families;
- quality improvement; and
- other leadership and management issues.

3.1 Clinical practice and performance

The Inquiry noted many instances of excellent clinical practice by Hospital staff, and many examples of individuals making a concerted effort to address long-standing clinical performance and management problems. These problems were associated with poor policies and practices adversely affecting the safety and quality of the Hospital's obstetric and gynaecological service and care, and poor outcomes for patients and their families.

Staff repeatedly raised serious concerns about management and clinical issues with their clinical director and with non-clinical administrators. However these matters remained unresolved, often being referred to unproductive Hospital committees. Over many years, the following problems persisted:

- non-existent or sub-standard care planning and coordination;
- poor management of high-risk cases and medical emergencies;
- lack of supervision of junior medical staff;
- inadequate staff skills profile in the Adult Special Care Unit;
- sub-standard documentation adversely affecting care continuity; and
- non-existent systems for identifying, reviewing and responding to adverse events.

Care planning and coordination

Detailed care plans were generally non-existent. Poor care planning was particularly a problem in cases of pre-term labour or pre-term rupture of the membranes. In some cases, consultants made major changes to care plans without providing any written rationale. Case reviews and staff interviews highlighted a repeated lack of care coordination and a sense that no-one was really in charge. Sometimes so many clinicians were involved in a case that patients, families and staff received conflicting advice and fragmented care.

Management of high-risk cases and complex care

Junior doctors delivered most of the care at the most crucial times for 70 per cent of the 372 high-risk obstetric cases reviewed. This care included clinical assessment, clinical management decision-making and intervention. Consultants were involved at the most crucial times in 21 per cent of high-risk cases and senior registrars were involved at the most crucial times in 9 per cent of these. Hospital management and staff frequently raised the inadequacy of the supervision of junior doctors. Particular problems were evident in the Delivery Suite, the Adult Special Care Unit and the Emergency Centre, where junior doctors gave unsupervised care to high-risk patients requiring complex care. There were many occasions when registrars (often juniors themselves) were busy somewhere else and unable to respond

to urgent requests. Junior doctors were often left to manage difficult cases without help and without the necessary skills to do the job safely.

As an example, junior doctors were often responsible for women who presented to the Emergency Centre with potential ectopic pregnancies. Sometimes they failed to discuss a case or to have the case reviewed by a registrar or someone more senior. The Hospital lacked a policy to support the management of ectopic pregnancy.

Another long-term and widespread problem was junior doctors' inability to accurately interpret and respond to abnormal fetal heart traces (cardiotocography or CTGs), a task assigned to them for which they lacked training and supervision.

Medical and obstetric emergencies

There were many serious problems found with the management of patients with post-operative shock and haemorrhage. Fluid and electrolyte balance was poorly managed, and case reviews revealed inadequate management of antepartum haemorrhage, ruptured uterus in labour, major post-partum haemorrhage, hypertensive crisis and newborn resuscitation. The Hospital lacked clear and current policies for such cases and lacked suitable staff training programs that addressed these situations.

Adult Special Care Unit

Women needing full intensive care were put at risk by being admitted to the Adult Special Care Unit because care was left to unsupervised junior doctors. The Unit had no specialist "intensivists" on its team and only one nurse on the Unit had intensive care training.

The Unit had a history of poor care coordination and inadequate supervision of junior doctors. Junior doctors lacked a designated supervisor and they, and non-specialist nurses, were often left to deal with highly complex, sometimes life-threatening situations. Clinical accountability was lacking, with no one doctor designated as "in charge" of a case.

Of the women who died in the Unit but were expected to live, a high proportion had radical gynaecological and bowel surgery. These were recognised high-risk cases requiring intensive care in the immediate post-operative period.

Documentation

Documentation was often incomplete, lacking important clinical information needed to support continuity of care. Of all cases reviewed, the care plan was inadequate or non-existent in 20 per cent of cases and important documentation was inadequate in 35 per cent of cases and missing in 15 per cent of cases.

The quality and completeness of documentation varied across the Hospital. Outcomes of discussions with senior staff were rarely noted. In most cases it was impossible to determine the extent of a consultant's involvement in decisions about care. Senior medical staff provided some of the worst examples of poor record keeping and it was rare for a consultant to document a plan or record care.

Most entries were illegible and most signatures were indecipherable. File notes were disjointed, incomplete and disorganised. Pre-operative assessment was usually absent and many notes were sketchy and difficult to understand. Private physicians generally failed to record antenatal care as a reference for the Hospital clinicians.

Clinical errors

The cases reviewed included complex cases known to be at increased risk of clinical errors. Of the 372 high-risk obstetric cases reviewed, errors were common, and the most frequent

were "failure to recognise a serious and unstable condition" and "inappropriate omissions". Of the cases reviewed:

- one or more clinical errors occurred in 47 per cent of cases;
- 50 per cent of these were very serious;
- junior residents made errors in 76 per cent of high-risk cases;
- junior registrars made errors in 65 per cent of high-risk cases;
- midwives made errors in 60 per cent of high risk cases;
- levels 5 and 6 registrars made errors in 34 per cent of high risk cases; and
- consultants made errors in 28 per cent of high-risk cases.

A high proportion of errors were rated as very serious, and for all obstetric and gynaecology cases reviewed:

- more obstetrics case errors occurred outside business hours when there were fewer staff and less supervision for junior doctors;
- obstetrics case errors occurring outside business hours were often rated as very serious;
- obstetrics case errors were more common during labour and delivery;
- gynaecological case errors were more common post-operatively;
- common contributing factors were poor care coordination, delayed care and unsupervised junior staff; and
- non-existent or inadequate policy was a more prominent contributing factor in gynaecology cases.

Refer to Appendix 4 for a summary of findings from the clinical file review.

Comparing performance

The Inquiry established a consortium to compare the Hospital's obstetric, neonatal and gynaecological practices and performance with those of 13 tertiary-referral hospitals in New South Wales, Queensland and South Australia using routinely collected perinatal, hospital-morbidity and neonatal data. In summary, the Consortium:

- supplied detailed specifications of the items required;
- specified the preferred source databases;
- collected and examined 37 clinical information items;
- focused on statistically significant differences; and
- defined statistical significance as a difference of at least three standard errors.

The Consortium acknowledged that the Hospital treated a higher proportion of the most difficult cases than the other hospitals and that some items were primarily for administrative purposes. Other limitations included:

- insufficient detail for some items making it impossible to explore differences;
- incomplete or unreliable data for some items;
- inconsistent data collection and coding; and
- limited capacity to adjust for known and likely confounding variables.

The Consortium emphasised that the results should be considered in light of these factors, but despite limitations, the findings were sufficiently valid to identify major differences among hospitals. Appendix 3 summarises the results.

The Consortium recommended that the Hospital further investigate its:

- high rate of stillbirths;
- high rate of obstetric interventions;
- relatively large number of hysterectomies following post-partum haemorrhage;
- maternal deaths;
- deaths following gynaecological procedures; and
- high proportion of women transferred to the Adult Special Care Unit during admissions for laparoscopic procedures and hysterectomy.

The Consortium also recommended that the Hospital:

- improves the quality and completeness of data collected at the Hospital, particularly morbidity data;
- maintains obstetric, perinatal and gynaecological services outcome data and surveillance for:
  - demographic and clinical characteristics of patients
  - details of patient referrals
  - details of service delivery; and
- ensure surveillance is sufficiently comprehensive to pinpoint service-delivery problems.

3.2 Clinical policies and guidelines

Policy and guideline development, deployment, compliance monitoring and review were lacking during the review period. Clearly some individuals made a concerted effort to improve policies and guidelines, however the Hospital lacked an effective organisation-wide approach to these activities. Over many years, the following problems persisted:

- ad hoc, untimely and infrequent development and review processes;
- lack of a person or committee responsible for managing the processes;
- delayed or non-existent approval of revised or new policies and guidelines;
- lack of commitment to a multidisciplinary involvement;
- retained obsolete policies contrary to best available evidence;
- inadequate involvement of patients and families in policy and guideline development;
- inadequate consultation with staff about policy and guideline changes;
- inadequate distribution and deployment of policies and guidelines;
- unclear distinction between mandatory and discretionary policies and guidelines;
- inconsistent terminology;
- unclear lines of authority for policy and procedure review or deviation;
- lack of a strategy to monitor and ensure compliance;
- examples of ongoing non-compliance for many years; and
- particular issues with sessional consultants' compliance with policies and guidelines.

Senior doctors were sometimes reluctant to involve themselves in policy matters due to the time required to do this work. Junior doctors or midwives and nurses tended to work on these matters. Achieving a consensus often appeared to take priority over the best available evidence. However consensus was seldom reached, so indecision remained, resulting in outdated policies and practices.

The following are some examples of problems with policies and guidelines.

Vitamin K Administration Protocol

It took the Hospital four years to amend the Vitamin K Administration Protocol after an incident with Vitamin K administration in October 1997. A baby received two Vitamin K doses in the birthing area. Several email exchanges about the incident failed to result in action to address the problem. In April 1999, more email exchanges focused on a reputable interstate position statement on Vitamin K advising against its administration in a birthing area. Again the email discussions failed to result in action. More email discussions followed and a new Vitamin K protocol was eventually finalised in May 2001.

Ectopic pregnancy

The poor management of patients with ectopic pregnancies was identified as an ongoing problem in January 1998, however the Hospital remained without a policy at the end of 2000. In 1998 a patient's ectopic pregnancy was missed in diagnosis. The current evidence suggested that the preferred method of managing ectopic pregnancies was by laparoscopic procedure but the Hospital continued to perform laparotomies rather than laparoscopy for ectopic pregnancy. The incident and the evidence generated much discussion, but the discussion failed to effect change. The issue was considered by some to be too complex to overcome.

Bladder care policy

The Bladder Care Policy took 24 months to formulate. The final document provided no evidence of literature review or clinical trials as the basis for its development. Most of the development time was spent trying to achieve consensus.

Cord blood Rh testing procedure

There were problems with this procedure from September 1997 to July 1999. It was introduced as a new routine test, however doctors often did not sign the form. The Hospital's Pathology Service estimated the Obstetrics Service missed approximately 20 per cent of Rh negative women. Audit results indicated that at least 63 Rh-negative women were missed in 18 months. Eventually midwives were given authority to sign the form.

Residents signing consent forms

Hospital policy stated that a senior doctor must sign the consent forms for major surgery, however junior doctors were signing consent forms for caesarean sections. Evidence suggested that for at least two years, residents had little option but to sign consent forms for major surgery.

Review of selected policies and guidelines

The Inquiry commissioned four expert consultants to review several Hospital policies and guidelines:

- *Clinical Guidelines* (1998);
- *Junior Medical Staff Manual* (1998);
- *Guidelines for Midwifery Practice Obstetric Wards* (1999);
- *Emergency Centre Manual* (1998);
- *Protocol for Fetal Heart Monitoring* (1996); and
- *Protocol for Perineal Suturing* (date omitted).

The consultants identified the following deficiencies:

- no reference to best available evidence and insufficient referencing;
- brevity and incomplete coverage of the topic;
- no development or review date and no author(s) listed;
- insufficient guidance on when to refer a case to a more senior clinician;
- inadequate delineation and description of the responsibilities of clinical staff;
- no minimum skill level specified;
- inconsistencies between the manuals;
- invitations to staff to modify the guidelines; and
- irregular and infrequent document updating.

3.3 Incident reporting and management

There were significant problems with incident and adverse event reporting and follow-up from 1990–2000. Management of complaints and potential medical negligence cases was also poor during this time. Over many years, the following problems persisted:

- lack of a clear, current policy on reporting and responding to incidents and adverse events;
- lack of a system to report, review and respond to incidents and adverse events;
- lack of reports for, and follow-up to, serious incidents and adverse events;
- lack of accountability on the part of senior clinicians for identifying, reporting and responding to adverse events;
- lack of information, support and follow-up for patients and families experiencing adverse events;
- sub-standard management of complaints and poor treatment of complainants and their families; and
- medical mismanagement of cases resulting in serious adverse events and death.

Hospital policy, staff attitudes and opinions

The Hospital defined an incident as "any event or circumstance which could have caused, or did cause, harm, suffering or loss to a patient or visitor". Two Hospital documents referred to the requirements for incident reporting — a policy on accident and incident reporting and an accident/incident form were in place throughout much of the review period. These documents applied to all incidents including "near misses" and required staff to report all incidents immediately, followed by a written report to the divisional director within 24 hours of the incident occurring.

