Patient Safety

A comparative analysis of eight Inquiries in six countries

A review for the Clinical Excellence Commission
The Centre for Clinical Governance Research in Health undertakes strategic research, evaluations and research-based projects of national and international standing with a core interest to investigate health sector issues of policy, culture, systems, governance and leadership.
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Patient Safety: a comparative analysis of eight inquiries in six countries
1 Summary

This is a report of eight Inquiries into alleged poor health care. Three are from Australia: from Perth (King Edward Memorial Hospital), Melbourne (Royal Melbourne Hospital) and Sydney (Campbelltown-Camden). The remainder are from Scotland (Glasgow’s Victoria Infirmary), England (Bristol Royal Infirmary), Slovenia (Celje Hospital), New Zealand (Southland DHB) and Canada (Winnipeg Health Sciences Centre).

All the inquiries concerned allegations of poor clinical practice. The King Edward Inquiry concerned the treatment of obstetrics and gynaecology cases over several years at a major tertiary referral and teaching hospital. Royal Melbourne involved inappropriate treatment of patients, unprofessional behaviour and medication errors. The Campbelltown-Camden Inquiry related to a wide variety of elements of care, predominantly for individual patients. Glasgow concerned outbreaks of healthcare associated infections that seemed to have been poorly managed, and Bristol largely related to poor outcomes after paediatric heart surgery. Celje involved alleged inadequate reporting of pathology results mainly relating to suspected malignancies. Southland centred on the care of patients with mental illness. Winnipeg also concerned paediatric heart surgery. A summary of the key recommendations and findings of the reviews is presented in Appendix 1.

1.1 Aspects of most or all the Inquiries

This study draws on a small and purposive sample. The predominance of English-speaking countries partly reflects the difficulties in accessing and then interpreting reports in other languages. Slovenia appears by accident: one of the authors has been working in Slovenia.

The extent to which the findings are generalisable is therefore left to the reader’s judgment. However, it is relevant to note the common features of the sample, as follows in Table 1.

Table 1: Common features of inquiries

- The inquiry teams were largely impartial and objective
- Some health care was far below standard
- Quality monitoring processes were deficient
- Individual care providers and patients raised the concerns
- Critics were often ignored or abused
- Teamwork was deficient
- Patients and families were not informed members of the team

The inquiry teams were largely impartial and objective

All the inquiries were conducted in an impartial way by dedicated investigators who cannot be questioned in terms of their motives, energy and attention to detail. It is highly unlikely that their conclusions are erroneous. At least, it is doubtful there will ever be any alternative sources that present a better picture.

The teams had slight differences of emphasis that probably reflected the personal views of their leaders to some extent, but mostly reflected differences in their terms of reference. For example, most were conducted under a specific legislative instrument that constrained the course of the investigation.
The most obvious difference concerned the balance to be struck between finding individuals who were culpable, and learning lessons of relevance to the health care system. This said, all the inquiry teams had difficulty in avoiding consideration of both aspects. There were greater differences in the terms of reference than in the content of the final reports.

**Some health care was far below standard**

In every case, the investigators concluded that some of the care was below reasonable standards. In a few cases, the care was judged to be far below what the patients had the right to expect.

**Quality monitoring processes were deficient**

The agencies that had been established to monitor quality of care and therefore to protect patients from harm were almost uniformly ineffective. In some cases, those agencies were a significant constraint to the discovery and rectification of errors.

The role played by the medical professional associations was the most common target of criticism. While they tended to argue that professions should be given the freedom to manage themselves, they failed on frequent occasions to indicate that they knew what professional responsibility really meant.

**Individual health care professionals and patients raised the concerns**

None of the incidents of poor care would have come to the public’s attention when they did, if it had not been for a combination of dedicated health professionals and concerned patients (and their families). One common thread is that patients or their families were persistent in the face of reluctance on the part of health care organisations ‘to do the right thing’. In most cases, the patient and families persisted with their complaints largely because no one was willing formally to admit to errors and apologise.

Health care organisations who supported investigation mostly did so in informal ways. In several cases, this obviously included giving informal encouragement to patients and families to pursue their complaints.

**Critics were often ignored or abused**

Where individual health professionals chose to speak out, they were almost uniformly ignored at best. They were treated with contempt and abuse at worst.

**Team work was deficient**

Many individuals who were largely competent and dedicated had ineffective working relationships. All the inquiry reports described the various manifestations of poor team work. For example, all of them mention low levels of sharing of clinical documentation, and inadequate understanding of and respect for the contributions of other clinical professions.

**Patients and families were not informed members of the team**

Each inquiry makes mention of poor communication between health care organisations and patients and their families or other carers. The main features are more or less constant: patients were not adequately involved in care planning (and did not always have an adequate basis for informed consent); they were unsure of their rights (and frequently afraid of exercising them); were sometimes treated in inconsiderate ways (mainly by doctors); and seldom received sympathetic and helpful support when they made complaints.
1.2 Differences

Five of the inquiries have hardly any differences of substance: Bristol, Winnipeg, King Edward, Southland, and Celje. The inquiries from Glasgow and Campbelltown-Camden are outliers in a few respects, as is clear from the following comments. Table 2 summarises the main differences between the inquiries.

Table 2: Differences between inquiries

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The distribution of case types

The inquiries at Bristol, King Edward, Southland, Celje, and Winnipeg focused on a narrow range of case types and care processes (paediatric cardiac surgery at Bristol and Winnipeg, oncological pathology at Celje, mental illness at Southland, and obstetrics and gynaecology at King Edward). This was true to a lesser extent at Glasgow, with its emphasis on hospital acquired infection. The Campbelltown-Camden report is an outlier here, since it was directed at a set of incidents crossing several clinical specialties.

However, the difference may be only minor in some respects. The mix of case types at Campbelltown-Camden was at least partly a consequence of the way that the concerns emerged: the nurses who made the formal complaints happened to have a variety of places of work. Moreover, there is some kind of focus on emergency care. If the complaints had arisen in a different way, there might conceivably have been more similar patterns. The Campbelltown-Camden team that undertook the final investigations chose to restrict themselves to allegations regarding individual patients – and indeed were directed to do so. They might have produced different findings if (say) they had been asked to investigate emergency services or palliative care.

The balance between individual and collective responsibility

The inquiry reports from Bristol, King Edward, Celje, and Winnipeg place great emphasis on collective responsibility. There is recognition of problems of team work in Glasgow, but it tends to be less explicit for the most part.

The same may be true of Southland: much of the report focuses on what individual health care professionals did. However, in both cases (and especially in the case of Southland) the nature of the legislation under which the inquiries were conducted required there to be such a focus.

The Campbelltown-Camden report is again an outlier. The authors place much more emphasis on individual responsibility, and make particular mention of the need to ensure that health professionals who perform poorly are censured. Indeed, the Campbelltown-Camden Inquiry was relatively critical of those who seemed to want to emphasise systems problems, such as the Health Care Complaints Commission. This seemed to reflect the initial confusion of the inquiry team over the meaning of systems problems, the systems approach, and a ‘no blame’ culture. The Winnipeg Inquiry and (perhaps to a lesser extent) the remainder may have been less confused.
Legal aspects of care

Again, the notable outlier is Campbelltown-Camden. Legal aspects dominated its report, and much time was given to explaining the ways in which an earlier inquiry by the Health Care Complaints Commission had failed to apply the relevant laws.

Specific mention was made of the local peculiarities: “The relevant standards and systems, both for the delivery of health services and for dealing with complaints about them, are creatures of New South Wales law and government. There is no avoiding the specific texts of New South Wales legislation governing the matters examined by this Inquiry.”

Again, however, the dominant factor might have been the differences in terms of reference. The inquiry team of Campbelltown-Camden had a clear direction that emphasised individual accountabilities under the law. Moreover, the inquiry team itself seemed to be more familiar with (and consequently more interested in) the legislative rather than the health care systems aspects of poor care.

The severity of the problems

Glasgow is a clear outlier in respect of severity. Unlike the others, the inquiry team only made mild criticisms, and its main conclusion was that there was no evidence that the deaths at Glasgow’s Victoria Infirmary could have been avoided. However, they made a large number of recommendations for change, and some would at least imply there had been weaknesses in the provision of care. Speakers at a conference called to discuss the findings were more critical on the whole. Terms related to cultural change, improved communication, better coordination, and improved team work were frequently used.

1.3 … and the answer is …

Readers will form their own views about the totality of the diagnoses and recommended treatments. However, it seems to us that most of the messages are clear and they are relevant to most health systems around the world.

They are such compelling, universal narratives in their own right that we have mostly used their own words to tell the story, rather than ours. Indeed, one of us has recently been reviewing problems in two quite different countries – Japan and Mongolia – and another of us has done work in Singapore, East Timor and Papua New Guinea – and it is hard to spot the differences relative to the eight stories recounted here. This suggests that aspects of the ways of thinking and behaving are common to health care (and to medical and nursing in particular) and they tend to be more significant than differences in social or economic circumstances from country to country.

One of the messages worth repeating has been well summarised by Siddins (2000) and we will therefore use his words. “The Douglas Inquiry has clearly illustrated systematic deficiencies in the delivery and regulation of obstetric and gynaecological services. Such problems are not unique to the King Edward. Irrespective of the specialty, seven million dollars of careful analysis at any Australian tertiary hospital would have yielded the same conclusions. What lies at the core of the problem are grossly deficient industry standards for quality, safety and efficiency.” That his views are so similar to many of those expressed about the other inquiries suggests he may have captured something essential.

Two final points are worth making at the risk of labouring these issues. The first that there is a strong argument for inquiries, and the health system generally, to take a systems as opposed to prosecutorial view of these cases. Hardly anyone in these cases knowingly or deliberately tried to harm anyone. The actors in the cases were not like Dr Shipman, the British general practitioner
who systematically killed at least 250 patients in a cold blooded, calculating manner (Smith 2005). A prosecutorial approach, if overused or employed bluntly, will likely have undesirable consequences: clinicians, especially doctors, will be less likely to participate in change initiatives (Braithwaite 2005a).

The second point is that culture change in medical and health settings is needed. By this we do not mean structural change (Braithwaite et al 2005) as so often happens in health care, but change to the fundamental ways stakeholders work together and relate to each other and their patients over time. This is likely to require concerted effort over the medium or long term in order to achieve sustainable results. There is little substitute for longitudinal effort. Short term fixes have been tried many times in many settings, and these have not made the progress needed.

2 Bristol Royal Infirmary, United Kingdom

Of the various inquiries in recent years, Bristol is probably the most widely known. It has been the subject of wide discussion in the mass media as well as in the technical literature.

There are various reasons why it has attracted so much interest. One is the degree of demonstrable harm: the victims were children, and many of them died or were permanently disabled. Another is the thoroughness of the inquiry process: relatively detailed and objective inquiries were undertaken both by the General Medical Council (GMC) and the Department of Health, and their reports were made publicly available at the earliest possible opportunity. Perhaps the main reason for interest, however, is that the weaknesses were so obvious and yet nothing happened for so long. In short, it is a story that is hard to accept.

We begin by describing the events that led to the inquiries. Brief mention is then made of the inquiry conducted by the GMC, but we focus on the larger inquiry subsequently conducted by the Department of Health.

2.1 Context

The Bristol Royal Infirmary (BRI) and the Bristol Royal Hospital for Sick Children (Children’s Hospital) are teaching hospitals associated with Bristol University’s Medical School. Together, they formed the United Bristol Hospital Trust – one of the partly corporatised components of the National Health Service (NHS) that emerged from Thatcher’s internal market reforms of the late 1980s. We will refer to the BRI and the Children’s Hospital to cover the two hospital sites at which care occurred that was the subject of the Inquiry. Where both are involved, we will refer to them simply as Bristol.

An important area of specialisation is heart disease in adults, children and infants. The cases reviewed in this report concerned congenital heart disease – babies born with heart problems, and their subsequent treatment predominantly through open-heart surgery.

Open-heart surgery on babies is a risky enterprise. Bristol undertook pioneering work in this clinical area during the 1980s, in order to provide services for its catchment area – much of south west England and south Wales, which had historically been neglected in terms of its share of the resources of the NHS. This neglect was reflected in the resources available for cardiac surgical care. There were national shortages in paediatric cardiologists and paediatric nurses, but they were particularly evident in Bristol’s catchment area. Shortages of resources were not
only reflected in the revenue available to employed staff, but also in the capital available for buildings and equipment.

In the early 1980s, the then Department of Health and Social Security (DHSS) established a process whereby certain very specialised services should be funded centrally. The aim was to concentrate resources and expertise. The process, establishing what were called Supra-regional Services (SRS), was intended to control the proliferation of units.

In turn, this would avoid the risk of too many units expending large amounts of resources doing only a few procedures. It would also mean that the clinicians involved would encounter a sufficient number of what were rare cases to acquire the necessary experience and expertise.

Paediatric cardiac surgery was one of the services deemed suitable for categorisation as an SRS. The service was limited to paediatric cardiac surgery on newborn and infant children up to one year of age. Bristol was made one of the nine designated centres in 1984. At the same time, Bristol also continued to carry out heart surgery on children over one year of age.

In 1984, at the start of the period that was subjected to review, there was a designated service for babies under one year old, which involved open-heart surgery at the BRI and closed-heart surgery at the Children’s Hospital. There was also a service funded from local sources for children over one year of age, similarly divided between the two hospitals. However, the combined volumes of open-heart operations never reached the numbers deemed appropriate to ensure economies of scale and appropriate quality.

Adverse comments about aspects of Bristol’s performance surfaced from time to time. However, the interpretation of good performance was understood in different ways. The economic rationalism of the Thatcher government encouraged the view that performance was best equated with throughput. This was relevant both because of the assumption of a relationship between the volume of cases treated and the development of professionals’ skills, and also because funding was based on treating a targeted number of cases. Performance could also refer to the quality of care and patient outcomes, but there was less interest and more confusion about such definitions.

It was recognised in Bristol and in the Department of Health that the circumstances under which paediatric cardiac surgery was carried out in Bristol were capable of improvement. From the early 1980s, proposals were developed to consolidate the service on one site in the wholly paediatric-oriented environment at the Children’s Hospital. This would avoid the need to carry out the open-heart surgery at the BRI in a context in which children were treated and cared for alongside (and to a degree in competition with) adults. It was also planned to appoint a paediatric cardiac surgeon – one who would operate only on children and not, as was the case with the cardiac surgeons in Bristol, also carry out operations on adults with acquired heart diseases. These plans did not come to fruition until 1995.

From the late 1980s, doubts and concerns about aspects of the performance of the Bristol’s Paediatric Cardiac Surgery Unit (PCS) were increasingly expressed in a variety of contexts. Some of these concerns were expressed by health care professionals working in the PCS. Others were expressed by individuals in a variety of contexts outside the Unit. Concerns also circulated in the form of rumour and some appeared in the form of unattributed reports in the media. An operation performed on Joshua Loveday on 12 January 1995 proved to be the catalyst for action. Joshua died on the operating table. An outside review was instituted. Paediatric cardiac surgery was all but halted until a new surgeon was appointed (Joffe 1995).
2.2 The Inquiries

2.2.1 Inquiry by the General Medical Council (1998)

Complaints were subsequently made to the General Medical Council (GMC) concerning the conduct of two cardiac surgeons (Dr Wisheart and Dr Dhasmana), and of the Chief Executive of the Trust (Dr Roylance). The complaints were instigated by an anaesthetist who had been working at BRI, Dr Steven Bolsin.

The GMC’s Inquiry was limited in scope. It only considered the roles of the three doctors against whom the complaints had been made. It also only considered the cases of 53 children of whom 29 had died, and focused particularly on one type of surgical procedure (the Switch operation).

The three doctors were found guilty of serious professional misconduct. Dr Roylance and Dr Wisheart were removed from the Medical Register. Dr Dhasmana’s registration was continued, subject to a three year restriction that he did not operate on children.

2.2.2 Inquiry by the Department of Health (2001)

A group of parents of children who had undergone cardiac surgery at the BRI organised themselves to provide mutual support. In June 1996 the group first called for a public inquiry into the paediatric cardiac surgery services at the BRI. They fought against strong opposition and finally succeeded in achieving their goal in June 1998, when the Secretary of State for Health announced to Parliament the establishment of the Inquiry that is the main source of information for this paper. The Inquiry’s report was released in 2001.

The indications of poor care

Concerns about the paediatric cardiac surgery service in Bristol were first raised as early as 1986 in a variety of largely informal ways. From 1988, concerns began to be raised inside the BRI. The lead was taken by the junior anaesthetist Dr Steven Bolsin, who wrote formally to the Chief Executive (Dr Roylance) in 1990 expressing his concerns about practices in the operating room.

He subsequently collected data and took them to an increasing number of colleagues. According to the inquiry team, he was typically “… advised to take care to verify his information and discuss it with colleagues, including those whose work gave rise to his concern.” Dr Bolsin’s own account, as presented below, is somewhat different in emphasis. In particular, he claims that his concerns were largely ignored by his medical colleagues.

A member and an official of the Department of Health’s Supra-regional Services Advisory Group (SRSAG) had evidence by 1992 that Bristol was performing poorly in terms of mortality, yet did not share this information with the SRSAG as a whole.

The clinicians in Bristol at least by 1990 had data on their own poor performance relative to that of other centres in the UK, which could have caused them at least to pause and reflect. Instead, in keeping with the mindset of the time, they pressed on, drawing false comfort from their figures for 1990 (which proved to be an exception), and only belatedly ceasing to carry out certain operations on children under one year of age.
An opportunity was not taken in July 1994 by an official of the Department of Health (DOH) to investigate more closely the outcomes of paediatric cardiac surgery in children under one year old. It was only in 1995 that paediatric cardiac surgery was formally stopped (although some operations were still carried out after then).

From the start of the 1990s a national database existed at the Department of Health (the Hospital Episode Statistics database) that held information about deaths in hospitals. However, it was not generally recognised as a valuable tool for analysing the performance of hospitals.

The analytical work undertaken by Dr Bolsin and others was subsequently reviewed and extended by experts appointed by the Inquiry. The experts concluded that the data available at the time showed Bristol had a significantly higher mortality rate for open-heart surgery on children under one than that of other centres in England. Between 1988 and 1994 the mortality rate at Bristol was roughly double that elsewhere in five out of seven years. This mortality rate failed to follow the overall downward trend over time that can be seen in other centres.

It was further concluded that a substantial and statistically significant number of excess deaths, between 30 and 35, occurred in children under one year of age undergoing cardiac surgery in Bristol between 1991 and 1995. ‘Excess deaths’ is a statistical measure of the number of deaths observed over what would be expected if the PCS had been typical of other paediatric cardiac surgery units in England.

The mortality rate over the period from 1991 to 1995 was probably double the rate in England at the time for children under one, and even higher for children under 30 days. This higher mortality rate in Bristol was not restricted to the neonatal switch and atrio-ventricular septal defect operations. Even without taking these two higher risk groups into account, there was considerable evidence of divergent performance in Bristol. Further, differences in mortality rates in Bristol could not be explained by differences in casemix (an explanation which some clinicians both then and even now have adopted).

The inquiry process

The Terms of Reference of the Department’s inquiry were “… to inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues; to make findings as to the adequacy of the services provided; to establish what action was taken both within and outside the hospital to deal with concerns raised about the surgery and to identify any failure to take appropriate action promptly; to reach conclusions from these events and to make recommendations which could help to secure high-quality care across the NHS.”

The inquiry team says it adopted “… a ‘systems’ approach to analysis, by which poor performance and errors are seen as the product of systems which are not working well, as much as the result of any particular individual’s conduct.”

The public inquiry was conducted between October 1998 and July 2001 in two phases. In phase one, the focus was on events in Bristol. Evidence from 577 witnesses, including 238 parents, was received in writing. The Inquiry also received 900,000 pages of documents, including the medical records of over 1,800 children. Oral evidence of selected witnesses was taken over 96 days. The focus of phase two was the future. Some 180 papers were submitted to seven seminars in which 150 participants from the NHS, and the public and private health care sectors, took part.
The inquiry team concluded there were individuals who could and should on occasions have behaved differently. In the final stages of the Inquiry, each individual was advised that the Inquiry was minded to comment adversely on some particular aspect of his or her conduct or behaviour, whether a particular incident or a pattern of behaviour, and was told of the evidence on which the Inquiry relied. Each had an opportunity to make representations. Those representations were taken account of by the Inquiry in reaching its conclusions.

2.3 Conclusions of the Inquiry

The DOH inquiry team wrote that the story of the paediatric cardiac surgical service in Bristol was not about bad people. “Nor was it an account of people who did not care, nor of people who wilfully harmed patients. It is an account of people who cared greatly about human suffering, and were dedicated and well motivated. They almost wholly had good intentions and worked long hours with great dedication.”

However, they were part of a system that delivered demonstrably poor care. The main reasons, as judged by the inquiry team, are summarised below, and for the most part were systemic. The inquiry team simply says that “… the health care professionals at Bristol whose work was found to have harmed patients were, for the most part, products of a system that had fundamental weaknesses.”

Underfunding was not the cause of poor care

Throughout the Inquiry, there were regular references to underfunding in Bristol. Those who raised the matter mostly implied there was a gap between the level of resources needed properly to meet the stated goals of the paediatric cardiac surgery unit and the level actually available.

In some sense, these claims were justified. The inquiry team noted there were constant shortages in the supply of trained nursing staff, both for the operating theatre and the Intensive Care Unit (ICU). The complement of cardiologists and surgeons was always below the level deemed appropriate by the relevant professional bodies. The consultant cardiologists lacked junior support.

They were expected to care for children in the Children’s Hospital, and in the BRI operating theatre and ICU several hundred yards away down a steep hill, and to hold outreach clinics all over the south west and south Wales. The care of children undergoing paediatric cardiac surgery was split between two separate sites. Facilities for parents, and necessary medical equipment for children, had to be funded through a charitable agency, The Heart Circle.

However, the inquiry team accepted the claims only to a limited degree. First, it noted that the inadequacy in resources for paediatric cardiac surgery at Bristol was typical of the NHS as a whole, and yet other similar health care organisations were not making the same number of catastrophic errors. The inquiry team therefore concluded that “… whatever went wrong at Bristol was not caused by lack of resources. Other centres experienced the same or similar difficulties. For example, the shortage in qualified nurses and in cardiologists was a national phenomenon, affecting all centres. We therefore emphasise the point again that, while underfunding blighted the NHS as a whole, it does not alone provide the explanation for what went wrong in Bristol.”
We note in passing that, in 2000, the UK government announced a major increase in funding for the NHS as a whole. It committed itself to matching the average level of health spending for the European Union. However, we also observe that hardly any of the increased spending (which amounted to an increase from about 7% to 9% of GDP in three years) was reflected in increased service volumes. Most seems to have disappeared into salary and wage increases, and catching up on the decades of underspending on capital-related assets.

However, the main point made by the inquiry team is surely correct. If resources were insufficient to meet the demand, it would have made sense to reduce the demand, to look for efficiency savings, to transfer the children to other centres to gain economies of scale and quality improvements, and so on.

**The NHS made errors in approving the service**

The inquiry team expressed serious doubts about the appropriateness of establishing the Supra-regional Services at Bristol. The team said that “… designation has all the qualities of a Greek tragedy: we know the outcome and yet are unable, from our point in time, to prevent it unfolding.”

It was unwisely assumed at Bristol that, if there were weaknesses, they would be overcome in time. The politics of regional equity, professional association support, and so on were given excessive weight and this clouded objectivity. In fact, the service failed to improve in the manner that many people had hoped. Bristol’s high aspirations, including attempts to become a centre for heart transplantation, were not matched by its capabilities. The circumstances that caused Bristol to be an inappropriate candidate in the first place were not changed by the act of designation. Rather, the sense of self-importance and competence was reinforced. Subsequently, it was the set of existing conditions that were the barriers to further improvement. The inquiry team said that “… exhaustion and low morale led to stagnation and an inability to move forward in response to new developments, despite the stimulus provided by a new generation of consultants.”

**The service at the BRI was poorly organised**

Poor organisation of the service was reflected in several ways. For example, the service offering paediatric open-heart surgery was split between two sites. It had no dedicated paediatric intensive care beds, no full time paediatric cardiac surgeon, and too few nurses trained in paediatrics.

A particular concern was that the cardiologists were based in one hospital and surgeons in another. The cardiologists, who were well regarded throughout the south west, were understaffed. There was a national shortage of specialists in paediatric cardiology. This meant that the cardiologists at Bristol could not effectively participate in surgery or intensive care. In addition, the prevailing national shortage in nurses trained in paediatric care was reflected in Bristol. The surgeons operated on adults as well as children, and the children were nursed alongside adults in a mixed ICU. While there was an effective child-centred approach to care at the Children’s Hospital, this was not so in the BRI where open-heart surgery was carried out and where the management of care in the ICU was described as ‘highly disorganised with conflicting decisions’. It was never really clear who was in charge.

The split site and consequent split service were major factors affecting the adequacy of care. Unifying the site did not attract sufficient priority in the bargaining for resources: the claims for the paediatric cardiac surgery service made by some of the clinicians were not seen as important enough. However, this did not cause the clinicians to cease to offer the service. There seems to have been an overriding sense of pressing on and hoping that one day the service would be moved
onto one site, that the new hospital for children would be built, that the new surgeon would arrive, and that all would then be well.

**Inequitable treatment of the various clinical professions**

Senior doctors (consultants) enjoyed (and still enjoy) what is virtually a job for life. Their relationship with the health care organisation that employs them makes it difficult to bring about change. Far less attractive employment conditions arrangements applied for most other categories of staff.

The inquiry team argued that all employees should be treated in a broadly similar manner. Doctors, nurses and non clinicians must work together as health care professionals, with comparable terms of employment and clear lines of accountability, if they are to provide the best possible care for patients.

For this and other reasons, doctors had excessive power and too little accountability. In total, the inquiry team concluded that there was “…an imbalance of power, with too much control in the hands of a few individuals.” Many groups, but particularly the senior doctors, had established a ‘club culture’ whereby their views could be reinforced and imposed on others (Dyer 2001).

**The absence of defined standards of care**

There were no agreed standards of care for paediatric cardiac surgery or for any other specialty at Bristol, but patients were not aware of this. The inquiry team argued that parents taking their children to be treated in Bristol assumed that the level of care provided would be good, given that the care would be provided by a supra-regional centre selected by the Department of Health. They trusted the system without good reason.

**Failure to share information**

The inquiry team said that “… Bristol was awash with data.” There was enough information from the late 1980s onwards to cause questions about mortality rates to be raised both in Bristol and elsewhere had the mindset to do so existed.

However, little if any of this information was available to the parents or to the public. Such information as was given to parents was often partial, confusing and unclear. There should have been more openness about clinical performance. Patients should have been able to gain access to information about the relative performance of a hospital, or a particular service or consultant unit.

**No structured monitoring of quality**

The clinicians in Bristol had no one to satisfy but themselves that the service that they provided was of appropriate quality. There was no systematic mechanism for monitoring the clinical performance of health care professionals or of hospitals.

The absence of adequate management was simply not recognised by most staff. The inquiry team said that “… it would have taken a different mindset from the one that prevailed on the part of the clinicians at the centre of the service, and senior management, to come to this view. It would have required abandoning the principles which then prevailed: of optimism, of learning curves, and of gradual improvements over time. It would have required them to adopt a more cautious approach rather than muddling through.”
At a local level, there was some relevant activity. The clinicians involved in providing the paediatric cardiac surgery service collected analysed data on procedures and deaths, established and maintained computerised information systems, produced and circulated statistics and analytical reports, made annual returns to the national UK Cardiac Surgical Register and received back aggregated data about national performance. They also held regular meetings to discuss the results of audits, and reviewed individual and series of cases. However, these processes were made largely ineffective because of the culture. Statistics were collected that represented ends in themselves, views about quality were already established and were largely not influenced by evidence, and anyone questioning performance was considered to be inexperienced or mischievous.

At a national level, there was confusion as to who was responsible for monitoring quality of care. The SRSAG thought that the health authorities or the Royal College of Surgeons had the matter under control, the Royal College of Surgeons thought the SRSAG or the Trust were supervising the activities, and so on. The inquiry team said that the reality was “... no-one was doing it. We cannot say that the external system for assuring and monitoring the quality of care was inadequate. There was, in truth, no such system.”

