

Lessons from the Inquiry into Obstetrics and Gynaecology Services at King Edward Memorial Hospital 1990-2000

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Abstract

The Douglas Inquiry investigated the Obstetrics and Gynaecological services at King Edward Memorial Hospital from 1990-2000. Performance deficiencies were identified at state, board and hospital level contributing to poor outcomes for women, babies and families. The Inquiry raises important issues about clinical governance, leadership and culture, accountability and responsibility, safety and quality systems, staff support and development, and concern for patients and their families.

The King Edward, Bristol and Royal Melbourne Hospital inquiries reveal important similarities and key lessons for governments, health care leaders and providers. The health care industry must ensure effective clinical governance supporting a culture of inquiry and open disclosure, and must build rigorous systems to monitor and improve health care safety and quality.

Identifying and investigating performance issues

In 1999, the recently appointed Chief Executive at King Edward Memorial Hospital (KEMH), Mr Michael Moodie, gave evidence to the Western Australia Metropolitan Health Service Board (MHSB) of poor management and clinical performance at the Hospital. His concerns included the Hospital's lack of an overall clinical quality management system, failure by senior management to resolve long-standing clinical issues and inadequate systems to monitor and report adverse clinical incidents. Other issues included the absence of a proper and transparent system to deal with patient complaints and medico-legal claims, a shortage of qualified clinical specialists particularly after hours, the inadequate supervision of junior medical staff and evidence of sub-standard patient care.

After some delay, the MHSB commissioned a review of the Hospital's Obstetric and Gynaecology services by an independent clinician. The review raised more management and clinical performance issues and recommended further investigation. In consultation with the Health Commissioner and the Minister, the Chief Medical Officer and the MHSB Chief Executive Officer subsequently commissioned another review (Child and Glover 2000). This two-week review identified significant system and performance issues. As a result, the Minister in consultation with the Premier commissioned Mr Neil Douglas (a lawyer) to lead an inquiry into obstetrics and gynaecological services at KEMH (Douglas, Robinson and Fahy 2001). This report uses the terms "Inquiry" and the "Douglas Inquiry" interchangeably.

Over eighteen months, the Inquiry investigated clinical and management practices at the Hospital from 1990-2000 and recommended changes to address service deficiencies.

Quality council role

The Australian Council for Safety and Quality in Health Care (2002) commissioned the authors to report the key findings and lessons arising from the Douglas Inquiry. The Council's purpose was to make the findings easily accessible across the industry to support the efforts of health care leaders, managers and staff to improve health care safety and quality. This report summarises those key findings and lessons. The Council's full report is available at www.safetyandquality.org/articles/publications/king_edward.pdf.

King Edward Memorial Hospital – profile and context

As the state's only tertiary referral service for obstetrics and gynaecology, KEMH receives and treats the most difficult and complex obstetric cases in Western Australia. The Hospital is the state's only major teaching hospital in obstetrics and gynaecology, and is a centre for midwifery training and postgraduate medical training.

With 250 in-patient beds, sixty neonatal cots, intensive care services and a range of outpatient services, KEMH performs approximately 5,000 gynaecological operations and delivers 5,000 babies annually. Its emergency centre receives 8,000-10,000 women annually for gynaecological or obstetric treatment.

The years 1990-2000 saw a significant increase in the number of complex obstetric and gynaecological cases treated at KEMH. More women were presenting to the Hospital uninsured and more required complex care. Many came from poor socio-economic backgrounds, had not booked in for birth or treatment and presented late in pregnancy. More women had morbid obesity, substance abuse and serious social problems.

KEMH also experienced significant organisational re-structure and upheaval, having appointed two new Chief Executives and merged with Princess Margaret Hospital for Children. Devolved management was introduced in 1996, with directorates established for obstetrics, gynaecology and neonatal services. In 1997 the MHSB replaced the Board of Management.

Strong public debate arose from the Hospital's high public profile during the late 1990s. Individual doctors and the Western Australia branch of the Australian Medical Association actively debated the issues, resulting in public criticism of the Child and Glover findings. These factors created uncertainty among staff and the public as to the Hospital's future. The Douglas Inquiry's findings were consistent with those of the Child and Glover Review.