Many incidents were reported orally and never documented. It was difficult to determine who reported an incident, how it was reported, to whom it was reported, and if any action was taken following the incident. The reporting process changed little over the 11 years and a "culture of blame" prevailed during this time. Staff generally agreed that:

- accident/incident forms were for reporting incidents about intravenous drug use and patient falls, rather than adverse patient outcomes or near-misses;
- incident reporting was voluntary;
- adverse events were reported "only if the staff member feels strongly enough about it"; and
- the incident reporting process applied exclusively to midwives and nurses.

When asked about reporting incidents and adverse events, senior doctors raised concerns about:

- the time and paperwork involved;
- fear of error, blame and litigation;
- their discomfort with reporting serious incidents and being accountable for actions and decisions;
- suspicions that midwives reported incidents to cause discomfort for doctors; and
- the potentially adverse effect a formal incident reporting system would have on communication and teamwork.

Under-reporting

In the absence of a functioning Hospital system, midwives established their own procedures to report adverse events in the form of a paper-based register. The register was an unofficial and incomplete record identifying 47 incidents for the period July 1998 to June 2000. Of these, the Inquiry reviewed 30 in detail, and 19 involved moderately unsafe or very unsafe practices.

Of the 605 clinical files reviewed, 71 cases with moderately unsafe or very unsafe practices occurred in the Obstetrics Clinical Care Unit from July 1998 to June 2000. Of these, only 19 were recorded in the register. Staff frequently used email to report obstetric incidents.

Staff in the Gynaecology Clinical Care Unit relied on word of mouth rather than email to report incidents. The Unit had no register of incidents and less documentary evidence of incident reporting. When asked about the rate of incident reporting, senior clinicians were confident that all incidents were reported.

In 1999, problems with incident reporting were frequently discussed. Staff were confused about who was clinically accountable for reporting and responding to incidents and adverse events. This confusion resulted in the Director of Medical Services often not receiving incident reports or only receiving them if they were associated with potential litigation. Hospital Counsel became aware of under-reporting of serious incidents in 1999 and reported concerns to the recently appointed Chief Executive about the lack of:

- incident reporting policy, reported incidents and adverse events;
- lack of staff understanding of the requirements for incident reporting; and
- a proper register of reported incidents.

Potential medical negligence claims

In 1999, evidence pointed to clinical mismanagement of at least five cases, with three resulting in babies dying and two being brain damaged, and potentially multi-million dollar claims against the Hospital. Staff failed to report many serious incidents, including incidents resulting in medical negligence claims against the Hospital. On some occasions, the first notice of an adverse event was a lawyer's letter or other correspondence from outside the Hospital.

Chief Executive's response

The Chief Executive responded by:

- directing that all incidents be reported to him;
- directing that the Hospital's legal cases be handled by Hospital Counsel;
- commissioning an independent audit by Ernst and Young of the Hospital's incident reporting processes; and

- reporting the situation to Metropolitan Health Service Board.

The Ernst and Young Report found:

- no definition of what constitutes a clinical incident;
- no current procedure requiring the reporting of clinical incidents; and
- no practical method of identifying clinical incidents hidden in the case files.

Problems with the Quality Improvement Act

The Western Australian *Health Services (Quality Improvement) Act 1994* provides for the protection of a quality improvement committee from disclosing its proceedings if the committee is registered under the Act and if it consistently and continuously meets the requirements of the Act.

By the end of 2000, the Hospital had not registered any of its committees under the Act.

Senior doctors said they failed to document incidents and adverse events because they believed the requirements of the Act were impractical. They were concerned that the Act restricted the distribution of minutes of a registered committee to other committees, and that members were restricted from discussing the content of a meeting in other venues. This being the case, an incident might be raised in any of several committees, requiring the Hospital to register a large number of committees to protect such discussion from disclosure – this was considered unworkable.

The Inquiry found available evidence indicated that perceived problems with the Act were overstated. For example, the prohibitions on disclosure did not apply to reports to a "relevant governing body" and the Hospital had the option of reducing the number of committees reviewing incidents, thereby limiting the number requiring registration under the Act.

Management of medical negligence cases

There was evidence of significant delays from the time an incident occurred to lodging a report. These delays raised doubts about the timeliness of preparing the report after the incident, and the report content and accuracy. In this regard, the Hospital failed to meet public expectations about investigating serious complaints, and had little capacity to learn from failures.

Following are some examples of mishandled potential medical negligence cases examined by Hospital Counsel in 2000.

Perforated artery

A woman's artery was perforated during surgery and she required corrective surgery. Staff involved failed to report the incident. Four months later Hospital Counsel received a Freedom of Information application from the patient's lawyers. Until then, Counsel was unaware the incident had occurred. Clinicians involved in the incident failed to complete witness statements at the time of the incident or soon after, and management failed to investigate the incident and notify "RiskCover".

Complicated delivery and ongoing problems

A woman was admitted in labour. She had a history of permanent back injury from a serious car accident and attended an anaesthetic pain clinic twice prior to delivery to ensure adequate and appropriate pain relief in labour. Staff delayed inserting the epidural and once inserted, it failed to provide adequate pain relief. Her baby was delivered by vacuum extraction, followed by manual removal of retained placenta. The woman experienced a massive post-partum haemorrhage, she and her baby were in shock and required resuscitation. The woman was admitted to intensive care and the baby was admitted to the Special Care Nursery.

The woman was discharged against her wishes and re-admitted two days later with endometritis and "retained products". She remained in the Hospital for five days on intravenous antibiotics and suffered ongoing pelvic pain, dyspareunia and pelvic infection following the birth.

One month after the birth, the woman formally complained to the Hospital about her treatment. At the time of the complaint, nurses completed witness statements and forwarded them to the Nursing Director. Two months later the woman met with three staff members to discuss her issues. A month after this meeting, the woman wrote to the Chief Executive stating that her complaint remained unresolved, and she had yet to receive copies of the witness statements as promised at the meeting.

Five months after this letter, the Hospital received notice of an impending claim against the Hospital from the woman's solicitors and two months after that notice (ten months since the incident) the doctors involved in the case forwarded their witness statements to their Director.

Meetings to review and respond to incidents and adverse events

Some meetings were held to consider incidents and adverse events, however reportable incidents, definitions and procedures for incident reporting and lines of responsibility for incident reporting remained unclear. The meetings also failed to address:

- the strong culture of blame;
- unclear accountability for reporting and responding to incidents and adverse events;
- unacceptable delays in response or lack of response to incidents and adverse events;
- doctors' resistance to the involvement of nurses and midwives in incident review; and
- ineffective or absent measures to ensure changes occurred and were communicated to clinicians.

Under the direction of the recently appointed Chief Executive, the Hospital introduced several measures to improve incident reporting in 2000. Considerably more work was required to address long-standing problems in this area.

3.4 Reporting deaths to the Coroner

The Inquiry found evidence that the Hospital failed to report several reportable deaths to the Coroner during the review period. Reportable deaths included those that appeared to have been unexpected, unnatural or violent, or those occurring during an anaesthetic. Of the 605 cases reviewed, eight reportable deaths were found and sent by the Inquiry to the Coroner. Of these, the care of the woman and baby was graded as very unsafe in six cases and as moderately unsafe in one case. The Coroner advised that none of these deaths had been reported previously.

Committees established under the Health Act

The Western Australian Government established the Maternal Mortality and the Perinatal and Infant Mortality Committees under the *Health Act 1911* to examine maternal and perinatal deaths. Both committees functioned ineffectively over the 11 years covered by the Inquiry, and there appeared to be significant flaws in legislation and compliance associated with reporting and investigating maternal, perinatal and infant deaths.

Various provisions of the Health Act govern reporting of perinatal and infant deaths, and many of these are inconsistent, imposing multiple reporting requirements on hospitals. For example, a single stillbirth may require six reports regulated by five separate statutory provisions.

Many aspects of the legislation governing the reporting and investigation of maternal, perinatal and infant deaths appear to have been ignored or overlooked by the Committees in the 11 years, including provisions with substantial penalties for non-compliance.

Significant definitional differences existed between the Committees and the Act, further compounding the problems associated with reporting these deaths. The Executive Director for Public Health failed to comply with statutory obligations for issuing an investigator a direction to complete an investigation within a set timeframe. The result was delays of up to five years for investigations of deaths.

While investigating the Hospital's maternal deaths, the Maternal Mortality Committee delayed investigations for approximately five years for three of the four identified deaths. The fourth investigation was delayed over two years. The Committee produced one two-page report for the years 1989 to 1991.

Of the 2,476 identified perinatal and infant deaths in Western Australia from 1990–1999, only 150 were investigated and reviewed by the Perinatal and Infant Mortality Committee. The Committee rarely met in the 11 years and there was evidence that it acted beyond its powers by excluding categories of deaths from investigation and review. The Committee also failed to reveal the "de-identified" substance of comments to anyone beyond the people directly involved in managing particular cases. Before 1991, the Committee produced 10 reports and published 17 educational papers and since then, has failed to produce any reports or papers.

3.5 Staff and staffing issues

The Hospital had significant long-term problems with consultant cover, accountability for clinical care, supervision and training of junior doctors, credentialling and provision of admitting privileges. There was also evidence of serious problems with performance management as well as consultant appointment and re-appointment processes. Over many years, the following problems persisted:

- deficiencies in consultant cover and chronic under-staffing;
- lack of succession planning;
- poorly defined clinical responsibility and accountability;
- inadequate supervision of junior doctors, particularly when managing complex cases;
- inadequate orientation and training programs for junior doctors;
- lack of a formal and effective credentialling program for doctors;
- inadequate arrangements for approving admitting rights for visiting doctors;
- inadequate recruitment, appointment and re-appointment procedures for senior doctors; and
- lack of an effective performance management program.

Consultant cover

There was evidence of many discussions over many years about the problems with consultant cover, particularly for high-risk cases. Factors compounding the problem included:

- small consultant numbers and inadequate consultant use;
- budget constraints and recruitment difficulties;
- the mix of full-time and sessional consultants; and
- the decreasing profile of the University Department.

However, little was done to change the situation until the arrival of the new Chief Executive in 1999 and even then there were delays. Clinical leaders failed to provide a clear quantitative

evaluation of present and future consultant cover needs for their area of responsibility, despite repeated requests from the Chief Executive. Joint input from the Hospital Executive and the Directorates to determine required cover was a difficult and drawn-out process. The Chief Executive finally received a list of a unit's medical staffing requirements after eight months and repeated requests. There was also a significant delay in securing sufficient cover for the Delivery Suite, with the role of Delivery Suite Consultant lapsing for approximately three years from mid-1996.

Clinical accountability

There were serious and ongoing problems with clinical accountability over the 11 years. Staff spent much time discussing the issue, to the point that it was described as a "running sore".

Consultants identified as responsible for clinical care were no more than nominally responsible. There were numerous discussions about which doctor's name should appear on a patient's bed card, but the issue was never satisfactorily resolved. During all this, junior doctors faced with difficult clinical cases hesitated and often did not call a consultant for advice for fear of being labelled as unable to cope. Despite Hospital policy requiring junior doctors to seek senior clinician advice when necessary, the culture was unsupportive of this approach, resulting in delayed or deficient care.

There were repeated problems concerning consultant lines of responsibility in the Labour Ward. The problems appeared to be due to clinicians repeatedly failing to comply with policy, and clinical managers failing to enforce compliance. The problem was debated for more than two years, and despite solutions being offered, remained unresolved.

Junior doctors' supervision

Hospital leaders, managers and senior clinicians were aware that since the early 1990s, supervision of junior doctors was inadequate, however they did not act on these concerns until early 2000.

More than two-thirds of the Hospital's caseload occurred after business hours when junior doctors were on duty. Case complexity after business hours was consistent with that in business hours. Junior doctors received little or no supervision by the consultants, who were considered the "last link in the chain of command" and were only rostered on duty in business hours.

Hospital policy was to have a senior doctor on-call rather than on-site after hours, so there was no on-site 24-hour coverage by a senior doctor. Junior doctors were expected to know when they needed supervision rather than senior doctors determining when a junior was sufficiently competent to provide unsupervised care. Junior doctors were reluctant to call senior doctors and there was evidence that senior doctors sometimes failed to respond to junior doctors' calls for assistance. Midwives played an unofficial and instrumental role in training junior doctors.