**Poor team work**

The inquiry team said it was able to reach one conclusion “… that owes nothing to hindsight.” There was poor team work and this had implications for performance and outcome. The crucial importance of effective team work in such a complicated surgical area was very widely recognised, but Bristol was unable to put this in place. Everyone just accepted that team work was poor, and assumed that nothing could be done to improve it.

There were logistical reasons for this: for example, the cardiologists often could not be where they were needed because of the split site. However, the main reasons were cultural. The inquiry team said that “… relations between the various professional groups were on occasions poor. All the professionals involved in the paediatric cardiac surgery service were responsible for this shortcoming.” However, it was concluded that the poor team work was primarily a consequence of “… a clear lack of effective clinical leadership. Those in positions of clinical leadership must bear the responsibility for this failure and the undoubtedly adverse effect it had on the adequacy of the paediatric cardiac surgery service.”

**Inappropriate management culture**

Like most health care organisations in the UK, Bristol was managing the transition from the known (the old NHS) to the unknown (Trust status) during most of the period under review. However, unlike most other health care organisations, the style of management was such as to make any kind of reform difficult and risky. The inquiry team says that “… the systems and culture in place were such as to make open discussion and review more difficult. Staff were not encouraged to share their problems or to speak openly. Those who tried to raise concerns found it hard to have their voice heard.”

The Chief Executive was judged to be thoughtful and principled in his development of a more appropriate management system, and he succeeded in meeting the principal obligation of balancing the books. However, he created fragmentation and ignored ways of alleviating the consequent problems. He established a system of separate and virtually independent clinical directorates, and gave a clear message that problems were not to be brought to him for discussion and resolution. The inquiry team says “… there was power but no leadership. The environment was one in which problems were neither adequately identified nor addressed.”
**Inappropriate involvement of the Board of Management**

The style of downward management was reflected in the way the Chief Executive handled the Board. The Chairman and the Trust Board were either part of the ‘club’ or treated as outsiders.

Referring to information about the outcome of care, Mr McKinlay, the Chairman of the United Bristol Hospital Trust (UBHT) from 1994 onwards, told the inquiry team that: “… there was no tradition or culture in UBHT that the Board or the committees of the Board should be involved. I thought that was something that was wrong. I thought the Board should have some knowledge of statistical outcome, but there was a tightrope to be trod to find a way of easing it into place.”

**Inappropriate NHS management**

The problems should have been identified through external monitoring at some level in the NHS. However, what was happening at BRI was certainly not adequately indicated from routine reporting systems (or more precisely from the continual interpretation of those systems).

This was partly a consequence of the prevailing dogma. The internal market had been pushed onto an unsuspecting (and largely confused or uninterested) health care system, and the prescribed goals were business plans, competition, and market forces. The inquiry team says “… this was a feature of the NHS reforms in 1989-1991: senior managers were invited to take control, but little or no system existed to monitor what they did in the exercise of that control.”

This is not surprising in view of the many mantras that promoted the view of business independence, such as ‘local autonomy’, ‘freedom to innovate’, and ‘market competition’. These kinds of ideas might have made sense in some sectors, where patients have the knowledge and power to demand better quality, but they did not make much sense in the health sector.

**Poor ways of dealing with patients**

Some parents were highly satisfied with the care they received from doctors, nurses and others and other parents were highly dissatisfied. The main complaints were directed at the doctors, and particularly the surgeons, who were claimed sometimes to be uncaring and to have given misleading information.

In total, while the evidence is polarised, there is a strong sense that on many occasions communication between parents and some staff was poor. There does not appear to have been any deep thinking about how to communicate information to parents in advance of surgery, nor any systematised approach to doing so. Some parents felt that they had been significantly helped to understand what the surgery and subsequent intensive care involved, but there were also reports from parents of doctors and nurses drawing diagrams on scraps of paper, or even a paper towel. The process of informing parents was apparently seen to be a chore by the surgeons.

Particular criticism was directed at the matter of informed consent, particularly to the surgical procedure. The criticism took account of the high needs of parents for adequate information at an extremely stressful time. The inquiry team said that parents were faced with decisions about a major operation with an uncertain outcome and yet they were often treated peremptorily or with nothing close to respect and understanding.
There was no obvious process: no carefully written materials; no scheduled time for parents to reflect on the information and then ask for more; and no formal attempt to invite questions and answer them. The inquiry team noted that there were seriously inadequate practices at Bristol but how the doctors behaved would not have been regarded as poor practice elsewhere at that time.

Some parents said they were given support and counselling, and commented favourably on it. However, other parents said that they received no counselling at all. Many parents were critical about the way in which they were informed of their child’s death. Again, the criticisms were mostly directed at doctors: parents were generally favourably impressed by the sensitivity and support shown by the nursing staff. The UBHT conceded in its evidence that the service it provided was insufficient to meet the needs of some parents.

The central problem: destructive organisational cultures

It is clear from the conclusions summarised above that the main problems were cultural rather than consequences of (say) logistical problems, resource limitations, or a lack of knowledge. Indeed, the inquiry team made repeated reference to the organisational and professional cultures – the established ways of thinking and acting that were accepted without question by most people involved. Some (but not all) of those patterns were judged to have contributed to care that was demonstrably poor in both objective and subjective terms.

The inquiry team said, in conclusion, that some of those involved “… lacked insight and their behaviour was flawed. Many failed to communicate with each other, and to work together effectively for the interests of their patients. There was a lack of leadership, and of team work.”

Attribution of primary responsibility

For the most part, the inquiry team chose to emphasise that everyone was to blame and yet everyone was a prisoner. However, it made specific mention of a few individuals who “… displayed flaws in their approach to management … showed a lack of leadership and insight … or … failed to treat parents with appropriate respect and candour.” In addition to the three doctors censured by the GMC, the inquiry team criticised the Clinical Director of Children’s Services and the Director of Operations (and Nurse Adviser) at the UBHT.

The inquiry team also named people at higher levels in the NHS, mainly for their failure to take action with respect to strong evidence of inadequate care at Bristol. They were the Medical Secretary of the SRSAG, a Senior Medical Officer in the Department of Health, and the President of the Royal College of Surgeons (who was also a member of the SRSAG).

2.4 Recommendations of the Inquiry

The inquiry team stressed the importance of learning lessons from Bristol. In its view, it was not possible to say that “… events similar to those which happened in Bristol could not happen again in the UK, or indeed that they are not happening at this moment.”

Its main recommendations are outlined below. In making them, the inquiry team stressed some guiding principles including the following:

- The complexity of the NHS must be recognised. There are no easy solutions
- Patients must be at the centre of the NHS, and thus the patient’s perspective must be included in the policies, planning and delivery of services at every level
- Systems of care, and facilities, as well as individuals, affect the quality of health care. Quality must include all aspects of care: clinical and non-clinical. Patients’ safety must be the foundation of quality
Learning from error, rather than seeking someone to blame, must be the priority in order to improve safety and quality. Openness and transparency are as crucial to the development of trust between health care professionals and patients, as they are to the trust between the NHS and the public.

The care of children

Several recommendations were made in this regard, and they need only be summarised briefly here. First, there must be more coordination, and greater integration should be a consequence of design rather than the actions of a subset of dedicated individuals.

Second, the ideal arrangement for children’s acute hospital services is a children’s hospital, close to an acute general hospital. Specialist care must be concentrated in a limited number of centres where the staff have the necessary skills and experience.

Third, there must be standards for the care of children, some of which must be mandatory. There must be incentives to improve children’s care. There must be plans for the publication of information about the quality and performance of children’s health care services.

Fourth, all health care staff who treat children must have training in caring for children. They should also be trained in communicating with young people and parents.

Respect, honesty, and good communication between patients and clinicians

The quality of health care would be enhanced by a greater degree of respect and honesty in the relationship between health care professionals and patients. Future doctors, nurses and other health care professionals must be adequately trained in communication skills during their initial education.

The inquiry team argued that good communication is essential. However, it was informed by the Royal College of Surgeons of England that “… it is the area of greatest compromise in the practices of most surgeons in the NHS and the source of most complaints”.

The basic driving force should be a sense of partnership between the patient and health care professionals. Partnership depends critically on the free and honest exchange of information. This is particularly important when things go wrong. Not only does this show respect to patients. An error, once acknowledged, also allows lessons to be learned.

The inquiry team argued there are four fundamental principles in this regard: trust can only be sustained by openness; openness means that information be given freely, honestly and regularly; it is of fundamental importance to be honest about the twin concerns of risk and uncertainty; and the informing of patients must be regarded as a process and not a one off event.

Hospitals must have an integrated system of support and counselling for patients and carers, staffed by well trained professionals with links to systems outside. Such a system is central to care, not an afterthought. There should be a clear system in the form of a ‘one stop shop’ in every Trust for addressing the concerns of patients about the care provided or the conduct of a health care professional.

Finally, it should not be a question of the health care professional judging what the parent needs to know: it is the parent who should make that decision. The old way of thinking must be abandoned – that patients should be protected from too much information.
Leadership and management

The inquiry team argued that the highest priority needs to be given to improving the leadership and management of the NHS at every level. First, there are implications for the government with respect to the health sector: it must manage the NHS; and it must establish effective systems to regulate the quality of health care that are appropriately competent and independent. The inquiry team did not define independence. From what is stated elsewhere in its report, we must assume the main requirement was independence from those agencies or individuals delivering care. Perhaps the inquiry team meant independence from government.

Second, chief executives of health care organisations (Trusts in this case) must be supported and enabled to carry out their task of monitoring and improving the quality of health care. This is particularly the case, given that they have become legally responsible for this task. Inter alia, this requires the chief executives to ensure that all employees, including consultants, have a similar employment relationship with the Trust.

Third, the management boards of health care organisations must be able to lead health care at the local level. Executive directors should be selected on agreed criteria and appropriately trained. Non-executives should play an active role in the affairs of the organisation.

Finally, the quality of health care should be regulated through bodies such as the National Institute for Clinical Excellence and the Commission for Health Improvement. These bodies should be independent of government. There should be an independent overarching body, the Council for the Quality of Healthcare, to coordinate and integrate the activities of these bodies. This Council should report both to the Department of Health and to Parliament.

Competent health care professionals

Health care professionals must have relevant and up to date skills and expertise, and educational systems are fundamentally important in this respect. They must be educated in communication skills as well as the principles and organisation of the NHS, the development of team work, shared learning across professional boundaries, clinical audit, and leadership.

Medical schools, schools of nursing and management schools should be encouraged to develop joint courses. Future health care professionals must work in multidisciplinary teams; shared learning should therefore begin as soon as possible. A common curriculum for the first year of undergraduate education of all health care professionals should be developed.

A system of regulation should be in place to ensure that health care professionals acquire and maintain professional competence. Regulation includes education, registration, training, continuing professional development, revalidation and discipline.

Medical schools must ensure that the criteria for selecting future doctors include the potential to be versatile, flexible and sensitive. They must also ensure that health care professionals are not drawn from too narrow an academic and socioeconomic base.

Continuing Professional Development (CPD), periodic appraisal and revalidation must be compulsory for all health care professionals. There should be an overarching mechanism to coordinate and align the activities of the various bodies (such as the General Medical Council and the Nursing and Midwifery Council) to ensure that they serve patients' interests.

This mechanism should be a new independent Council for the Regulation of Healthcare Professionals. This Council too should report to the Department of Health and to Parliament. Senior managers in the NHS should be subject to CPD, periodic appraisal and revalidation.
There should be positive incentives to encourage senior clinicians to take on senior managerial roles, including special categories of registration with professional bodies and the ability to move out of and back into clinical practice after suitable retraining. There should be appropriate training for senior clinicians before taking on these roles.

Where surgeons or other clinicians undertake an invasive clinical procedure for the first time, they should be properly trained and directly supervised, if the procedure is already established. In the case of a new, untried invasive clinical procedure they must seek permission from the local research ethics committee. Patients are entitled to know about the experience of surgeons or other clinicians before giving consent.

Finally, the employer must carry the primary responsibility for dealing with poor performance and misconduct. Professional codes of conduct should be incorporated into health care professionals’ contracts. It is for the relevant professional regulatory body to decide whether the health care professional’s registration should be affected.

The safety of care

The inquiry team noted that about 5% of the 8.5 million patients admitted each year to hospitals in England and Wales experience an adverse event that may be preventable with the exercise of ordinary standards of care. How many of these events lead to death is not known but it may be as high as 25,000 people a year.

The components of safe care are much more than the actions or competence of health care professionals: they include the physical environment, equipment, working arrangements, teamwork and good communication.

The NHS is still failing to learn from the things that go wrong and has no system to put this right. Therefore a culture of safety in which safety is everyone’s concern must be created. Safety requires constant vigilance. Given that errors happen, they must be analysed with a view to anticipate and avoid them. A culture of safety crucially requires the creation of an open, free, non-punitive environment in which health care professionals can feel safe to report adverse events and near misses (sentinel events). The Government’s proposed National Patient Safety Agency should be an independent agency to which certain sentinel events are reported for analysis with a view to disseminating lessons throughout the NHS.

The culture of blame is a major barrier to the openness required if sentinel events are to be reported, lessons learned and safety improved. The system of clinical negligence is part of this culture of blame. It should be abolished and replaced by effective systems for identifying, analysing, learning from and preventing errors and other sentinel events. An expert group should consider alternatives to clinical negligence, including an alternative administrative system of compensating those who suffer harm arising from medical care.

Incentives for reporting sentinel events should be introduced, whereby health care professionals’ contracts would provide that they would be immune from disciplinary action from their employer or professional regulatory body if they were to report a sentinel event within 48 hours. Confidential reporting should be ensured and failure to report should attract possible disciplinary action.

An approach to safety based on designing safer systems and equipment should be encouraged. The National Patient Safety Agency should bring together interested parties to tackle some of the more persistent causes of unsafe practices. Finally, an executive director on the Board of Management should be responsible for putting into operation the organisation’s strategy and policy on safety and a non executive director should provide leadership to promote a culture of safety.
Care of an appropriate standard

Patients are entitled to care and treatment of an appropriate standard informed by current knowledge. However, until well into the 1990s, the notion did not exist that there should be explicit standards of care that all health care professionals should seek to meet and which would apply to patients across the NHS. It is now widely accepted that this state of affairs has to change. Patients are entitled to expect that their care will be of such quality as is consonant with good practice, based on sound evidence. Recent developments give cause for optimism. These include statutory responsibility of Trusts for the quality of health care, the development of clinical guidelines through the National Institute for Clinical Excellence, and the monitoring of performance through the Commission for Health Improvement.

There remains insufficient coordination in setting standards. Guidelines appear from a variety of bodies giving rise to confusion and uncertainty. Moreover, there are weaknesses in monitoring performance in relation to these standards, whether at the level of the Trust or nationally. In particular there is no mechanism for surveillance to ensure that patterns of poor performance are recognised and addressed.

For the future, standards for clinical care must be set by the National Institute for Clinical Excellence. In doing so, it must draw on the expertise particularly of the Royal Colleges. Standards must be patient centred. They must not be the product of individual professional groups talking to themselves. They must incorporate the concept of team work and the respective responsibilities of members of the team. Some standards should be obligatory, whereas others should be achieved over time.

Parents taking their children to be treated in Bristol assumed that the level of care provided would be good, given that the care would be provided by a supra-regional centre selected by the Department of Health. They trusted the system. Few had any idea that there were no agreed standards of care for paediatric cardiac surgery or for any other specialty.

In summary, there must be two developments. First, there must be agreed and published standards of clinical care for health care professionals to follow, so that patients and the public know what to expect. Second, there must be standards for hospitals as a whole. Hospitals that do not meet these standards should not be able to offer services within the NHS.

Generic standards for health care organisations (licensing and accreditation)

The inquiry team recommended what it termed generic standards. By these it meant standards that define the minimum capabilities below which organisations should not be permitted to provide NHS services. The standards relate to such matters as the state of the buildings and of equipment, the quality of leadership and the health care organisation’s policies and procedures for ensuring that care is safe and of good quality.

Health care organisations must periodically undergo a process of revalidation. Revalidation would mean that the organisation could continue to offer health care services. The Commission for Health Improvement would be responsible for the process of validation. In time the process of validation should be extended to discrete, identifiable services within a health care organisation.

Monitoring of performance depends on access to relevant information, but in the past there have been great difficulties in collecting it. There has also been a separation between administrative and clinical systems that the inquiry team’s experts described as ‘wasteful and anachronistic’.
In future, the multiple methods and systems for collecting data must be reduced. Data must be collected as the by product of clinical care. At a national level, the monitoring of clinical performance should be brought together and coordinated by one body, an independent Office for Monitoring Healthcare Performance that would be part of the Commission for Health Improvement. It could also carry out a surveillance role.

**Public involvement through empowerment**

The public are entitled to expect that means exist for them to become involved in the planning, organisation and delivery of health care. A patient centred service is one that is designed to address the needs of the particular sectors of the public it exists to serve. Strategic planning at national level, and decisions at local level must involve the public.

The principles that should inform future policy about involving the public and patients in the NHS include the following:

- Patients and the public are entitled to be involved wherever decisions are taken about care in the NHS
- The involvement of patients and the public must be embedded in the structures of the NHS and permeate all aspects of health care
- The public and patients should have access to relevant information
- Health care professionals must be partners in the process of involving the public
- There must be honesty about the scope of the public’s involvement, since some decisions cannot be made by the public
- There must be transparency and openness in the procedures for involving the public and patients
- The mechanisms for involvement should be evaluated for their effectiveness
- The public and patients should have access to training and funding to allow them fully to participate
- The public should be represented by a wide range of individuals and groups and not by particular patient groups.

The NHS must take account of and respond to the interests and needs of the public on a daily basis. Patients must be involved in those processes designed to secure the competence of health care professionals, and particularly in those bodies charged with setting standards for education, training and Continuing Professional Development.

The priority for involving the public should be that their interests are embedded into all organisations and institutions concerned with quality of performance in the NHS: in other words, the public should be ‘on the inside’, rather than represented by some organisation ‘on the outside’.

**2.5 Discussion**

There are two indisputable aspects of the Bristol case. First, the care provided was poor. Second, many people, both powerful and powerless, knew this to be the case but did little or nothing to resolve the problems.
As we noted at the start, it is a story that is hard to believe. This is not because the underlying problems were found to be unique. Indeed, we seem to be able to find them whenever we want to do so. As Siddins (2003) puts it in the context of the similar inquiry of obstetric and gynaecological services at a Perth hospital, "... such problems are not unique to (that hospital). Irrespective of the specialty, seven million dollars of careful analysis at any Australian tertiary hospital would have yielded the same conclusions." This view has been expressed about hospitals in other countries. For example, Maisonneuve, Matillon, Millat and Marescaux (2004) made a similar claim about the situation in France.

The main reason for incredulity about the Bristol story may be the evidence of the degree to which the problems were demonstrably widespread. The Department of Health’s Inquiry produced a long list of senior, powerful, and knowledgeable health professionals who would have done something in a world full of objective and value free scientists. There was at least good reason to ask if there might be a problem worthy of investigation. For many of the health professionals, the evidence should have been seen to be overwhelming. It is not that we doubt we are all prisoners of circumstances to some degree, but that we find it hard to have to accept that this is true.

The main conclusions of the Department of Health’s Inquiry are hardly disputable. The problems were deep rooted and largely concerned organisational cultures, and clinical professional cultures in particular. Many authors have subscribed to this view. For example, Van Der Weyden (1998) argued that it was less a matter of human imperfection than of systemic failure.

Hindle (1998) argued that "... evaluation based on evidence must play a part, but it is insufficient by itself. Dr Bolsin was involved in the development of tools for the measurement of risk adjusted outcomes in cardiac surgery, and they served to confirm his concerns about clinical practice at Bristol. However, his scientific analyses failed to persuade senior managers to take action."

The large quantity of literature describing lessons to be learned from Bristol might lead one to believe the problems will be rapidly solved. However, it could be argued that the ‘clubs’ are already rebuilding their firewalls. Treasure (1998), writing in the British Medical Journal, noted that the Royal College of Surgeons of England and the Society of Cardiothoracic Surgeons established a ‘rapid response group’ so that a member of the council of the college and a senior cardiac surgeon can be on site within 48 hours, to listen and advise on action. “This is an attempt by the profession to protect patients from continuing poor performance and also to safeguard surgeons from inappropriate fault finding (since cardiac surgeons now feel very much under scrutiny and vulnerable in a climate of criticism and blame).” The emphasis might be on the latter purpose. He said that, “… if we do not monitor ourselves effectively there is little doubt that it will be imposed upon us.” He expressed the hope this would be sufficient to “… allay anxieties about the profession supposedly monitoring itself.”

He noted that cardiac surgeons established bases for performance assessment long before most other specialties. However, when the processes were established, there was “…a tacit assumption that the patients and surgeons in the dataset were anonymous and would remain so.” The use of the database “… to assess one’s own practice was a matter of honour and personal reflection.” However, changes were taking place whereby coding would allow unsatisfactory results to be traced to the surgeon and poor performance investigated. The anonymity offered by coding is notional “… and may be the last vestige of a belief in confidentiality for surgical results that for years was held to be sacrosanct.”
There is also a sense of pessimism in the anonymous article published in the British Medical Journal (Anon 1998) shortly after the results of the GMC became public. The author reported witnessing similarly disturbing patterns of poor care, and described their frustration and regret at not feeling able to intervene.

Two distinguished clinicians were invited to comment on the anonymous author’s question as to what should have been done. One of them said the appropriate action was clear: the junior doctor should use an existing mechanism described in Department of Health guidelines as predisciplinary procedures. However, this commentator admitted that the junior doctor, like many doctors, may not have known about the existence of this mechanism. Strangely, this first commentator focused on clinical incompetence arising from impairment due to age or illness.

The second commentator clearly accepted that poor clinical practice is not restricted to those who will soon die or be sent to pension. He noted that a focus on the individual is illogical anyway, since “… most avoidable errors in health care are not due to the incompetence of individuals.”

It was also pointless to assert the author’s duty to protect patients because this would require an unusual degree of heroism. “We should applaud heroes, and hope that they are among us, but to base our hope of remedy in ordinary systems on the existence of extraordinary courage is insufficient.”

Rather, the first essential step to improved patient safety is disclosure of risk. He presented the analogy of the airline industry, in which the prevailing culture is that junior pilots are trained to speak up. His superiors would have both praised him for doing so and taken his information into a sophisticated and respectful system of investigation and remedy.

The Bristol inquiries stressed one point and it cannot be ignored. There were systems problems, and systems problems require systems solutions. This surely discounts any act that applies to selected individuals (such as compulsory retirement). Less obvious, but surely equally valid, it discounts any possibility that clinicians, however well represented they might be by their professional societies, are capable of curing themselves.

2.6 Footnotes

2.6.1 Dr Steven Bolsin's perspective on Bristol

As noted earlier, an anaesthetist who had been working at BRI, Dr Steven Bolsin, formally complained to the GMC concerning the conduct of two cardiac surgeons (Dr Wisheart and Dr Dhasmana), and of the Chief Executive of the Trust (Dr Roylance). His complaints were one factor that led to the GMC’s Inquiry in 1998. However, his involvement went back much earlier, as he has explained in several published papers.

One of the more interesting and accessible is that published by the Medical Journal of Australia (Bolsin 1998). Dr Bolsin described how, as early as 1987, there was talk behind closed doors in the UK Department of Health about worrying results of paediatric cardiac surgery at the BRI.

In 1988, Dr Bolsin began work there. He had not heard the whispers, but soon became concerned and began to compile data. Dr Bolsin noted the long surgery times overall, and the long duration of the period during which the heart was offline (and hence deprived of oxygen). He suspected this could be associated with higher death rates and injuries (like brain damage).
In 1990, he began asking questions at internal clinical team meetings, but was told that his expressions of concern “… were neither helpful or constructive”. He therefore wrote to senior management at the BRI, stating his view that something was wrong.

Events during this period are confirmed in the report of the Department of Health's inquiry team. They reported that, in mid 1990, Dr Bolsin “… spoke of his concerns to Dr Brian Williams, Chair of the Division of Anaesthesia at the BRI. Dr Williams stated that Dr Bolsin had no data at the time. In August 1990, Dr Bolsin wrote to Dr Roylance about what he considered to be a misleading statement in the appendix to the application for Trust status submitted by the UBHT. In his letter, he also referred to mortality for open-heart surgery for under-ones as “… one of the highest in the country, and the problem should be addressed”. He subsequently told the inquiry team that he expected this letter to be treated as raising a concern and that he expected a response.

The inquiry team reported that several other people were aware of the contents of the letter. One was Dr Trevor Thomas, Chair of the Medical Audit Committee at UBHT, who had advised Dr Bolsin on the drafting of this letter. Inter alia, he suggested that Dr Bolsin should send a copy of the letter to Mr Geoffrey Mortimer, then Chair of the Health Authority. A copy was also sent to Mr Christopher Dean Hart as Chair of the Hospital Medical Committee at the BRI. Mr Hart later told the inquiry team that he saw the letter as concerned with the application for Trust status rather than a complaint about poor clinical practice. Dr Roylance also told the inquiry team much the same story: that he saw the letter as being about Trust status, and that he telephoned Dr Bolsin to respond on that issue. Dr Roylance said that he did not see the letter as requiring an investigation of open-heart paediatric cardiac surgery.

Many other senior doctors became aware of the claims at about this time. For example, in mid 1991 there was a meeting between the cardiac anaesthetists at UBHT, the Clinical Director of the Directorate of Anaesthesia, and the President of the Association of Anaesthetists of Great Britain and Ireland (Dr Peter Baskett) at which Dr Bolsin’s concerns were discussed. At this meeting, Dr Baskett said that Dr Bolsin should not be the vehicle for criticism of the PCS service, and should ‘keep his head down’.

On 28 July 1991 an audit meeting was held jointly between the cardiologists, cardiac surgeons and anaesthetists. Dr Bolsin drafted minutes, referring to a problem with mortality which he expressed as having been “… thought to be reaching crisis proportions”, based on the differences between the figures in the Annual Reports and the national figures. Dr Bolsin thought he was reflecting what the Audit Group told him, but he was subsequently told after producing the minutes that they were not representative and he was not to produce them ever again. Dr Bolsin was told by Dr Wisheart that “… these minutes will not be circulated, this is not how we do things. I do not want you keeping minutes again.”

Thus according to Dr Bolsin’s account (which was confirmed by the Inquiry), nothing happened even though his claims would surely have been of concern to most laypeople and had been seen by several senior officials with clear responsibilities for patient care. The surgery therefore continued as before.

Indeed, there was growing concern about the situation at Dr Bristol in the community at large. For example, in 1992 the satirical magazine ‘Private Eye’ published six articles (14 February, 27 March, 8 May, 3 July, 9 October and 20 November) criticising the PCS services at the BRI. The articles in ‘Private Eye’ were raised informally at a meeting of the Trust Board of Management but treated as no more than malicious gossip. No record of the discussion was made in the minutes. Incidentally, the author of the articles was subsequently found to be a general practitioner. Among others with
whom Dr Bolsin discussed his data at that time were senior doctors in the University of Bristol (including the Dean of the Faculty of Medicine), at various other tertiary hospitals and medical faculties, and at the Department of Health.

Dr Bolsin tried to reduce his involvement in paediatric cardiac surgery. However, he continued to collect data, and presented a detailed analysis to the Bristol Royal Infirmary’s senior management in 1993. His data suggested children were three times more likely to die than the national average, and one surgeon had 20 times higher mortality rates for some procedures.

This period in the Bristol story was also reported by the Department of Health’s inquiry team. They noted that Dr Bolsin began to gather data about the PCS service in 1989. In 1991 he showed them to Professor Prys-Roberts, Professor of Anaesthesia at the Bristol University Medical School (and later President of the Royal College of Anaesthetists 1994-1997). Professor Prys-Roberts advised him to collect more data before reaching any view. In the summer of 1991 Dr Bolsin circulated minutes of a meeting between the anaesthetists, the surgeons and the cardiologists, which included reference to an audit of the outcomes in children undergoing PCS.