Methods

The Inquiry's brief was "to inquire into the provision of obstetric and gynaecological services at KEMH" over the period 1990-2000. The Inquiry considered systemic and organisational deficiencies relevant to management and clinical practices, policies and processes, and recommended changes to address these deficiencies. Case review focused on the management of selected high-risk obstetric and gynaecological cases requiring complex care.

More than 1,600 KEMH patient clinical files were studied. Of these, 605 patient clinical files were analysed in detail both qualitatively and quantitatively. Approximately 300 written submissions were reviewed and seventy former patients were interviewed. The Inquiry also compared aspects of the Hospital's clinical performance with similar Australian services and reviewed 106 transcripts from current and former Hospital staff.

Major findings

The Inquiry noted many instances of excellent clinical practice and a concerted effort by some to address long-standing clinical performance and management problems. These problems resulted in poor outcomes for patients and their families.

Care planning, delivery and documentation

The Inquiry found evidence of non-existent or sub-standard care planning, coordination and documentation and lack of supervision of junior medical staff. Other findings included poor management of high-risk cases and medical emergencies, and non-existent systems to identify, review and respond to adverse events.

Documentation was often incomplete, lacking important clinical information for continuity of care. Outcomes of discussions with senior staff were rarely noted and in most cases it was impossible to determine the extent of a consultant's involvement in decisions about care.

Junior doctors were often left to manage difficult cases without help and without the necessary skills to do the job safely. In the Delivery Suite, the Adult Special Care Unit and the Emergency Centre, junior doctors gave unsupervised, complex care to high-risk patients. Post-operative shock and haemorrhage, as well as fluid and electrolyte balance were poorly managed. 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 the training programs necessary to ensure staff were suitably skilled to manage these situations.

The Adult Special Care Unit (offering intensive care services for women) had no specialist "intensivists" and only one nurse in the team had intensive-care training. Non-specialist nurses were often left to deal with highly complex, sometimes life-threatening situations. Of the women who unexpectedly died in the Unit, a high proportion had radical gynaecological and bowel surgery. These were recognised high-risk cases requiring intensive care in the immediate post-operative period.

Clinical errors

Errors were common in the 372 high-risk obstetric cases reviewed, the most frequent being "failure to recognise a serious and unstable condition" and "inappropriate omissions". One or more clinical errors occurred in 47% of cases and 50% of these were very serious. Of the high-risk cases reviewed, junior residents made errors in 76% of cases, junior registrars 65%, midwives 60% and levels 5 and 6 registrars 34%. Consultants made errors in 28% of high-risk cases.

Inter-hospital performance

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

The Consortium acknowledged that KEMH treated a higher proportion of the most difficult cases than other hospitals and that some items were primarily for administrative purposes. Despite limitations, the Consortium concluded the findings were sufficiently valid to identify major differences among hospitals, and recommended KEMH further investigate its:

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

The Consortium also recommended improving the quality and completeness of data collected at the Hospital (particularly morbidity data), and that KEMH should maintain obstetric, perinatal and gynaecological services outcome data.

Clinical policies and guidelines

Policies and guidelines were ad hoc, untimely and infrequently reviewed. KEMH failed to assign resources to manage the processes and as such, development and review processes were inadequate with insufficient staff consultation, inconsistent terminology and lack of commitment to a multi-disciplinary approach. Obsolete policies were retained despite inconsistencies with best available evidence and it was impossible to distinguish between mandatory and discretionary policies and guidelines. Patients and families were rarely involved in

policy and guideline development and KEMH lacked processes to monitor and ensure policy compliance.

A good example of such problems at KEMH is the Vitamin K protocol. The Hospital took four years to amend the "Vitamin K Administration Protocol" after an incident with Vitamin K administration in October 1997 when a baby received two Vitamin K doses in the birthing area. Several e-mail exchanges about the incident failed to result in action to address the problem. In April 1999, more e-mail exchanges focused on a reputable interstate position statement on Vitamin K advising against its administration in a birthing area. Again the e-mail discussions failed to result in action. More e-mail discussions followed and a new Vitamin K policy was eventually finalised in May 2001.

The Inquiry commissioned four expert consultants to review a range of KEMH policies and guidelines. Manuals were inconsistent, omitting references to best available evidence and poorly covering important topics. Document updates were irregular, development and review dates were omitted and staff responsibility profiles were inadequate.