Despite the improvements to junior doctors' supervision made in 1999, further changes were needed to maintain safe levels of supervision.

Credentialling

The Hospital defined credentialling as the process by which management "determined the clinical privileges that … allow a medical practitioner to practice in the Hospital". The Hospital lacked a formal credentialling process until June 2000, yet the subject was raised as a serious issue in 1991.

When asked how junior doctors' performance was assessed, a senior doctor explained, "we just have a feel for these people". The Australian Council on Health Care Standards

recommended the Hospital review its credentialling process during the 1991 and 1994 accreditation process. There was no evidence that these recommendations were acted on.

With the advent of new technologies (endoscopic procedures) in 1995, the Director of the Gynaecology Clinical Care Unit advised Unit staff that a credentialling status list would be developed. However there was no evidence that this list was published until 1997, nor was it regularly updated or widely circulated.

There was no evidence of a credentialling committee meeting from 1997 to 1999 and in 1999 Gynaecology and Operating Suite staff were still relying on the original credentialling list. The credentialling committee was finally established in February 2000, however the credentialling process was yet to be established. There were many examples of a director verbally granting credentialling status over many years with little basis. Operating Suite and booking staff often received no notification of these arrangements.

There was no evidence of a proper credentialling program in 2000 at the time the Child and Glover report was handed down, however the terms of reference of the Credentialling Committee were endorsed in June 2000 and the Committee met in August 2000. The Committee adopted a formal credentialling policy and a credentialling application form was accepted at its September meeting. The Committee did not meet again until March 2001.

It is important to note that the Committee omitted from its terms of reference, any reference to credentialling of registrars or junior medical staff by June 2000. Consultants judged registrars' competency without any clearly defined criteria for this process.

Admitting privileges

Admitting privileges for associate consultants was another area of confusion over the 11 years. The policy issued in June 2000 on this matter remained unchanged from the 1994 version, and required a small committee to review associate consultant admitting privileges annually. However, there was no evidence of reviews or any accreditation of general practitioner obstetricians.

Orientation and training programs

The Hospital lacked a needs-based orientation program for junior doctors. Focusing primarily on administrative aspects of work, the Hospital's program failed to train doctors in the clinical skills required to give good, safe care immediately. Nor did the program provide any support for a junior doctor starting in a new clinical area.

The Hospital also lacked an orientation program for registrars, and the needs of junior doctors from overseas were overlooked despite there being evidence that taking their knowledge for granted led to mishaps. Despite staff raising many suggestions to change the orientation program, it remained the same over the 11 years.

Following are some examples of deficient or non-existent training programs.

Post-graduate medical program

This program was a "haphazard collection of tutorials and clinical meetings" without formal planning or an educational framework. The program failed to identify or address post-graduate learning needs in any organised way and failed to consider the residents' and registrars' rosters. As a result, the program was poorly attended because residents and registrars were not given time off from their clinical responsibilities to attend. Senior clinicians attributed poor attendance to lack of commitment on the part of the junior doctors.

The Hospital was an accredited Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) training hospital, and as such, was required to meet

RANZCOG standards. The 1991 RANZCOG accreditation report identified "significant deficiencies" including inadequate supervision of junior doctors by consultants outside business hours, an inadequate ongoing tutorial program, and inadequate program scheduling. The report arising from the 1993 RANZCOG review visit indicated that "deficiencies had been remedied", however the Inquiry found that many years later, these deficiencies remained. RANZCOG did not assess the Hospital again during the review period.

Gynaecological surgical training

Doctors experienced less gynaecological surgical training opportunities due to:

- shortage of available gynaecological surgery;
- cancellation of elective surgery due to budget cuts; and
- more patients using other hospitals for gynaecological care.

Consultants rather than registrars received supervision and training in laparoscopic surgery in the mid to late 1990s. In October 2000 the Hospital introduced a compulsory training program in endoscopic surgery, however the Hospital failed to establish a formal ongoing surgical training program.

Cardiotocography (CTG) interpretation

Doctors and midwives used CTG to monitor a fetal heart. Senior doctors at the Hospital recognised the importance of training clinicians in CTG as early as 1989. Concerns about the skills of residents and registrars interpreting CTGs were widely discussed over many years. The Hospital's 1990 *Fetal Monitoring Service Manual* directed that:

- all new staff must be competent in CTG;
- training courses must be conducted every three to four months; and
- competency must be verified by written exams.

However, practice was inconsistent with written policy. Recommendations to implement compulsory CTG training courses for registrars and residents were not acted on. The Hospital lacked a system to ensure that registrars and residents attended formal training, were trained before working in the Labour Ward, and had their competency checked before they assessed and managed a patient using CTG.

There were inconsistent approaches to training midwives and doctors in CTG interpretation. Junior doctors' training was irregular and infrequent, often resulting in midwives interpreting CTGs in the Labour Ward. The midwives, rather than the registrars, were often the clinicians teaching the residents how to interpret a CTG trace in the Labour Ward. No one person had responsibility for coordinating CTG training for junior doctors. Midwives had a well-organised and regular CTG training program. At the end of 2000, training inconsistencies in CTG interpretation remained.

Perineal suturing

Similar problems existed with junior doctors' lack of skills in perineal suturing. The Hospital failed to implement a suitable education program to address this issue. No one person was responsible for ensuring doctors were trained in the procedure and the Hospital lacked a system to ensure doctors were competent to perform the procedure.

Both midwives and doctors did perineal repairs and midwives had a well-developed training program including a system for supervision and competency assessment. Doctors had no formal training program and the training they received was ad hoc and informal with no skills assessment.

Junior doctors were expected to call for supervision if they felt they needed it, however there were examples of incompetent practice in perineal suturing involving residents and registrars. The Hospital held perineal-suturing workshops for doctors in 1997 and 2001. A midwife conducted the workshops and attendance was voluntary.

Employment issues

There were significant deficiencies with the appointment of the medical director of a directorate and senior consultants. With its devolved management structure, the Hospital relied heavily on the clinical directors' ability and willingness to manage the clinical care unit operation, and the medical director's position description reflected the importance of these management skills. However, the 1996 appointment process for the Medical Director, Obstetrics Clinical Care Unit, failed to consider the management skills of the applicants. The Hospital restricted advertising to internal applicants.

The Inquiry was able to obtain documentation relating to only 10 consultant appointments occurring between August 1997 and September 2000. All other documentation was destroyed by the Hospital. One of these appointments was a sessional consultant anaesthetist who was appointed:

- without submitting a formal application;
- without being interviewed; and
- without a response from either of his/her two referees.

Five months after the anaesthetist started work at the Hospital, the doctor's clinical judgement and skills were questioned on several occasions regarding adverse patient outcomes. The anaesthetist's appointment was terminated a month later.

Deficiencies in the other nine cases included:

- incomplete documentation;
- failure to contact referees;
- failure to use a consistent selection process; and
- lack of input from a medical administrator or a human resources specialist.

There were also problems with consultant re-appointment. Under the 1987 Award, sessional consultants should have been appointed for five years, so the Hospital sessional consultants should have been considered for re-appointment in 1992. However, the first recorded re-appointment of consultants occurred in March 1997. The re-appointment process was superficial and the Electoral Committee's performance was sub-standard. The Committee regarded itself as having responsibility for the final step in appointing and re-appointing consultants, however this was the role and responsibility of the Chief Executive. The long history of Committee appointment recommendations being automatically "rubber stamped" ceased in 1999 when the new Chief Executive was appointed.

Performance management

There was little evidence of management or senior doctors participating in performance management, and the Hospital had no formal performance management program until 1997. There was evidence that this formal program was unsuitable for midwives and as such, they established their own informal performance management process.

Consultant performance appraisals were rarely done, although Hospital policy required them to occur every three years via a committee. Registrars' performance appraisals were conducted by the Hospital until 1996, and then by RANZCOG, which failed to give the Hospital access to the reviews. Residents' performance appraisals were conducted regularly

from 1990 to 2000. However, some appraisal forms were completed after a resident left an area, and the registrars assessing the residents may have had insufficient experience to appraise performance.

3.6 Involving women and their families

The Inquiry considered the perceptions of women and their families regarding their involvement in treatment and their interactions with staff. Methods used included secondary analysis of 605 clinical file reviews and 68 interviews of women who attended the Hospital. The clinical files reviewed were high-risk obstetric and gynaecological cases, and the interviews were with former patients who forwarded submissions in response to the Inquiry's newspaper advertisements.

The perceptions of many women and their families were that they received little or no information about their treatment options, risks or errors of care. During the review period, women and their families reported:

- inadequate information about their treatment and little or no involvement in decisions about care;
- inadequate or no information about things that went wrong and what was being done about the situation;
- poor treatment and disrespect when making a complaint;
- lack of support when they experienced poor outcomes or adverse events; and
- poor or no communication from Hospital staff during potential medical negligence case reviews.

Following are some examples of the perceptions of women and their families about poor treatment and poor communication by staff.

Failure to provide an adequate explanation of poor outcome

A woman believed she received incomplete and inaccurate information about the reasons why her baby died and felt blamed for the complications that occurred.

Failure to include a woman and her partner in decisions

A private patient wanted to be treated as a public patient, but was subsequently given private status, which resulted in expenses she could not afford to pay.

A woman alleged that a doctor refused to perform a caesarean section when the woman felt her life was in danger. The caesarean was eventually done but the woman had to be managed in intensive care.

Parents stated that staff failed to communicate with them for some hours after their baby became unexpectedly ill.

Lack of sensitivity, respect, dignity and support

A woman described the difficulty she experienced with her very unsettled baby post partum and postnatal depression — she said she felt misunderstood and unsupported.

Grieving parents stated they were put in an old ward alone and no one came to inform or support them for several hours.

Customer complaints policy

This was one of the few examples of Hospital policy that dealt comprehensively and clearly with the subject. However, problems with the complaints management process included:

- no clear advice given to patients and families about the complaints process;

- lack of respect among hospital staff for complainants;
- poor coordination of response to complaints;
- insufficient information to patients and families about what went wrong and what was being done to rectify the situation;
- no single filing or coordination system;
- complainants receiving several letters rather than one; and
- complaints generally not considered improvement opportunities.

3.7 Quality improvement

There was no evidence of an effective Hospital-wide program to monitor and improve the safety and quality of care during the review period. Over many years, the Hospital lacked:

- effective systems to monitor key aspects of care and to respond to poor performance;
- appropriate responses to recommendations arising from accreditation processes;
- any evaluation of the effectiveness of department-level quality improvement activities; and
- any evidence that the devolved management structure supported ongoing improvements in the safety and quality of care.

The Hospital was accredited by the Australian Council on Healthcare Standards, however the standards used to assess its performance primarily reflected hospital structures and processes rather than the quality of care. Assessment of quality of care was generally left to Hospital staff through internal quality improvement programs. There was evidence that accreditation was insufficient to provide assurance of quality at the Hospital.

Evidence of quality assurance activity from 1990–1993 was patchy. Some departments conducted activities, but the extent and effectiveness of these activities was unclear. In late 1993, staff developed new documentation on the nature of and plans for Hospital-wide quality improvement. However, the processes and systems to implement quality improvement remained substantially unaltered.

Management devolved responsibility for identifying and addressing problems in patient care and safety to the departments. There was no evidence that the directorates established effective quality monitoring and improvement systems, and the Executive and Board of Management played no part in this process.

The quality improvement committee structure was established, but quality activities and outcomes were seldom reported beyond department level. The Inquiry found no evidence of clinical quality activities being considered and coordinated by the Executive or the Board and no evidence of leadership to ensure safe and appropriate patient care.

Identified problems

The Chief Executive reported the following deficiencies to the Metropolitan Health Service Board in 2000:

- failure to implement processes and systems to identify problems in patient care and safety, or to measure the standard of patient care;
- failure to coordinate and oversee the management of the clinical quality program;
- failure to conduct clinical audits of patient care and safety;
- no continuous or ongoing quality improvement, but rather ad hoc quality activities;
- failure to focus on the outcomes of quality activities, or to follow-up and implement the results of those outcomes;

- lack of coordination beyond department level of the clinical quality program; and
- varying levels of support from staff for quality improvement, and particularly little support from the medical staff.

3.8 Other leadership and management issues

Management failed to address problems with the devolved management structure, and failed to resolve long-standing clinical and management problems affecting the safety and quality of care.