Later that same year, Dr Bolsin was helped by a senior lecturer (Dr Black) in anaesthesia from the University of Bristol and they began to compile and collate data in a more rigorous way. In early 1992, Dr Bolsin again saw Professor Prys-Roberts with handwritten data. He was advised to get further data that could then be shared with others. Dr Bolsin then worked with Dr Black to produce data which were shown to colleagues in the Department of Anaesthesia in the spring of 1993 in the form of a report titled ‘Analysis of Paediatric Cardiac Mortality Data from UBHT 1990–92’. Dr Bolsin subsequently showed his data to an ever widening group, but not to the surgeons whose practice was most in question – Dr Wisheart and Dr Dhasmana.

Still nothing was done, and therefore Dr Bolsin approached the Department of Health. This led to an informal agreement in December 1994 that some of the risky procedures would not be performed pending further investigations. However, Dr Bolsin discovered that one of these procedures had been scheduled anyway, on an 18 month old child called Joshua Loveday. He urgently began to talk with anyone who would listen about having it moved to another hospital.

The Department of Health told the Hospital’s Chief Executive to do just this, but he refused. On the night preceding the operation, there was a meeting of anaesthetists and surgeons at which Dr Bolsin argued the operation should not proceed. He was in a minority of one, and the following day the child died on the operating room table.

Dr Bolsin and his wife were very upset. They had thought of going to talk with the child’s parents about the risks (even though this might represent professional misconduct), but had not done so, and felt guilty. In short, he had found it difficult to break the long standing tradition that one consultant does not interfere in the clinical judgement of another.

This event was recounted by the Department of Health’s inquiry team. They said that a clinical meeting was held shortly before the scheduled operation on Joshua at which all senior medical staff were present. The purpose of the meeting was to discuss whether to proceed with the operation, and it was decided at the start that only clinical factors should be considered. All those present agreed that there were no clinical reasons for not proceeding with the operation. While not objecting on clinical grounds, Dr Bolsin dissented on the basis of what Dr Wisheart remembered as ‘institutional reasons’ with ‘political consequences’. Dr Wisheart was aware that Dr Roylance was considering the institution of an independent review of paediatric cardiac surgery – but Dr Wisheart did not reveal this to others. Thus there was no sense of openness in pursuit of the truth. One of the cardiac surgeons at the BRI explained the style of this meeting:
there was a culture “… of explaining or justifying … mediocre or poor results on the basis of case severity rather than directing attention to producing better results”. If problems were admitted at all, then it was in accordance with the argument that “… actually the results are not very good but it is because they are bad patients … and we are doing our best”.

In early 1995 the Department of Health finally did what it should have done at least eight years previously: requested an inquiry by external experts. The appointed experts, Dr Stuart Hunter and Professor Marc de Leval, submitted a report that was highly critical in draft, but they were pressured by the Bristol Royal Infirmary Chief Executive to eliminate the more negative comments before it was formally presented to UBHT. However, it was still significantly critical. The Department of Health’s inquiry team subsequently reviewed it carefully, and quoted the authors as saying that “… it is not possible to determine the cause of these poor results (of the neonatal Arterial Switch operation). To blame surgical skill as the sole reason would be short sighted. It is most likely a multifactorial and multidisciplinary problem.” If nothing else, it was a major stimulus to action, because some of its conclusions found their way into the mass media, and the story finally broke on the front page of the Daily Telegraph in April 1995.

Dr Bolsin received few kind words as a result. He had ‘let the side down’ and ‘brought medicine into disrepute’. BRI managers threatened him with dismissal and changed his duties to his disadvantage. This contributed to his decision to move to The Geelong Hospital in Victoria in February 1996. Shortly afterwards, he wrote to the GMC, asking that an inquiry be conducted. This might seem a sensible and obvious action to take, given that the GMC is defined by legislation to have primary responsibility for maintaining professional standards. However, the reality bears little relation to logic. Dr Bolsin noted his belief that he is the only doctor ever to have taken such action – to have been a doctor who made a formal complaint about another doctor. As noted above, the GMC Inquiry completed its investigation in June 1998, finding three paediatric cardiac surgeons guilty of serious professional misconduct.

Incidentally, Klein (1998) argued that the GMC’s actions were welcome. “If there were any doubts about the GMC’s commitment to its contract with the public, about its determination to demonstrate the profession’s collective acceptance of responsibility for maintaining competence in practice, they have been dispelled. And that should send a powerful message both to the profession itself and to the public.” This seems to undervalue the significance of Dr Bolsin’s claim that he was the first ever to seek its support.

Dr Bolsin argued that he did his best “… to stand up for the best interests of the patient and for that I suffered at the hands of a profession that locally was not prepared to stop children from dying unnecessarily in the practice of powerful men”. The Department of Health’s inquiry team expressed a similar view: that he did what was generally the right thing to do, although with hindsight he might have been more effective in a few circumstances. That said the inquiry team accepted he had been brave and ethical in an incredibly difficult situation. “The difficulties he encountered reveal both the territorial loyalties and boundaries within the culture of medicine and of the NHS, and also the realities of power and influence.”
2.6.2 The final words of some of the other main players

The inquiry team in its report, gave selected quotes from the testimonies of some of the main players. The following seem to be of particular relevance.

Present Chief Executive of the United Bristol Health care Trust.

“On behalf of the Trust, I should like to say sorry to the children and families of those who used the paediatric cardiac services in Bristol in the past. It is clear to me that a substantial number of parents and children did not receive the standard of care they were entitled to expect. I have seen at first hand how painful and distressing it has been for many parents to remember and reflect again on the events of the past. I would like to pay tribute to their bravery and composure under the most extreme circumstances.”

Counsel for the Department of Health.

“The Department of Health accepts that it is responsible and is accountable for any failings of the systems that were in place during the period covered by the Inquiry. Ultimate responsibility rests with the Department of Health and the Secretary of State.

It now seems clear that there was confusion and therefore systemic failings with regard to the way in which the SRSAG dealt with the specialty of neonatal infant cardiac surgery. The diligence of the inquiry team has uncovered this confusion and the systemic failing that was previously not known to the department. All these are accepted and are a cause of great regret.”

One of the censured consultant cardiac surgeons.

“All these things have ruined me professionally, financially, my family life has gone and I have lost confidence in myself. This is the first time in the last two years that I have been able to speak to any audience for three days.

All this courage has really come from support that I had from my close relatives, and there are still patients and parents who have continued to support me, making me feel that I am still trusted in some corners. Again, I emphasise, whatever suffering I have gone through, and I am going through, is no match to the suffering that you had with the loss of your child, and I wish I could turn the clock back. I cannot say any more.”

Another of the censured consultant cardiac surgeons.

“I wish this evening to repeat and to offer again my deepest regret and sympathy to all parents whose children died at the time of or after their operation. In saying this, my sympathy and regret go to parents and families on all sides of this particular debate. The lowest point of a surgeon’s life is when a child dies under his or her care.”

2.7 References and selected bibliography


3 Campbelltown and Camden, Australia

The process of this investigation was prolonged, mainly because of the alleged slow and technically flawed first attempt of the external investigation made by the Health Care Complaints Commission (HCCC) that began in November 2002 and was replaced by a Special Commission of Inquiry in December 2003. The Commission released an interim report in March 2004 to redress some of the widespread public concern. It corrected most of the flaws but contained incomplete findings. The final report was released in July 2004, but most of the allegations against individual clinicians were referred for investigation by other bodies, such as the NSW Medical Council.

3.1 Context

The Campbelltown and Camden Hospitals are the main health care organisations in the Macarthur Health Service. This in turn is part of the organisation constituted by (the then) South Western Sydney Area Health Service, one of the seventeen authorities to which significant resource allocation and care provision responsibilities were then delegated by the NSW Department of Health.

Rumours of significant discontent regarding the quality of care at Campbelltown and Camden began to circulate within the NSW health sector as early as 1998, and were rampant by 2001. However, it was not until late 2002 that the rumours were officially recognised and became frontpage news. At that time, a group of nurses formally presented its concerns to the Department and the first of two major and high profile inquiries was initiated.

The allegations resulted in widespread concern in the community at large, and in New South Wales in particular. This is reflected in the comments expressed in calls to radio talk shows, letters to the editor in newspapers, and contributions to various internet chat sites that have continued for 18 months. The following are examples taken from the Sydney Morning Herald’s internet feedback site shortly after the contents of the first formal Inquiry were released.

Nurses are at fault

“Nurses are not professionals but mere workers. Their attitude towards doctors is appalling with a constant power struggle about tasks to be done when all the doctor wants is for the patient to get better. Nurses rarely work overtime whereas doctors can work 36-hour shifts.”

Bureaucrats are at fault

“The system is rotten. Those who work at the coalface know it. The bureaucrats who look on from the comfort of their air-conditioned offices will never acknowledge it.”

“The administrators who know nothing about “health” or “medicine” cause the problems. More beds and more quality nursing staff are needed.”
Lawyers are at fault

“The lawyers have been making an absolute packet with their legal actions against doctors who work unbelievably long hours to save people’s lives.”

Doctors are at fault

“I have experienced the most disgusting treatment and witnessed the most appalling behaviour by clinicians in recent years.”

“Why was it that only nurses had the strength and resolve to blow the whistle? Where were the doctors? They have failed their duty of care by not reporting system failures.”

Politicians are at fault

“We shouldn’t blame the doctors and nurses. They’re doing their best to work with very limited resources while working very long hours. The blame should be aimed toward the politicians.”

“The main problem is not the federal government but the state government. Why have two government levels involved, thus giving them the opportunity to blame each other?”

“It is not surprising the government didn’t know what was happening in Saddam’s Iraq, given they know nothing about what is happening in our hospitals”

“Most patients who wait in emergency for hours before treatment or admission to a hospital bed think their case is the exception. There is no accountability for patient care by hospital boards and governments who try to fool the public into thinking that problems are due to the accused doctors.”

Nurses are the heroes

“Why were the nurses who became whistleblowers crucified by the health care sector? Why didn’t the hospital actually support these plucky individuals? If they had obeyed instructions, we would not have had an inquiry into the level of care in our hospitals.”

“Congratulations for all who brought this latest scandal to the public’s attention. You deserve to be nominated for Australians of the year!”

These do not represent a representative sample, of course. Nor is there any guarantee that the comments are well informed or impartial. They are presented here merely to indicate the degree of concern in the community at large, and the extent to which views have been polarised.

The events were subject to extensive public exposure in the professional media. For example, it was claimed by one of the nurses who brought the formal complaints that the process of investigation adopted by the Health Care Complaints Commission (see below) was poorly planned, and failed to address many of the allegations. She argued that the Commission “… seemed reluctant to investigate anything that management were directly responsible for” (Stateline, ABC Television, 14 November 2003).

On the same television program, a Democrats’ member of parliament argued that, regardless of the veracity of the incidents under investigation, there were deep rooted problems of quality of care. “I don’t think there’s ever been a really good quality control program throughout the health system. As resources get tight (and obviously in hospitals that are harder to staff) the problems are worse.” He also criticised the ‘adversarial’ medical indemnity system that creates incentives to hide mistakes.
“That means you never learn from them and you keep on making the same mistake.” Also in the same program, the Chair of The Health Care Quality Taskforce argued that the problems were exacerbated by aspects of medical education, which have “… produced a culture that does not allow for error, that doctors are not supposed to make mistakes.”

Many associated issues were raised while the first and the second inquiries were under way that increased the degree of political debate and added confusion to the central issue of questionable clinical practice. For example, impropriety was claimed with regard to the reappointment to a senior position in NSW Health of the CEO of Macarthur Area Health Service after she was apparently pressed to resign because of the incidents that led to the Inquiry.

Also there were several actions taken by the Minister that might have been considered to prejudice the inquiry process. Inter alia, he made what were termed sweeping management, supervisory and recruitment changes at Macarthur Area Health Service. When questioned, the Minister said “… there had to be a change in the management culture. There had to be a change in management approach, and to get that, you have to get a change in the team.” In short, while attempts were being made to conduct an open and fair consideration of the allegations, many people were confused and others seemed to be prejudging the findings.

The history of the complaints

The history comprises four main phases to date, each of which is described in turn below. First, there was a period of discontent lasting at least four years, during which informal and partly formal complaints were made, mainly by nurses, about medical care at the Campbelltown and Camden Hospitals. Second, there was a short period in November 2002 during which the Minister for Health and the Department of Health heard formal complaints and directed the Health Care Complaints Commission (HCCC) to investigate them.

Third, there was the period of investigation by the HCCC that lasted from November 2002 to December 2003. Several reports were issued during the period that raised a significant degree of concern about the effectiveness of this investigation.

Finally, there was the Special Commission of Inquiry that was appointed by the NSW government on 26 December 2003. The Commissioner observed during a public hearing on 26 March 2004 that the Special Commission of Inquiry was “… appointed by reason of dissatisfaction with the outcome of complaints process in the Health Care Complaints Commission.” An interim report was issued on 31 March 2004, and a final report on 30 July, 2004, from which most of the following has been taken.

The nurses’ complaints are frustrated

The nurses claimed they made a variety of attempts to encourage action with regard to poor care for three or four years before they delivered their formal complaints to the Department of Health. These claims were contested. However, there is good reason to believe at least some of the nurses’ claims may be substantiated.

In short, it was advanced that many nurses, and not only those who brought the formal complaints, made a range of informal and informal complaints but no serious efforts were made to address them. One of the nurses advanced she and other nurses were called ‘troublemakers’ by managers, and were encouraged to leave. Other nurses claimed they were harassed, intimidated and ostracised when they tried to alert authorities to entrenched problems (Stateline, ABC Television, 14 November 2003). Other assertions included the destruction of records
by hospital administrators and managers in Macarthur Health Service – both medical records in which there was evidence of poor care and reports of incidents made by nurses and others. One of the nurses claimed that she and others who made adverse incident reports were given financial incentives to encourage them to leave, after which documents were destroyed.

The Minister takes action

The issue first came to the formal notice of the Department of Health on 5 November 2002. At that time, four nurses and a solicitor met with the then Minister for Health. Each of the nurses had been employed at or was on leave from Campbelltown or Camden Hospitals. They made a range of allegations of mismanagement, patient neglect and a failure of management to address their concerns. On that day the Minister asked the Director-General of the Department of Health to investigate the allegations immediately and interview the nurses as a matter of urgency. He in turn asked the Director of Audit in the Department of Health to make an initial investigation.

On 12 November 2002, the Director of Audit reported to the Director-General. She provided a summary overview of her findings, which had been made following interviews with most of the nurses who attended the meeting with the Minister as well as two other nurses.

On 18 November 2002, the Director-General referred the allegations made by the nurses to the HCCC for investigation. The HCCC was provided with a summary of the initial allegations made and the preliminary findings of the Director of Audit. Some 18 files of further materials were provided on 21 November 2002, together with a statutory declaration verifying the complaint by the Director-General.

The Health Care Complaints Commission investigation is conducted

The HCCC appears to have interpreted the complaint to be against Macarthur Health Service, rather than against individual health care professionals. This was subsequently argued to have been a mistake, as will be seen below. It produced an ‘Interim Phase 1’ report at the end of January 2003. This followed interviews with some but not all of the nurses and some managers and other staff in the Macarthur Health Service.

A copy of its report was provided to the Director-General of the Department of Health, the Chief Executive of South Western Sydney Area Health Service and the Minister for Health. The letter accompanying that report to the Director-General stated “…there have been no substantiated allegations of significant departures from State or national standards in health care”. The report noted that its purpose was to update the parties to the complaint about the progress of the investigation, but it contained some conclusions.

Another report was released 18 August 2003 (eight months later) that was titled “Preliminary Investigation Report”. It was provided only to South Western Sydney Area Health Service for the stated purpose of providing it with an opportunity to make submissions. South Western Sydney Area Health Service's response was provided on 20 October 2003.

The final report was provided to the Director-General of the Department of Health and the Acting Chief Executive of South Western Sydney Area Health Service on 9 December 2003. It is entitled ‘Investigation Report – Campbelltown and Camden Hospitals – Macarthur Health Service’. The HCCC reported its analysis of 47 specific clinical incidents that occurred between June 1999 and February 2003. In the executive summary, the HCCC stated that the evidence obtained about those incidents strongly supported the allegations by the nurse informants about the standard of care, in some incidents so poor that the patients suffered severe deterioration in health. The
Investigation Report claimed to have identified patterns of inadequate care and treatment at the Hospitals. The HCCC delivered its Report to the Director-General, who published it as was understood to be necessary under the Health Care Complaints Act.

In December 2003 the Minister moved to dismiss the Health Care Complaints Commissioner for NSW. He also announced the establishment of a Special Commission of Inquiry on the matter.

The Special Commission of Inquiry is appointed

In December 2003, the Governor of NSW appointed Bret Walker SC to lead a Special Commission of Inquiry into Campbelltown and Camden Hospitals. His report titled ‘Interim Report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals’ was released on 31 March 2004. For convenience, we will refer to the Special Commission as the inquiry team in the following discussion.

### 3.2 The Inquiry

#### 3.2.1 The First Interim Report of the Special Commission of Inquiry

The inquiry team was instructed to inquire into and report on allegations of unsafe or inadequate patient care at Campbelltown and Camden Hospitals and other related matters made in a set of Letters Patent – formal documents resulting from formal complaints made by a group of nurses. The scope was subsequently widened to cover all the nurses who had made relevant allegations about patient care at the two hospitals.

The Inquiry was conducted under the Special Commissions of Inquiry Act 1983. Details of its provisions and its relationships with other legislation are described in some detail in the Report but are not relevant to the purpose of this paper.

The term ‘interim report’ is clearly explained. First, there are other relevant matters about which investigations are incomplete. Second, with respect to those matters discussed in the report, the findings are final. The inquiry team says “…it is not a provisional report: the views in it and the recommendations made in it are final with respect to the matters that are addressed in this interim report.”

The inquiry team chose not to give the concerned doctors and nurses the opportunity to question its findings. Rather, it simply recommended that their conduct be the subject of statutory investigation and consideration of disciplinary prosecution, during which process they would be afforded ample opportunities to refute any allegations against them. The report does not name the concerned doctors and nurses. The power to discipline medical practitioners or nurses resides with the Medical Tribunal, Nurses Tribunal and those who administer other forms of professional discipline. The HCCC has the power to initiate proceedings before a Medical or Nurses Tribunal.

The inquiry team’s comments on the investigation by the Health Care Complaints Commission

As we indicated above, the inquiry team was highly critical of the investigation undertaken by the HCCC, and we will only briefly cover the reasons here. The focus will be on the health care aspects.
First, the inquiry team believed the HCCC was wrong in treating the Macarthur Health Service to be the subject of the complaint. Second, once this decision had been made, the HCCC should not have reported that complaints against specific clinicians had been substantiated. Third, the report should not have been published before the clinicians had been through disciplinary adjudications.

The inquiry team rejected the idea that the nurse informants’ allegations were against a health organisation (the Macarthur Health Service) rather than against clinicians. It stated that a complaint concerning the conduct of a doctor alleging that he or she has demonstrated inadequate care is “… undoubtedly a complaint against the doctor.” The HCCC was wrong in issuing a report that substantiates allegations of inadequate care on the part of identifiable doctors, without regarding those allegations as a complaint against that doctor. “This was offensive to a sense of fairness. It denied the doctors an opportunity to make submissions against the conclusion that the allegations were substantiated”.

**Why an interim report?**

Failures on the part of the HCCC were the main reasons why the inquiry team chose to release an interim report: it was a device for ensuring as prompt a resumption or commencement of formal investigation of the more serious allegations as possible. The inquiry team undertook a process of rating the seriousness of the allegations, so that they might be addressed in order.

The most serious cases were judged to be those where the important function of dealing with complaints against doctors (or nurses) had been inadequately handled by the HCCC. A table was published by the inquiry team that was said to illustrate “… how badly the Health Care Complaints Commission performed in complying with the straightforward requirements of the complaints system in force.” This had not only led to unfair treatment of the clinicians concerned, but also “… denied for more than a year the efficient administration of the assessment, investigation and decision by the Health Care Complaints Commission of many complaints against a number of doctors and nurses.”

In a public hearing on 26 March 2004, shortly before release of the interim report, the Special Commissioner emphasised the importance of prompt action. “It is difficult to overemphasise for a commission of the kind I am conducting, the high public importance of ensuring that laws which regulate those who may administer medical procedures with all the risks to life and limb, the high public importance of ensuring that those laws operate swiftly and after thorough investigation.”

**The method of inquiry**

In December 2003, the inquiry team placed advertisements in newspapers in Sydney (and specifically in the Macarthur area) seeking information and the expression of views. The inquiry team also received 115 written responses, many about the treatment received by individuals and some commenting on issues of reform of the health system.

**Consideration of the Health Care Complaints Commission Report**

The first term of reference required the inquiry team to consider the HCCC’s report. In particular, the inquiry team should consider the findings concerning allegations made about the treatment provided to 69 patients at Camden and Campbelltown hospitals between 1999 and 2003.

The HCCC provided 180 folders containing information gathered during its investigation. The contents of those folders were reviewed by inquiry staff. The report did not name the patients or the practitioners but simply allocated code numbers. In 21 of the 69 cases the HCCC had been unable to identify the patient from the information provided by the nurse informants or from other available sources, and consequently they were not investigated by the HCCC.
The inquiry team categorised the 48 identified cases according to the seriousness of the conduct of individuals involved in the care. The most serious were reviewed first.

The inquiry team communicated with each patient or family member whose treatment was the subject of review. It obtained the medical records for each patient from Macarthur Health Service and any other hospital where they relevantly received treatment. Summons for the production of documents were issued in seventeen cases, mainly to Macarthur Health Service, seeking medical and other records. Macarthur Health Service assisted with the identification of the names and positions of various medical practitioners and nurses, which was a difficult task due to the near illegibility of some of the medical records.

The Inquiry also considered the submissions made by the nurse informants, submissions by the patient or family of the patient and the findings of any review conducted by Macarthur Health Service into the treatment of the patient.

Six experts were then engaged by the inquiry team in the fields of emergency medicine, psychiatry, anaesthetics, nursing, obstetrics and gynaecology and surgery. The inquiry team met each expert one or more times to discuss the treatment provided to each patient and the standard of care provided by each relevant medical practitioner or nurse. Their assistance was judged to have been “...extremely valuable and indeed essential”.

After gaining an understanding of the clinical issues, the inquiry team interviewed each nurse informant in relation to each case in which they were involved. All eight nurses were interviewed, one over a number of sessions. The interviews generated over 500 pages of transcript. During the interviews, most of nurses were legally represented. At the interviews, the views of each nurse were sought on the clinical issues involved and importantly, what further action they believed should be taken in addition to, or different from, that recommended by the HCCC. Interviews also took place with other participants in the treatment or with family members of patients.

The initial goal of the inquiry team was to identify those health practitioners whose apparent conduct warranted investigation with a view to some form of action being taken. In this way, conclusions were drawn about the standard of care delivered in 44 cases. The final four were to be resolved later.

The inquiry team then informed the HCCC of its opinions, thus providing a complaint on which the HCCC is required to act. Each practitioner will thus be afforded the opportunity to know the complaint against him or her and respond to it and to any action the HCCC may propose at the end of the investigation.

Conclusions of the Special Commission: conduct warranting investigation

The inquiry team recommended that the HCCC investigate the conduct of 12 medical practitioners in respect of the care of ten patients. The team reported it had made “... substantial progress in identifying those nurses whose conduct warrants investigation by the Health Care Complaints Commission”.

The Report did not name the doctors, but rather labelled them Dr 1 through to Dr 12. These labels are used in our summary below.
MASTECTOMY OF THE WRONG BREAST
Dr 1 was a visiting medical officer (surgeon). Drs 2 and 3 were surgical registrars. Dr 1 obtained consent from the relative of a patient to perform a mastectomy on the patient. The consent form was incomplete and referred to the wrong site for the mastectomy. The procedure was performed with each of Drs 1, 2 and 3 participating. The wrong breast was removed. The diseased breast was later removed.

FAILURE TO RECORD PELVIC FRACTURE
Dr 4 was a career medical officer (locum). In relation to a patient who had fallen next to the bed, he recorded in the medical notes the results of his examination of the patient. An x-ray and examination the following day detected a pelvic fracture. Dr 4 had not recorded that he detected a pelvic fracture. It is alleged by a witness that Dr 4 did not carry out the examination that he had recorded in the medical records.

COMPLICATIONS OF A LAPAROSCOPIC CHOLECYSTECTOMY
Dr 5 was a visiting medical officer (surgeon). Dr 2 was a surgical registrar. Dr 5 performed a laparoscopic cholecystectomy on a patient, with the assistance of Dr 2. The patient died five days after the surgery, apparently from postoperative intra-abdominal sepsis. This complication had not been promptly diagnosed or treated.

INAPPROPRIATE DISCHARGE OF TWO PATIENTS
Dr 6 was a visiting medical officer (physician) who had visiting rights at the Campbelltown and Camden Hospitals. He discharged two patients from hospital. One of them died before reaching home, and the other died within less than 24 hours after discharge.

FAILURE TO DIAGNOSE ISCHAEMIC FOOT
Dr 7 was a visiting medical officer (surgeon) who had visiting rights at Campbelltown and Camden Hospitals. Dr 8 was a career medical officer (emergency). They had responsibility for the care of an elderly patient who developed an ischaemic foot. Dr 8 did not diagnose the condition. Dr 7 did not review the patient when the diagnosis was made by a third medical practitioner.

FAILURE TO ACT PROMPTLY REGARDING A POSSIBLE PERFORATED PEPTIC ULCER
Dr 7, a visiting medical officer (surgeon) and Dr 8, a career medical officer (emergency) treated a patient who presented with a possible perforated peptic ulcer. A period of about 12 hours elapsed before the patient was transferred from a hospital that did not perform other than day surgery to one that did. The patient died six days after the transfer.

PRESCRIBING OF DRUG TO WHICH PATIENT WAS KNOWN TO BE ALLERGIC
Dr 9 was a career medical officer (emergency) who attended a patient who had attempted suicide. He is recorded as having prescribed and administered a drug to which the medical notes indicated the patient was allergic.

INCORRECT TREATMENT OF ACUTE ASTHMA
Dr 10 was a career medical officer (anaesthetics). Dr 11 was a visiting medical officer (physician). Drs 10 and 11 treated a patient who had acute asthma. Dr 11 is recorded as providing certain advice to Dr 10, but Dr 10 did not follow it. Dr 10 administered certain drugs to the patient, who died four hours after admission to the hospital.
FAILURE TO ACT PROMPTLY TO RESUSCITATE
Dr 12 was a career medical officer (emergency) who treated a patient who attended acutely unwell. The patient’s systolic blood pressure was low and the patient required resuscitation. Dr 12 did not contact the visiting medical officer promptly. He did not resuscitate the patient, and the patient died 12 hours later after being transferred to another hospital.

Conclusions of the Special Commission: conduct warranting performance assessment
The HCCC can refer a complaint, or part of a complaint to another person or body if it appears to raise issues requiring investigation by the other person or body. The Medical Practice Act permits the Medical Board to assess the professional performance of a registered medical practitioner if there is reason to suspect that person’s professional performance is unsatisfactory. Professional performance refers to the knowledge, skills or attitudes possessed and applied by the practitioner in the practice of medicine. Unsatisfactory means below the standard reasonably expected of a practitioner of an equivalent level of training or experience.

The inquiry team recommended that the HCCC should consider referral to the Medical Board the conduct of five medical practitioners in relation to their treatment of five patients. The inquiry team labelled them Dr A through to Dr D, and Dr 12 (the emergency doctor as noted above).

FAILURE TO REQUEST SPECIALIST CONSULTATION FOR PREGNANT WOMAN
Dr A was an obstetrics and gynaecology registrar who treated a pregnant woman with a history of asthma. The specialist obstetrician was not asked to attend the patient until about four hours after her presentation. She was transferred to another hospital where she and her baby survived.

INAPPROPRIATE DISCHARGE
Dr B was a career medical officer (emergency) who treated a patient who had presented with sharp pain. Dr B recommended to the visiting medical officer Dr 6 that the patient be discharged, ten hours after presenting. The patient died less than 16 hours later.

FAILURE TO COUNSEL ON END OF LIFE MATTERS
Dr C was an intensive care registrar who conservatively treated an elderly patient. There was no record of discussions between Dr C and the patient or the patient’s family concerning end of life matters.