Incident reporting and management

Over many years, the Hospital lacked a clear, current policy and an effective system to report, review and respond to incidents and adverse events. A "culture of blame" prevailed, and the responsibilities for investigating and responding to incidents and adverse events lacked accountability.

On some occasions, the first notice of an adverse event was a lawyer's letter or other external correspondence. In 1999, Ms Jennifer Beck (Hospital Counsel) reported her concerns about under-reporting of serious incidents to Moodie. Evidence pointed to clinical mismanagement of at least five cases, with three resulting in babies dying and two being brain damaged, and potential multi-million dollar claims against KEMH. Beck also raised serious concerns about inaccurate and inadequate reports resulting from (among other things) significant delays in lodging reports.

At this point, Moodie directed staff to report all incidents to him and advised that Beck would handle all KEMH legal cases. Moodie reported the situation to the MHSB and commissioned an independent audit by Ernst and Young of the Hospital's incident reporting processes. Findings indicated KEMH had failed to define the term "clinical incident", lacked a functional clinical incident reporting procedure and had no practical method of identifying clinical incidents from case files.

During 2000, Beck identified many poorly managed potential medical negligence cases. One involved a woman admitted in labour with a history of permanent back injury from a serious car accident. She 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. She was discharged against her wishes and re-admitted two days later with endometritis and "retained products". She remained at KEMH for five days on intravenous antibiotics and suffered on-going pelvic pain, dyspareunia and pelvic infection.

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 later, 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.

The Hospital introduced several measures to improve the management of such cases in 2000. Considerably more work was required to address long-standing problems in this area.

Reporting deaths to the Coroner and mortality review committees

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

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 many years, and there appeared to be significant flaws in legislation and compliance associated with reporting and investigating maternal, perinatal and infant deaths. The Committees appear to have ignored or overlooked many aspects of the legislation from 1990-2000, including provisions with substantial penalties for non-compliance.

Various provisions of the Health Act 1911 govern reporting of perinatal and infant deaths, and many of these are inconsistent and impose multiple reporting requirements on hospitals. For example, a single stillbirth may require six reports regulated by five separate statutory provisions. The Committees' definitions were inconsistent with 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 to investigate a death.

While investigating maternal deaths at KEMH, 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 period, 1989-1991.

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 eleven years and the Inquiry found it acted beyond its powers by excluding categories of deaths from investigation and review. Since 1991, the Committee has failed to produce any reports or papers.

Staff and staffing problems

KEMH had inadequate consultant cover, chronic under-staffing and lacked succession planning. Clinical responsibility and accountability were poorly defined and supervision of junior doctors (particularly when managing complex cases) was inadequate. Also, junior doctors were inadequately orientated and trained. KEMH lacked a formal and effective credentialling program for doctors and arrangements for approving admitting rights for visiting doctors were unsatisfactory. Recruitment, appointment and re-appointment procedures for senior doctors were sub-standard and KEMH failed to establish an effective performance management program.

Consultant accountability and cover

Consultants identified as responsible for clinical care were no more than nominally responsible. Despite Hospital policy requiring junior doctors to seek senior clinician advice when necessary, the culture dissuaded this approach, resulting in delayed or deficient care.

Factors compounding the problem of consultant cover included low consultant numbers and inadequate consultant use, budget constraints and recruitment difficulties, the mix of full-time and sessional consultants and the University Department's decreasing profile. This situation changed little until Moodie's arrival 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 Moodie's repeated requests. Discussions between the Hospital Executive and the Directorates to determine required cover were difficult and drawn-out.

Junior doctor supervision and training

Junior doctors' supervision was inadequate from the early 1990s, however management failed to act on this matter until early 2000. Junior doctors received little or no supervision by consultants, who were considered

the “last link in the chain of command” and were only rostered on duty in business hours (despite two thirds of the Hospital’s caseload occurring outside business hours).

Hospital policy required a senior doctor to be on-call rather than on-site after hours, so on-site twenty-four-hour coverage by a senior doctor was lacking. Junior doctors were expected to know when they needed supervision rather than senior doctors deciding on a junior doctor’s competence 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 improvements to junior doctors’ supervision made in 2000, further changes were needed to maintain safe care.