The 1995 Business Plan to change to devolved management structure involved establishing "Clinical Directorates Product Line Management". The primary goal was to devolve responsibility and authority to clinical staff to support better patient care. This structural change failed to resolve and in some cases, exacerbated:

- unclear accountability and responsibility for the quality and management of clinical care;
- unclear lines of authority and responsibility for compliance with Hospital policy;
- ill-defined or absent systems for care coordination, safety and quality; and
- lack of decision-making on important and long-standing patient and staff welfare issues.

The management structure was meant to devolve responsibility and authority to clinical staff to support clinical decisions and improve communication for more integrated quality patient care. But the structure had no senior management involvement to strengthen and support the devolution and clinical service decisions, and no one made decisions or changes to address problems. Decisions were put in the "too hard" basket. Problems were ignored or denied, or the people raising an issue were criticised. Long-standing matters were referred to one or more committees, generating a lot of correspondence with little or no subsequent action or problem resolution.

In some cases, the reason given for failing to change outdated policies or to compare performance with similar services, was that the Hospital was "a unique, world-class service" and it was assumed that clinical service compared favourably with other organisations, although this was never tested. There was also little effort on the Hospital's part to improve its relationship with the University. A strong, effective relationship had the potential to improve the Hospital's evidence base for obstetric and gynaecological practice.

A "sink or swim" mentality prevailed during the review period and junior doctors were expected to manage complex cases without supervision, and were expected to know when they needed supervision. There was no rigorous process to determine when junior doctors were competent to provide care, junior doctors were reluctant to seek help from senior doctors and senior doctors were unresponsive when asked to help.

4 Action to address problems

This section provides some examples of changes and improvements made since the Inquiry. The previous and current Chief Executives have led the considerable effort made by many Hospital staff to respond to the Inquiry recommendations.

Along with specific process and policy changes, particular effort has gone into improving staff morale, managing adverse media coverage and establishing a media strategy, supporting patients and their families and reintroducing a range of management strategies. Of particular note is the establishment of the Departmental Steering Committee chaired by the Deputy Director General of the Health Department of Western Australia, which meets monthly to oversee the changes and improvements arising from the Inquiry recommendations. The Minister reports quarterly to Parliament on the implementation process. Following are some examples of improvements:

Supervision of junior doctors

In early 2000, management improved supervision of junior doctors, with level 1 registrars being supervised by a senior registrar when a junior is rostered to work after business hours. Revised Hospital policy also requires a level 1 registrar working in the Labour Ward to be supervised by a senior registrar on-site at all times.

After-hours consultant cover

In September 2000, management approved the "On-call Agreement", requiring the on-call consultant to do three clinical rounds during the weekdays and a late night round on weekends in the Delivery Suite and Adult Special Care Unit. In 2000, there was still no requirement for 24-hour on-site senior medical staff presence.

Incident reporting

The Hospital established an incident reporting committee in 1999, a single incident reporting system is in place, and more incidents have been reported since then. The Inquiry considered these to be rudimentary changes, with more work needed to create a positive work environment where errors are transparent, and people feel comfortable to discuss and respond to incidents as improvement opportunities.

Other changes and improvements

These include:

- revising and updating clinical guidelines for doctors in the clinical handbook;
- updating and referencing the midwifery policy and procedure manuals;
- developing a list of sentinel events and indicators to identify high-risk cases;
- reviewing and revising the doctors' orientation program;
- reviewing all doctors' position descriptions;
- reviewing the terms of reference of key executive committees;
- receiving approval from the Health Department of Western Australia to purchase new centralised fetal monitoring equipment;
- making good progress with medical and nursing performance appraisals;
- establishing quality plans;
- rejoining the Australian Council on Healthcare Standards and undergoing full survey in March 2002;

- establishing the Credentialling Committee and defined credentialling criteria; and
- appointing four senior academic obstetrics and gynaecology doctors.

Appendix 6 summarises current Acting Chief Executive Dr William Beresford's October 2001 presentation to the Ministerial Inquiry into the Obstetric and Gynaecological Services at King Edward Memorial Hospital.

5 King Edward and Bristol — comparisons

This section outlines the Bristol (UK) case (Swan 1997a; Swan 1997b; Kennedy et al 2001; UK Department of Health 2002) and compares the main issues with those arising from the King Edward Inquiry.

The Bristol Case involved heart surgery on babies in the Bristol Royal Infirmary from 1988 to 1994. Dr Steve Bolsin, an anaesthetist now working at Geelong Hospital, was employed at Bristol as a cardiac surgery anaesthetist. He was concerned that the number of deaths following arterial switch operations (a procedure performed on babies with congenital heart abnormalities) and the time taken for the procedure were considerably higher than the national average. He repeatedly raised his concerns with the surgeons, colleagues and the chief executive to no avail. He also contacted the President of the Royal College of Surgeons in the UK who subsequently informed the UK Department of Health. Two surgeons and the chief executive faced charges of serious misconduct. The parents of children who died in this case, feel they received misleading information about the risks associated with the procedure.

Both the Bristol and the King Edward case arose from "whistle-blowers" reporting serious problems rather than from established safety and quality monitoring systems. In Bristol's case the whistle-blower was an anaesthetist and in King Edward's case, it was the recently appointed Chief Executive. In both cases, either directly or indirectly, the department of health received information about management and clinical performance problems that had not been addressed over a significant period of time. Both cases revealed evidence of:

- a closed culture and environment unsupportive of openly disclosing errors and adverse events;
- failure of management to respond effectively to clinical problems raised by staff;
- non-existent or ineffective quality systems to monitor, report and respond to performance problems;
- non-existent or ineffective systems to identify, report and respond to errors and adverse events;
- poor communication with patients and families, particularly when things went wrong;
- poor management of complaints and potential medical negligence cases;
- inadequate training and credentialling to ensure clinicians were sufficiently skilled;
- inadequate state-level morbidity and mortality monitoring and review systems; and
- poor clinical and emotional outcomes for patients and families.

However there were differences in the Hospitals' response to the inquiries. Bristol welcomed an inquiry and actively supported the process. In contrast, King Edward tolerated the process and the Western Australian branch of the Australian Medical Association actively and publicly fought it (Media search: King Edward Inquiry). Media reviews (Media search: Bristol Inquiry) suggest Bristol actively engaged public interest and participation in the process. A website was established to inform the public on the Inquiry's proceedings and progress.

Both cases called for changes at government, board and management level to establish a culture of inquiry and open disclosure, and to introduce systems to monitor and improve the safety and quality of health care.

6 Regulations, governance and inquiries

This section deals with health system issues and the role and usefulness of health service inquiries. The Inquiry raised important governance issues about the roles and responsibilities of health departments, health service boards and chief executives in ensuring the safety and quality of health care services.

Roles of Health Departments, Boards of Management and Chief Executives

Under the 1998 Australian Health Care Agreement established between the Western Australian Government and the Commonwealth, the state received funding for five years from 1998 to improve health care safety and quality. However, there appeared to be no system-wide quality monitoring and improvement processes established during the review period that assured or improved the safety and quality of obstetrics and gynaecological services at the Hospital.

Three bodies governed the Hospital during the review period:

- the King Edward Memorial Hospital Board of Management until June 1994;
- the King Edward Memorial and Princess Margaret Hospitals Board of Management from July 1996 to June 1997; and
- the Metropolitan Health Services Board of Management from July 1997.

Under the *Hospitals and Health Services Act 1927*, the Boards were responsible for "the control, management and maintenance" of the Hospital, and this provision clearly included the provision of safe, appropriate care. *The Strategic Quality Plan Western Australia 1998/99–2002/3* identified the hospital Board of Management as responsible for implementing a program to improve the safety and quality of patient care.

However there was no evidence that any of the Boards during the review period, played an active role in establishing or monitoring a quality program. Although Hospital management and quality unit staff generated documents describing quality structures and plans, the Hospital lacked any organisation-wide, effective means of measuring, monitoring or reporting key aspects of its service, and there was no evidence to indicate services were providing safe, appropriate care.

The lack of safety and quality systems at state, board and hospital levels was evidenced by:

- an accreditation system that maintained hospital accreditation status despite a hospital failing to address recommendations relevant to the safety and quality of care
- no framework or standard requirements for inter-hospital comparative data analysis
- local credentialling systems that failed to ensure clinicians were adequately skilled
- no reliable incident or adverse event reporting systems and follow-up processes
- confusing and contradictory statutory requirements for mortality review and investigation, under-performing statutory mortality committees and long delays in review of deaths.

The appointment of the new Chief Executive in 1999 saw the first of any active involvement in safety and quality issues at this level. As the "whistle-blower", the Chief Executive advised the Metropolitan Health Service Board of significant problems at the Hospital and of actions taken in response to these problems. There was no functioning clinical governance committee to support his efforts by systematically reviewing and responding to safety and quality issues.

Role, structure and outcomes of health service inquiries

There appeared to be some contradiction between the role of the Inquiry and the final content of its report. The Inquiry's brief was to examine systems issues rather than the performance of individuals. However, throughout the report, individuals were named and individual behaviour and actions were recorded in detail. Readers could question the value of such material (particularly to the broader health care public) and its contribution to understanding and learning from systemic problems.

The Inquiry experienced statutory authority restrictions that hindered the efficiency and effectiveness of its work. Witnesses and counsel had insufficient statutory protection from personal liability under the Hospitals and Health Services Act and the Public Sector Management Act, and the Inquiry had insufficient power to refer serious matters to the relevant state or Commonwealth authority. The Inquiry also lacked assurance that information and evidence given to or obtained by the Inquiry would be protected from publication after the Inquiry was complete.

When an inquiry is necessary, it may be more appropriate and useful to the health care system, to give the inquiry the power and protection available under the Royal Commission Act.

Another consideration is the time and resources required to complete the Inquiry and its overall impact on the safety and quality of the health care system. The Inquiry occurred over 18 months and cost $7million, primarily to identify management and clinical problems at one hospital. Such resources could be channelled into establishing effective, routine safety and quality monitoring structures and processes across the health care system that support and enable the improvement of safety and quality of health care.

7 Conclusions

This section considers the main issues arising from the Inquiry and their implications for health care services.

The Inquiry found evidence of exemplary clinical and non-clinical care. There was also evidence of many serious problems with the Hospital's clinical and administrative practices, and evidence to suggest the Hospital should further investigate a range of obstetric and gynaecology clinical indicator results. Inadequate systems and lack of an effective response to important issues resulted in serious adverse events and poor clinical outcomes for women and their families.

The health care system at state, board and hospital levels needs safety and quality systems and processes that support the provision of safe and appropriate care. For system-wide safety and quality of care we need:

- strong, sustained leadership supporting a culture of open disclosure, transparency and effective response to performance problems
- a rigorous third party accreditation system that assures acceptable practice and performance standards
- practical and useful data collection systems for inter-hospital comparisons
- standardised credentialling systems that ensure clinicians have appropriate skills and training
- reliable and consistent incident and adverse event reporting systems and follow-up processes
- clear and tenable statutory requirements and systems for mortality reporting and investigation.

Governments, health service boards, health care leaders, managers and staff have the opportunity to consider key findings and lessons arising from the Inquiry, as the basis for identifying and responding to improvement opportunities.

Appendices

1 Recommendations — Summary

This summary has fewer recommendations listed than reported by the Inquiry because of differences in presentation style. In some cases, the summary lists several related recommendations as dot points under one heading rather than as separate recommendations.

Medical board referrals

1. Refer the doctors' conduct referred to in the confidential attachment to the Medical Board.

Inquiry establishment and conduct

2. Amend the Hospitals and Health Services Act and the Public Sector Management Act so that an inquiry under either Act assures:

- witnesses and counsel have the same protection as is available under the Royal Commission Act;
- those assisting in the inquiry have clear and adequate statutory protection from personal liability;
- confidential information and evidence given to or obtained by the inquiry is protected from publication and access after the inquiry is complete; and
- the inquiry has the power to:
  - refer any matter arising to the relevant State or Commonwealth authority to investigate or act on matters;
  - protect from publication, information given to it in confidence by a person not appearing as a witness.

Structure, role and management of King Edward Memorial Hospital

3. Evaluate and revise the devolved management structure.

4. Evaluate whether the Delivery Suite organisation supports timely and safe patient care.

Supervision and cover in the Delivery Suite

5. Introduce 24-hour on-site senior obstetric cover.

6. Establish clinical practice guidelines for acceptable progress of spontaneous or induced labour or attempted vaginal delivery after caesarean.