FAILURE TO PRESCRIBE ANTIBIOTICS
Dr D was a medical registrar and Dr C an intensive care registrar. The medical practitioners treated a patient who attended the hospital at about 4.30 am and ultimately died some seven hours later. For a lengthy period following the admission, the medical practitioners did not prescribe antibiotics.

The way the clinicians were identified
As noted earlier, the inquiry team held a public hearing on 26 March 2004. Both the involved doctors and involved nurses were legally represented. The main purpose was to allow the inquiry team to outline its likely conclusions and recommendations, and receive comments from legal representatives and other interested parties.
Its main concern was whether, even though names were not disclosed in its Report, there might be sufficient information to allow for the identification and public disclosure of identities. At the hearing, the inquiry team referred to “…some of the most serious allegations one could imagine against medical practitioners, including allegations of grossly substandard technical skill as well as grossly uncaring attitudes.” An additional cause of concern was that the inquiry team’s findings were mostly related to care provided by two or more health professionals. Allegations of substandard care or of uncaring conduct “… cannot be done as job lots.” The individuals must be held responsible individually if they have individually fallen short of the appropriate standard, and each individual must have the proper opportunity to dispute his or her culpability.

**Comments on the quality of medical records**

The inquiry team took care to avoid addressing systemic issues, for reasons noted below under its planned follow up actions. However, the Commissioner did make some general comments during the course of the public hearing on 26 March 2004.

The Commissioner noted that “… the Inquiry has been hampered by defects in records which may or may not be sinister.” He held the opinion at that time that the defects that most hampered the Inquiry were not sinister – that is, a consequence of a deliberate attempt to conceal information. Rather, he argued they were most commonly a consequence of the inability or unwillingness of the clinicians “… to follow the basic instruction that they should prepare their records legibly and clearly, making sure that they name, sign, date and time all entries.”

He noted that the designers of the medical record forms were presumably aware of the importance of so doing, and of the likelihood that there would be low compliance. This was concluded from the fact that most of the medical record forms examined during the Inquiry repeated the elementary message on every page. The Commissioner thought that the message might have “… become outworn by repetition.”

He then speculated that his was probably not the first Inquiry to experience the problem. It was possible that much time and money had been wasted during inquiries into medical conduct in the western world, as a consequence of “… the inability or refusal of practitioners – alas mostly doctors, not nurses – to prepare records in a way that those following in the care of the patient, and certainly those following in the scrutiny of their conduct, would find straightforward to use.” He further speculated that it was “… a cause for humour on the part of some medical practitioners that their handwriting is illegible. It should be clear from the experience of wasted money in this Inquiry trying to decipher the handwriting of doctors, that there is no cause for humour at all in this imposition on the public.”

“That matter means that the records are not always straightforward to decipher and, in the ordinary way of any records kept by human beings, it means that they may not always be relied upon with confidence at every point. That, again, need not be a sinister matter. It is commonplace that people make errors and dates and times and sometimes about matters more serious than that. However, there has already been occasion in the interviews with nurse informants for them to draw to my attention and for me to agree with their observations that in quite a few reporting cases the records are deficient – that is, things are not recorded which, in the nature of things, should have been recorded.”

Finally, the Commissioner noted that some of the most serious allegations of poor clinical practice involved matters not appearing in medical records. He also noted the obverse, where there were records that the allegation substantially demonstrated could not be true.
Planned follow up work by the inquiry team

At the time of publication of its interim report, the inquiry team was investigating seven other cases where there were unidentified allegations. The outcomes would be described in the inquiry team’s final report. Investigations would also continue regarding the possibility of inappropriate conduct by nurses.

In the next phase of the Inquiry, consideration would be given to the suggestion that the medical and nursing disciplinary system is excessively concerned with blame and thereby sacrifices systemic improvement. The inquiry team would provide opportunities for those who took that view to explain and defend it. The inquiry team did, however, indicate its preliminary opinion that the Inquiry “… discredit[s] the notion that individual accountability through professional discipline is inconsistent with systemic improvement of clinical care and institutional administration.”

The inquiry team further argued that the health system requires individual professionals to do their work well. System wide improvement “… cannot possibly require removal of the possibility of disciplinary sanction for those who fall badly below proper standards of conduct. It will be interesting to discover in the next phase how serious these suggestions are, which have been reported to the effect that the disciplinary system is an impediment to improvement of the health system.”

The next phase of the Inquiry would also consider some ideas arising from the first stage of the Inquiry whereby “… formal arrangements are made for continuous attention to systemic improvement, apart from, independent of but informed by the disciplinary system administered by the Health Care Complaints Commission and the registration authorities.” The inquiry team saw these ideas as being founded on some kind of ‘clinical excellence commission’, and taking account of recent experience with The NSW Institute of Clinical Excellence that has involved attempting to enhance its kind of approach.

Finally, the inquiry team expressed its view that the body charged with addressing health care complaints should not have, or see itself as having, a frontline role in the monitoring, for the purpose of improvement, of clinical care. Rather, the intelligence which should be used for continuous improvement will include but will not be restricted to the harsh lessons of disciplinary complaints determined adversely against doctors, nurses and hospitals. The inquiry team argued that “… it is inherently unlikely that an approach to continuous improvement which restricted itself to the lessons thrown up by dealing with delinquent or incompetent practitioners would be an adequate means of discharging that function.”

Changes at the Health Care Complaints Commission in 2004

An Acting Commissioner of the HCCC was appointed in December 2003, who immediately began to make structural and administrative changes. Inter alia, he established a new team of investigators to address issues relating to the Campbelltown and Camden complaints. It did not contain any of the HCCC staff previously involved, and was headed by counsel from the private bar and located away from the HCCC’s offices.

Other changes have included improved ways of involving legal and medical experts at an earlier stage of inquiry, and the setting of a performance standard that requires 90% of investigations to be completed within 12 months of commencement. This is consistent with the views of the inquiry team. Inter alia, the team said that the delay in investigations and prosecutions over the Campbelltown and Camden affair had been deplorable.
3.2.2 The Second Interim Report

The inquiry team issued another report in June 2004. It focused almost exclusively on the legal processes of the inquiry. In particular, it addressed criticisms of the HCCC’s processes by a faculty member of the NSW Institute for Clinical Excellence, which were widely distributed through a technical publication.

The core of the criticism was that the inquiry team had been unfair in referring doctors for possible disciplinary action, without their being given an opportunity to give their views about events either to the HCCC or the Special Commission. The Commissioner strongly refuted the criticism mainly on the grounds that they would have the opportunity at a later date. In total, the inquiry team defended its approach on the grounds that it “... was intended to secure the proper balance mandated by law between accountable complaints procedure, patient confidentiality and the appropriate privacy for health practitioners against whom complaints may have been made but against whom no adverse findings could yet be made lawfully, if ever.”

The Report added little else, other than providing an update on the state of the investigations. It noted that all 48 incidents identified by the HCCC had been investigated, as had 56 of the additional allegations from the nurse informants.

Finally, the Report included an Appendix listing the doctors and nurses who should be investigated, or have their performance assessed. The Appendix was submitted with a recommendation that it should not be published.

3.2.3 The Final Report

The final report of the Special Commission of Inquiry into Camden and Campbelltown hospitals was released on July 30, 2004. Much of the work of most interest here, however, had been completed through publication of the interim reports. Thus decisions had already been taken regarding the large majority of the allegations of poor care, and views formed regarding the treatment of those complaints in the earlier investigations of the HCCC. With regard to the substance, the final report consequently added very little. For example, it repeated its recommendations regarding further investigation of some doctors and nurses but added a small number for whom its investigations had not been completed when the interim reports had been published.

The inquiry team again stressed that the two previous reports were in no way superceded by the final report. There are hardly any references to the need to adjust the contents of those reports, and adjustments are almost wholly amplifications.

In total, the final report is largely a bag of loose ends – as will be evident from the following description. The main part is a detailed review of the investigations undertaken by the HCCC. Other lengthy sections concern changes that have taken place within the Macarthur Health Service and elsewhere in the last few years with regard to patient safety, and discussion of technical issues such as the balance to be struck between individual accountability and continuous quality improvement.

It is far from easy to read, mainly because of the complexity (and questionable logic) of its structure. For example, recommendations appear in two chapters (and not at the end of the document as is claimed in the Preface). There is no easily located summary. The section that most resembles a summary is contained in a chapter headed ‘Preface’. Discussion of the investigations conducted by the HCCC is mainly contained in three chapters (where one is largely devoted to recommendations) and one Appendix, but it appears in several other chapters.
There is a section titled ‘Introduction’ that does little more than inform the reader of what he or she already knows – that this section is somewhere near the start of the report. Under this heading is a variety of only loosely connected topics such as the nature of the Macarthur Health Service, and differences between this Inquiry and others such as Bristol and the King Edward Memorial Hospital.

We have done our best to present the report’s contents in a form that is meant to be easier to understand, but have avoided any major departures from the structure of the original document. This might mean we have fallen between two stools.

A balance is needed between individual accountability and systems improvements

Clinical professionals must be accountable for their errors, but legal processes should be the last resort. They comprise “… an almost marginal – but very important – component designed for relatively rare and extreme events.”

Other routine processes for identifying and investigating problems, and the taking of corrective actions, are likely to be more beneficial overall. They should include techniques like root cause analysis as being promoted by the newly established Clinical Excellence Commission.

Comparisons with the Bristol and King Edward Inquiries

Chapter 1 briefly summarised the Bristol and King Edward Memorial Hospital Inquiries in its own final report. Rather imprecisely, the Report said “… there have been two significant Inquiries into the delivery of health care at specific institutions over the last five years, in England and Western Australia.” We assume the inquiry team meant to say there have been two that caught its attention.

Otherwise, the summaries are reasonably accurate (if missing some important details). Of particular relevance here, the inquiry team failed to report the Bristol Inquiry’s starting conclusion that it was not an account of bad people. Rather, the health care professionals at Bristol “… whose work was found to have harmed patients were, for the most part, products of a system that had fundamental weaknesses.” The inquiry team did, however, note that the King Edward Memorial Hospital Obstetrics and Gynaecological Services were characterised by “… a culture of blame, unsupportive of open disclosure of errors and adverse events.”

It is not surprising that the inquiry team therefore emphasised the local peculiarities. “The relevant standards and systems, both for the delivery of health services and for dealing with complaints about them, are creatures of New South Wales law and government. There is no avoiding the specific texts of New South Wales legislation governing the matters examined by this Inquiry.”

We would argue, however, that there were more important differences in the process of inquiry than in the kinds of health care problems being investigated. The inquiry team had a clear direction that emphasised individual accountabilities rather than systemic problems. Moreover, the inquiry team itself seemed to be more familiar with (and consequently more interested in) the legislative rather than the health care systems aspects of poor care.

Assessment of care on the basis of comparative statistical analysis

Chapter 1 includes some comments on the extent to which it was possible to assess hospital performance on the basis of statistical analysis. A feature of the Bristol and King Edward Memorial Hospital Inquiries was that statistical comparisons were made that showed there were significantly higher rates of poor patient outcomes than at similar hospitals for the case types under investigation.
In contrast, the inquiry team was unable to find any comparative statistics that suggested significantly different outcomes for the Campbelltown and Camden Hospitals. Three comments of the inquiry team on this state of affairs are worthy of note.

First, the inquiry team concluded that "... unfortunately it is not possible to gauge the genuine qualities of health care at the Campbelltown and Camden Hospitals by use of the kind of figures that are available."

Second, the inquiry team referred to articles published in the Medical Journal of Australia in April 2004 by several doctors associated with the Macarthur Health Service, in which the authors implied that the hospitals had extremely low rates of adverse events (Frankum et al., 2004). The inquiry team asked the primary author to explain the basis for his conclusions. The author "... agreed that there were no data ... which enables one to apply any benchmark or comparison for the Campbelltown and Camden Hospitals." The inquiry team’s report thus implies that the contents of the letter were at least misleading.

Third, the inquiry team reported discussions with the former General Manager of Macarthur Health Service, during which she described benchmarking activities in which the Service had been involved since 1996. The activities were conducted by the Health Roundtable Limited (in which many other Australian hospitals have been involved). The inquiry team concluded that the information thus generated was limited in its utility in many ways, at least for the purpose of assessing quality of care.

Taken together, these comments are of some future relevance. They suggest that routine statistical collections were inadequate in terms of the monitoring of aspects relating to patient safety. However, it should also be noted that the cases covered by the Campbelltown and Camden Hospitals were different from those covered at Bristol and King Edward Memorial Hospital in that they involved low numbers of cases of many types. There was more inherent variability, and the focus of the Inquiry was towards specific allegations from many sources rather than a global concern for a particular type of treatment.

**Using the ‘systems approach’**

The inquiry team was not familiar with the term ‘systems approach’ at the start of its work, and had not grasped the idea adequately at the end. Thus it makes use of the term in inaccurate and misleading ways, as illustrated by the following extract from Chapter 1 of the final report. 

*The Bristol Inquiry adopted a systems approach to its analysis. By this they mean poor performance and errors were seen as the product of systems which were not working well, as much as the result of any particular individual’s conduct.*

In the scientific context, systems are objects and events, and the cause and effect relationships between them. The relationships can be simple and unidirectional or they may be linked together in long chains. Any one factor can exert a control function (causing a change in another) and a dependent function (being changed by another). The essence of the systems approach involves placing as much emphasis on identifying and describing the connections between objects and events as on identifying and describing the objects and events themselves.

Thus the inquiry team’s description is illogical. The systems approach is exactly what one might expect: it is an approach to analysis rather than a particular kind of finding. *Inter alia*, it involves taking special care to ensure relationships are taken into account. Given that relationships are typically complicated in health care, it might be expected that the systems approach would be particularly useful.
The approach, when applied, does not necessarily lead to the conclusion that problems are a consequence of a multiplicity of interconnected factors. It might be that the causes are located in only a part of the system. A systems approach to a recent train crash in the UK led to the conclusion that only one factor was important — that of the train driver experiencing serious ill health.

The Bristol inquiry team did seem to have adopted a systems approach. In our view, they did little more than follow as many lines of investigation that they (or others) thought might be relevant. However, it is reasonable to say that they found systems problems (or problems that were systemic).

This would have been the case, regardless of the investigative approach they had taken, as long as they were dedicated in their task of understanding what had happened. On this analysis of the Walker inquiry, however, it is plain that it did not apprehend what a systems analysis of care might add to understanding.

The relevant legislation

The largest part of the final report concerns legislation. Chapter 2 describes the process of investigation of the complaints regarding the Campbelltown and Camden hospitals (and the Macarthur Health Service) by the HCCC. It repeats and amplifies the concerns of the inquiry team.

Chapter 3 extends the discussion of the Health Care Complaints Act, and adds discussion of related legislation – and the Medical Practice Act and the Nurses Act in particular. Chapter 4 then proposes legislative changes. The inquiry team’s main conclusion is that the legislation needs only minor modifications.

Individual accountability and the no blame culture

There are frequent references to the ideas of ‘individual accountability’ and the idea of the ‘no blame’ culture. By the individual accountability approach, the inquiry team suggests ensuring that action is taken against individuals where their conduct was significantly inappropriate. By the no blame approach, the inquiry team meant the increasingly popular idea that the focus should be on finding and fixing problems so they are less likely to occur in the future — and that this requires health care organisations to be confident they will not be censured. The relationships between these two approaches were discussed in several parts of the Inquiry’s reports, but the whole of Chapter 5 of the final report is devoted to them.

For some reason, the inquiry team came to believe at an early stage that there were serious advocates of the view that these were mutually exclusive. This is understandable, because some people interviewed during the course of the Inquiry were either unable to explain their ideas clearly, had not thought through the matter, or both. It is evident that the ‘no blame culture’ has become a catch phrase in health care, like many others before it. Many people use it regularly in order to be seen to be up to date, but fail to take the trouble to understand what it means.

In its final report, the inquiry team recognised it had been misled to some extent. It said that “… the purported opposition of these dual approaches to investigating events or incidents in health care was fictitious. No one seriously maintained that we should never blame (that is, attribute fault to) a delinquent doctor or nurse. If anyone had persisted with such an extreme view, one question for him or her in this Inquiry would have been whether this immunity from individual accountability would extend to criminal responsibility as well. The posing of these approaches as
rivals or mutually exclusive alternatives was mere rhetoric. It was a catchy way to emphasise that insensitive or overly vindictive disciplinary action can be counterproductive in relation to the overall improvement of health care standards.”

The inquiry team said it was obvious that, in some cases “… there needs to be individual accountability. In other cases, in the nature of things much more numerous, seeking to assign blame or fault in a derogatory way should be avoided.” Several experts were invited to meet with the team, and the discussions showed “… the no-blame idea to be somewhat of a straw man.” It was “… high time that the two camps struck their separate tents and travelled together. The chimera of no-fault in health care should be banished. But the equal absurdity of expecting that all adverse outcomes – or even many of them at all – are due to some hapless doctor’s or nurse’s fault for which they should be blamed or condemned should also be exploded.”

The arguments are not well presented but are surely correct. To paraphrase the findings, there are circumstances in which fear of discovery and public blame can indeed cause individuals to conceal errors – and consequently delay the taking of corrective actions to reduce clinical errors in future. However, there are also circumstances in which, if there is no risk of individual blame and sanction, health care organisations will fail to take adequate care.

A balance has to be struck that is far from easy to find. One complicating factor is the extent to which the individual knew the act was erroneous at the time. Another is whether punishment of a mistake will serve as a guide to others to avoid similar mistakes in future, or simply encourage them to conceal the mistakes. In short, there is almost always a complicated set of relevant factors that are difficult to assess.

Perhaps the most serious error of all is that of assuming there are simple answers. In the past, there have been many people who have promoted increased punishment as the solution to poor clinical practice. They were mostly wrong, but that is no excuse for presenting an equally simplistic model of ‘no blame’. Health care is a complicated enterprise, and it is understandable why many people choose to adopt slogans. In the past, it was quality assurance. This was followed by TQM and TQI, and now we have patient safety and no blame.

The inquiry team has rightly criticised an oversimplified view of the world. However, it might have committed a similar error by its oversimplified view of the combined approach “… that bodes well for medical and nursing professions intent on continuous improvement and fiercely opposed to the betrayal of public trust threatened by undetected and unsanctioned delinquencies.”

We agree that a mix of approaches is needed, but this leaves several aspects unresolved. If the nurse or doctor is unsure what to do, and subsequently concludes a mistake was made, he or she must decide whether to report the incident (and hope to benefit from a no-blame view) or not to report it (for fear of being found guilty of a delinquent act). The issue not adequately addressed in the inquiry team’s report is how borderline cases should be handled. We believe it is necessary to err on the side of avoidance of censure, but this view needs to be operationalised. The present guidelines and operating rules attempt to do this but there are surely some opportunities for improvement. Equally relevant, it is necessary to address not only the points of law and regulation, but also the perceptions of clinicians. This last matter is not explicitly addressed in the inquiry team’s report.
Summary of the findings

Chapter 6 summarises the complete set of allegations that were investigated. As noted earlier, they are also summarised in tabular form in an Appendix. The process was largely determined by the allegations that had been considered by the HCCC, although related allegations were uncovered by the inquiry team that had been overlooked for a variety of reasons.

In total, 67 allegations were investigated, of which 11 were referred for further consideration by other bodies (mainly by the HCCC). Some were dismissed because they were inconsistent with the available evidence. Others were not referred because the evidence was inconclusive (and there was little likelihood of additional evidence being located).

Cover up allegations

In Chapter 7, the inquiry team discusses the three allegations made by nurse informants to the effect that persons in authority had attempted to conceal evidence of poor care. One claim was that a doctor had been asked to delete reference to unreasonable delay in seeking a consultation for a patient in the Emergency Department. The inquiry team said it was not desirable practice for such a request to be made, but the doctor had not in fact agreed to the request. Therefore no further action was required.

A second allegation was that managers had removed or destroyed patient records. The inquiry team decided not to explore this allegation in detail, but rather referred it for investigation by the Independent Commission Against Corruption.

The third allegation was that staff of the HCCC had refused to initiate investigations on two cases as requested by a nurse informant. The inquiry team concluded that there had been no cover up. Rather, there had clearly been “… an unfortunate misunderstanding or crossed purposes.” The nurse-informant’s experiences “… made her sensitive to anything in the nature of a rebuff to what she saw as an attempt to raise matters for official attention”. The HCCC staff member’s reluctance to act was understandable if not necessarily correct.

Raising concerns about patient care

Chapter 8 discusses the issue of raising concerns about the appropriateness of clinical practice. In the context of this Inquiry, several nurses had made allegations of difficulties encountered when they raised concerns about patient care. One was that the formal process of reporting by way of incident reports was flawed in several ways. In particular, nurses alleged that some of the reports were mislaid or destroyed, that there was discouragement of the process of reporting, that there was little or no feedback regarding the processing of their reports, and that there seemed to be no attempts to address the causes of poor care that they had reported.

LOSS OF INCIDENT REPORTS

The inquiry team attempted to trace the incident reports submitted by the nurses. It was concluded that the system of receipt, registration, processing, and filing of reports was inadequate in many respects. Paper copies seemed to have disappeared, and the partial process of maintenance of computer records also had elementary weaknesses.

However, the inquiry team could find no evidence of deliberate loss or destruction of the incident reports. It concluded that there was no reason to believe that “… Macarthur Health Service attempted to cover up any incidences of allegedly unsafe patient care or treatment by the removal or destruction of incident reports.”
ACTION AND FEEDBACK TO REPORTERS OF PROBLEMS

The inquiry team did not find evidence of deliberate attempts to avoid giving feedback to those who reported problems, or to take corrective measures where necessary. The system was simply inefficient, and this was formally acknowledged by senior managers. The inquiry team conclude this was unfortunate. "It is a basic principle of good complaint management to respond to those who take time to register their concerns, and advise them of the actions that have been taken as a result of the information they provided. Any systematic failure to do so will inevitably lead to a justifiable frustration by the authors of concerns, probably resulting in a disinclination to speak up in the future."

The inquiry team was also critical of the processes of review of incident reports. This was particularly the case for the Critical Care Review Committee. It "… did not operate as well as it should have. The time which elapsed between an incident and its consideration … was unacceptable in a number of cases."

A CULTURE OF DISCOURAGEMENT OF INCIDENT REPORTING

Nurses had asserted that, at all stages of reporting and acting on incident reports, there was a culture of discouragement. The inquiry team concluded this might be the case, but if so there was no evidence to suggest any particular individuals merited censure.

Its findings were equivocal regarding nurses’ allegations of bullying and harassment of them by senior staff, on the grounds that they were being excessively critical of safety management. The inquiry team was concerned, however, about the way that complaints were addressed that related to a third party – such as where one nurse had complained about care provided by another nurse and the responsible manager had declined to take action because the complainant was not on duty at the time the incidents occurred. The inquiry team noted that first hand knowledge was preferable, but "… nurses should not be prevented or discouraged from submitting an incident report about matters they have not witnessed."

The inquiry team concluded that there were problems, but they were more a reflection of poor staff relations than of insufficient concern for patient safety. The allegations mostly served "… to illustrate the nurses’ frustrations with aspects of the Macarthur Health Service and highlight the level of interpersonal conflict which appears to have existed in some areas within the hospitals."

We would note here that interpersonal conflicts can have serious effects on performance in all types of systems, and the inquiry team might have expressed a greater degree of concern over this aspect of operations. For example, there have been well documented incidents in the airline industry, including the case of a British Airways crash that took place when a cockpit argument was under way – and where the pilot consequently ignored clear warnings of imminent disaster.

The inquiry team simply said that poor relations "… should not be left to fester but should be dealt with promptly by management through forums which are established and known." It failed to suggest exactly how such a process might be established and maintained.

The inquiry team reviewed various steps that have been taken recently with regard to the handling of adverse events. These included outputs of the Australian Council for Safety and Quality in Health Care (such as the Open Disclosure Standard), the NSW Department of Health, and the South Western Sydney Area Health Service. The inquiry team was generally satisfied with recent progress.

Particular attention was given to the process of root cause analysis, which was judged to have some utility. The debate about confidentiality was described, including the argument that at least some elements of the analysis might be concealed in order to ensure full participation of health care staff. The inquiry team concluded there was currently no evidence to suggest that fears of harm through
full disclosure are justified, but recommended that a review of these matters be conducted after three years of use of root cause analysis involving limited protection of confidentiality. It supported the statement of the Chair of the Australian Council for Safety and Quality in Health Care that “… (root cause analysis) must be used as something to inform the system and improvement, not something to hide behind to avoid the truth”.

**Employment discipline against nurse informants**

Chapter 9 discusses the employment disciplinary actions that were taken by the Macarthur Health Service against four of the nurse informants who argued that the actions were inappropriate. Two of the nurses claimed that a culture existed whereby the management of Macarthur Health Service implemented unfair disciplinary processes, which involved procedurally unfair investigations and the imposition of sanctions, after the nurses raised allegations of inadequate patient care. As a consequence, their allegations were discredited and ignored.

The inquiry team concluded there was no evidence linking the incident reporting by the nurse informants to the subsequent disciplinary action taken by Macarthur Health Service. However, the South Western Sydney Area Health Service accepted that the actions taken against the two nurses were procedurally flawed, and made a full apology in January 2004 for the treatment they received.

A third nurse against whom disciplinary action was taken by Macarthur Health Service in 2002 argued that the action against her had been harsh and unwarranted. She subsequently received an apology from the New South Wales Department of Health.

The fourth nurse who was the subject of disciplinary action by Macarthur Health Service also argued that this was a consequence of her making complaints about patient care. Again, the inquiry team concluded that the disciplinary action was not in response to her raising concerns about patient care. Again, she received an apology from Macarthur Health Service with regard to the disciplinary action taken against her and the details were removed from her disciplinary file.

**Records of individual patients’ care**

In Chapter 10, the inquiry team again raised its concerns about the quality of routine patient care records. It stated that its investigations had been seriously impeded by the poor quality of notes in the patients’ medical records. Most of the problems related to doctors. Nursing entries were generally of a superior quality with not only legible writing but the name of the nurse printed next to his or her signature.

It said that “… without exception, enormous difficulties were experienced by all concerned.” Although there was a clear statement at the top of the page of each record that the clinician must sign and print his or her surname and designation (initials) for all entries, most of the entries by medical practitioners were either totally or partly indecipherable. “In many cases the name of the doctor who apparently had signed his or her name remains a mystery.” The inquiry team said that the situation was not to the credit of those responsible for training or supervising the doctors. The inquiry team did not know whether doctors were unable or simply unwilling to follow the instructions.

Sympathy was expressed for the degree of work pressure for most doctors. The inquiry team did not say whether they believed all doctors were always under similar pressure of work, or whether it believed that nurses’ higher levels of compliance were a consequence of being less busy.
The inquiry team seemed to believe that there were technological solutions. Given modern technologies “… it is extraordinary that no system has been identified to overcome the obvious difficulty with handwritten records.” Reference was made to one hospital’s practice of using typewritten notes and typewritten records of those who have entered and are responsible for the notes, and of another hospital’s use of partly computerised notes. Reference was also made to the system that was activated in May 2004 (Health elink), which gives general practitioners, specialists, Emergency Department clinicians and allied health workers online access to their patients’ medical histories. Mention was also made of trials under way of the national electronic health record system, HealthConnect.

The report does not draw conclusions about the extent to which computerisation should be used. The team said it was beyond the scope of this Inquiry “… to solve this seemingly endemic problem.” However, in the absence of an electronic record, there must be improvements in the way that handwritten records are maintained.

Clinical practice issues: end of life care and medical emergencies

Chapters 11 and 12 discuss two aspects of clinical practice that were raised in several of the cases where the inquiry team found reason to refer for further investigation. Care shortly before death was an issue in 10 of the 47 cases examined. The inquiry team noted recent changes in the guidelines provided to clinicians. It decided not to give specific advice. It simply noted that such guidelines should exist and be updated as necessary. Moreover, serious efforts should be made to educate staff as to the importance of the principles and the need for documentation of any discussions.

With respect to medical emergencies, the Macarthur Health Service introduced a care process involving medical emergency teams in 1996. The main component of the process is that clinical staff can call for the assistance of experienced staff when they believe a medical emergency exists. Some nurse informants were critical of the way the process was used, and the inquiry team tended to agree.