The orientation program for junior doctors focused primarily on administrative aspects of work. KEMH failed to train doctors in the clinical skills required for prompt, safe care. Nor were junior doctors starting in a new clinical area given any support via a training or mentor program. KEMH also lacked an orientation program for registrars, and the needs of junior doctors from overseas were overlooked despite evidence of clinical mishaps among this group.

Cardiotography (CTG) interpretation provides a good example of deficient or non-existent training programs at KEMH. Doctors and midwives used Cardiotography to monitor a foetal heart. Concerns about the skills of residents and registrars interpreting CTGs were widely discussed over many years. The Hospital’s 1990 Foetal Monitoring Service Manual directed that all new staff must be competent in CTG, training courses must be conducted every 3-4 months, and competency must be verified by written exams.

However, practice was inconsistent with policy. Junior doctors’ training was irregular and infrequent, with midwives often interpreting CTGs in the Labour Ward. KEMH failed to act on recommendations to implement compulsory CTG training courses for registrars and residents. The Hospital lacked a system to ensure registrars and residents attended formal training, were trained before working in Labour Ward, and checked their competency before they assessed and managed a patient using CTG.

The midwives, rather than the registrars, often taught residents how to interpret a CTG trace in the Labour Ward. The CTG training program for midwives was well organised and held regularly. At the end of 2000, training inconsistencies in CTG interpretation persisted.

Credentialling and admitting privileges

The Hospital defined credentialling as the process by which management “determined the clinical privileges that ... allow a medical practitioner to practice in the Hospital”. KEMH had no formal credentialling process until June 2000. KEMH failed to maintain a current and accurate credentialling list and there were many examples of a director verbally granting credentialling status with little basis. Operating Suite and booking staff often received no notification of these arrangements.

The credentialling committee failed to meet from 1997 to 1999 and was finally established in February 2000. However the credentialling process was yet to be established. The Committee’s Terms of Reference were endorsed in June 2000 and it met in August 2000. In September a formal credentialling policy and a credentialling application form was adopted, however the Committee failed to meet again until March 2001.

The admitting privilege policy issued in June 2000 remained unchanged from the 1994 version, and required a small committee to review associate consultant admitting privileges annually. However, there was no evidence of such reviews or any accreditation of General Practitioner obstetricians.

Employment issues

Significant deficiencies were noted with the appointment of a medical director and senior consultants. With its devolved management structure, KEMH relied heavily on the clinical directors’ ability and willingness to manage the clinical care unit operations, and the medical director’s position description reflected the importance of these management skills. However, the 1996 appointment process for the Obstetrics Medical Director position failed to consider applicants’ management skills. As well, KEMH restricted advertising to internal applicants.

The Inquiry was able to obtain documentation on only ten consultant appointments occurring from August 1997 to Sept 2000 because the Hospital destroyed all other documentation. 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 KEMH, 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 or 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 reappointments. The Hospital sessional consultants should have been considered for reappointment in 1992. However, the first recorded reappointment of consultants occurred in March 1997. The reappointment 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 Moodie was appointed.

Performance management

Hospital policy required performance appraisals to occur regularly. However, there was little evidence of management or senior doctors participating in performance management, and the Hospital had no formal performance management program until 1997. Midwives established their own informal performance management process and consultant performance appraisals were rarely done. 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 in some cases, registrars (possibly inexperienced in assessing clinical skills) completed appraisals after a resident left an area.

Involving women and families and managing complaints

Many women and their families reported receiving insufficient information about treatment options, risks or errors of care. They perceived little or no involvement in decisions about care, poor treatment and disrespect when making a complaint and lack of support when they experienced poor outcomes or adverse events. The Inquiry received reports from women about poor or no communication from Hospital staff during potential medical negligence case reviews.

The Customer Complaints Policy was one of the few KEMH policies that dealt comprehensively and clearly with the subject. However, KEMH provided no clear advice to patients and families about the complaints process and failed to provide sufficient information to complainants about incidents and adverse events and action to rectify the situation. KEMH had no single complaints filing or coordination system and as such, complainants often received several (sometimes contradictory) letters. Complaints were generally not considered improvement opportunities.