7. Give consultants responsibility for:

- reviewing clinical practice guideline variances;
- being present for all vaginal breech deliveries;
- reviewing all women with rare fetus presentations labour (eg brow); and
- when on-call, attending after a failed attempt to achieve instrumental vaginal delivery.

8. Make another senior doctor available in the Hospital if the Delivery Suite consultant or registrar is performing an emergency caesarean section.

9. Ensure the morning and evening ward rounds are attended by:

- the on-call consultant;
- an anaesthetist (or registrar);
- a neonatologist (or registrar);

- the Delivery Suite Midwife Coordinator; and
- the Delivery Suite registrar and resident.

Caesarean sections

10. To better manage emergency caesarean sections:

- give general or spinal anaesthesia priority over epidural block;
- roster sufficiently skilled anaesthetic staff on all shifts;
- establish an effective strategy to manage these cases when the theatres are in use;
- record the "decision-to-delivery" for all cases; and
- establish and audit the "decision-to-delivery" standard of less than 45 minutes.

CTG interpretation

11. Provide mandatory, free CTG interpretation training for all doctors and midwives in work hours and:

- release staff attending the training from other duties; and
- keep attendance records for CTG training.

12. In uncertain cases, the consultant must review the trace and the woman as soon as possible.

Medical and obstetric emergencies

13. Establish a "mock emergency" program of common serious emergencies including:

- collapsed or fitting adult;
- large antepartum haemorrhage;
- cord prolapse;
- prolonged fetal bradycardia;
- shoulder dystocia;
- very pre-term birth;
- emergency caesarean section when rostered staff are busy;
- post-partum haemorrhage; and
- baby requiring resuscitation.

14. Inform the on-call consultant and anaesthetist as soon as possible during a post-partum haemorrhage; they should attend as soon as possible.

15. Manage all hypertensive crises in a high dependency unit.

16. Notify a consultant or senior registrar immediately of any serious high-risk situations (pre-eclampsia, moderate or large antepartum haemorrhage).

17. Establish clinical guidelines on ectopic pregnancy, bleeding in early pregnancy and abdominal pain.

Gynaecology–oncology

18. Review this service to determine whether it should be transferred to another teaching hospital with full intensive care unit facilities.

Adult Special Care Unit

19. Clarify lines of responsibility for care in documented guidelines for the Adult Special Care Unit including:

- criteria for patient transfers to a full intensive care unit; and
- management of post-operative shock and haemorrhage.

Clinical care planning

20. Establish guidelines for clinical care planning including contingency planning and rationale for unusual plans or change of plans.

21. Establish written care plans for women at moderate to high obstetric risk and have these approved in writing by an experienced registrar or a consultant.

22. Inform the on-call consultant of all new admissions in high-risk categories and have him/her approve the care plan in writing.

23. Ensure the care plans for women with pre-term labour or pre-labour membranes rupture and marginal viability, state explicitly how labour, birth and neonatal care should proceed, and that the women help formulate their care plan.

Care coordination

24. Establish a clear communication policy for midwives or nurses who are dissatisfied with a junior doctor's response to concerns about patient safety or comfort.

25. Establish a policy for the medical care of privately insured women in emergencies, in consultation with private specialists using hospital facilities.

26. Establish a policy for following up important test results, including clear lines of communication and accountability.

27. Ensure each antenatal inpatient is seen daily, including weekends and public holidays, by a registrar or a consultant.

28. Ensure women who are admitted with serious non-urgent conditions, are seen by a consultant within 24 hours of admission.

29. Have all care plans of women attending the Emergency Centre approved by an experienced registrar or a consultant.

Communication

30. Before commencing a woman's treatment:

- discuss treatment options and document these discussions in the clinical file;
- provide written information about treatment options;
- give sufficient time to review the information;
- use interpreter services where needed before obtaining consent; and
- inform the responsible consultant if a woman withholds consent.

31. When a baby dies:

- review the circumstances with the woman and her family;
- discuss the post-mortem results with them; and
- provide a plain-English post-mortem report.

General psychosocial concerns

32. Use small teams of six to eight midwives to improve care continuity, with each team having responsibility for a woman's care.

33. Conduct regular workshops for doctors, midwives, nurses and allied health staff with subjects such as:

- responding sensitively to women;
- responding to subjective symptoms that differ from objective signs;
- involving women in decision-making; and
- responding to women who have had poor outcomes.

34. Ensure case discussions include the woman to whom they pertain.

35. Evaluate women's experiences of care and give feedback to staff through newsletters and workshops.

Responses to poor outcomes

36. Train the staff involved in identifying fetal death or abnormality, to discuss the circumstances sensitively with the woman and her family.

37. Offer women who have poor outcomes for themselves or their baby at least one appointment with the consultant or senior registrar to discuss the outcomes.

38. Establish guidelines for discussing poor outcomes with women and their families.

39. Where a woman's baby has died, arrange for her postnatal visit to be somewhere other than the antenatal clinic and with someone who knows the woman and her circumstances.

40. Establish a Clinical Midwifery Consultant position that:

- ensures care continuity for higher-risk women;
- consults and supports women with higher-risk pregnancies; and
- supports and educates midwives.

Involving women in decision-making

41. Establish a policy that supports involving women and families in clinical decisions about the women or her baby.

42. Discuss changes in clinical status and options for care with the woman and her family.

43. Train staff to consider women's subjective experiences in their assessment.

Documentation

44. Improve documentation so clinical files are sufficient to inform other health care staff caring for a woman and/or baby.

45. Modify the "partogram" or second-stage observation sheet to provide space for five-minutely recording of fetal heart rate in the second stage of labour.

46. Establish consistent documentation standards for public and private patients and monitor compliance.

47. Establish a standard organisational format for patient clinical files.

48. Establish multidisciplinary integrated progress notes.

49. Complete timely file notes about crisis situations.

50. Introduce a hand-held (patient-held) antenatal patient record.

Comparative data analysis

51. In collaboration with other similar Australian services, the Health Department of Western Australia and King Edward Memorial Hospital should:

- compare and publish data on stillbirths;
- compare and analyse data similar to that done for the Inquiry by the Consortium;
- establish benchmarks and/or performance indicators for obstetric and gynaecological practice and outcomes; and
- establish benchmarks and/or performance indicators based on the standardised primigravida.

52. Establish processes to review all maternal, perinatal and gynaecological deaths in the Hospital.

Consultant and senior medical cover

53. Immediately introduce on-site obstetric cover by senior doctors 24 hours a day, 7 days a week.

54. Share the on-site cover equitably among the senior doctors to ensure adequate supervision of junior doctors after hours.

55. Provide a back-up consultant at all times, but until introduced, have a back-up consultant on-call after hours when the on-site senior doctor is a senior registrar or a sub-specialty fellow.

56. Provide after-hours on-call gynaecological cover.

57. Establish a strategic plan to address medical staff coverage requirements.

Dedicated Delivery Suite staff

58. Retain the position of Delivery Suite Consultant and:

- develop this role and responsibilities;
- clarify weekday responsibilities;
- stop rostering this position to other areas.

Emergency centre

59. Review the Emergency Centre requirements for consultant presence and other medical cover.

60. Ensure the consultant on call for the Emergency Centre spends adequate time providing service, teaching and supervision in the Centre.

Clinical accountability

61. Clinic team leaders should be full-time King Edward Memorial Hospital consultants.

62. Consider implementing a team model of care, such as having a small team of consultants and junior staff looking after a patient cohort.

63. Inform patients attending clinics of the names of consultants attached to the clinic.

64. Include the "day designation" and the list of consultants attached to the clinic in the patient's file.

65. For gynaecology clinic patients, and for gynaecological inpatients, ensure that:

- each case is discussed with the consultant;

- the care plan is approved by the consultant;
- the consultant is responsible for the care plan;
- other clinicians are responsible for their own actions; and
- low-risk patients have their care coordinated by midwives unless otherwise arranged.

66. If consultants wish to be clinically responsible for low-risk patients, King Edward Memorial Hospital should establish a mechanism for this to occur.

67. Ensure clinical information systems record the consultant providing each significant component of care.

68. Emphasise the importance of notifying the responsible consultant of un-booked admissions and referrals to other consultants in junior medical staff induction programs.

69. The person named for funding by Diagnosis-Related Group must be the consultant responsible for the most significant episode of care.

Credentialling

70. The terms of reference of the Medical Credentialling and Clinical Privileging Advisory Committee's should include:

- its role in overseeing the credentialling of junior medical staff;
- at least quarterly meetings;
- approving clinical privileges granted to each medical staff member;
- providing the conditions applying to the privileges granted;
- ensuring each doctor is notified in writing of privileges application outcomes and the conditions applying to the grant;
- the list of privileges held by that doctor;
- timely amendment of the credentialling list;
- making the credentialling list readily accessible;
- including credentialling requirements in employment contracts;
- reviewing each consultant's clinical privileges at least every three years;
- identifying procedures for which clinical privilege application is required; and
- refining the credentialling process.

71. Monitor procedures performed and enforce practice consistent with the credentialling list.

72. Consider applying for protection of the Committee under the *Health Services (Quality Improvement) Act 1994.*

73. Establish guidelines to determine:

- whether a new surgical procedure should be performed at the Hospital;
- the conditions for it being performed; and
- the respective roles of the Credentialling Committee and Ethics Committee.

Associate consultants

74. Establish a policy and procedures to grant and renew admitting privileges to associate consultants with these conditions:

- valid 12 months;

- extension subject to clinical review;
- thereafter no more than three years;
- subject to clinical review; and
- readily available and updated list of consultants holding admitting privileges.

Establishing policies and guidelines

75. Establish a policy on how the Hospital develops, deploys, monitors and reviews clinical policies and guidelines and:

- publish and make it readily available;
- identify people responsible for the process components;
- include timeframes for timely formulation and follow-up;
- nominate a guideline coordinator; and
- educate staff on this process.

Initiation and formulation

76. Establish formal procedures to develop and deploy new or updated policies and guidelines and:

- feedback processes for reporting issues with or the need for new or updated policies;
- establish a multidisciplinary group including a consumer, to review and develop policies;
- base policies and guidelines on the best available evidence;
- include reference to the level of evidence; and
- use consistent and clear terminology.

Distribution and implementation

77. Establish formal procedures to distribute and deploy new and amended guidelines including electronic distribution and consultation.

Monitoring and enforcement

78. Establish formal procedures to monitor and enforce compliance with new and amended policies and guidelines and:

- differentiate between mandatory policies and discretionary guidelines;
- identify which clinicians can deviate from particular policies or guidelines and under what circumstances;
- identify the person or people responsible for ensuring compliance;
- deal with non-compliance in a timely manner; and
- audit compliance and appropriateness.

Review of selected guidelines

79. Review the Hospital clinical practice guidelines and:

- include all clinical practice policies and guidelines in the folder “Clinical Guidelines”;
- locate these in all clinical areas;
- provide a “pocket book” version;
- continue providing guidelines on the intranet; and

- consider internet access.

Incident reporting

80. Establish an incident reporting process with accompanying policies and procedures that:

- specify the incidents to be reported;
- state by whom, how, to whom and when;
- state the form to be used;
- impose obligation on all clinicians to report incidents;
- require a comprehensive, current register of incidents;
- require staff training in incident reporting policies and procedures;
- include incident reporting responsibility in clinicians' employment contract;
- relevant managers to monitor and ensure compliance with incident reporting and be accountable for non-compliance; and
- subject the incident reporting system to regular external audit and review.

Management of individual incidents

81. Include special measures to report and manage incidents where patients have been harmed, particularly serious harm, and poor health care management may have contributed to the harm.

82. Report and manage complaints about service and care.

83. Report serious incidents to the Chief Executive.

84. Subject a clinician failing to report an incident to disciplinary action.

85. Encourage transparency and disclosure of incidents to patients by educating, encouraging and supporting staff.

86. Offer an apology to patients and families who have experienced incidents and adverse events.

87. Review the patient complaints policies and procedures to ensure that:

- complaints management is better coordinated;
- there are regular complaints audits;
- complaints are used to make improvements;
- consumers are given clear advice about the complaints process; and
- clinicians deal with patients with greater openness and respect.

88. Review and reformulate the "Critical Incident Debriefing" policies and procedures to be more relevant and useful, and take action to ensure clinicians have appropriate support, including counselling and debriefing.

Incidents review

89. Establish a formal policy and procedures to deal with the review and follow-up of incidents.

90. Review all incidents to determine what went wrong, whether the incident was preventable and how things could be improved.