The inquiry team concluded that one important problem was that there were different views as to whether the procedure was mandatory or discretionary. South Western Sydney Area Health Service accepted the HCCC’s findings that there had been four incidents where no call for assistance was made when it was indicated. The inquiry team said that a mandatory procedure makes no sense if staff are not adequately educated in its use or where there are no sanctions for non compliance.

The roles of the Clinical Excellence Commission

Chapter 13 of the final report discussed the proposed Clinical Excellence Commission, which is to have five main activities: a patient safety risk identification program; regular audit of patient safety systems in health care organisations; training and development programs; development and implementation of clinical risk frameworks; and research into patient safety systems and quality improvements.

The inquiry team noted the overlap and consequent potential for misunderstandings between the Clinical Excellence Commission (CEC) and the Health Care Complaints Commission (HCCC). It therefore expressed its views on the respective roles of the two agencies, as follows.

1. The CEC should be responsible for investigating and making recommendations with respect to systems issues that have the potential to have an area or Statewide significance.

2. Complaints about patient care received in public hospitals can be made to the clinician concerned, the hospital, the Area Health Service or the HCCC. In the event the CEC receives a complaint it should be referred to one of the above.
3. The HCCC has the primary responsibility for investigating serious complaints against individuals and initiating any necessary disciplinary action.

4. Where an investigation by the HCCC raises questions of a systemic nature, and those issues are specific to the individual organisation or person the subject of the allegations, the HCCC should enter discussions with the CEC as to the best forum in which they should be investigated.

5. Following any discussions between the CEC and the HCCC with respect to any investigation being undertaken by the HCCC with systemic implications, and when the result of that discussion is that the HCCC is to continue that investigation, any recommendations made by the HCCC together with any other information required by the CEC should be forwarded to the Clinical Excellence Commission.

6. While it is not expected that in the ordinary course of its work the CEC will receive information concerning the conduct of individuals, should that arise, the CEC should report any concerns it has to the Director-General of Health. The three levels of concerns set out in the November 2001 Department of Health publication "Model policy on the management of a complaint or concerns about a clinician" should guide the Clinical Excellence Commission. It will then be a matter for the Director-General to consider whether a complaint should be made to the HCCC.

7. The CEC should have access to all complaint data held by the HCCC. It would be expected that that would amount to a small component of the information available to the CEC because, by definition, that material is biased towards the exceptional or the egregious. It would be expected that its work would be informed by research, medical literature, its own audits and information generated by the Colleges, to name a few obvious sources.

8. The CEC should have access to all causation statements and recommendations made as a result of a root cause analysis in New South Wales.

9. The CEC should not be bound, as the HCCC is, by any equivalent of sec 91 of the Health Care Complaints Act.

The inquiry team argued that there could be many difficult issues in practice. It would be extremely important to ensure there is good communication so that the HCCC involves the CEC in discussions where a complaint may well have a significant systemic component.

**The state of play at mid 2004**

Chapter 14 contains information about the changes that had occurred since the time the incidents had occurred that led to the Inquiry. The information was derived from several sources including interviews with senior staff of the South Western Sydney Area Health Service, and various reports from bodies such as the Australian Council of Health Care Standards.

Perhaps the most useful part of this Chapter is a summary of the conclusions of a review commissioned by the Department of Health and undertaken by Professor Barraclough, the Chair of the Australian Council for Safety and Quality in Health Care. The report notes that the Macarthur Health Service had lower ratios of staff to inpatient bed days than similar health care organisations, and particularly low ratios of doctors. It also had a disproportionate number of inexperienced staff.
Weaknesses were identified in care processes including discharge planning, collaboration between hospitals and non hospitals, and multidisciplinary team work. Particular mention was made of the cultural problems. They included a lack of willingness to encourage the open discussion of problems in the interests of continuous improvement.

**Mandatory reporting of patient safety problems**

In Chapter 15 of the final report, the inquiry team noted there were two main options with regard to reporting – voluntary and mandatory. Voluntary reporting might involve a mix of encouragement, persuasion, and assistance to clinicians. The inquiry team noted that, at present, there is a variety of systems in place that include codes of conduct, contractual provisions, and unwritten professional ethical obligations.

The inquiry team was unsure as to the appropriateness of requiring the reporting of problems. If this approach were taken, it would be necessary to have sanctions for non compliance that might involve criminal punishment, removal of rights to practise, or various financial penalties. The Commissioner said these sanctions would be harsh “… and I suspect not fitting to the crime. I have not been persuaded of the benefits of universal mandatory reporting with respect to all adverse events in health.” However, he said that consideration should be given to incorporating mandatory reporting into health care organisations contracts. This seems an imprecise conclusion: mandatory reporting presents the same general problems regarding sanctions, regardless of the instruments used to specify compulsion.

### 3.3 Conclusions of the Inquiry

The conclusions may be grouped under four main headings: nurses’ allegations of poor care; the investigations of the HCCC; the internal systems that were intended to control patient safety in the two hospitals; and the balance to be struck between individual clinician responsibility and the systems view of errors.

**SOME OF THE NURSE S’ ALLEGATIONS OF POOR CARE MERITED FURTHER INVESTIGATION**

Many of the claims seemed to be supported by sufficient evidence to justify their being investigated further. The inquiry team presented a summary table that shows precisely which allegations justified investigations by the appropriate body, and which did not.

Other allegations made by the nurse informants were dismissed, mainly because it was not possible to find adequate evidence. In a small number of cases, the inquiry team concluded there had been misunderstandings, or that the alleged behaviour could be judged inappropriate but not deserving of censure. An example was where one doctor was asked by another doctor to modify her account to the inquiry team so that it was less critical of the hospital’s performance.

**THE INVESTIGATIONS OF THE HEALTH CARE COMPLAINTS COMMISSION WERE DEFICIENT**

The nurse informants’ dissatisfaction with the investigations of the HCCC were largely justified. Its investigations were inadequate in several respects. Minor changes may be needed in the legislation, but the main problem was that the HCCC failed to follow the existing legislation in this case.

**THE HOSPITALS SHOULD HAVE HAD BETTER WAYS OF HANDLING PATIENT SAFETY PROBLEMS**

The managers at the Campbelltown and Camden hospitals, and in the Macarthur Health Service, did not act illegally or in an unethical way. Rather, they failed to establish adequate systems for patient safety or failed to ensure compliance.
Many of the problems that led to the inquiries could have been handled through “... better internal hospital procedures, more open discussion between professional colleagues, and fuller disclosures to patients and families.” Improvements are already under way within the Macarthur Health Service that should address the inquiry team’s main concerns if they are appropriately implemented.

3.4 Recommendations of the Inquiry

We noted the several recommendations on legislative change that appeared in Chapter 4 of the final report. The last Chapter contains two other recommendations.

First, South Western Sydney Area Health Service should ensure that policies are in place that are consistent with the principles in the several documents noted elsewhere. These include the Open Disclosure Standard, Best Practice Complaints Handling, and the Model for Managing Concerns about a Clinician.

Second, attention should be paid to root cause analysis. *Inter alia*, teams undertaking root cause analysis should be fully aware of the levels of severity with particular reference to the guidelines regarding the conduct of an individual that should be referred to senior managers for further action. They should also be aware of confidentiality guidelines – and particularly the need to protect individuals in accordance with the Health Administration Act while ensuring there is publication of a causation statement and recommendations (and direct provision of the publication to involved patients).

Furthermore, a review should be conducted of the effectiveness of root cause analysis about three years after the recommended protection is provided, in order to ensure there is an appropriate balance between the usefulness of the information generated and the protection afforded. Finally, documents created by the root cause analysis process should be made available to the HCCC when it has a relevant complaint. That information should not be admissible in statutory disciplinary proceedings or elsewhere.

3.5 Discussion

The events at Camden and Campbelltown hospitals sparked a series of inquiries and reviews which in turn resulted in significant changes to the New South Wales health system as a whole. The Inquiries conducted by the HCCC and the Special Commission were only the beginning. These were followed by a review by Parliamentary Committees of the HCCC and its associated legislation, as well as a separate Parliamentary review of complaints handling systems across New South Wales.

Of the 47 incidents which led to the inquiries at Camden and Campbelltown, 21 were referred to the NSW Coroner by the HCCC and the DOH, with an additional four cases referred by the Leader of the Opposition and the New South Wales Attorney General. A further 14 cases were referred to the Coroner by the South Western Sydney Area Health Service (SWSAHS) Clinical Reference Group. A number of the health professionals involved were also referred to various bodies. In total, 15 doctors, 11 nurses and one physiotherapist were referred to the HCCC. Of the doctors, five were also sent to the New South Wales Medical Board. The Mister for Health at the time of the events was referred to the Independent Commission Against Corruption (ICAC) over allegations about his intimidation of the ‘whistleblower nurses’ as were the original allegations made by the nurses.
During or after the process of the inquiries the CEO and the entire Board of SWSAHS, as well as the Health Services Commissioner were dismissed, as was the General Manager of the Macarthur Area Health Service (although she was redeployed to another Area Health Service). The NSW health system was restructured, reducing the number of Area Health Services to eight. As a result of the Commission’s recommendations the Clinical Excellence Commission was established, with responsibilities as previously discussed. So too was a state wide system for assessing and reporting adverse events was instigated, along with an obligatory root cause analysis process.

In 2004, the NSW Deputy State Coroner held an inquest into 14 of the deaths found that there was no further cause for investigation. An additional 20 cases were finalised by the Deputy State Coroner either by his dispensing of holding of an inquest, or by declining to assume jurisdiction. The final five cases were still under investigation by the NSW Police Force Strike Force Cossa.

The legislation determining the powers and duties of the HCCC was amended and came into effect in 2005, giving the HCCC the power to require the provision of evidence, including all types of medical, hospital and practice records. Information collected by the HCCC as part of an inquiry can now be used in disciplinary proceedings, although not in civil or criminal suits. Whistleblowers were given extra protection under the act and the HCCC obliged to ensure that all relevant parties to an inquiry.

In September 2005 ICAC released a report on their investigations of SWSAHS. In that report (and associated documents) they exonerated the Minister of charges of intimidation, the HCCC Commissioner of charges of corruption and found that there was no, or insubstantial, evidence of corruption in general at Camden and Campbelltown Hospitals. ICAC also found against the allegations that the whistleblowers had been subject to reprisals and that some of the nurses involved had been offered ‘hush money’. They did, however, formally refer allegations of the falsification of patient records, by a doctor at the hospitals to the Special Commission of Inquiry into Camden and Campbelltown Hospitals, who determined that the allegation of falsified patient notes warranted investigation with a view to disciplinary proceedings, and so in turn referred the matter to the HCCC.

The HCCC sent letters to 14 of the doctors, nine nurses and the physiotherapist, regarding their conduct at Camden and Campbelltown. Another three doctors and four nurses received peer counselling. Of the doctors sent to the New South Wales Medical Board, two of the five have been cleared of the complaints against them.

3.6 References and selected bibliography


4 Celje Hospital, Slovenia

The following is a summary of the official report on problems of patient safety at Celje Hospital in Slovenia relating to pathology. The report itself, titled *Report on the delays of the laboratory results at the Department of Morphology and Cytology at Celje Hospital, May 2003* is available in the Slovenian language on the website of the Slovenian Ministry of Health (Slovenia Ministry of Health 2003). We will refer to its authors as the review team below.

4.1 Context

**An overview of the Slovenian health system**

More detailed descriptions of the context are available in English in several documents available in the literature. See, for example, Keber (2002) and Albreht, Cesen, Hindle et al (2002). This brief summary is taken from Hindle (2003).

When the opportunity arose in 1990, many of the constituent parts of Yugoslavia were ready to press their long held aspirations for independence. Slovenia was the most fortunate: it was wealthier, more homogeneous in ethnic and social respects, and was first to establish itself.

It began its independence with a complicated system of health insurance that had grown in scope and organisational complexity over time. By 1993, it had enacted legislation to create a universal and compulsory health insurance scheme operated by a government agency, and created a small voluntary insurance sector mainly to cover copayments.

Before 1990, the pattern of health services provision was largely based on population-based norms and was highly equitable for the most part. Services were almost exclusively government owned, and health professionals salaried employees. Public health services and hospital care have remained largely in government hands since independence. However, there has been an increase in non government participation in community based services (and especially primary medical care). Whether government salaried or private practitioners, GPs are paid mainly on a capitation basis.

In total, Slovenia was sensitive to worldwide trends that emerged in the mid 1980s: economic rationalism; reduction of government involvement in (and hence responsibility for) health care; emphasis on organisation rather than clinical practice changes; and attempts to increase competition in financing, purchasing, and care provision. However, its history of socialism and strong sense of national identity were mitigating factors. In the event, the government has chosen to retain its dominant position in the health sector, while encouraging a high degree of privatisation elsewhere.
The per capita GDP of Slovenia (population 2 million) only fell marginally after 1990, and increased steadily since then to reach US$9800 in 2000. This places it below the European Union average, but higher than Greece and Portugal. It spends about 8% of GDP on health.

The health status of the Slovenian population is relatively high for several reasons, including the sound investments that have been made in primary health care and environmental health. Slovenia has had a long history of successful public health services and research, and has also established a well trained clinical workforce.

The level of efficiency of the health sector is not well understood, but it appears to be higher than in all other transition economies in Central and Eastern Europe. Many efforts have been made to contain health care costs, especially since 1990, with moderate success. For example, it has introduced per case payment of hospitals by DRG, and is currently redesigning many of its services to promote care integration across settings. However, it suffers from remnants of the systems and cultures established in socialist days that failed to encourage and reward initiative.

Quality of care may approach European Union levels in some respects (Keber 2002). However, there is a shortage of reliable data that is partly a consequence of weaknesses in clinical work process control. A major reform project has been under way that is directed at resource allocation and care provision on the basis of clinical pathways.

**A short history of the problems at Celje Hospital**

The Inquiry arose out of significant errors made by Celje Hospital (the Hospital) with respect to treatment of patients who required pathology tests relating to a range of symptoms including suspected cancer. Most of the problems originated in practices of the Department of Morphology and Cytology (the Department) regarding the examination of tissue specimens and reporting of the results.

The process was typical for hospitals in developed and reasonably well funded health systems with well trained staff. The attending doctor would order a test, specimens would be taken on the ward or in the outpatient clinic and dispatched with a test order form defining the patient, the responsible doctor, and type of investigation, the specimen would be tested, a report would be written by a pathologist, and the report delivered to the ordering doctor. There was the opportunity to indicate the degree of urgency but it was rarely relevant. The ordering doctor assumed that the pathology staff would do their best with their limited resources, and anyway it would not be appropriate to interfere in their decisions.

One feature is worth mentioning that differentiates the typical process in Slovenian relative to OECD hospitals, at least to a small degree. Nursing staff in Slovenian hospitals are more likely to act in supporting administrative roles. This is a reflection of the possibly greater gap between doctors and nurses. In short, some administrative tasks (in this case, the completion and dispatch of the order form and specimen to the Department) are handled by nurses that would be more likely to be handled by the ordering doctor or a junior doctor elsewhere. This may be of relevance here, because it adds more people to the chain of communication.

Activities in the Department were themselves complicated and poorly coordinated. For example, there was poor management of workflows, allocation of workloads, and monitoring of performance. Of particular relevance here, the assignment of work to the two full time pathologists was managed in a largely idiosyncratic way. Unprocessed test results were allowed to remain in a seriously unbalanced state for several years. The main problem was not, however, inappropriate allocation of
the work but rather a gross imbalance in the rate of processing by the two pathologists. The main consequence was an accumulation of unreported test results with one of the pathologists.

Delays in the return of the pathologists’ reports were consequently common. In these circumstances, it was usually the ordering doctor who took action. In principle, the ordering doctor (or another clinician at the ordering doctor’s request) could telephone the Department, ask about the current status of the report, and if necessary talk directly to the person best able to clarify the situation.

In the case under study, the most appropriate person was the pathologist who was building the backlog of unreported tests. However, this rarely resulted in an adequate response. It did, however, result in a sense of disturbance of the peace (the state of uneasy coexistence of the tribes) and therefore over time the direct route of telephone communication with person responsible for the delay became a rare event. It was more trouble than it was worth, especially in view of the fact that the process of telephone inquiry was time consuming and often unsuccessful. As is common in such circumstances, the weaknesses in the system became acceptable because there was no solution apparent to those involved. Over time, the weaknesses ceased to be recognised.

The most common method of inquiry about delayed results came to be through a less direct channel: the responsible doctor would request action by the nursing staff; the nursing staff would telephone the administrative staff in the Department; the administrative staff would write a note to the pathologist; and the pathologist would then read the note and pass a message back through the same channels. Sometimes the pathologist would fail to respond at all. In other cases, he would give excuses such as pressure of work, and on occasions he would place the particular order higher in his priority list. A part of the game was an implicit acceptance of the rule that, if one offended the pathologist, this might mean a loss of favourable treatment in future. Another rule was that it was easier in many ways to accept than to challenge the excuses. If the pathologist were to give the excuse that the Department is underfunded and overworked, it is plausible to most people in an organisation with a culture of blaming all internal problems on external agencies – the ignorant insurers, the traitorous Minister, or the patients with unreasonable expectations and unwillingness to pay to obtain care from the private sector.

The ability of clever people to be able to accept illogical but more comfortable answers is well illustrated in the review team’s report. It noted that the ordering doctors were frequently irritated by the absence of timely results. The review team reported that this led the doctors from time to time “… to express formal and informal criticisms of most of the staff in the Department, but not of the pathologist who was responsible for most of the problems.” It became clear during the subsequent Inquiry that the ordering doctors were mostly well aware of the real cause.

Indeed, the review team concluded that nearly everyone involved was aware of the problems. “The pathologists in the Department knew about the delays as did the doctors who ordered the tests, the heads of departments, the hospital’s Medical Director, the executive committee of the Hospital, the nurses, the laboratory technicians, and other staff. Yet, the problem remained unsolved.”

Over time, it became an unspoken but almost universally accepted rule of operation that tests, when ordered, should not be expected to be received on time – or indeed received at all. This may seem surprising. However, similarly illogical behaviours are common in all systems. The patterns of illogical behaviour are easier to see (or are more likely to be unacceptable) in systems other than one’s own.
The pattern of acceptance extended to senior managers in the Hospital. For nearly a decade, the Hospital’s managers made no serious attempt to enquire formally into the problem. From time to time, the matter was raised and then excuses were made: we are underfunded; we could disturb relations with medical staff at a time when there are more urgent matters to attend to that require the doctors’ support; we do not have the data; more research is needed; and so on.

The Hospital’s Board of Management claimed it did not know of the situation, except in outline. Some Board members said during the Inquiry that they had heard there was a problem, but senior executives had advised them that it was probably minor or temporary.

The review team concluded that Board members and senior Hospital executives should have known – it would have been easy to find out. At least some of them knew enough to have been concerned, but preferred not to take the lead in finding out for sure. The review team wrote that “… the most disturbing aspect is that hospital managers did nothing.”

**Processes for the control of clinical work**

There were seven main systems in place to control clinical work – and hence to avoid the problems that arose. Indeed, in Slovenia the systems are required by law.

All of them were seriously inadequate. First, there was a system of internal audit, operated by a set of what are termed Clinical Experts Supervisory Committees linked through a Clinical Council. Each committee had clear terms of reference, similar to those of quality assurance committees in Australian hospitals. Thus there was a committee at the Hospital that was specifically required to monitor the quality of pathology services. Its membership included senior staff with clear responsibilities to the Board of Management for supervision of quality. It also included clinicians directly involved in the processes of ordering, undertaking, reporting, and analysing results of pathology tests on a daily basis. Changes were made in 1995 to improve the processes, but the review team observed that they were “… carried out on the basis of gut feeling”.

Second, there was the Slovenian Medical Association, which is required by law to take responsibility for the establishment and monitoring of professional matters. Processes in place included the right to undertake inquiries, to encourage and then review complaints from health professionals and patients, periodic review of the performance of teams and individual clinicians, provision of advice as required, and the reporting of concerns to the Ministry of Health where performance placed patient safety at risk.

Third, there were the individual specialty associations. In this case, the societies of pathology and oncology were clearly expected to exert some degree of control. However, as has commonly been noted elsewhere, the associations acted to control the risks of adverse publicity (and to protect their members’ livelihood) rather than to protect patients.

Fourth, there is routine administrative supervision carried out by the Ministry of Health. This takes many forms and includes the appointment of a senior Ministry of Health official to the management boards of care provider agencies.

Fifth, there are various control methods applied by the Health Insurance Institute of Slovenia. This is a semi-independent agency that acts as the primary purchaser of services from health care organisations that are covered by the national compulsory health insurance scheme. Its powers are significant in principle: it is empowered to audit care and deny payments if it is judged to be inappropriate. It can (and does) negotiate the inclusion of particular standards of care into the annual purchaser-provider contracts. It has a large team of auditors (predominantly doctors) who have the power to require the submission of clinical documentation for review and to make site
visits for inspection purposes. Health care organisations regularly complain about the excessive power of the auditors and the degree to which they examine the details of individual patient care episodes before approving payment. However, it has been observed that the inspection methods have systematic weaknesses including a dominant interest in controlling costs rather than contributing to improved quality of care. It has also been claimed that there is a lack of evidence against which the appropriateness of care is judged – much of the auditing depends on the application of the auditors’ personal judgements to the retrospective review of individual cases. The problems at the Hospital seem to support the claim of ineffectiveness, at least in terms of identifying problems of patient safety.

Sixth, there are periodic external audits in which participation is voluntary for the most part. For example, the Hospital underwent two major reviews during the period that demonstrably poor care was being provided by the Department under the auspices of the European Foundation for Quality Management pilot study for an Excellence Award. The reviewers never came across any problems in the Department. As it was a self assessment exercise, none of the problems of delayed laboratory results were reported; the evaluators did not find out about the poor quality of care or severe problems.

Finally, there are systems in the Department itself that were intended to improve control of work. They included relatively sophisticated equipment with the ability to compile computer records and hence provide management information. However, during the period under study, the Department had hardly any auditable performance standards, no short- or long term plans, and kept no formal records of meetings.

Towards public disclosure

It is not entirely true that “… hospital managers did nothing” for more than a decade. Rather, they did as little as was judged necessary to keep the problem under control (rather than as much as possible to solve it).

The first signs of concern among patients appeared in 1994. The records are poor regarding the details. However, it is certain that the number of complaints increased after that, probably because concerns spread by word of mouth among patients and their families. Confidential comments by some nurses are likely to have stimulated the patients and families to act. As is common in most health care systems, nurses are more easily approachable and more likely to speak the truth – at least with regard to doctors’ behaviour – if there is little risk of being identified as a troublemaker.

The Hospital took various steps to control the publicity that were largely successful. They included the conduct of an inquiry, the improvement of internal supervision processes (at least in principle), and counselling patients and families about the lack of evidence that any of the care was inappropriate. In contrast, the Hospital did almost nothing to define and resolve the underlying problems. For example, no attempt was made precisely to measure the numbers and types of tests that had not been completed. There were no written reports on the nature and size of the problem.

The errors continued to occur after 1994, and there were periodic increases in risks of public disclosure. There was an increase in internal concerns in 1999, when there was a change in the management of the Department. This led to decisions to reduce the delays in future, and these were largely successful: the rates of delay and non completion declined sharply. However, the new manager stopped short of reviewing the previous problems. It was hoped that the remaining backlog would largely remain unnoticed and the underlying causes would dissipate in due course.
This was unfortunate because much would have been learned about ways of avoiding similar problems in future. Moreover, it would have been appropriate to consider the extent to which previous practices had harmed patients, particularly in view of the fact that many recent patients might continue to be exposed to risks through the absence of test results.

In 2001, the Medical Director reached agreement with the Clinical Council to increase the degree and rigour of periodic internal reviews. In January 2002, the Medical Director determined that a formal internal inquiry should take place regarding pathology, which at least acknowledged (but understated) the problems. The Medical Director then took the first formal action to inform the outside world: he wrote a confidential letter to the Slovenian Medical Chamber – the official body responsible for medical professional matters that is roughly equivalent to the Medical Council in the UK. The letter was directed to the Ethics Committee of the Medical Chamber, and suggested it might wish to consider whether actions were needed.

For a mix of reasons, the Medical Chamber took no official action for six months. It is unclear whether it would ever have acted, because its deliberations were overtaken by events: the story broke in the mass media in early October 2002.

The circumstances are not entirely clear, but the weight of evidence is that it finally became evident that the matter could not be contained. One of the contributing factors was a meeting between the Hospital’s General Manager and the Board, at which he was informed his contract would not be renewed. Before leaving the building, he noted some problems that the Board itself should have identified and assisted with resolution, including the unprocessed pathology reports. One step led to another, and interested parties began to become extremely active in anticipation of open investigations. It was therefore only a matter of time before the media became involved.

The Minister for Health, a distinguished clinician, took immediate action: he had not previously known there was any kind of problem. He requested a report from the Hospital and immediately appointed a Committee of Inquiry with involvement of the Medical Chamber. Shortly after the Committee began work, the Police announced it was initiating investigations in response to public complaints. The Ministry of Health and the Police held discussions and agreed a collaborative process whereby any legal actions would be delayed until a technical inquiry had been conducted. However, the Police would remain fully informed of the Inquiry’s progress.

### 4.2 The Inquiry

The review team acted with considerable speed and diligence. It conducted its initial investigations over a period of four weeks, including site visits and interviews, and provided an initial report for comment by the Hospital. Careful reviews were made of the clinical records, questionnaires were widely distributed to Hospital staff and the results analysed, opinions were sought on the initial findings from the Association of Pathologists and Forensic Medicine, and members of the Hospital Board were investigated.

The Medical Chamber was fully involved, and its comments were taken into account at all stages. Indeed, it was requested to provide written comments at several stages in part to ensure that the findings of the review team would be endorsed by the Medical Chamber once they became public.

The review team established a rigorous and logical method of investigation. First, it examined performance in terms of the processing of pathology tests. A total of 2815 delayed or incomplete test reports was identified in the period between 1985 and 2000. This was far more than was estimated from all other hospitals over the same period, and entirely inconsistent with established guidelines for the Slovenian health care system – and indeed with the Hospital’s own standards and operating rules.
Second, all plausible hypotheses that might explain the poor clinical practice were tested. These included attempts to associate the errors with the volume or type of pathology testing undertaken. This was inherently sensible. It was also unavoidable in the event, because it was repeatedly claimed by some parties during the course of the Inquiry that the workload was excessive, and this contributed to the backlog of testing. The claim was questionable in the extreme: if the workload were excessive, it would be within the power of the Hospital to make formal complaints to funding agencies. Moreover, it could simply have turned patients away, thus giving the public the opportunity to register their views about resourcing.

Nevertheless, the review team correctly chose to take the claims seriously, and therefore made a variety of analyses to test its veracity. For example, workloads were compared across pathologists and over time at the Hospital, and compared to the workloads over the same period at other hospitals. The international literature was reviewed to assess differences in workloads and clinical practice. In these and other cases, the hypotheses were rejected. The Hospital had an average volume of work per pathologist, compared with other Slovenian hospitals. The total work of the Hospital fluctuated over the period from 1985 to 2000, but the number of errors was not associated in any significant way. The number of errors by pathologist was unrelated to their individual workloads.

In short, many hypotheses were tested and subsequently rejected and the only one that was supported by the evidence was that one senior pathologist had been inefficient or otherwise had failed to perform in accordance with reasonable expectations. It is interesting that the same pathologist had been given a national award in 2002 for distinguished service to the health of Slovenians.

The review team’s final report was presented to the Minister in May 2003, seven months after it began its investigations. The Minister took one week to review the report, and issued his comments in writing and through a press conference. The report was subsequently the subject of intense review and discussion in the media. The headline in the main national newspaper on the day after the press conference says “Minister blames the system”.

4.3 Conclusions of the Inquiry

There are many related conclusions that reflect the linkages between the underlying causes. We have arranged them under six headings below, but they are not mutually exclusive.

Management information

With regard to information, the review team noted there was hardly any that might facilitate the monitoring of performance. It expressed the view that information systems able to support both internal and external benchmarking needed to be established. This should be possible by 2005, by which time “… the hospital accreditation process will have been established.”