Quality improvement and accreditation

KEMH lacked an effective Hospital-wide program to monitor and improve service standards. The Board of Management played no part in ensuring the safety and quality of care. The Hospital lacked systems to monitor key aspects of care and respond to poor performance. KEMH neither evaluated the effectiveness of department-level quality improvement activities, nor could it demonstrate that devolved management supported ongoing improvements in safety and quality.

KEMH failed to react to recommendations arising from accreditation processes. The ACHS standards used to assess performance primarily reflected hospital structures and processes rather than the quality of care. This was generally left to Hospital staff through internal quality improvement programs. During the review period, accreditation was insufficient to assure the safety and quality of service and care at KEMH.

In 2000, Moodie reported these deficiencies to the Metropolitan Health Service Board:

- lack of a hospital-wide clinical quality program;
- 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;
- failure to focus on or follow-up the outcomes of quality activities;
- varying levels of support from staff for quality improvement, and little support from doctors.

Devolved management

The primary goal of the devolved management initiative was to devolve responsibility and authority to clinical staff to support and enable better patient care. This structural change failed to resolve (and in some cases exacerbated) serious clinical issues. These included unclear accountability and responsibility, non-compliance with Hospital policy, poor care coordination, and lack of decisions on important and long-standing patient and staff welfare issues.

The structure lacked senior management involvement to strengthen and support devolution and clinical service decisions, and problems remained unresolved. Long-standing matters were referred to one or more committees, generating much correspondence but little or no action or resolution. Reasons for failing to change outdated policies or compare performance included perceptions that KEMH was “a unique, world-class service” and that clinical service compared favourably with other organisations. These perceptions remained speculative only.

Regulation and clinical governance

Under the 1998 “Australian Health Care Agreement” established between the Western Australian Government and the Commonwealth, the state received funding for five years 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 to assure or improve the safety and quality of obstetrics and gynaecological services at the Hospital.

KEMH had three governing bodies from 1990-2000. Under the Hospitals and Health Services Act 1927, the Boards were responsible for “the control, management and maintenance” of the Hospital, and this clearly included the provision of safe, appropriate 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. 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 about the safety and quality of care;
- no framework or standard requirements for inter-hospital benchmarking;
- local credentialling systems that failed to ensure clinicians were adequately skilled;
- unreliable incident or adverse event reporting systems and follow-up processes;
- confusing and contradictory statutory requirements for mortality review and investigation, underperforming statutory mortality committees and long delays in review of deaths.

The appointment of Michael Moodie as Chief Executive in 1999 saw the first of any active involvement in safety and quality issues at this level. He advised the MHSB 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.

Actions to rectify problems

Moodie initiated the considerable effort made by many KEMH staff to respond to the Inquiry recommendations. Along with specific process and policy changes, the focus was on improving staff morale, managing adverse media coverage, supporting patients and families and reintroducing a range of management strategies. The Departmental Steering Committee (chaired by the Deputy Director General of the Health Department of Western Australia) was established to oversee the changes and improvements arising from the Inquiry recommendations. The Minister reports quarterly to Parliament on the implementation process.

Improvements include better supervision of junior doctors by senior registrars and establishing the “On-call Agreement” to increase consultant cover after-hours and in special care areas. KEMH established an incident reporting committee and a single incident reporting system. Clinical guidelines and manuals were updated and a list of sentinel events and indicators was established to identify high-risk cases. The doctors’ orientation program, position descriptions and performance management processes were improved, and the terms of reference of key executive committees were reviewed. KEMH received approval from the Health Department, Western Australia to purchase new centralised foetal monitoring equipment and four senior medical academic Obstetrics and Gynaecology positions were established. Quality plans were developed and KEMH underwent full ACHS accreditation survey in March 2002.

These changes are a good start, however the Inquiry indicated that much more work was needed at State, Board and senior management levels to ensure KEMH meets its statutory responsibilities and stakeholder expectations.

Strengths and limitations – some considerations

The Douglas Inquiry is a landmark in the evolution of health care safety and quality policy and practice in Australia. The clear, strong focus on infrequently discussed clinical practice issues effectively maps the current concerns and challenges facing the health care industry. The detailed analysis of safety and quality issues and revealing case studies provide invaluable teaching and learning opportunities. The Inquiry clearly has strong positive features and provides an invaluable insight into important health care safety and quality issues.