91. Conduct reviews using a "systems" approach that focuses more on organisational factors and less on the individuals who made the error.

92. Conduct reviews in a supportive environment that encourages open discussion of mistakes, adopting a culture where errors are recognised as an inevitable part of health care.

93. Give clinicians involved in the reviews prompt, sensitive and effective feedback.

94. Make changes to policies and procedures from the lessons learned in the review process.

95. Communicate these changes to clinicians.

96. Ensure compliance with policy and procedure changes.

97. Establish an incident review committee that:

- is multidisciplinary;
- comprises mostly clinicians;
- meets monthly;
- receives and reviews incident reports;
- refers serious incidents to an appropriately qualified clinician, preferably from interstate; and
- seeks external audit and review of incident review practices.

Reporting to the Coroner

98. Formulate or adopt procedures to ensure that deaths required by law to be reported to the Coroner, are reported.

99. The Chief Executive and Clinical Directors are to be made responsible for enforcing and compliance with these procedures.

Statutory Mortality Committees

100. The Western Australian Government should establish an effective system to identify, investigate, review and report maternal, perinatal and infant deaths.

101. Attend to matters such as:

- including or amending definitions of maternal, perinatal and infant mortality;
- streamlining and integrating requirements and procedures to identify and report deaths, including removal of inconsistencies within the Health Act, and between the Health Act and the Births, Deaths and Marriages Registration Act;
- reviewing the current reporting obligations of doctors and nurses under Section 335 and 336 of the Health Act to determine whether:
  - those statutory obligations and associate administrative requirements can be streamlined;
  - the practical benefits of retaining some or all of the obligations outweigh the administrative burden on doctors and nurses in complying with the obligations;
  - in practice, compliance with the obligations can be enforced;
  - there should be a power to exclude categories of deaths from those being investigated, and if so, the extent and criteria for the exercise of that power;
- legal and administrative arrangements to ensure investigations and reviews are completed in a timely manner;
- legal and administrative arrangements to ensure that the mortality committees carry out their educative roles, including producing timely reviews, case summaries, recommendation, constructive comments and statistical data;

- legal and administrative arrangements to ensure proper reporting by and public accountability for, mortality committees; and
- the membership, including the leadership, of the mortality committees.

102. Broaden the definitions of death and stillbirth under the Health Act so they are consistent with the definitions adopted by the National Health and Medical Research Council.

103. Amend the Western Australian Medical Certificate of Cause of Death to include two tick boxes indicating the existence of:

- pregnancy within the last 42 days; and
- pregnancy between 42 days and 365 days prior to death.

104. Continue an independent check of relevant records and data (currently carried out by the Executive Director of Public Health) to identify the maternal deaths and also the perinatal and infant deaths, in the state.

105. Observe and enforce obligations for statutory reporting and establish administrative arrangements to ensure they are observed and enforced.

Supervision

106. Make the consultant rostered to the Delivery Suite on each weekday responsible for clinical training of junior medical staff working in the area.

107. Require that all senior doctors attend a "train the trainer" course within 12 months of the date of this report.

108. Give consultants the prime responsibility for supervising and training registrars in training. Develop hospital policy to recognise and specify this responsibility.

109. Allocate each registrar to a consultant who will be a mentor. The consultant will meet with the registrar at least monthly and will be the registrar's RANZCOG training supervisor. Every full-time consultant should participate in this scheme.

110. Allocate each resident to a mid-level registrar who will be a mentor and will meet with the resident at least monthly.

Post-graduate medical program

111. Give registrars and residents time off from clinical work to attend a prescribed number of educational meetings each week.

112. Incorporate educational meetings in the registrars' and residents' rosters.

113. Keep a record of attendances of residents and registrars at educational meetings; include attendance as a part of performance appraisal.

114. Require each resident and registrar to attend and participate in educational meetings.

115. Take notes of educational meetings and make them available to doctors who cannot attend.

116. Give the Post-graduate Education Committee responsibility for developing, conducting and evaluating a post-graduate medical program for residents and registrars — nominate a consultant to undertake these responsibilities on the Committee's behalf.

117. Develop an education program that links clinical experience with theory, allowing for the varied educational needs of residents and registrars.

Orientation

118. On the first day of employment, ensure all new residents and registrars attend an orientation program that:

- covers the administrative aspects of the Hospital;
- is at least two days long;
- covers clinical issues;
- includes skill development in perineal suturing and basic CTG interpretation;
- includes follow-up sessions throughout the first three months; and
- explore the use of facilities such as the Collaborative Training and Education Centre (CTEC) and the Centre for Advanced Surgical Training (CAST) and develop and orientation or induction program for residents and registrars with a view to developing skills and knowledge before providing patient care.

Surgical training

119. Develop a formal program of compulsory training in surgical skills to reflect the needs of the various levels of training of the residents and the registrars.

120. Incorporate the facilities provided by CAST and CTEC in the program.

Midwifery training

121. Base the length of preceptorship on individual needs.

122. Fill the position of Clinical Development Midwife on a permanent basis.

123. Monitor the position's role and responsibilities to ensure that supervision of trainees continues as a substantial part of the role and responsibilities.

CTG interpretation

124. Require residents to attend a basic course in CTG interpretation before commencing work in a clinical area.

125. Require registrars to attend an advanced training course in CTG interpretation before commencing work in the Labour Ward. Ensure residents and registrars are certified as competent before interpreting CTG traces and managing a patient with a non-reassuring trace.

126. Require midwives to attend the advanced CTG interpretation training course within 12 months of commencing work in the Labour Ward.

Perineal suturing

127. Require residents to undergo training in perineal repair before commencing work in the Delivery Suite.

128. Assess registrars, residents and midwives as competent in perineal repair before they perform perineal repairs on patients without supervision.

129. Make a senior clinician who is competent in perineal repairs responsible for training junior doctors in the procedure.

130. Within three months of this report, all Levels 1 and 2 registrars and residents should be required to:

- undergo a formal assessment of their perineal repair skills; and
- unless formally assessed to be competent, attend a compulsory perineal workshop.

Employment Issues

Appointment of consultants

131. Establish a policy and procedures for the appointment of consultants.

132. Make the policy and procedures consistent with, and require compliance with, the Public Sector Standards.

133. Include in the selection panel for a consultant appointment, a senior human resources officer who is responsible for ensuring that the Hospital's policy and procedures are followed.

134. Only appoint a consultant if a properly constituted selection panel is satisfied, through appropriate referee reports and other means, that the consultant has the skills necessary to carry out his or her responsibilities.

135. Don't make an appointment at the end of a consultant's probation before doing a thorough review.

Appointing registrars

136. Require closely supervision of all newly appointed registrars by a more senior doctor until they have demonstrated sufficient skills to be able to function more independently.

137. While the director positions continue to have major management responsibilities:

- advertise vacancies widely to attract the best applicants;
- fill positions with people who have the skills (particularly management skills) needed to attend the responsibilities of the position; and
- provide appropriate training to ensure occupants of the positions have and maintain the necessary management skills.

138. Ensure medical directors of the clinical care unit remain active clinicians and undertake a minimum of two clinical sessions per week and a share of on-call duties.

Appointing midwives and nurses

139. Include a member from outside the area recruiting for the position on selection panels.

140. Include a midwife or a nurse from outside the hospital on selection panels for Level 3 positions.

141. Ensure that referees are contacted and in formulating their appointment recommendation, ensure selection panels take into account the responses from referees.

Performance management of consultants and directors

142. Establish a performance evaluation and management policy and procedures for consultants and directors of clinical care units.

143. Hold the Chief Executive and clinical care unit directors accountable for the timely conduct of performance evaluation and management for staff members for whom they are responsible.

Performance management of registrars

144. Establish a performance evaluation and management policy and procedures for registrars.

145. Have a full-time consultant who is not a director of a clinical care unit coordinate this process.

146. Seek feedback from senior staff about registrars' performance.

147. A coordinating full-time consultant is to collate comments about registrars' performance before submission to Medical Administration.

Performance management of residents

148. Ensure performance appraisals for residents are completed and returned to the residents before they leave a clinical area.

149. Ensure there is a follow-up discussion between the registrar or consultant who completes the appraisal and the resident.

Performance management of midwives and nurses

150. Establish a performance appraisal policy and process that meets the specific needs of nurses and midwives.

151. Ensure the standards of satisfactory clinical performance for nurses are based on Australian Nursing Council Inc competencies.

152. Clearly identify the roles and responsibilities of those conducting and ensuring compliance with the process.

Re-appointment of consultants

153. Formulate and implement a formal policy and procedures for re-appointing consultants that specifies:

- the roles (including power and obligations) of those involved in the re-appointment process, including the relevant directors, the Electoral Committee and the Chief Executive;
- the criteria for making recommendations for re-appointment and in decisions to re-appoint;
- all relevant factors including management issues, to determine whether a consultant should be re-appointed; and
- the requirement that the Chief Executive (whether a medical person or not) is obliged to independently assess a recommendation for re-appointment.

Accreditation

154. King Edward Memorial Hospital is to be accredited by an approved external body.

155. The process should include clinical audits.

Quality improvement

156. Establish policies and procedures to incorporate the following recommendations.

157. Hold the governing body accountable for quality improvement processes and systems that ensure the delivery of safe patient care at the Hospital.

158. Hold the Clinical Governance Committee responsible to the governing body and:

- give it the minutes and recommendations of the Incident Review Committee;
- give it authority to assign quality improvement activities to staff members, and to monitor the progress and results of those activities;
- give it responsibility for regular (at least annual) clinical audit of patient care;
- ensure it incorporates the audit results into its documentation;

- ensure it seeks governing body approval for the details of clinical audit including numbers and types of cases examined, the process for selecting cases and the follow-up of results of the clinical audit;
- ensure it reports annually to the governing body on:
  - the details and results of the clinical audit;
  - the extent and nature of other quality improvement activities in the Hospital;
  - proposals for future quality improvement activities, including medical quality activity, nursing and midwifery quality activities, and multidisciplinary quality activity; and
- allow staff assigned to quality improvement activities sufficient time to complete them.

159. Ensure the Hospital Executive reports annually to the Director General of the Health Department of Western Australia on the results of clinical audit and other quality improvement activities in the hospital and publishes those results.

2 Clinical File Review — framework

Following is a summary of the framework used for the Clinical File Review.

The Inquiry commissioned consultants to assist with the Clinical File Review including:

- Healthcare Risk Resources International (HRRI);
- thirteen medical consultants (five from HRRI); and
- eight consultant midwives or clinical nurse specialists.

All medical consultants were from outside Western Australia. Clinical judgement was central to determining whether an error (clinical or systemic) had occurred.

Case selection

The reviewers purposefully sampled cases at increased risk of poor clinical management and/or outcomes, and as such the findings could not reasonably be generalised to other categories of cases. The cases reviewed included:

- maternal deaths, neonatal deaths and stillbirths;
- death following gynaecological surgery;
- term infants who have a fit;
- low Apgar at five minutes after birth;
- term admission to neonatal intensive care unit;
- admission to an external adult intensive care unit;
- major post-partum haemorrhage;
- unintended damage to an organ;
- caesarean section after failed forceps and/or vacuum;
- non-elective caesarean section; and
- primary and secondary analysis (rating scale for clinical errors and contributing factors).

Service factors

The Inquiry considered:

- clinician knowledge and skills;
- experience level of the clinician providing care;
- the extent of involvement of senior clinicians in care;
- appropriateness of care planning, delivery and continuity;
- documentation standard;
- consent for treatment and communication with patients; and
- factors contributing to clinical errors.

Safety and clinic error ratings

Care was rated as:

- safe — timely, by suitably qualified staff, evidence-based;
- somewhat unsafe — elements of safe practice, some minor problems with care;
- moderately unsafe — serious problems with care (eg failure to detect deterioration early); and
- very unsafe — extremely serious problems or questions about quality of care provided.

The Inquiry defined clinical errors as "human errors judged to have the potential to cause, or to contribute to, adverse clinical outcomes". The five broad types used were:

- failure to recognise a serious, unstable situation;
- failure by senior staff to assess a woman/baby in a serious and unstable situation;
- inappropriate intervention;
- inappropriate omission; and
- incorrect action relating to CTG.