However, this might be missing the main point: information indicating that performance was poor was everywhere – many clinicians knew it for sure; many patients were aware there were problems; and the mass media found it immediately they were advised to look. As noted elsewhere, hospitals where similar disasters have occurred have typically passed successfully through accreditation processes during the periods when poor care was being delivered. The problem is hardly ever a lack of data but rather a reluctance or inability to act on them.
Authority, responsibility, and accountability

For the most part, the review team did not believe the problems were caused by individuals. In this respect, its conclusions are very similar to those from inquiries in other countries. For example, the inquiry report notes that, like Bristol, this was “… not a story of good or bad people, or good or bad doctors and nurses. It was not a story about people who intentionally wanted to harm patients.”

It was noted that most doctors appeared to take seriously their responsibilities to their own patients. For the most part, they appeared to order tests appropriately, tissue samples were competently taken, testing was handled in effective (although not always in efficient) ways, test results were competently analysed, and sensible decisions taken regarding subsequent care. The problems lay mostly at the interfaces. For example, if test results were not returned in a timely manner it was assumed that either the delays were unavoidable or that someone else would note the problem and take appropriate action. It was rare that complaints were openly made (although many doctors informally admitted their ongoing concerns). Over time, what might have seemed at first to be intolerable performance became the accepted norm.

The report identified two important aspects of medical culture that affected views about responsibility. First, the individual doctors believed their work should not be subject to oversight by anyone else: unlike (say) nurses, doctors spoke of ‘my patient’ rather than ‘our patient’. This was associated with the belief that, if one doctor’s work should not be the subject of comment by other doctors, then that doctor should extend the same privilege of autonomy to all other doctors. Second, there was no one who believed he or she had a responsibility to manage the entire experience of patients from admission to discharge.

The significance of medical culture was strongly emphasised in the review team's report. They noted, for example, that many of the Hospital staff interviewed (from virtually every profession) volunteered the opinion that “… protection of medical ascendancy was far more important than solving the problem.”

The weaknesses were not, however, restricted to medical culture. Nurses, doctors, administrators, and other groups did not have a common understanding of the distribution of responsibilities. For example, nurses did not believe they were responsible for commenting on errors made by senior doctors. Administrators at all levels did not believe it was their responsibility to criticise clinical practice. The review team said that medical culture was defined largely by a sense of individual autonomy, and that “… tribal behaviour was far too developed.”

The report says that, although one of the pathologists was the most culpable, the system as a whole was at fault in that “… it was designed to prevent such a situation. It is precisely because of the lack of a successful supervision and undefined processes that it was not possible to find out what was actually happening within Department.”

A related concern was that “… power was in the hands of a few people” and that there was a mismatch between power and responsibility. Further, responsibility was not clearly associated with accountability. Some doctors claimed they were accountable only to their patients. Even where there was a demonstrable commitment to accountability, however, the processes whereby it was exercised were grossly inadequate.

For example, if a doctor wishes to be fully accountable to his or her patients, there must be a process whereby it occurs in a satisfactory way. For the most part, patients did not know they had a right to review their doctors’ actions. Where they were aware of their rights, there were no adequate processes whereby patients were advised and supported in establishing a process to exercise those
rights. They were not informed about normal practices of care provision (what they had a right to expect), or of ways of interrogating health care organisations so they might determine whether care processes were adequate.

In total, there were mismatches between power, responsibility, and accountability. Those with the most power did not always accept responsibility, and they were hardly ever accountable in a satisfactory way. The report said that “… it was rarely clear who was responsible, and those in charge largely ignored their responsibilities.”

**Inadequate empowerment of patients**

While a few patients took action, and therefore contributed to public disclosure of the situation, most simply accepted doctors’ explanations without question. The review team reported that “… most patients were convinced that the level of care they received was good. They trusted the hospital. No one knew things were not taken care of properly.”

It was noted that patient empowerment was generally unsatisfactory. An example was given of the situation where results were delayed indefinitely and patients asked why. The review team reported that it was not uncommon for the responsible doctor simply to say that “… it is not my fault if the pathology results are not ready” and “that the patient should telephone the Department if he or she wanted something done.”

On rare occasions, patients became increasingly complaining of delays. In some of these cases, it became the practice to return their samples and suggest the patients should themselves take them to another laboratory elsewhere for examination.

As the truth progressively became evident to large numbers of Hospital staff, there was the opportunity to accept some of the responsibility and at least to apologise in a general way. The review team's report notes, however, that this was not happening even in the last phases of their work. “No-one apologised to the patients, even to those who had subsequently been found to have been seriously harmed.”

**Discouragement of complaints**

There was an organisational culture that discouraged the admission of errors. Staff were discouraged from raising problems, and particularly from raising problems that implied medical mistakes. “If anyone did complain, no-one took any notice or no one took the complaint seriously.” There was a sense that, if complaints were made repeatedly, it was a sign of incompetence or disloyalty.

**A failure to use formal instructions**

Most of the rules and guidelines regarding operation of pathology services were not written down. If they had been written down at some stage, the overwhelming majority of staff would not have known where to find them. Where changes in procedures were to be made, the advice was almost always provided orally.

This appeared largely to be a consequence of the dominance of medical culture. Senior doctors were not expected to have to make the effort to write instructions to subservient staff (meaning in effect almost everyone). If subservient staff wished to make notes based on oral instructions, they might do so of their own initiative.
A different view of management

There was an almost complete absence of recognition that clinical work needed to be collectively managed, at least in part. One of the pathologists not responsible for the errors became increasingly concerned – not only about the incomplete tests but also of other aspects of pathology services. In 1996 (and again in 1997) he raised his concerns with senior hospital managers and proposed that his own workload be reduced so he might devote 30% of his time to clinical management. His proposals were rejected on the grounds that there were serious budgetary problems. The Hospital was in fact experiencing deficits, but should have been able to manage as effectively as other hospitals given the essentially equitable methods of resource allocation.

A more appropriate response from Hospital managers might have been increased effort to control the waste. However, the pathologist was given the message that his advice on budget planning was not appreciated. The inseparable links between financial and clinical management were ignored or at least undervalued. The report says simply that “… systems, processes and available resources influence the quality of work within the institution as well as care itself.”

4.4 Recommendations of the Inquiry

The recommendations of the review team may be easily deduced from its conclusions. The central recommendation was that there must be improvements in clinical team work. This depends on increased understanding and respect of differences between clinical professions, establishing forums in which multidisciplinary teams can openly discuss multidisciplinary problems, the refocusing of attention on the patient and away from profession and enterprise, establishing a view that admission of errors is a sign of strength rather than of weakness, and so on. The patient “… must be placed at the centre of the care process.” Mistakes are inevitable, and when they occur we should learn from them. We must “… avoid placing the blame on individuals, and instead interpret them as system problems for which we are all responsible.”

The review team referred several times to the need to accept that changes in clinical culture will take some time and effort. However, it envisaged the potential for early improvements mainly by making greater use of clinical practice guidelines and clinical pathways as practical manifestations of a new form of clinical culture. These instruments “… are not magicians’ wands, but they could have solved many of the complexities that led to bad care at the Hospital. At present there are no better ways anywhere in the world to move forward in providing the kind of care that all citizens have a right to expect.”

Little was said about the context within which changes in clinical practice should be made. However, the review team said that “… it is important to define the mission of the Hospital and share it with all staff.” There should be more trust and more communication. For example, it would help if “… awards for effective work … are shared among all staff, rather than only to the Board of Management” and that the practice of passing the blame downwards were to cease. There was also an acceptance of the contribution of other elements of the system to what had happened at Celje Hospital. “Changes need to take place at all levels from the government to care provider agencies.” Moreover, patients need to be key players in the process of reform. It was not only necessary to provide care with respect and honesty, but also to incorporate patients in every process from planning to evaluation.
4.5 Discussion

One of us (Professor Hindle) was working in Slovenia in 2002, when rumours about the possibility of a review were beginning to circulate. He was invited at that time to make a presentation at a conference of hospital directors in Ljubljana and he chose to describe the case of paediatric surgery at the Bristol Royal Infirmary and ask whether it was relevant to Slovenia. One hospital General Director said “… you have pretended to talk about Bristol but you are actually holding up a mirror in which we might see ourselves.” He happened to be the General Director of one of the best hospitals Professor Hindle has seen anywhere in the world.

This seems relevant in two ways. First, the Celje Hospital story says little about the Slovenian health care system and much about problems of health care anywhere in the world. Second, there are ways to make radical improvements; even if the world is unkind a small group of hospital staff can start a revolution if they have the understanding and the commitment to do so.

Shortly after the official report was released, the Ministry of Health introduced a requirement in the hospitals’ annual agreements whereby they would each perform a self assessment of the appropriateness of admissions making use of an adaptation of the Appropriateness Evaluation Protocol (Ceglar, Hindle, and Marusic 2003). Most hospitals reported low levels of inappropriate admission, but there was an outlier: what had appeared to Professor Hindle to be the best hospital had the highest rates of error. The Ministry of Health subsequently introduced an additional budget element from which funds were allocated in direct proportion to the size of the reported errors. There are two ways of interpreting this: that the hospitals with the worst performance were being quite inappropriately rewarded; or that the Ministry was making a small contribution to changing the culture whereby admission of errors has in the past led to penalties. The latter is the correct interpretation, and this suggests that Slovenia is on the right track.

4.6 References and selected bibliography


5 Glasgow’s Victoria Infirmary, Scotland

5.1 Context

Several inquiries, both formal and informal, took place in Scotland in 2002 and 2003 with regard to outbreaks of health care associated infection (HAI) that occurred over several years. Actions were deemed necessary mainly because of widespread public concern (and mass media interest) that arose from the outbreaks of salmonella infection at the Victoria Infirmary, Glasgow, in December 2001 and January 2002 (Meikle 2002). Three people died and a large number were injured or placed at risk.

5.2 The Inquiry

The main instrument of inquiry was a group (hereafter called the inquiry group) that was established by NHS Scotland under the chairmanship of Dr Brian Watt (2002). As a consequence of publication of its report, the Minister for Health and Community Care called a Convention of experts and interested people from across Scotland in June 2002, to which several overseas experts were also invited (NHS Scotland 2002). In the following section we summarise the Watt Report. In section 5.6, footnotes, we outline the main conclusions from the Convention, and present the contents of the NHS Scotland Action Plan (The Scottish Executive 2002) which was shaped, in part, by the outcomes of the inquiries.

The inquiry group worked as a team, interviewing individuals from relevant organisations as a whole where possible. The inquiry group drew on these interviews, and interviews conducted with staff from the Scottish Executive, professional opinion and relevant guidelines, in order to make their findings.

5.3 Conclusions of the Inquiry

The main conclusion was that the outbreak of salmonella infection was unfortunate, but there was “...no evidence that the deaths at Glasgow’s Victoria Infirmary could have been avoided.” The inquiry group argued that it was possible to reduce the chances of hospital acquired infection, but they cannot be eliminated entirely.

Critics of the findings have mainly concentrated on what they see as a logical flaw. If the deaths were not preventable, why did the inquiry group make so many recommendations for change? Much depends on how the main conclusion is interpreted. For example, it might mean that the deaths were not preventable given the resources and processes in place at the time. On the other hand, it might be interpreted to mean that the resources and processes were adequate given the knowledge and willingness to pay that applied at the time, but the community’s expectations were changed by the public debate about the deaths.

The only reasonable basis for judgement is an analysis of the recommendations that are summarised below. The reader must ask whether any of the recommended actions could and should have taken place before the outbreaks and consequent publicity. It is our view that at least some of the recommended actions should have been in place – they would have cost little or nothing, and did not present any significant logistical or technical problems.
Dr Watt argued that the risk is always present, no matter what is done. “You cannot bring it down to an absolute zero. It is like the brakes in your car failing. You can minimise the risk by having the car serviced but the brakes can still fail. Our measures against hospital acquired infection are rather like a dam against water. We have identified 47 holes in the dam. If we can plug the 47 holes that will obviously help.”

5.4 Recommendations of the Inquiry

The following summary was compiled from the Report of the review of the circumstances surrounding the onset of the outbreak of salmonella infection at the Victoria Infirmary, Glasgow, in December 2001 and January 2002.

In its preamble, the Report notes the significance of hospital acquired infection (HAI). It not only affects individuals but frequently transmit to others who rightly have an expectation that they will be protected from cross infection. There is a distinct and immediate public health implication and the public has an expectation that coherent advice to them will be forthcoming. Even quite small outbreaks of cross-infection will have an impact on health service provision, because more resources will be required and also (and of further concern to the public) there is likely to be temporary closure of services such as wards or whole hospitals.

The inquiry group made 47 major recommendations. There is no easily understood structure, and we have created a structure below to facilitate understanding. Each of the headings is, however, derived from terms used in the inquiry group’s report.

Compliance with existing rules and guidelines

The inquiry group often implied (and occasionally made specific reference to) the appropriateness of many of the existing operating procedures. However, it noted there was seldom full compliance and referred to the need for authorities to address this. For example, it stated that “… the Scottish Executive Health Department should reinforce the good practice contained within the Scottish Health Facilities Note 30 (Infection Control in the built environment: design and planning).”

Auditing

The inquiry group linked poor compliance to inadequate auditing processes that were observed at most levels in the system. In health care organisations, it was necessary for managers to “… put in place structured audits of hand washing for all groups of staff, including medical, bank, agency and night staff.” There should be regular auditing of compliance with food handling rules, and “… appliances used for storing or preparing food (whether in the ward or elsewhere) should be subject to appropriate inspection and the results recorded.”

External agencies were also advised to be more vigilant. For example, the Clinical Standards Board for Scotland was urged to make sure there are reliable mechanisms in place to monitor compliance with its cleaning services standards. Health care organisations were advised to pay more attention to external audit reports. For example, managers of Trusts should pay more attention to reports from Audit Scotland, and then take appropriate action to respond to them.
Refinement of operating procedures

Many of the recommendations concern the need to make minor changes in the operating rules themselves. For example, clinical staff should be more closely involved in the review of cleaning methods. The inquiry group said that “… the cleaning specification in wards and departments should be set by the senior nurse responsible for the area, and each ward or departmental manager, in collaboration with the relevant Infection Control Team (ICT) and Domestic Services Manager. Cleaning against this specification should be subject to rigorous monitoring and action to correct deficiencies. Failure to meet the specification should be subject to formal audit and review within each hospital and be subject to public disclosure.”

Further, there should be more specificity with regard to dealing with gross contamination from body fluids (blood, urine, faeces and so on). Detailed guidelines should be available in every hospital for the decontamination of staff, together with appropriate facilities (washing, showering, cleaning uniforms). All health care organisations should have a staff uniform policy that ensures all staff uniforms are laundered by a service accredited by the NHS, the widespread practice of staff travelling to and from work in (potentially contaminated) uniforms ceases, and that adequate staff changing and decontamination facilities are provided. There should be improvements in guidelines for the handling of patients with loose stools or diarrhoea.

Several recommendations were made with regard to patient movements. For example, there should be national consideration of options to reduce the movement of patients between wards in hospitals “… so that the likelihood of outbreaks occurring is minimised and when they do occur they are contained within as defined a location as possible.” Further, control of an outbreak must include restriction of staff movement between wards and departments. When patients require infection control precautions to be implemented, the nurses providing the care should where possible be the ‘named nurse’. This should minimise the number of contacts of both the patient and the nurse.

Other improvements to operating procedures concern standards relating to new buildings and refurbishment projects, more precision with regard to advice for temporary staff including those from nursing agencies and banks, and rules for staff screening in outbreaks of infection.

Accountability

One of the most important sections of the inquiry group’s report concerns accountability: too many staff were aware of potential problems but did not believe it was their responsibility to act. The inquiry group recommended that ward or departmental managers “… should have unambiguous responsibility and be held accountable for all aspects of hygiene in their area. They must have commensurate authority, skills and resources (time and money) to discharge this responsibility.”

Trust managers needed to ensure there are policies that clearly identify the accountabilities of nursing and domestic staff in the cleaning of ward furniture and apparatus including baths, food trolleys and clinical equipment. The policies must precisely identify who has overall responsibility.

It was important to ensure there were staff specifically responsible for infection control. Each health care organisation should have a designated and trained infection control doctor “… who will normally lead the Infection Control Team.” This should normally be a consultant microbiologist who will have designated sessions and a clearly defined job description. In the case of a health care organisation without laboratory facilities (such as a Primary Care Trust) it should formalise arrangements with a suitably trained and appropriately resourced individual.
Clear accountability should exist with regard to management of incidents. The inquiry group recommended there should be an ‘issue manager’ as soon as a serious outbreak occurs and irrespective of the route through which notification has come. There should also be clear accountability for information management including briefings for staff and the public associated with an outbreak.

Several additional (and diverse) comments were made about accountability. For example, there should be a lead Infection Control Nurse (ICN) in each Trust. There should be ‘infection control champions’ at ward level that can complement, but not replace, the roles of the ICT. They should not be used as substitutes for ICNs. Rather, they should assist in the delivery of a comprehensive infection control service and be integral members of an enlarged ICT. They should have clearly defined roles, allowed dedicated time for infection control duties and be appropriately trained and supervised.

**Reporting systems**

Several recommendations are made regarding routine documentation processes. For example, exposure of staff to faeces should be documented through the Incident Reporting Procedure as thoroughly as exposure to any other biological (body) fluids. Nursing notes and care plans should clearly reflect the need for enteric precautions in individuals suffering from loose stools or diarrhoea. In general, nursing documentation should be improved so that key information and advice relating to infection control measures can be communicated to all relevant staff.

Contacts with, and advice given by, any member of the ICT should be documented by both the individuals providing and receiving the advice. This would be in addition to infection control care plans. Nursing documentation should be improved so that key instructions relating to infection control measures can be communicated to all relevant staff.

When problems arise, there should be specific documentation processes. For example, all incident reports should provide sufficient details of key factors in the spread of infection to allow proper audit. The recommendations of an earlier report (Pennington 1997) should be extended to cover all outbreaks. In particular, on completion of investigations, a minimum data set should be provided to relevant authorities in a standardised way. For large (or otherwise significant) outbreaks a full written report should be completed and consideration given to its publication.

Appropriate documentation should be made of screening of relevant staff in the case of an outbreak. Health care organisations should take measures to improve the quality of clinical information on laboratory request forms for investigation purposes.

A classification system for infection outbreaks should be developed and implemented. The inquiry group provided an example of a classification and reporting system in its report. The classification and counting rules should apply in all circumstances. Thus the NHS should make use of “… a consistent set of criteria that is linked to a risk management classification describing infection outbreaks.” The level of outbreak (in terms of risk category) must determine the level of action required and the level of communication.

Finally, there should be more and better information about costs. The inquiry group recommended that NHS Scotland should adopt a program budgeting approach to infection control and that each Trust and each Board be required to provide details of the resources devoted to infection control. The details should be supplied as part of the documentation provided to the Clinical Standards Board for Scotland at the time of individual health care
organisation reviews. The NHS Scotland should convene a working group to develop methods of tracking and calculating the costs of infections and their control.

Communication processes

The inquiry group was particularly concerned about the way news of the outbreaks was communicated. Much of the concern related to mass media reports. Thus the inquiry group recommended that “… Trusts and Boards ensure that there are sufficient resources to appoint adequate levels of communication professionals.” However, they did not want to leave everything in the hands of such people. They argued that ‘Press Office to Press Office’ communication should be additional to, rather than a substitute for, professional communication.

Communication between officials needed to be improved. For example, if any outbreaks were considered at any stage to be food-borne, both the NHS Scotland and the Food Standards Agency should be promptly informed.

Education and training

Almost every part of the health care system was considered by the enquiry group to require more training. Thus a scientific meeting should be organised at which experience and ideas relating to the specific infection control challenges of old buildings be shared, and the findings should be widely distributed to those with responsibility for the upgrading and maintenance of buildings.

All health care organisation should regularly assess the competencies of nursing staff in infection control, and ensure that structured training programs were established. NHS Scotland should work with nursing agency proprietors to establish ways of managing competencies in infection control. Similar assessment and training programs should be put in place for medical and allied health professionals. All staff at ward or department level that handle food should receive training in food hygiene commensurate with their duties and in compliance with food safety regulations.

The managers of safety in health care organisations (and especially the responsible clinicians who should include consultants in Public Health Medicine) should be trained in the management of HAI and play a more prominent role in surveillance and hospital outbreak management. They should normally lead all infection outbreaks within their organisation. Each Health Board should hold regular simulated outbreak exercises (possibly every two years), with adequate debriefing afterwards. The documentation of such exercises is to be provided to the Clinical Standards Board at the time of their inspections.

More resources

Of the 47 major recommendations, only two refer directly to resource shortfalls. First, the managers of each health care organisation must ensure that levels of basic ward equipment (such as hoist slings and commodes) are sufficient to reduce the communal use of such equipment and reduce the risk of cross-infection due to inadequate decontamination.

Second, managers must ensure that resources are in place to ensure there are sufficient numbers of infection control staff. The staff should be sufficient to have daily contact with wards or other health care premises, visit each facility at least weekly, provide advice to ward and departmental nursing staff on the nursing care of patients who are at risk of or who have infection, be responsible for a systematic competency program in infection control for all health care workers at their place of work (including medical, agency and bank staff), undertake systematic hand washing audits
including those involving night and weekend health care workers, and provide an on call service to advise on infection control matters on a 24 hour basis.

The inquiry group did not make any estimates of the cost implications. However, during the Inquiry it was argued that the cost of adequate resources to reduce infections to an acceptable level was probably no more (and possibly less) than having inadequate resources that resulted in major outbreaks of the kinds that had recently been experienced.

Team work and leadership

The inquiry group's report places much emphasis on the need for better team work. No great effort was made to define what this might mean, but may be deduced from a general theme that pervades the report: too many people in all parts of the system were working on the basis that someone else was in charge, but there was no common understanding as to whom that might be.

The inquiry group recommended that the team established to manage outbreaks (the Outbreak Control Team or OCT) should always be chaired by someone with competence and authority in health care associated infection. The local Consultant in Public Health Medicine (CPHM) should chair OCTs for major outbreaks. In this way, there will be a clear indication that the Team is led by an individual external to the health care organisation who has close links with the local NHS Board and with community surveillance. In the case of other hospital outbreaks the CPHM should be consulted regarding chairmanship of the team.

There should be clear role definitions for the members of the OCT, and their responsibilities should be documented. The team should develop and publish an Outbreak Control Plan.

Senior managers of each health care organisation (at the level of Executive Director and above) should be fully engaged from an early stage in managing outbreaks either as full and active members of the OCT or as a separate support team to the OCT. Senior management support should include a senior communication manager who can ensure that staff, relatives and the public are promptly informed of the outbreak and are given appropriate public health messages.

The Chief Executive of a health care organisation or Health Board (depending on whether the outbreak is primarily in the hospital or community respectively) should assume the unambiguous responsibility for ensuring effective internal and external communication including the media, and appropriate government departments and agencies.

Each Health Board should have an appropriately constituted ICT which takes the lead in strategic aspects of infection control in their area, formulates and agrees infection control policies, coordinates the management of all outbreaks where the Major Outbreak Plan is invoked, has a designated leader, links effectively with risk management committees and clinical governance committees, and provides assistance and advice to Trust ICTs when requested and when appropriate.

Large Trusts should have an appropriately constituted ICT which prevents and manages health care associated infection within their Trust, implements agreed Board and Trust policies in infection control, has a designated leader, links effectively with risk management committees and clinical governance committees, and liaises closely and cooperates with, and provides membership for the Health Board ICT.
The culture of openness

There is surprisingly little direct mention of the need for more effective communication within health care organisations. However, a degree of concern can be deduced from the general diagnosis of causes of failures to act within those agencies to reduce risks and take prompt action to control outbreaks. The inquiry group focused on recommending changes that would improve openness but avoided directly linking its measures to prevailing clinical cultures.

It was, however, less reticent to criticise other parts of the health care system. For example, it argued that internal communication within and between the Scottish Executive and NHS organisations must be “… improved and clarified so as to reflect the openness culture and this is emulated in communication with relevant agencies (such as the Food Standards Agency, Scottish Water, and the Scottish Environmental Protection Agency).

It also recommended changes in dealing with the mass media (and hence the public at large). It recommended that, at both local and Scottish Executive levels, more strenuous efforts should be made “… to tap the potential of the media to improve the public understanding of infection control issues. This will require a more open relationship to be developed between the NHS and the media based on mutual trust. There should be presumption of early disclosure to the public and the media of outbreaks of infection.”

5.5 Discussion

The objectives of the Watt Inquiry were to a) review the circumstances surrounding the outbreak of salmonella infections, b) assess the management of the outbreak and reduction of further exposures, c) assess how the NHS Trust managed the overall situation including communication with the public and other organisations, and d) draw conclusions and make recommendations to help reduce risks of future outbreaks. Despite the major finding of the Inquiry that little could have been done to avoid the deaths at the Glasgow Infirmary, the Inquiry produced 47 recommendations for various levels of the health care system in Scotland ranging from the Scottish Executive and the NHS, through to hospitals and their Boards, to individual clinicians. The main findings and recommendations of the inquiry group in relation to these objectives were accepted by most knowledgeable people, although a small minority was critical – mainly on the grounds that some of the investigators were too closely associated with the sponsoring agency.

The Inquiry had two major flow on effects. As a result of recommendation 13 “that a scientific meeting be organised at which experience and ideas relating to infection control challenges … be shared… “ a Ministerial Convention (discussed in 5.6.1 below) was convened, bringing together experts and practitioners in an innovative approach to understanding and preventing HAI. The second was the embedding of a number of the Inquiry’s recommendations in the NHS Scotland Action Plan (discussed in section 5.6.2). The Plan reflected many of the major concerns of the Inquiry report, including the need for an increase in resources for health services, and a focus on improving the teamwork of staff.
5.6 Footnotes

5.6.1 The Report from the Ministerial Convention

The Convention took place on 28 June 2002 at Glasgow Caledonian University. There were three main aims: to discuss the current HAI agenda with a view to strengthening consensus among key players; to develop a plan for taking forward action to reduce the risk of HAI in Scotland; and to raise the profile of steps being taken to tackle HAI in Scotland.

It drew together senior people from a range of backgrounds. They included public health specialists and pathologists from around Scotland and from overseas. The Minister attended, together with ward-based professionals and support staff.

The Convention had two components. The first was a series of presentations on policy and practice as they relate to HAI and infection control. These provided context for more focused discussions.

The second was composed of eight parallel workshops on HAI-related topics. The intention of the workshops was to draw together conclusions on what was happening, the strengths and weaknesses, and what actions might be needed in the future. The workshop themes were developed after a review of feedback from health care services about HAI. They were led by individuals with recognised expertise and experience in the topics under discussion.

The Chairs of the workshops submitted a summary of the key points arising in them at the end of the day. The key issues raised and discussed and the conclusions reached in the presentations and workshops are presented in the next section of this report.

Part 1: presented papers

The following are summaries of the most relevant aspects of the presentations. No attempt has been made to report all contents of the papers.

Consultant Microbiologist, Clinical Standards Board for Scotland

“The recent increase in HAI partly reflects more efficient reporting of cases. However there are factors that increase the likelihood of infection including changes in the patient mix, more complicated treatments, and inappropriate use of antibiotics. Health care methods and funding levels have not always kept pace with increased expectations of patients.

Actions are being taken to increase patient safety. They include better plans that incorporate auditable targets, improved information systems, and increased training. There must be a cultural change and additional resources.”

CEO of Highland Acute NHS trust

“Implementation of better methods of care requires effective leadership, clear accountability, the “right” values, and increased resources. Leadership is important at all levels. Boards and CEOs have an essential part to play. Equally important, senior clinicians from all disciplines should recognise the priority of the issue. Getting these different parties to feel ownership of infection control is the main challenge.

The right values include a no blame culture, openness, partnership with patients and ongoing learning and development. Additional resources are needed but they are not sufficient. There is always scope for innovation in the application of existing resources.”
Consultant Microbiologist, Tayside Acute NHS Trust

“Effective action to control HAI requires changes in systems, culture and management and there is no quick or easy solution. Systems include structures and processes, policies and procedures, education and training, audit and surveillance. Culture includes public perceptions which may underestimate the risks, giving HAI low priority relative to other health issues, while public demands may exacerbate the problem.