However, some consideration of the less positive aspects of the Inquiry’s brief, powers and approach may help provide a balanced perspective of the value of such inquiries and their place in future strategies to improve health care safety and quality.

Statutory protection

Statutory authority restrictions hindered the Inquiry’s efficiency and effectiveness. Under the Hospitals and Health Services Act and the Public Sector Management Act, the Inquiry had insufficient statutory protection from personal liability and insufficient power to refer serious matters to State or Commonwealth authorities. The Inquiry also lacked assurance that information and evidence given to or obtained by it would be protected from publication once the Inquiry was complete. When an inquiry is necessary, it may be more appropriate (and useful to the health care system) to give it the power and protection of the Royal Commission Act.

Bias and focus

The Inquiry’s Terms of Reference directed it to examine management and clinical practice problems and recommend improvements. This established a negative bias for reporting poor performance rather than good performance. The Inquiry was also intentionally biased to high-risk cases requiring complex care (as these were the cases the Hospital was expected to manage). Rather than reviewing a representative sample of all cases (a costly and resource-intensive exercise beyond its brief), the Inquiry reviewed a sample of high-risk cases.

Comparing performance

Limitations were evident in the comparative analysis of perinatal, obstetric and gynaecological clinical indicator results between KEMH and thirteen other Australian hospitals. These included demographic differences, reliance on routinely collected data and difficulties adjusting for variability. Despite these limitations, the

Consortium believed their findings were sufficiently valid to identify major differences between the hospitals and to recommend further investigation into several KEMH results.

However, with the exception of this clinical indicator comparison, the Inquiry focused on one hospital's performance. In all other aspects, the Inquiry did not assess 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.

Approach

There appeared to be some contradiction between the Inquiry's role and the final content of its report. The Inquiry was meant to focus and report on systemic problems rather than individual performance. However, some observers considered the Inquiry's approach adversarial and throughout the somewhat cumbersome report, individuals were named and individual behaviour and actions were recorded in detail. The value of this approach for understanding and addressing health care problems is questionable.

Resource allocation

The time and resources required to complete the Inquiry were considerable, with a timeframe of eighteen months and a cost of \$7million - primarily to identify management and clinical problems at one hospital. Such resources could be better channelled into establishing effective, routine safety and quality monitoring structures and processes across the industry to support and enable improvements in health care safety and quality.

Good policy, regulation, funding and governance

Finally, the Douglas Inquiry understates the consequences of poor policy and regulation. The report omits discussion on responsibility for the adequacy of and sustainable funding for key hospital infrastructure. There is little or no consideration of government responsibility for ensuring the adequacy of recurrent funding and allocation, nor is there sufficient commentary on clinical governance performance or associated recommendations. The Douglas report understates the risks associated with governments, Boards and hospital leaders focusing excessively on cost containment at the expense of safety and quality.

Comparing inquiries – King Edward, Bristol and Royal Melbourne Hospitals

The Bristol Case involved heart surgery on babies in Britain's Bristol Royal Infirmary from 1988 to 1994 (Kennedy 2001, United Kingdom Department of Health 2002). Dr Steve Bolsin, a cardiac surgery anaesthetist at Bristol, was concerned that the number of deaths following arterial switch operations (a procedure performed on babies with congenital heart abnormalities) and the procedure time 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 who subsequently informed the Department of Health. Two surgeons and the chief executive faced charges of serious misconduct. The parents of children who died in this case felt they received misleading information about the risks associated with the procedure.

More recently, the Victorian Minister for Health commissioned an inquiry into management and performance matters at Royal Melbourne Hospital (RMH) following allegations of serious misconduct by nurses at the Hospital (Health Services Commissioner 2002). The Health Services Commissioner led the Inquiry, focusing on nursing and nursing management issues associated with medication management, incident reporting, documentation standards and staff support systems. The Inquiry found numerous medication management systems problems, inadequate incident and adverse event monitoring and response systems, poor documentation standards and problems with staff support and supervision. The Inquiry acknowledged recent improvements and emphasised the considerable work still required for RMH to meet stakeholder requirements and public expectations.

Both the Bristol and King Edward cases arose from "whistle-blowers" reporting serious problems rather than from established safety and quality monitoring systems. In both cases, the Department of Health received information about management and clinical performance problems unresolved over a long period. In both cases, the Inquiries found inadequate state-level morbidity and mortality monitoring and review systems, inadequate monitoring of the effectiveness of safety and quality systems, and poor clinical and emotional outcomes for patients and families.