Contributing factors

The Inquiry defined contributing factors as "recurrent systematic factors contributing to the incidence and/or seriousness of clinical errors by increasing the potential for errors to occur". The types used were:

- delay in providing clinical care;
- lack of adequate clinical policy;
- lack of an adequate clinical care plan; and
- unsupervised junior staff assessing patients and providing complex clinical care.

Protective organisation factors

The Inquiry considered the following factors "protect" patients and strengthen organisations:

- adequate staffing and skills mix;
- evidence-based clinical policies;
- written care plans; and
- easy access to senior medical staff by junior medical staff.

Research questions

1. How often did the different types of clinical error occur?
2. How serious were the clinical errors?
3. Did the seriousness of the clinical errors change over the years?
4. During what stages of care did the clinical errors occur?
5. What proportion of clinical errors occurred among the various levels of clinical staff?
6. How serious were the contributing factors that occurred inside and outside business hours?
7. Was there a relationship between the occurrence of clinical errors and the occurrence of contributing factors?
8. Was there a relationship between the five types of clinical error and the five types of contributing factors?

3 Project consortium's comparative analysis of perinatal, obstetric and gynaecological information items — summary results

Patient profiles

King Edward Memorial Hospital had:

- significantly higher proportions of women aged less than 20 years;
- more indigenous women;
- more women booked and non-chargeable;
- differences in infant characteristics; and
- 1.7 times as many premature and low birthweight live births.

Perinatal mortality

King Edward Memorial Hospital profile:

- from 1994–99 the total number of perinatal deaths was significantly higher than the expected number;
- excess of perinatal death was due to an excess of stillbirths;
- excess (159) was reduced but did not disappear after adjusting for differences in several maternal and infant characteristics;
- adjusted estimates indicated that 53–55 more stillbirths than expected occurred in the Hospital over the six years;
- after differences in maternal and infant characteristics were taken into account, the Hospital had 61–66 fewer neonatal deaths than expected over the six years;
- despite lower neonatal mortality, researchers found higher levels of morbidity among pre-term newborns in the Hospital than in comparison hospitals;
- from 1995–99, a higher proportion of term babies in the Hospital received intermittent positive-pressure ventilation than in comparison hospitals; and
- rate of intraventricular haemorrhage grade 3 or 4 in pre-term babies of less than 30 weeks gestation was approximately 1.6 times higher in the Hospital than in comparison hospitals

Obstetrics services

King Edward Memorial Hospital profile:

- over the six years, the Hospital had higher rates of various types of obstetric intervention in comparison with other hospitals;
- some of these higher rates were found in the sub-group of lower-risk standard primiparae as well as the total population of women delivering in the Hospital;
- the Hospital had significantly higher rates of induced labour and deliveries where there was no labour (ie delivery by caesarean section prior to the onset of labour) than comparison hospitals among all women and also among standard primiparae;
- almost 51 per cent of women delivering in the Hospital had epidural analgesia or anaesthesia compared to 31 per cent in comparison hospitals;
- significantly higher proportions of women at the Hospital had assisted vaginal deliveries and caesarean sections;
- the Hospital had a higher rate in assisted deliveries — reflects more frequent use of vacuum extraction, but not of forceps in all women and among standard primiparae;
- the Hospital had a higher rate of caesarean sections among all women, but not among the sub-group of standard primiparae; and

- women at the Hospital were more likely to have a caesarean section after the onset of labour than before — the reverse of comparison hospitals — observed only in pre-term deliveries.

Maternal morbidity and mortality

King Edward Memorial Hospital profile:

- the women at the Hospital had significantly longer lengths of stay;
- the Hospital had a significantly higher proportion of women with excessive lengths of stay;
- the Hospital rate of 3rd and 4th degree perineal tears among women having vaginal deliveries was twice as high (likely to be related at least partially, to higher rates of assisted vaginal deliveries);
- the Hospital had 38 instances of hysterectomy following post-partum haemorrhage in six years (relatively large number compared to other hospitals); and
- the Hospital had two maternal deaths in the six years.

Conclusions about King Edward Memorial Hospital obstetric and perinatal outcomes

- High proportion of pre-term births.
- Excess of stillbirths.
- Relatively higher rate of obstetric interventions where there was no labour, epidural analgesia and anaesthesia, assisted vaginal deliveries and caesarean sections after onset of labour.
- Main findings warranting attention:
  - excess of term stillbirths;
  - high rates of induced labour and deliveries where there was no labour;
  - high rate of epidural analgesia and anaesthesia; and
  - high incidence of 3rd and 4th degree perineal tears.
- Findings giving confidence about care at the Hospital include:
  - relatively low neonatal death rate;
  - high rate of antenatal corticosteroid administration in premature labour;
  - tendency to use vacuum extraction rather than forceps in assisted vaginal deliveries; and
  - distribution of five-minute Apgar scores similar to other hospitals.

Gynaecological services

King Edward Memorial Hospital profile:

- some performance broadly consistent with other hospitals (eg fewer hysterectomies and less dilatation and curettage);
- 29 deaths in patients admitted for gynaecological procedures;
- 18 deaths in women admitted for laparoscopy, hysterectomy or dilatation and curettage;
- a further 11 deaths among women having other gynaecological procedures;
- cause of death information not available to assess whether deaths were inevitable however, death during a gynaecological procedure is a sentinel indicator of the most serious complications;
- deaths in the Hospital during admission for a gynaecological procedure warrant further investigation;

- the proportion of women having hysterectomy receiving blood transfusion was twice as high; and
- proportions of women transferred to the special care unit during admission for laparoscopy and hysterectomy were also considerably higher (this may reflect the higher level of morbidity, but could also reflect prevailing institutional practices of admitting patients with certain characteristics to the special care unit).

Conclusions about King Edward Memorial Hospital gynaecology outcomes

- Interpretation of the findings is heavily qualified due to:
  - concerns about reliability and data accuracy;
  - definitional and coding practice variation; and
  - inability to adjust for difference in patient characteristics.
- However, adverse findings (mortality and morbidity) could not necessarily be attributed to these qualifying factors.
- These adverse findings therefore warrant further investigation.

4 Clinical File Reviews — findings summary

Obstetrics Cases — selected high-risk groups

Error Rates in selected cases

- Of the 372 high-risk obstetric cases, 176 (47 per cent) had at least one clinical error. Of these, 101 (57 per cent) had very serious clinical errors. No occurrence pattern was found over the 11-year period. There was a noticeable drop in the seriousness of clinical errors in 2000 (9 per cent).
- Of all 176 cases where errors were identified, 137 (79 per cent) occurred during labour and delivery. Another 36 errors (21 per cent) occurred in the antenatal or postnatal phase.
- Consultants involved at crucial times provided error-free care 72 per cent of cases. Consultants' involvement was associated with multiple (3–5) types of errors in 3 per cent of cases.
- Senior registrars provided error-free care 66 per cent of the time. Level 3–4 registrars had an error-free rate of 60 per cent (9 per cent 3–5 errors) and level 1–2 registrars had an error free rate of 36 per cent (15 per cent 3–5 errors). Residents had an error-free rate of 24 per cent (27 per cent 3–5 errors). Midwives had an error-free rate of 40 per cent and were safer at crucial times than either residents or level 1 and 2 registrars.

Staff Involvement at crucial times

- Consultants were involved at crucial times in 21 per cent of cases.
- Senior registrars were involved at crucial times in 9 per cent of cases.
- Levels 3 and 4 were involved at crucial times in 23 per cent of cases.
- Levels 1 and 2 were involved at crucial times in 17 per cent of cases.
- Residents were involved at crucial times in 11 per cent of cases.
- Midwives were involved at crucial times in 19 per cent of cases.

Time of clinical errors

- 29 per cent of clinical errors occurred in working hours.
- 71 per cent (two-thirds) occurred outside working hours.
- The seriousness of the error was not linked to the time it occurred.

Contributing factors

- At least one contributing factor in 75 per cent of cases.
- 33 per cent of cases had three or more contributing factors.
- There was no pattern for seriousness of contributing factors over the 11 years.
- There was a noticeable drop in the seriousness of contributing factors in 2000.
- Contributing factors were noted most frequently during labour and delivery.
- Two-thirds of those errors with contributing factors occurred outside business hours.
- There was no link between time of occurrence and seriousness of contributing factors.
- 97 per cent of cases with clinical errors had one or more contributing factor.
- Policy-related issues were less prominent among the cases.

Obstetrics cases — legal/submission groups

- Clinical errors were very common among the 148 obstetric legal/submission cases.
- Of the 113 cases (76 per cent) with one or more types of clinical errors, 67 per cent were very serious.
- Clinical errors were most frequent during labour and delivery.

- 67 per cent occurred outside business hours.
- There was no difference in seriousness relating to time of occurrence.
- Of these 113 cases, 87 per cent had at least one contributing factor.
- Of those with one or more contributing factors, three-quarters were very serious.
- Contributing factors were most serious during labour and delivery.
- 98 per cent had one or more type of contributing factor.
- Among cases with a clinical error, about 50 per cent had one or more type of contributing factor.
- Delay in providing clinical care and lack of adequate care plan were common.
- Policy-related issues were less prominent with this group.

Gynaecology cases — selected high-risk groups

- 52 gynaecological cases reviewed — relatively small sample.
- At least one type of clinical error in 20 cases.
- Commonest errors were failure to recognise a serious, unstable situation and inappropriate omissions.
- Of the 20 cases with clinical errors, 14 were rated very serious.
- 12 cases with errors occurred in the post-operative period — reflects case selection.
- Occurrence times dispersed.
- Most after hours errors were very serious.
- At least one type of contributing factor in 26 (50 per cent) of cases.
- In most cases the five contributing factors were rated as very serious.
- All 20 cases with one or more types of clinical error had one or more contributing factor.
- Delay in providing clinical care, lack of an adequate policy, and lack of an adequate care plan were present together in more than 50 per cent of cases with clinical errors.

Gynaecology cases — legal/submission groups

- 33 cases reviewed – small and non-representative sample.
- Of these, 22 (two-thirds) involved clinical errors.
- Of the 22 cases, about half were very serious.
- More common prior to or after surgery.
- Errors occurring inside and outside business hours were similar.
- Lack of care coordination and unsupervised junior medical staff were prominent as contributing factors.
- Contributing factors were distributed evenly across different stages of care.
- Three or more contributing factors were found in two thirds of cases.
- Of these, the majority was rated as very serious.
- The proportion of cases with three or more contributing factors was higher outside business hours than inside.
- Presence of contributing factors was not always associated with clinical error.

5 Child and Glover Report on King Edward Memorial Hospital Obstetric and Gynaecological Services — findings summary

The Inquiry supported the findings of Dr Andrew Child and Ms Pauline Glover who, over two weeks, reviewed the quality of care provided by the King Edward Memorial Hospital obstetric and gynaecology services. Commissioned by the Metropolitan Health Service Board, they interviewed 41 people and reviewed selected case notes. Reporting their findings in April 2000, they identified many serious clinical and administrative problems affecting the safety and quality of care including:

- significant adverse events occurring out of hours especially in the Delivery Suite;
- no adverse events reporting or monitoring system in the Obstetrics Clinical Care Unit;
- lack of clarity about which senior doctor was responsible for which patients;
- junior doctors' reluctance to call senior doctors;
- obstetric management delays due to senior doctors' delayed attendance;
- little evidence of appropriate and effective peer review;
- little supervision of junior doctors by senior doctors;
- a perception that midwives and junior doctors run the hospital;
- no evidence of a formal credentialling process; and
- unsatisfactory rostering arrangements.

6 Action following the Inquiry — a Summary of Dr William Beresford's Presentation to the Ministerial Inquiry, October 2001

Recommendation

Conduct an in-depth review of the current medical and midwifery practices of the Delivery Suite.

Action

- Revised and updated clinical guidelines for medical staff in Clinical Handbook.
- Updated and referenced midwifery policy and procedure manuals according to best available evidence.
- Received approval for $60,000 funding by the Health Department of Western Australia for a project to develop state-wide evidence-based obstetric guidelines.
- Appointed Dr Pat Magann as consultant in charge of Delivery Suite September 2001.
- Prioritised clinical care.
- Guided medical staff on proper documentation for:
  - telephone instructions;
  - hand-over procedures; and
  - medical records documentation.
- Collated and sent list of specimen signatures of all junior doctors to Pharmacy and Pathology.
- Developed guidelines and procedures with criteria to determine urgency status of need for emergency caesarean section. Trial final draft before including in handbook.
- Provided statements to refute allegations that:
  - there are unusually high numbers of low Apgar scores;
  - there is a high intervention/interference rate;
  - policies and procedures subject to individual interpretation; and
  - preferences of consultants accommodated.
- Plan to provide an office in the Delivery Suite for the Delivery Suite consultant.
- Clearly identified inpatient teams via a roster, including team name and consultant on patient's bed card.