Management of facilities is essential to HAI control: space and configuration of patient areas; bed occupancy and patient movement may be critical factors. Delayed discharges, excessive workload and shortcuts of convenience can add to the problem, while adequate information technology structures and resources can form part of the solution.

Leadership is essential: strategic leadership in Boards and Trusts; clinical leadership by medical and nursing directors; professional leadership by infection control nurses and microbiologists; and general leadership at all levels of the health service to influence and persuade colleagues that infection control has high priority and practices must change. Experience suggests that a major problem in tackling HAI is a lack of accountability and unclear lines of responsibility, probably reflecting the low priority afforded to infection control in the recent past. This must change with chief executives putting measures in place to ensure good infection control within their organisations, with responsibilities clearly set down at all levels and clear lines of accountability.

Risk assessment in the context of HAI entails identifying, evaluating, ranking and treating risks, with ongoing monitoring and review. Full communication and consultation is essential. Values should include openness, partnership, learning and development, within a no-blame culture.”

Infection Control Nurse, Ayrshire and Arran Acute Hospital NHS Trust

“Effective action to control HAI necessitates a return to basics. We need to focus our action on hand hygiene, environmental cleanliness, decontamination, personal protective equipment, safe disposal practices, and isolation of patients where necessary.

All staff need to know their role in these areas. Combating HAI is therefore a key clinical governance issue. Trust need an appropriate framework to improve practice which involves education and training, risk management, research and development, and clinical audit, with infection control at the core.”

Consultant Microbiologist, Danish Ministry of Health

“HAI is not a problem peculiar to the UK. A study of the prevalence of nosocomial infection in university hospitals and tertiary care centres in various European countries between 1984 and 1996 found prevalence rates ranging from 4.4% to 14.8%; the UK figure was 11.2% in 1993. Denmark has a population (5.3 million) similar to that of Scotland. The prevalence of HAI in Denmark fell from 12.1% in 1979 to 8.0% in 1999, due to a series of measures especially improvements in catheterisation. Learning from what has proved effective in Denmark, can therefore usefully guide efforts in Scotland.

Since 1977 the National Centre for Hospital Hygiene has provided guidelines, surveillance, advice and research. In each county, one clinical microbiology laboratory, situated at the university hospital or the major regional hospital, has local infection control responsibility.”
Infection control doctors are clinical microbiologists and regular courses are run to give nurses specific infection control training.

Denmark has no regulations targeted at preventing HAI in hospitals, although there has been some political debate about this. National standards have been elaborated between 1998 and 2002. There is a growing focus on quality assurance in hospitals but so far only one hospital is fully accredited. The number of official complaints about treatment in hospitals is increasing.

Danish experience is that the prevalence of HAI is inversely to nurse patient ratios. A US study of the relation between adverse outcomes among medical patients and the proportion of registered nurse hours to medical patients found that urinary tract infections and hospital acquired pneumonias had strong statistically significant associations with low ratios.

There is a need for simple surveillance systems that provide effective feedback. There must be improved communication between clinical microbiologists and clinicians at local level, and education of infection control nurses.

A 1990 study compared antibiotic policy in intensive care units in a number of countries. In Denmark 32% of units had written guidelines and a restricted antibiotic list, 21% had informed mutual consent and a restricted antibiotic list, and 47% had neither. In Scotland the corresponding figures were 13%, 16% and 71%.

Part 2: parallel workshops

EQUIPMENT, ENVIRONMENT AND PATIENT MANAGEMENT
Effective action to reduce HAI by improving the clinical environment and equipment depends on risk management and prioritisation. Resources are limited and those managing hospitals and other clinical services need to secure agreement on targeting action on risk-based priorities. The role of the infection control doctor is pivotal, and they must have good communication with the managers of facilities including building design and cleaning.

THE PROMOTION OF GOOD PRACTICE IN HYGIENE AND INFECTION CONTROL
Education is vital but it must involve all staff: support services; nursing; and junior and senior medical staff. A standardised training package on hygiene should be developed.

However, education and training can only go so far. The promotion of good standards of hygiene behaviour is a corporate responsibility, but the behaviour of a poorly compliant member of staff can compromise the integrity of the entire system. Lines of responsibility must be clearer and the role of any infection control champion in relation to this must be clarified. Acceptability of the concept of cleanliness champions has still to be established.

Clinical governance systems should audit compliance with hygiene-related standards in clinical care. A multidisciplinary approach is necessary with as much emphasis on primary care as on secondary care.

ANTIMICROBIAL RESISTANCE AND PRESCRIBING
National monitoring of antibiotic prescribing is voluntary and therefore incomplete. In general, information about antibiotic resistance in Scotland is scarce, but we may be approaching a crisis.
Clear guidelines on antibiotic prescribing are lacking. Guidelines are more likely to be effective if resources are dedicated to their implementation and to monitoring. Junior medical staff should have clear guidelines on identification of sepsis, recognition of the severity of illness, and the use of antibiotics in treating it. Communication routes between services must be improved to ensure all relevant health care professionals are fully informed of a patient's medical history and thus minimise the chance of further infection.

Information systems should be developed to monitor and audit the prescribing of antibiotics. Multidisciplinary antibiotic prescribing teams should be formed to promote prudent prescribing throughout health care systems. The involvement of pharmacists in frontline education about antibiotics and monitoring antibiotic prescribing should be secured.

PUBLIC COMMUNICATION AND PATIENT INVOLVEMENT

The perceptions of HAI held by patients and the public are important. Patients need to know about that there are risks associated with health care. The methods used to inform them about this should seek to allay unnecessary anxiety.

The media constitute the principal source of public information. Media reporting on HAI can be unhelpful but it can have a valuable role in raising public awareness. Reporting of the current 8-9% prevalence of HAI in hospital inpatients, coupled with high profile reporting of outbreaks of HAI and associated deaths, is a cause of understandable public concern. It is important that the NHS encourages balanced and informed reporting.

Health care organisations should acknowledge that patients are entitled to appropriate information before hospital admission. There should be public involvement in planning and auditing local risk management programs. There should be central guidance to health care organisations regarding disclosure of information in relation to HAI, in particular in the case of outbreaks.

ROLES, RESPONSIBILITIES AND ORGANISATIONAL DEVELOPMENT

If infection control is to be managed effectively, it must become integral to the jobs of everyone involved in providing patient care, including non clinical support services. It is not sufficient for specialist services devoted to infection control to work in isolation, however well resourced they might be.

Managerial responsibility must be driven from the top of the organisation through the managerial line. There must be a culture where this is intrinsic, and which is reinforced by appropriate education and training.

The role of the infection control doctor is acknowledged to be of primary importance, but current levels of support rarely reflect this. Infection control doctors must have allocated sessional time to be effective, and should be a resource available to both acute and primary health care organisations. Surveillance is an important part of infection and communicable disease control, with appropriate allocation of responsibility.

THE RISK MANAGEMENT OF HAI BY HEALTH CARE ORGANISATIONS

The policy of NHS Scotland involves managing HAI through a risk-based approach. Risk management comprises a culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects. The approach is intended to satisfy ethical requirements, to protect health, to comply with legal obligations, to ensure political accountability, to reduce financial liabilities and to maintain reputation.
NHS care providers do not have sufficient resource or expertise to assess and manage the risk of HAI adequately. The challenge is to disseminate models of excellence, to ensure compliance, and to integrate infection control into the risk management process so that it becomes a core part of routine practice.

All staff should be aware of the essential contribution of infection control to patient safety. They must be continually educated, from induction onwards, to reinforce good practice. The need for commitment to reducing risks to patients must be embedded from the first day of training and reinforced continuously. Particular emphasis should be paid to members of the medical profession who are often seen as the worst offenders with regard to hand hygiene.

Risk managers ensure ongoing communication about patient safety issues throughout the organisation. There should be less focus on structure and process and more on cultural issues and sustained commitment to change.

Emphasis should be placed on assessing the risk of infection resulting from the patient’s journey through care, integrating where appropriate acute and primary care throughout a health episode. Risk management should entail a pragmatic, integrated, whole system approach.

There should be improved leadership and increased empowerment. A cultural change towards team work and mutual respect would motivate individuals, encouraging pride in the job and in patient care. There should be less regulation and more facilitation.

SURVEILLANCE AND RESEARCH

The development of a national HAI database is a significant step. But the program has limitations: data are collected in relation to a small number of procedures; they only covers bacteraemias; and incidence is not related to risk factors such as the use of intravenous devices. Priority should be given to methods for surveillance of infection presenting after discharge from hospital. It is also important to develop early warning systems for possible HAI outbreaks.

HAI-RELATED STANDARDS

Draft standards for infection control, decontamination of reusable medical devices and cleaning services were issued in 2001. All but one of the 15 standards reflect structures and processes supporting infection control and affecting clinical outcomes. The remaining standard, for hand hygiene, is most directly related to clinical practice and its inclusion reflects the importance of the topic and the strength of the supporting evidence base.

By January 2002, most health care organisations had reported self assessments against the standards. An interim report revealed several shortcomings. Most health care organisations did not have plans to address the full implications of HAI, and infection control often depended on limited resources with small numbers of staff expected to cover large sites. It was concluded that infection control is difficult to manage because of the diversity of individuals and groups with related interests and responsibilities. It was apparent that more efficient organisational and management processes could improve quality and reduce costs.

The organisational culture may encourage different staff members to have different perceptions of risk. All staff must share the same objectives and to accept that all have a responsibility for high standards of infection control. There must be emphasis on quality controls with open communication systems to facilitate learning from any mistakes made. Operational difficulties in implementing standards include staffing shortages, time constraints and contracting out, diminishing the opportunities for a team work, partnership approach. Excessive movement of
patients, shortage of beds and rapid patient throughput can all make infection control more difficult. Contracting out of domestic services can hinder maintaining infection control procedures and standards.

Infection control must be integrated into the mainstream risk management system of the organisation. Policies, procedures and guidelines must be up to date and accessible; there may be value in a central national resource of policies, procedures and guidelines. All staff should receive instruction on infection control at induction with ongoing education to maintain current knowledge. Awareness of core infection control topics should be compulsory for all staff, like other health and safety issues such as fire safety.

The basic issue of hand hygiene is how to change culture. This affects all levels of staff but there may be particular difficulty in convincing clinicians, including senior doctors, of the importance of infection control in general and hand hygiene in particular. Effective action must be taken on non performing staff within a culture of support rather than blame.

Compliance with standards can be monitored through peer review, patient inspection, health care accreditation, formal professional review, NHS inspection, external formal audit, statutory inspection or investigation. Peer review is currently the main instrument but is time consuming.

5.6.2 The NHS Scotland Action Plan

This Plan was released after the outbreaks and takes account of some of the findings of the Watt Report. It stresses four main principles, as follows:

- unified mechanisms for reporting and analysis when things go wrong
- a more open culture in which errors or service failures can be reported and discussed
- systems for ensuring that, where lessons are identified, the necessary changes are put into practice
- a much wider appreciation of the value of the ‘systems’ approach in preventing, analysing and learning from errors.

Additional measures are proposed under three headings: promoting good infection control and hygiene practice in wards, other clinical settings and support services; ensuring that good hygiene and infection control practice is in place and working throughout health care organisations; and ensuring that the performance of health care organisations in Scotland is of sufficient quality and effectiveness to reduce the incidence of HAI.

Considerable emphasis is given to media coverage. The foreword states that “…recent events have shown that there is danger of public confidence in the NHS’s ability to deliver good quality effective care to the population being eroded by ongoing coverage of infections in health care settings. The negative impact of scare stories on other sectors of society such as food production and retail is well recognised.” This seems somewhat misguided, given that the mass media have often been the most effective channels for informing the public of problems that the professional bodies have attempted to conceal.

The Plan’s authors claim that major improvements have occurred over the last two years by most of the NHS in Scotland to improve infection control services. However, more effort is needed including the investment of adequate resources to be used in the most cost effective manner possible, national coordination, and flexible and innovative local implementation of the Action Plan. Actions are specified with a view to more precise estimation of the cost implications of implementing the proposed measures, and of the system costs of infections.
Particular emphasis should be given to compliance with an NHS Scotland Code of Practice for the local management of hygiene in wards and other clinical units, mandatory hygiene and infection control induction training programs and other HAI-related educational initiatives, and the definition of technical requirements for cleaning processes. Finally, it is essential to increase the commitment of all staff to improve infection control, and this implies the empowerment of staff. Making this happen partly requires more resources. Equally important are attitudes and culture, increased acceptance of responsibility by local managers, and sharing and learning from good and poor experiences. NHS and professional and staff organisations have a key role in promoting good hygiene and infection control.

5.7 References and selected bibliography


6 King Edward Memorial Hospital, Australia

Concerns about obstetric and gynaecology services at the King Edward Memorial Hospital in Perth, a tertiary referral hospital increased progressively during the 1990s, not only among staff but also among patients. A series of informal and formal reviews took place, but they failed to resolve the problems or reduce public concern.

In 1999, a new Chief Executive was appointed. He immediately took action, and this led to the commissioning of a major external Inquiry by the Minister for Health in 2001.

The Inquiry reported that there was “… evidence of exemplary clinical and non-clinical care.” However, it also found that most of the concerns about poor care were justified. There were many serious problems with the Hospital’s clinical and administrative practices. Inadequate processes of care and of responses to problems “… resulted in serious adverse events and poor clinical outcomes for women and their families.”

Many changes needed to be made if the problems were to be overcome. They included changes in organisational culture that included acceptance of open disclosure of problems, improved methods of external monitoring, and better processes for recording and responding to incidents and adverse events.
6.1 Context

Kind Edward Memorial Hospital (the Hospital) provides inpatient and outpatient services, neonatal intensive care and specialist emergency services. At the time of the Inquiry it had 250 inpatient beds and 60 neonatal cots. It is the state’s only major teaching hospital in obstetrics and gynaecology, and is a centre for midwifery training and postgraduate medical training in obstetrics and gynaecology.

As Western Australia’s only tertiary referral service for obstetrics and gynaecology, it therefore receives and treats the most difficult and complex cases. About 5000 gynaecological operations are performed each year, there are about 5000 births, and almost 10000 females present at the Emergency Centre for gynaecological or obstetric treatment.

The socioeconomic mix of patients was changing in the period during which poor care was subsequently the subject of investigation. In particular, there was a decline in the number of privately insured low risk women. This was counterbalanced by an increase in the proportion of high risk patients. They included patients from poorer socioeconomic backgrounds, who were unbooked and presented late in pregnancy, some of whom had morbid obesity or substance abuse problems, and who were subject to domestic violence and other severe societal problems.

Further, the Hospital (like many others) was experiencing significant organisational and managerial changes. They included the merger with Princess Margaret Hospital for Children in 1993, two changes of chief executives, the establishment of a devolved management structure in 1996, and replacement of its own Board of Management with the Metropolitan Health Service Board in 1997 (which covered all government hospitals in the metropolitan area). The subsequent Inquiry concluded that the changes were not a primary cause of poor clinical practices, but they contributed to their severity.

Unresolved problems (1990 to 2000)

In 1990, the Health Department of Western Australia commissioned the Professor of Obstetrics and Gynaecology at the University of Western Australia 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, the recommendations were not implemented by the Hospital. This was despite the Hospital’s clinical staff repeatedly raising their 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.

The new Chief Executive takes action (1999)

The new Chief Executive on appointment was immediately concerned about several aspects of process and performance. He wrote to the Chief Executive Officer of the Metropolitan Health Service Board explaining his concerns. They included the absence of an overall clinical quality management system, problems in identifying and rectifying clinical issues by senior management, inadequate systems to monitor and report adverse clinical incidents, the absence of a proper and transparent system to deal with patient complaints and claims, a shortage of qualified clinical specialists (particularly after hours), inadequate supervision of junior medical staff, and the possibility of substandard patient care.
The 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 Chief Executive provided evidence of poor practice at the Hospital.

The Chief Executive’s concerns led the Metropolitan Health Service Board to commission a review by an independent senior clinician. This review supported the Chief Executive’s view, raised additional concerns, and recommended a more detailed investigation into the Hospital’s obstetric and gynaecological services.

6.2 The Inquiries


In consultation with the Commissioner of Health and the Minister, the Chief Medical Officer and the Metropolitan Health Service Board commissioned the Child and Glover Review in 2000 (Child and Glover 2000). This two week review identified significant process and performance issues.

The Review’s findings led to increased public concern, and a vigorous public debate took place through the mass media. The debate was heightened by a high degree of opposition to the findings from individual doctors and from the Western Australian branch of the Australian Medical Association. It was subsequently shown that the views of Child and Glover were fully justified.

6.2.2 The Douglas Inquiry (2001)

After some deliberation in 2001, the Minister for Health, in consultation with the Premier, agreed to establish the Douglas Inquiry under the Hospitals Act and the Public Sector Management Act. The Inquiry was led by Neil Douglas, a lawyer, and we refer to his inquiry team below.

The Inquiry’s terms of reference

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 was to recommend changes to address these deficiencies.

Method

Over 18 months the Inquiry accessed information from more than 1,600 patient clinical files from the Hospital. It also analysed 605 patient clinical files and 293 written submissions. It interviewed 70 former Hospital patients, reviewed various consultants’ reports, compared the Hospital’s clinical performance data with data from similar Australian services, read 106 transcripts from current and former Hospital staff, and reviewed 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.
Limitations of the Inquiry

The Inquiry’s brief was to examine management and clinical practices and recommend changes to improve the safety and quality of the care provided. It was 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 interhospital 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 the 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 consequently no way of knowing from the inquiry report alone how the Hospital’s performance compares with other Australian hospitals. However, there are some obvious opportunities for generalisation of both the problems and the required solutions.

6.3 Conclusions of the Inquiry

The conclusions of the Douglas Inquiry were arranged under eight main headings: clinical practice; clinical policies and guidelines; incident reporting and management; reporting deaths to the Coroner; staff and staffing matters; patient involvement; quality improvement; and other leadership and management issues. We have retained the headings below, although there is significant overlap across issues.

Clinical practice and performance

The inquiry team reported many instances of excellent clinical practice, and of serious efforts to improve. However, it was common that issues raised by staff with clinical directors and non clinical administrators were largely ignored. Other tactics were regularly employed, including referral of problems to largely ineffective committees.

The main problems that remained unaddressed were non existent or substandard 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, substandard documentation adversely affecting care continuity, and poor methods of 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% 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% of high risk cases and senior registrars were involved at the most crucial times in 9% 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 interpret accurately and respond to abnormal foetal 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 postoperative 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% of cases and important documentation was inadequate in 35% of cases and missing in 15% 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. 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% of cases and 50% were very serious. Junior residents made errors in 76% of high risk cases, junior registrars in 65% of high risk cases, midwives in 60% of high risk cases, levels 5 and 6 registrars made errors in 34% of high risk cases, and consultants made errors in 28% of high risk cases.

A high proportion of errors was rated as very serious. 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, and these were often rated as very serious. The errors were more common during labour and delivery. Gynaecological case errors were more common post-operatively. Contributing factors were poor care coordination, delayed care and unsupervised junior staff. Non-existent or inadequate policy was a more prominent contributing factor in gynaecology cases.

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. The Consortium supplied detailed specifications of the items required, noted the preferred source databases, collected and examined 37 clinical information items, and attempted to identify statistically significant differences.

There were analytical weaknesses, but the Consortium identified some problem areas. They included high rates of stillbirths, obstetric interventions, hysterectomies following post-partum haemorrhage, maternal deaths, deaths following gynaecological procedures, and transfers of females to the Adult Special Care Unit during admissions for laparoscopic procedures and hysterectomies. The Consortium recommended that the Hospital improved the quality and completeness of its monitoring information.

Clinical policies and guidelines

Policy and guideline development, deployment, compliance monitoring and review were noted as deficits during the review period. Some individuals made a concerted effort to improve, but the Hospital lacked an effective organisation wide approach to these activities.
Over many years, the Hospital failed to address several related weaknesses. They included ad hoc, untimely and infrequent development and review processes, absence of clear responsibility for managing the processes, delayed or non-existent approval of revised or new policies and guidelines, lack of commitment to a multidisciplinary involvement, retention of 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, an unclear distinction between mandatory and discretionary policies and guidelines, inconsistent terminology, unclear lines of authority for policy and procedure review or deviation, and lack of a strategy to monitor and ensure compliance (although compliance was low, particularly among sessional consultants).

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 inquiry team gave several specific examples of problems with policies and guidelines. One was that 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.

Another example was the poor management of patients with ectopic pregnancies, which was identified in January 1998. 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.

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.

There were problems with the cord blood Rh testing procedure from September 1997 to July 1999. It was introduced as a new routine test, but doctors often did not sign the form. The Hospital’s Pathology Service estimated the Obstetrics Service missed approximately 20% 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.

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.

The expert consultants identified many deficiencies. The most common were 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.

**Incident reporting and management**

There were significant problems with incident and adverse event reporting and follow up from 1990 to 2000. Management of complaints and potential medical negligence cases was also poor during this time. Over many years, persistent problems included the lack of a clear and 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 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 and support for patients and families experiencing adverse events, substandard 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 many concerns. They included the time and paperwork involved, fear of 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 team work.
UNDER REPORTING OF INCIDENTS AND ADVERSE EVENTS

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.

The Hospital Counsel became aware of under reporting of serious incidents in 1999. He subsequently reported his concerns to the recently appointed Chief Executive about the lack of incident reporting policy, the number of reported incidents and adverse events, poor understanding of the requirements for incident reporting among staff, and the absence of 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 multimillion 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.

The Chief Executive responded by directing that all incidents be reported to him, directing that the Hospital’s legal cases be handled by the Hospital Counsel, commissioning an independent audit by Ernst and Young, an audit company, of the Hospital’s incident reporting processes, and reporting the situation to the Metropolitan Health Service Board. The Ernst and Young Report found there was 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 concluded that the claimed problems with the Act were overstated. For example, the prohibitions on disclosure did not apply to reports to a relevant governing body. Moreover, 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.

Examples are given in the inquiry report of potential medical negligence cases that were examined by the Hospital Counsel in 2000, and found to have been mishandled. One concerned a woman whose artery was perforated during surgery, thus requiring corrective surgery. The involved staff failed to report the incident. Four months later, the Hospital Counsel received a Freedom of Information application from the patient's lawyers. Until that time, the 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 hospital managers failed to investigate the incident and notify the medical litigation insurer.

Another example concerned a woman who 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 readmitted 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 later, she 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 later, the Hospital received notice of an impending claim against the Hospital from the woman’s solicitors. Two months after receipt of the notice (and 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

Meetings were held from time to time 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.
The situation improved in 2000, after the newly appointed Chief Executive directed that changes be made in incident reporting and related matters. However, the inquiry team concluded that considerably more work was required to address the long standing problems.

**Reporting deaths to the Coroner**

The Inquiry found that the Hospital failed to report several reportable deaths to the Coroner during the review period. Reportable deaths include 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 team to the Coroner. Of these, the care of women and babies was rated ‘very unsafe’ in six cases and ‘moderately unsafe’ in one case. The Coroner advised that none of these deaths had been reported previously.

**ACTIVITIES OF THE MATERNAL AND THE PERINATAL AND INFANT MORTALITY COMMITTEES**

The Western Australian Government established the Maternal Mortality Committee and the Perinatal and Infant Mortality Committee under the Health Act 1911 to examine maternal and perinatal deaths. Both committees functioned ineffectively over the 11 years covered by the Inquiry.

There appeared to be significant flaws in the legislation. Various provisions of the Health Act govern reporting of perinatal and infant deaths. 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.

Compliance with reporting and investigating maternal, perinatal and infant deaths was inadequate. The inquiry team concluded that 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 study period, 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 specified 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, 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. After that date, it failed to produce any reports or papers.
Staff and staffing matters

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 evidence of serious problems with performance management and with the consultant appointment and reappointment processes. Over many years, persistent problems included deficiencies in consultant cover and chronic understaffing, 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 any formal and effective credentialling program for doctors, inadequate arrangements for approving admitting rights for visiting doctors, inadequate recruitment and 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 one 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, and the role of Delivery Suite Consultant lapsed 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

Senior Hospital staff had been aware of problems with the supervision of junior doctors since the early 1990s, but they took limited action until 2000. One problem was that a high proportion of emergency admissions occurred after business hours when (with a few exceptions) only junior
doctors were on duty. Case complexity after business hours was similar to that during business hours. However, junior doctors received little or no supervision from 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 onsite after hours.

Junior doctors were expected to decide for themselves when they needed assistance, rather than senior doctors determining when a junior was sufficiently competent to provide unsupervised care. When asked how junior doctors’ performance was assessed, a senior doctor explained to the inquiry team that “… we just have a feel for these people”.

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 (and other senior nurses) therefore played an unofficial but important role in training and advising junior doctors. However, as in many hospitals, there was no formal recognition of this channel of communication, and therefore it was largely unmanaged – and consequently not subject to formal review in the interests of improvement.

Improvements to junior doctors’ supervision were made in 1999. However, the inquiry team concluded that 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 practise in the Hospital”. Credentialling processes were long considered in need of improvement.

They were raised as a serious issue in 1991 and again in 1994 during the accreditation process undertaken by the Australian Council on Health Care Standards. *Inter alia*, the Hospital was advised to review its credentialling process as soon as possible. However, hardly any changes were made, and the Hospital lacked an adequate formal credentialling process until June 2000.

In 1995, partly in response to the introduction of new technologies (including endoscopic procedures), the Director of the Gynaecology Clinical Care Unit advised Unit staff that a credentialling status list would be developed. However, the list was not published until 1997, and it was not regularly updated or widely circulated.

There was no evidence of a credentialling committee meeting from 1997 to 1999. In 1999, gynaecology and operating suite staff were still relying on the original credentialling list that was developed in 1995. The credentialling committee was finally established in February 2000, but the credentialling process itself 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. The continuing inadequacies were noted in the Child and Glover Report in 2000.

The Terms of Reference of the credentialling committee were finally endorsed in June 2000. However, they made no mention of the credentialling of registrars or junior medical staff, and consultants continued to their competency without any clearly defined criteria. The Committee met again in August 2000. It 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.
ADMITTING PRIVILEGES
There was a similar degree of imprecision and confusion regarding admitting privileges for associate consultants over the 11 years that were reviewed. The policy was adjusted in 1994, and remained unchanged until June 2000. The policy required a small committee to review associate consultant admitting privileges on an annual basis. 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. The program mainly addressed administrative aspects of work, and did little to help doctors to understand clinical processes and develop their own clinical skills. Nor did the program provide any support for a junior doctor moving from a clinical area to another. The Hospital also lacked an orientation program for registrars.

The needs of junior doctors from overseas were overlooked despite there being evidence that taking their knowledge for granted led to mishaps. Staff raised many suggestions regarding improvements in the orientation program, but it remained unchanged over the 11 years. The inquiry report gave several examples of deficient or non-existent training programs, and some are summarised below.

POSTGRADUATE MEDICAL PROGRAM
This program was described as “… a haphazard collection of tutorials and clinical meetings” that had never been formally planned and had no learning framework. It failed to identify or address postgraduate learning needs in any organised way and took no account of the residents’ and registrars’ rosters. One consequence was that it was poorly attended because residents and registrars were not given time off from their clinical responsibilities. However, many 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 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 poor program scheduling. The Report of the RANZCOG review visit in 1993 stated that the deficiencies had been remedied. However, the Inquiry found that this was not the case. RANZCOG did not assess the Hospital again during the review period.

GYNAECOLOGICAL SURGICAL TRAINING
Doctors experienced too few gynaecological surgical training opportunities. This was mainly because of shortage of available gynaecological surgery, cancellation of elective surgery due to budget cuts, and more patients using other hospitals for gynaecological care.

Only consultants (and not registrars) received supervision and training in laparoscopic surgery from 1995 to 1999. In October 2000, the Hospital introduced a compulsory training program in endoscopic surgery but failed to establish a framework whereby training would be formal and ongoing.