The policy environment for both KEMH and RMH featured a disproportionate focus on financial matters and cost containment. All three inquiries revealed inadequate clinical governance, with those responsible failing to establish a culture, environment, systems and processes to effectively support and demonstrate the delivery of safe, quality care. In all cases, management failed to respond effectively to clinical problems and failed to establish reliable systems to identify, report and respond to errors and adverse events. Quality systems were absent or ineffective for monitoring, reporting or responding to performance problems. Links between complaints management and quality improvement were non-existent or ineffective, as were training, credentialling and performance management systems. These shortcomings contributed to potential or actual poor outcomes for health care consumers and their families.

The approaches used in these inquiries differed, as did hospital staff and public responses. The Bristol and RMH cases were consultative and hospital management actively supported the process. Media reviews suggest Bristol actively engaged public interest and encouraged participation in the process (BBC 1999). A web site was established to inform the public of the inquiry's proceedings and progress. In contrast, the Douglas Inquiry approach was considered by some to be adversarial with "name, blame, shame" elements evident in the report and "mud-slinging" matches in the media (Hickman, Egan, Cowan, Hills 2000). KEMH resisted the process and the Western Australian branch of the Australian Medical Association actively and publicly fought it.

All three inquiries point to the need for change at government, board and management levels to establish a culture of inquiry and open disclosure, and to introduce rigorous systems to monitor and improve the safety and quality of health care.

Lessons from the Douglas Inquiry

The Douglas Inquiry presents important lessons about the role of governments, Boards and hospital management in patient safety and service quality. These arise from issues of accountability and responsibility, leadership and culture, safety and quality systems, staff support and development, and concern and compassion for patients and families.

System governance

Governments must ensure health service Boards and statutory authorities meet their statutory requirements, and that hospitals are adequately resourced and funded to support safe, quality care. Hospital accreditation and other external monitoring systems need to mandate acceptable organisational performance. The health care industry requires rigorous systems to analyse and compare hospital performance. Matters for debate and decision include voluntary versus mandatory performance reporting, clinical privilege and public disclosure of performance.

Clinical governance and quality systems

Good clinical governance requires Boards and hospital management to focus strongly on building a positive culture of trust and inquiry aimed at meeting the needs of patient and families through good safety and quality systems. Assuming and stating that an organisation gives good care is just not enough to meet legal, ethical and public demands and expectations. Hospitals must have evidence-based policies and procedures, good policy compliance, rigorous data comparison and benchmarking processes, as well as effective incident monitoring and mortality review systems. Other essentials include good complaints and medico-legal case management, staff training, credentialling and performance management systems.

Concern for consumers and families

Hospitals are meant to be caring organisations. The Board, management and staff must recognise the importance of involving patients and families and must establish robust and sustainable systems to involve, support and inform people of their health care options and the associated risks. A concerned health service gives a full explanation when things go wrong and actively involves patients and families in error prevention strategies and improvement processes.

Wake-up call

The Douglas Inquiry is a wake-up call for governments, Boards, chief executives, managers and clinicians to understand and meet the responsibilities and challenges of safety and quality in health care. No longer is it acceptable for Boards and managers to treat the safety and quality of clinical services as the exclusive prerogative and responsibility of the clinician. No longer is it acceptable for boards and managers to ignore or override safety and quality concerns in the name of rigid adherence to externally imposed financial constraints.

At KEMH, inadequate clinical governance, poor or non-existent systems and ineffective responses to important issues resulted in serious adverse events and poor clinical outcomes for women, babies and families. The system-wide implications are significant and clear – to enable safe, quality care the industry needs:

- strong, effective clinical governance and leadership supporting a culture of open disclosure;
- commitment to and accountability for effectively addressing 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 to ensure clinicians have appropriate skills and training;
- reliable and consistent incident and adverse event reporting systems and follow-up processes;
- clear and practical statutory requirements and systems for mortality reporting and investigation.

Governments, health service boards, health care leaders, managers and clinicians have the opportunity to learn from the Douglas Inquiry's lessons and lead the way to improved hospital systems and better, safer patient care.

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