Recommendation

Establish a clear policy on the management of clinical cases with adverse outcomes in obstetrics and gynaecology, including specific information on reporting and managing such cases.

Action

- Developed a hospital-wide incident reporting and investigation process.
- Audited incident reporting and investigation process (Ernst and Young) in August 2001; re-audit after full implementation of AIMS2.
- Established and registered the Obstetrics Clinical Outcomes Management Committee under the *Quality Improvement Act 1994*.
- Established and made application for registration of the Gynaecology Clinical Practice Improvement Committee under the Quality Improvement Act.
- Implemented WA-wide computer incident monitoring system (AIMS2) September 2001.

Recommendation

Implement the Ernst and Young recommendations.

Action

- Developed a list of sentinel events and indicators to identify high-risk gynaecology and obstetrics cases.
- Established adverse event incident reporting and management policy.

Recommendation

Ensure all medical and midwifery/nursing staff in the Obstetrics and Gynaecological Critical Care Units have current appointment documents and they are working within the legal parameters of their appointment.

Action

- Medical staff must provide evidence of registration to the hospital on appointment and annually thereafter.
- Installed a database to track medical registrations, credentialling, performance appraisals, professional standards and clinical privileges.
- Reviewed appointment documents of all staff.
- Re-appointed associate obstetricians for three years.
- Performance of associate obstetricians to be appraised annually.
- Currently conducting performance appraisals for all senior doctors; each consultant will be appraised by a supervisor and a peer every three years.
- Instigated credentialling of doctors.
- Check midwifery and nursing registrations annually.
- Midwives and nurses undergo performance appraisal every 18 months, and update competencies are linked to their performance appraisals.
- Reviewed and revised orientation process after analysing results from evaluation survey and input from relevant staff. Changes to include:
  - clinical skills orientation to be included;
  - longer rotations of three months for resident doctors; and
  - allocation to a defined team/consultant.

Recommendation

Review the responsibilities of all medical and midwifery/nursing staff in the Obstetrics and Gynaecological Critical Care Units and make changes where necessary to ensure that the incumbents are fulfilling the responsibilities of the position.

Action

- Reviewed all medical staff job descriptions — every position has an attached position description that accurately details the duties of the position.
- Updated all midwifery job descriptions to reflect the Australian College of Midwifery standards.
- Included instructions in the revised Clinical Handbook that junior doctors must obtain and document approval from consultants before booking elective surgery.
- Patients participate in decision-making of care via birth plans, information pamphlets and pre-admission clinics.

- The allegation that midwives and registrars 'run the hospital' is refuted as there are consultant ward rounds in evenings and on weekends and 24-hour consultant cover in Delivery Suite.

Recommendation

Review the composition, terms of reference and the conduct of all current committees in Obstetrics and Gynaecology to ascertain their function and effectiveness.

Action

- Reviewed and approved the structure and terms of reference of these executive committees:
  - Medical Advisory Committee;
  - Electoral Committee;
  - Clinical Governance Committee; and
  - Ethics Committee.
- Reviewed the function and relationship of Obstetrics and Gynaecological Critical Care Unit committees as they relate to each other and other committees.

Recommendation

Review the reporting relationships of the new devolved structure (Unit Directors and CE) and how the management of King Edward Memorial Hospital will demonstrate an integrated service that reflects safety, quality and cost effectiveness.

Action

- Revised the organisational reporting structure under the WAWCHA.
- Almost completed the review of critical care units to meet requirements of new Women's and Children's Health Service.
- Appointed Business Managers to each directorate in March 2001.
- Developed a Strategic Plan.
- Implemented a Business Planning Cycle.

Recommendation

Review the outcomes of the Birth Centre with a view to providing obstetric cover and considering its use for low risk Aboriginal women.

Action

- The Medical Director of the Obstetrics Critical Care Unit provides medical support to the Birth Centre.
- All new low-risk obstetric patients are sent a letter offering them the choice of delivery at the Birth Centre, including Aboriginal women.
- An antenatal day assessment ward is part of future planning in the Obstetrics Critical Care Unit.

Recommendation

Rewrite the protocol and manuals for perineal repair and CTG monitoring professional development according to the latest evidence and best practice.

Action

- Reviewed, endorsed and re-printed the 4th edition of the Advanced Fetal Monitoring Course Manual, including "last reviewed June 2001" and a list of authors.

- Plan to revise and expand the Advanced Fetal Monitoring Course to include other methods of fetal assessment.
- Approved the purchase of new centralised fetal monitoring equipment by the Health Department of Western Australia — awaiting funding.

Recommendation

Develop a register of perineal repair and CTG monitoring competence of each member of the Delivery Suite staff (midwives, residents and registrars).

Action

- Registers of nursing staff competence in perineal suturing and CTG monitoring already in place.
- Each Delivery Suite roster has a minimum of three Level 2 midwives with perineal suturing and advanced fetal monitoring skills.
- Registers of medical staff competence in perineal suturing and CTG monitoring will be included in the credentialling database.

Recommendation

Develop and implement a process of peer review for all levels of staff in the Obstetrics and Gynaecological Critical Care Units.

Action

- PEDS to link employee functions with departmental and organisational goals.
- Performance appraisals current for:
  - all directors;
  - all nurses and midwives; and
  - all clerical and administrative staff in directorates.
- Good progress with performance appraisals for all consultant medical staff.

Recommendation

The Hospital formally adopts the Australian College of Midwifery *Competency Standards for Midwives* (1998) as a benchmark for midwifery practice and ensure that every midwife employed has their own personal copies of these competencies.

Action

- Each midwife now has a copy of the Australian College of Midwifery Competency Standards.
- Included the Australian College of Midwifery Competence Standards as part of the job descriptions for all midwifery positions.
- Integrated the Australian College of Midwifery Competence Standards into the current Graduate Midwifery Program.

Recommendation

The directors of the units and the Chief Executive develop a Corporate Quality Management Plan. The need for quality to be driven as a top down initiative and to be primarily patient-focused should be emphasised.

Action

- Constituted the Accreditation Committee.
- Had the Clinical Governance Sub-committee Terms of Reference ratified by WAWCHA

- Commenced Health Service Quality Management planning to reflect the new Women's and Children's Health Service.

Recommendation

The Medical and Nursing Directors of Obstetrics and Gynaecology develop a Quality Management Plan for their respective areas that meet the principles of the Corporate Quality Management Plan.

Action

- Submitted the Obstetrics Critical Care Unit Quality Management Plan.
- Submitted the Gynaecological Critical Care Unit Quality Improvement Register.
- Plan to align Directorate Quality Plans with Corporate Quality Plan.

Recommendation

A position be created in the short term (to be reviewed) to take a lead role in the development, implementation and evaluation of a Quality Management Plan for the Hospital.

Action

- Appointed Accreditation Coordinators at the King Edward Memorial Hospital and the Princess Margaret Hospital for Children.
- Bid made to the Health Department of Western Australia to establish Clinical Governance Unit.
- Finalised job description for Clinical Governance Coordinator.

Recommendation

King Edward Memorial Hospital seeks accreditation by a nationally recognised body by 2001.

Action

- Rejoined the Australian Council on Healthcare Standards in July 2000.
- Conducted self-assessment survey and completed corporate workbook.
- Underwent the Australian Council on Healthcare Standards survey in March 2002.
- Pathology received National Association of Testing Authorities accreditation to IEC 17025 in all departments.
- Ensured King Edward Memorial Hospital work practices regarding safe use of electricity in patient care conform to Australian Standard AS 2500.

Recommendation

A formal program for credentialling house staff be developed.

Action

- Established Credentialling Committee and defined credentialling criteria.
- Commenced credentialling July 2001.
- Require 1st year registrars to be supervised by a consultant until certified as competent in certain procedures.
- RANZCOG to evaluate the King Edward Memorial Hospital credentialling process.

Recommendation

The hospital keeps records of the six-monthly training assessments of the registrars.

Action

- RANZCOG declined the Hospital's request for copies of six-monthly assessment reports to be kept at the Hospital. Supervising consultants are to supply a copy of their evaluations of junior medical staff to the Hospital.

Recommendation

The Hospital urgently review the registrar rostering to ensure safe levels of cover out of hours with appropriate provision for consultant attendance.

Action

- A Level 5 or 6 registrar is on-site at all times to support level 1 or 2 registrars.
- A consultant will attend if there is a trial of vaginal instrumental delivery – compliance audit underway.
- No level 1 or 2 registrars are rostered on night shift.
- Appointed four senior academic obstetrics and gynaecological doctors.
- Establishing Associate Professor of Gynaecology position.
- Compliance with the Australian Medical Association (AMA) "safe hours" — poor response to AMA survey therefore details of timesheets and call back sheets of junior doctors to be sent to AMA.
- Established consultant ward rounds in evenings and on weekends.
- Establish on-site Obstetric Medicine Consultant and increased sessions.
- Conducted registrar rostering.

Recommendation

Clearly identify "patient complaint" and then review the position description of the patient Advocate and develop a method whereby all patient complaints can be effectively dealt with.

Action

- Clearly identified "patient complaint" in hospital policy.
- Integrated incident reporting system on Respond-3 database links FOI, Customer Complaints and Medicolegal cases.
- Commissioned Ernst and Young to audit complaints and satisfaction system — three recommendations otherwise positive results.
- Re-wrote and ratified job description for Patient Advocate.
- Submitted report by Customer Service Unit to demonstrate that the Hospital learns from patient complaints.

Recommendation

Undertake a staffing review of the mix of numbers of midwives in Delivery Suite.

Action

- Employed a ward clerk for Delivery Suite.
- Reviewed Delivery Suite midwifery staffing profile.
- Recruited midwives from the UK.

Recommendation

Undertaken a review of all sessional work of all consultant medical staff.

Action

- Developed a medical workforce profile including benchmarking with other hospitals in the eastern states.
- Progressing a five-year manpower plan.

Other hospital initiatives

Education and training

- Credentialling of junior and senior doctors.
- Proposed Chair in Midwifery.
- In-service clinical education.
- Increased use of CTEC for clinical skills development.
- Use of anaesthetic simulator for skills development of registrars and residents as well as compulsory annual appraisal of consultant anaesthetists.

Collaborative research vision

- Proposal by WAWCHA to establish a Centre for Women's and Children's Health Studies and Research with links to the universities.
- Appointment of a Professor of Obstetric Anaesthesia.
- Academic-based midwifery training from February 2001.
- Collaborative Centre Curtin University and Edith Cowan University Memorandum of Information signed August 2001.

Facility improvements

- Upgrade of facilities to include Delivery Suite, Emergency Centre, Neonatology CCU and the Main Foyer.
- Provision for unit as state centre of fetal assessment.
- Funds totalling $15 million to be made available over the next four years to achieve capital works at the Hospital.

Improved fetal monitoring

- Received approval for a centralised fetal monitoring system with remote access to CTG traces by consultant staff and digital storage.
- Proposal for state-wide fetal monitoring interpretation and support by the Hospital.
- Increased antenatal screening: nuchal, 1st trimester, red cell antibiotics.

Maternal–fetal medicine service

- Proposal to re-organise maternal–fetal medicine service under a single clinical service:
  - will combine a high-risk antenatal clinical with the current medical clinic;
  - all materna–fetal medicine patients will be admitted under the service and cared for by maternal–fetal medicine medical staff; and
  - maternal–fetal medicine specialists will attend ultrasound department every morning Monday to Friday to supervise scans on high-risk women.

Establishment of Telehealth Centre

- Approved telehealth submissions: midwifery education, emergency medicine, nursing education.
- Telehealth submissions in progress: 1st trimester screening, clinical perinatal loss, paediatric diabetes and general paediatrics.
- Telehealth services currently available to rural areas:

- physiotherapy department via Telehealth Kalgoorlie and Northam
- psychology medicine department, the King Edward Memorial Hospital — telepsychiatry involving video conferencing, telephone service via 1800 number and written communication.

Abbreviations

CAST	Centres for Advanced Surgical Training
CTEC	Collaborative Training and Education Centre
CTG	cardiotocography
HRRI	Healthcare Risk Resource International
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists

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