CARDIOTOCOGRAPHY (CTG) INTERPRETATION
Senior doctors at the Hospital recognised the importance of training clinicians in CTG as early as 1989. In 1990, the Hospital’s 1990 Foetal 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 examinations.
However, practice was inconsistent with written policy, and concerns were expressed regarding the skills of residents and registrars in interpreting CTGs over many years. Recommendations regarding compulsory CTG training courses for registrars and residents were not implemented. 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, and this meant that the responsibility for interpretation was often devolved to midwives in the Labour Ward. The midwives, rather than the registrars, were often the teachers of residents regarding the interpretation of CTG traces in the Labour Ward. No one had sole responsibility for coordinating CTG training for junior doctors. Midwives had a well organised and regular CTG training program. The inquiry report noted that training inconsistencies in CTG interpretation remained at the end of 2000.

PERINEAL SUTURING

Similar problems existed with junior doctors’ lack of skills in perineal suturing. The Hospital failed to implement a suitable education program, no one had sole responsibility for ensuring doctors were trained in the procedure, and the Hospital lacked a process 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, but there were examples of incompetent practice by 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 in processes of recruitment. The devolved management structure meant that reliance was placed on the clinical directors’ ability and willingness to manage, and their position descriptions reflected this. However, the reality was that at least some medical directors did not address their management responsibilities with diligence with regard to staff appointments.

Many examples were presented in the inquiry report, although its investigations were constrained because the Hospital had destroyed a large proportion of the documentation regarding appointments. One involved the appointment in 1996 of the Medical Director of the Obstetrics Clinical Care Unit, where no consideration was given to the management skills of the applicants.

Another example concerned the recruitment of a sessional consultant anaesthetist. He was appointed without submitting a formal application, without being interviewed, and without a response from either of the two referees. Five months after recruitment, the anaesthetist’s clinical judgement and skills were questioned on several occasions regarding adverse patient outcomes. The anaesthetist’s appointment was terminated a month later.
Deficiencies were identified in nine other cases of senior medical appointments that were able to be investigated. They 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 reappointment. Under the 1987 Award, sessional consultants should have been appointed for five years, and therefore they 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 Selection Committee’s performance was substandard. The Committee regarded itself as having responsibility for the final step in appointing and reappointing consultants, but the Chief Executive should have been responsible according to the Award. The long history of Committee appointment recommendations being accepted without question ceased when the new Chief Executive was appointed in 1999.

PERFORMANCE MANAGEMENT

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

Consultant performance appraisals were rarely done, although hospital policy required them to occur every three years through a committee process. Registrars’ performance appraisals were conducted by the Hospital until 1996, and then by the Royal Australian and New Zealand College of Gynaecology (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.

Patient involvement

The Inquiry investigated the perceptions of women and their families regarding their involvement in treatment and their interactions with staff. Methods included secondary analysis of 605 clinical file reviews and 68 interviews of women who attended the Hospital. The file reviews related to 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 information about incidents and their follow up, poor treatment and disrespect when making a complaint, lack of support when they experienced poor outcomes or adverse events, and poor communication with Hospital staff during potential medical negligence case reviews. The Report gave several examples of the perceptions of women and their families about poor treatment and poor communication by staff, as follows:

- 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 that she was being blamed for the complications that occurred. In another case, parents stated that staff failed to communicate with them for some hours after their baby became unexpectedly ill
- 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
- Lack of sensitivity, respect, dignity and support. A woman described the difficulty she experienced with her unsettled baby and with post-natal depression, and said she felt misunderstood and unsupported. In another case, grieving parents stated they were put in an old ward alone and no one came to inform or support them for several hours. Another example concerned a woman who alleged that a doctor refused to perform a caesarean section when she felt her life was in danger. The caesarean was eventually done but the woman had to be managed in intensive care.

CUSTOMER COMPLAINTS POLICY

The inquiry team concluded this was one of the few examples of hospital policy that dealt comprehensively and clearly with the subject. However, there were problems in practice. They included no clear advice for patients and families regarding 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.

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’s procedures were inadequate with regard to monitoring key aspects of care and responding to poor performance, responses to recommendations arising from accreditation processes, evaluation of the effectiveness of department level quality improvement activities, and management support for ongoing improvements in the safety and quality of care.

The Hospital was accredited at one stage by the Australian Council on Healthcare Standards. However, the focus was on 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. The inquiry team concluded that the accreditation process of that time were insufficient to provide assurance of quality at the Hospital.

There was little evidence of quality assurance activity from 1990 to 1993. 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, activities on the ground remained substantially the same.

The responsibility for identifying and addressing problems in patient care and safety was devolved 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.

The Chief Executive reported several deficiencies to the Metropolitan Health Service Board in 2000. They included 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).

**Other leadership and management issues**

The Hospital failed to address problems associated 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 the 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 much 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.

### 6.4 Recommendations of the Inquiry

The inquiry team made 159 recommendations, and this last section provides some examples of changes and improvements which have begun to be made since the Inquiry. The process of improvement has been monitored in several ways, including a monthly review by a committee chaired by the Deputy Director-General of the Health Department of Western Australia. The Minister has reported 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 one registrars being supervised by a senior registrar when a junior is rostered to work after business hours. Revised Hospital policy also requires a level one registrar working in the Labour Ward to be supervised by a senior registrar onsite at all times.
AFTER HOURS CONSULTANT COVER

In September 2000, management approved the ‘On call Agreement’, requiring the oncall 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 onsite 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 incidents as improvement opportunities.

Several other changes and improvements have been initiated or are planned. They 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 foetal monitoring equipment, making progress with medical and nursing performance appraisals, establishing quality plans, rejoining the Australian Council on Healthcare Standards and undergoing a full survey in March 2002, establishing the Credentialling Committee and defined credentialling criteria, and appointing four senior academic obstetrics and gynaecology doctors.

6.5 Discussion

A report on the King Edward Memorial Hospital Inquiry was issued by the Australian Council for Safety and Quality in Health Care in 2002. One of its sections provides a comparison of the King Edward and Bristol cases, and we summarise and comment briefly on it as a way of drawing out the issues identified in the KEMH report.

The Australian Council for Safety and Quality in Health Care (the Council) describes the general context of the Bristol case, drawing mainly from four sources (Swan 1997a; Swan 1997b; UK Department of Health 2002). It then notes several similarities.

First, both cases “… arose from whistleblowers reporting serious problems rather than the problems being identified and addressed or prevented through rigorous and routine safety and quality monitoring systems.” It is further stated that the whistleblower at Bristol was an anaesthetist (Dr Bolsin) and at King Edward it was the recently appointed Chief Executive.

This seems a reasonable statement to us, although an oversimplification in the Bristol case. As we have noted elsewhere, Dr Bolsin was a primary actor but many more other people were involved in various roles – and not only as whistleblowers.

The reports from the inquiries both recommended widespread changes at government, board and management level. The core of the recommendations was the establishment of “… a culture of Inquiry and open disclosure” and the introduction of “… systems to monitor and improve the safety and quality of health care.”
In both cases, either directly or indirectly, the respective Department of Health received information about management and clinical performance problems that had not been addressed over a significant period of time. Here again, there may be an oversimplification. The UK Department of Health was surely more culpable in that it had been informed of problems over a period of eight years before it took action.

We agree with the list of problems provided by the Council. Its report notes that both the Bristol and the King Edward Inquiries found 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
- poor clinical and emotional outcomes for patients and families.

There were differences of emphasis, however. For example, in the case of Bristol there was some relatively good comparative information on performance (including the statistics compiled by Dr Bolsin under a national research grant).

The Council then noted some differences. In particular, it argues that “... 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.” (Australian Council for Safety and Quality in Health Care 2002:27).

We do not agree entirely with this view. It is true that Bristol established processes to inform and involve the public at large, but this largely occurred only after the inquiry process was under way. As we state elsewhere in this monograph, senior staff of the hospital fought fiercely to avoid public disclosure over a period of several years. Nor can we see any reason to believe that the medical professional associations in the UK were less insular than the Australian Medical Association.

### 6.6 Footnote

The report issued by the Australian Council for Safety and Quality in Health Care (2002), also includes comments on the process of the Inquiry itself. The comments are worthy of attention here.

First, the Council argued that there were contradictions between the Terms of Reference of the Inquiry and the final content of the Report. In particular, the inquiry team had been directed to focus on systems issues rather than the performance of individuals. However, throughout the Report, individuals were named and individual behaviour and actions were recorded in detail.
The Council argued that the value of the information about individuals was questionable, particularly to the community at large. Moreover, it probably made little contribution to understanding and learning from systemic problems.

Second, it was noted that 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. The Council argued that, when an inquiry is necessary, it may be more appropriate and useful to the health care system, to give the inquiry team the power and protection available under the Royal Commission Act.

Finally, the Council was concerned about the time and resources consumed by the Inquiry, in relation to its overall impact on the safety and quality of the health care system. The Inquiry occurred over 18 months and cost $7 million, primarily to identify management and clinical problems at one hospital. The Council argued that the resources might have been better applied to the establishment of “… 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.”

As a footnote, we believe these criticisms may be unjustified. We are particularly doubtful of the logic of the last. Siddins (2003) noted that the Commonwealth-States Medicare Agreement of 1995 allocated $658 million to five years of quality improvement. “This expenditure may have silenced a community demand. Regrettably, it has contributed little towards meeting an urgent community need. In 2003, no fundamental reform has been achieved where it is most needed – at the coalface of daily clinical practice.” Given that a significant proportion of the funding was to support the work of the Australian Council for Safety and Quality in Health Care, we think it is a little unfortunate that the Council should imply that $7 million spent on the Douglas Inquiry was of questionable value.

6.7 References and selected bibliography


7 Royal Melbourne Hospital, Australia

7.1 Context

In March 2002, serious allegations were made public concerning the conduct of nursing staff at the Royal Melbourne Hospital (RMH), which is part of the larger care delivery agency called Melbourne Health. The allegations became the subject of investigation by the Coroner and Victorian Police. The Nurses Board of Victoria suspended the registration of two nurses but postponed its investigations until the Coroner’s investigation had been completed. The Executive and Board of Melbourne Health each conducted separate investigations into issues associated with the allegations. The outcome of legal proceedings is presented in the final section of this paper.

7.2 The Inquiry

In view of the high level of public concern, the Minister for Health immediately requested the Health Services Commissioner (HSC) to conduct an independent inquiry. It was to address general issues, rather than the particular complaints that were the subject of legal proceedings. Most of the following has been taken from the HSC report (Health Services Commission 2002).

The Terms of Reference indicated some broad topics on which the HSC was to report. They reflected matters that were under investigation by the Coroner and the Police: medications management; incident reporting systems; standards of documentation related to patient care; nursing management and overseeing of clinical practice at ward level; and systems for staff support.

The underlying agenda was that of reassuring the public at large that steps would be taken to protect their safety. Thus the HSC was specifically requested to advise on any aspects of care that might be improved in the Victorian hospital sector as a whole.

The HSC received cooperation from the RMH and the Department of Human Services, and it was therefore not necessary to invoke formal powers. For these and other reasons, the Inquiry reported here represents a study of potential risks to patient safety rather than an investigation of particular failings.

Method of conduct of the Inquiry

The HSC was expected to report within three months. The short time frame was understandable, given the government’s concern for reassuring the public as rapidly as possible. It significantly constrained the investigation team. It had to rely heavily on the assembly of opinions through interviews with individuals and groups, the examination of a small sample of medical records, onsite observations, and consultation with experts.
Such an approach was inevitably open to bias on the part of investigators to a greater degree than might be expected from other inquiries such as Bristol and Campbelltown-Camden. Other limitations admitted by the HSC team included a lack of comparative data, an inability to interview staff who would have been important informants but they no longer worked at RMH, the infeasibility of conducting interviews of patients and their families or carers, and insufficient time for there to be a comprehensive call for written submissions.

7.3 Conclusions of the Inquiry

The conclusions are arranged under 12 main headings in the summary of the inquiry team’s report, and a slightly different structure is used in the main body of its report. We have retained the general structure of the summary section, but modified some of the headings and split two of the sections to make 15 headings in all.

Sector wide organisational changes that affected RMH

Hospitals in Victoria (and particularly the large metropolitan public hospitals like RMH) had been subjected to many changes since 1995. One major change was the formation of hospital networks, whereby 35 previously separate facilities had been aggregated to form seven hospital groups (Health Care Networks) on a predominantly geographical basis. In 2000, changes were made with the intention of reducing the degree of aggregation, and the seven hospital groups became 12. Another stated goal of the review was to counteract “…an undue emphasis on commercial viability at the expense of considerations such as the quality of patient care.”

The inquiry team concluded that the predominantly structural changes that occurred between 1995 and 2000 had had an adverse impact on staff morale and standards. They coincided with complexities experienced by all metropolitan hospitals including the financial implications of scientific and technological changes, increased public scrutiny, increasing demands for services, long waiting lists, higher patient acuity and shorter length of stay, widespread nursing shortages and increasing use of casual staff.

Effects of frequent changes in senior management

From 1995 until 2000 RMH experienced considerable leadership instability, which was the source of much critical comment by staff. The inquiry team noted that staff considered there had been a lack of accountability, a failure to include staff in decision making, a lack of vision and too much focus on fiscal matters. This resulted in mistrust of management, poor staff morale and a drop in standards of care for patients.

Staff expressed more confidence in current leadership. However, they argued that there were still few tangible results at the level of service delivery.

Nursing leadership

There had been five Directors of Nursing between 1995 and 2000. Their workloads were heavy, in part because of the organisational changes and the increased emphasis on productivity.

Their difficulties were increased as a consequence of a large reduction in middle management positions in nursing. The inquiry team concluded that nursing managers were “…unable to make the necessary structural adjustments to provide adequate support and mentoring to the large nursing workforce.”
The situation appeared to have improved after 2000. The inquiry team concluded that the new nursing managers have a strong commitment to “… re-establish structures to ensure staff are well supported to provide good patient care.”

**The corporate vision**

The inquiry team concluded there had been a lack of organisational cohesion in the past. It was reported that ‘some senior administrators’ believe “… a culture of elitism exists which has been conducive to an attitude of complacency and lack of accountability. Although there is individual and team-based commitment to excellence in-patient care at RMH, organisational goals, values and mission have not been well articulated.”

However, improvements were being made. They included “…the development of a fully integrated and systematic approach to patient care including the implementation of a consultative framework to achieve changes in staff development, research and education programs, promotion of ethical behaviour, and patient-focused care and team work.” A strategic plan had been completed and approved by the Board.

**Organisational structures**

Weaknesses of fragmentation, and of confusion over responsibilities and accountabilities, had characterised the RMH in the past. However, management teams had been established to provide relevant leadership at the divisional level. Such teams were committed to being fully informed about local and corporate issues in order to be competent, to feed information up and down the organisational structure and influence policy. Divisions now have a comprehensive infrastructure that included financial and human resource management expertise.

The inquiry team noted that the new organisation structures appear to be widely supported by managers. “Consensus of opinion among senior managers is that the new structure is the best they have experienced within RMH. They consider it well planned and resourced, providing good access to the CEO and line management. However, it was also noted that some nurses are critical of the failure of RMH management to include them in decision making. They consider management to be overly medically oriented, and that nursing expertise is neither sought nor valued” (page 22).

**Methods of management of clinical work**

Operating rules and guidelines were inadequate in the past, and were associated with low levels of compliance in some respects. Improvements had been made of late. However, they appeared to be poorly understood below management level. RMH still did not have a documented nursing philosophy or nursing objectives.

The inquiry team argued that clinical governance was still not widely understood and the necessary structures and processes were still evolving. Before a new organisational structure was implemented in 2002, clinical divisions were under resourced in terms of administrative and supervisory capacity.

RMH had a range of quality assurance and improvement programs, but they were not effectively integrated. Staff said during interviews that there had been a failure to invest in infrastructure, including capital equipment and administrative support. The various clinical groups therefore had to rely on their own resources, and this led to inconsistencies including in data collection and storage methods.
There were differences in organisational structures. For example, medical staff had a divisional reporting system for quality activities whereas nursing assigned quality management to the Nurse Unit Manager and clinical nurses. One consequence was that much depended on the knowledge and interest of each Nurse Unit Manager. Some clinical units had moved towards a multidisciplinary approach, and it was claimed that this often meant the nurses had to carry the burden due to a lack of interest among other professions.

The inquiry team suggested there should be “… a formal system of recognition and reward for individuals and groups who achieve significant quality improvements.” This would provide positive staff reinforcement, and a vehicle for publicising quality improvement activities.

**Relationships between professions**

The inquiry team concluded that relationships between medical and nursing staff at RMH were generally satisfactory. However, some respondents suggested there were circumstances in which relationships had deteriorated over the years, to the detriment of patient care. For example, the inquiry team was advised that nursing staff in some wards and units were reluctant to accompany doctors on ward and unit rounds – and the informants suggested this required immediate attention. The reasons for reluctance are not given in the inquiry report.

Some respondents were concerned about “… what they perceived as a divide between medical and nursing staff and wanted to improve the situation.” However, they were not able to make any specific suggestions about appropriate corrective action. The inquiry team concluded that further investigation and evaluation by RMH managers was required.

The inquiry team recognised that there were problems of communication of various other kinds. Indeed, the majority of respondents mentioned poor communication “… as a major source of patient and staff dissatisfaction.”

One of the corrective measures already taken involved defining lines of communication and providing information sessions at which they could be clarified. The channels have been linked to position descriptions.

However, there may be a long way to go. The inquiry team noted there were large differences of opinion about the adequacy of corporate communication at senior management, middle management and operational or clinical levels. Nurse clinicians said they felt powerless and frustrated by a failure on the part of management to listen to their concerns, ideas and opinions. One comment made in an interview is quoted in the inquiry team’s report.

“One of the great difficulties is communication, particularly for a person on night duty – things hardly ever reach you. There is a huge neglect in that respect. The current leaders do listen. Before that – no, absolutely not. Nursing staff do not receive feedback on issues they raise with administration.” However, some nurses acknowledged that staff do not always take advantage of opportunities made available to them by management and fail to accept their own responsibilities for informing themselves of organisational issues.

**Management of medications**

The inquiry team noted that most adverse events relating to medication error do not occur as a result of a single mistake by a particular individual, but because of a fault in the health care system that does not allow the error to be recognised. The error rates are higher where ward stock supply systems are used.
The team further noted that error rates can be reduced by guidelines and protocols, drug information and advisory services, computerised decision support systems, and routine evaluation. Special measures are required for dangerous drugs.

The Inquiry was advised that there had been a decline in the rigour of medication control at RMH in recent years. However, steps were being taken to improve the situation. For example, nursing policies and procedures relating to drug administration and control at RMH had been under review since 2001. Specific problems were noted by the inquiry team to have now been addressed: drugs awaiting return to pharmacy were sometimes not stored in locked facilities but left in open ward areas; keys to the dangerous drug cupboard and the drug cupboard were kept together and were not always appropriately located; the checking for drugs of addiction did not always occur in accordance with standards; and there were inadequate controls over drugs loaned between wards.

However, some problems remained to be adequately resolved. Staff interviewed by the inquiry team argued that the replacement of imprest drugs by technicians had reduced efficiency, specialist areas such as the Intensive Care Unit and Emergency Department that require speedy access to life saving drugs stored them in unlocked facilities, and some nurses were administering drugs that were outside their scope of practice. The inquiry team argued that control of some types of dangerous (Schedule 4) drugs could be improved. Auditing procedures should be strengthened, and there should be an explicit ‘zero tolerance’ policy towards the theft or misuse of drugs.

Staff were working with a dual system of old and new policies, and this was causing confusion and needed to be addressed. Before the allegations of misconduct, there had been no hospital wide monitoring of compliance with medication policies and procedures, including compliance with legislative requirements. The inquiry team suggested that the responsibility for improving the situation would be most appropriately assigned to the Director of Pharmacy.

Management of incidents

RMH had a Clinical Risk Management Committee, but it was deficient in many respects – including the absence of nurse clinicians. RMH had not established systems for collecting data on sentinel events and for undertaking limited adverse occurrence screening, although the Department of Human Services requires public hospitals to do so.

A new process for the management of adverse events was introduced in March 2002. However, staff suggested many weaknesses during interviews. For example, they resented the wording on the reporting form that implied the cause was a failure to provide adequate nursing care, whereas the incident may have been stimulated by other processes.

They also told the inquiry team that many incidents, including serious ones, were not being reported. There was a lack of consistency throughout RMH with regard to determining the range of incidents to be reported. Staff complained that they received little or no feedback about incident reports, and this had had a detrimental effect on staff relationships and morale. Finally, some staff considered that, in the past, the RMH had a culture of blame that discouraged reporting. It was unclear to the inquiry team whether this had been overcome.

Management of complaints from staff and patients

In the recent past, many staff had taken the view that there was little point in making complaints. Their complaints were seldom appreciated, and they rarely resulted in action by the Hospital management.
Patient complaints were handled more effectively. The RMH had a full time complaints liaison officer, who provided staff training in addition to direct support for patients, their families and carers. The inquiry team argued, however, that the complaints liaison officer did not have adequate administrative support.

Nursing staffing

Like other hospitals, the RMH had been adversely affected by the widespread shortage of nurses and had been obliged to employ a high number of casual staff. However, funding had been improved of late to increase the number of permanent nursing staff and this had begun to have a positive impact.

The inquiry team noted that the number of nurse educators had been reduced dramatically between 1995 and 2000. Over a two year period the situation had improved as a consequence of increasing the number of nurse educators from three to 20. Priority had been given to supporting newly graduated nurses, and the professional needs of other nursing staff were not yet being met. Nursing staff indicated that RMH did not have formal mechanisms for nurses to raise ethical issues, receive feedback, or gain immediate advice and support when dealing with ethical problems encountered in their work.

Support systems for nursing staff

The inquiry team argued that resource constraints during the late 1990s had had a serious adverse impact on nursing support services at the RMH. A combination of factors including high workloads, exposure to stressful situations, poor roster and shiftwork arrangements, and a reduction in staff support positions resulted in low staff morale and a drop in standards of care. More recently, budgets had been improved to redress these problems but full recovery would take time.

The inquiry team noted that nurses were as susceptible as any other professional group to emotional and physical hazards in the workplace. Nurses with impairments (for such reasons as through illness or substance abuse) required assistance, but this had not been forthcoming until very recently at RMH. It was suggested that a health program for nurses should be established that could be modelled on that for Victorian doctors.

The RMH had recognised the need to develop processes that value, support and develop the skills of nurses. The inquiry team argued that there was a need to manage complicated interactions between diverse professional groups, and between them and highly vulnerable, often traumatised, patients and families. “Situations of conflict can occur” and “… it is the responsibility of the organisation to have processes in place to reduce these risks and to resolve conflict as quickly as possible. RMH had an aggression management committee but this has not been operational for some time. Clear and consistent policies need to be developed to ensure aggression, whatever its source, is reduced and addressed.”

The orientation of new staff

RMH had a general orientation program that was intended to serve all kinds of new staff, and the program was periodically reviewed by the Human Resources Unit. The general program was augmented by programs that were relevant only to specific professions or units within the Hospital. These more specific programs were designed and managed by the professions or units concerned. The inquiry team concluded that they differ in effectiveness. This is to be expected, given that some were formal and others informal, and some were evaluated while others are not.
Clinical departments allocated time to allow for staff orientation. Most of them had a mentorship scheme that was initiated during or shortly after the orientation period. The most significant components of orientation (those relating to patient care) were therefore less subject to evaluation and continuous improvement. The same may be said of mentoring.

The inquiry team noted there was no orientation program that was specific to the needs of nurse unit managers. This was considered to be a missed opportunity because “… a well-designed and effectively implemented formal orientation program for nurse unit managers that incorporates management expectations of clinical governance, communication and staff support, would provide opportunities for enhanced leadership and be a catalyst for cultural change.” The inquiry team made no mention of the risk that, if orientation and mentoring were largely specific to particular functions or professions, this might serve to reinforce professional subcultures.

Standards of clinical documentation

The standards had declined in some respects in recent years, and RMH had recently given this matter increased attention. However, the inquiry team concluded that much remained to be done. For example, a new procedure manual was produced in 2001 that mainly addressed documentation in medical records. However, there were no standards regarding many aspects of medical records management.

At the time of the Inquiry, the Health Information Manager reported he was unaware of any recent content audits of medical records, but expressed a commitment to conducting such audits in the future. The inquiry team therefore conducted a limited medical record audit that revealed poor standards of documentation, and recommended the problems be addressed with some urgency.

The audit involved a sample of 60 medical records of patients discharged over a two week period in February 2002. The focus was the quality of nursing documentation, which was evaluated against standards in the medical records procedure manual noted above. It was noted, however, that many aspects of documentation were not covered by the manual in terms of prescribed standards.

There was little uniformity of content, and additional confusion had been caused by the partial use of clinical pathways. The pathway forms were intended to document the entire episode of care, but this was not the case in practice. Rather, there was a mix of pathway and non pathway documentation.

There were many specific problems. For example, the wards in which patients were located were not identified in the progress notes, signatures were often illegible, alerts were not appropriately documented for three patients who had a reported allergy to a medication, irrelevant and redundant information was frequently included, there was a high level of duplication of information, and some of the entries were not dated.

RMH nurse managers were almost universally critical of the quality of documentation of patient care, while nurse clinicians were less inclined to comment. Nurse managers were conscious of the formal lack of monitoring and evaluation of documentation standards. Several interesting comments were made during interviews. For example, it was said that paperwork varies from ward to ward. If you are part of the nursing staff bank and floating as an agency nurse, this was very difficult. Staff were not familiar with the patients. Documentation was done every time people see a patient, whether or not we they give them a wash or they have a full bed change.

Finally, many of the audited records demonstrated a poor understanding of the need to document the implementation and evaluation of care. For example, there was a lack of documentation of the outcomes of care. In almost all of the audited records, there was a failure to indicate follow up assessment. Serious omissions included failure to document the outcomes of medications
administered for pain. One medical record documented 11 doses of a narcotic administered for pain without written evaluation of effect. Among the records where there was follow up documentation, it was often substandard in terms of its specificity.

**Care planning and evaluation**

Many weaknesses were reported by the inquiry team. First, there was no hospital wide standard for nursing assessment. The documentation audit showed that assessment was frequently inadequate, and often related only to presenting symptoms.

Assessment processes were better in specialist areas. For example, documented assessment of elective surgical patients was of a higher standard because they undergo preadmission screening that provides data from which care is planned. Discharge planning was evident on most records, and the Discharge Risk Assessment form was usually completed. Medical assessment was usually clear and comprehensive, although not always dated.

Second, a variety of methods and tools were used to plan and document patient care. Clinical pathways were in use, but there were notable weaknesses. The inquiry team noted there was little consistency of design and no apparent organisation wide rules, many pathways were not multidisciplinary, poor form design meant many were time consuming to use, and there was little evidence of structured approaches to the recording and analysis of variances.

**7.4 Recommendations of the Inquiry**

The inquiry team made 73 recommendations, most of which can be deduced from the diagnostic information provided above. We will group them below and give emphasis to those recommendations that seem most important in the context of our review of inquiries.

**PARTICIPATION AND OPENNESS**

RMH should continue to cultivate trust in management by maintaining consistent and transparent management practices, communicating the RMH vision, and encouraging participation from all staff in decision making. Leadership decisions should be documented, communicated and evaluated.

**RESPECT AND INVOLVEMENT OF NURSES**

RMH should demonstrate that it values the knowledge and expertise of nurse clinicians by involving representative clinical nurses on RMH committees, including strategic planning and policy making committees. This should include involvement of clinical nurse representatives on the Clinical Risk Management Committee.

Nursing leaders should engage all nurses in the development of a nursing philosophy that incorporates the art and science of nursing as practised at RMH, and communicate it to existing and new nursing staff. Formal mechanisms should be established whereby nurses may raise ethical issues, receive feedback, and gain immediate advice and support when dealing with ethical problems encountered during the course of their work.

**COMPLIANCE WITH RULES AND GUIDELINES**

RMH should ensure that all standards, policies and procedures are developed according to best practice approaches. They should be easily accessible for consultation by staff, training should be provided to ensure staff understand them, and compliance should be monitored.
CONTINUOUS QUALITY IMPROVEMENT
RMH should finalise a quality management plan that integrates with Melbourne Health’s strategic directions and meets the quality requirements of external accrediting bodies and the Department of Human Services. The plan should include a clinical governance policy and a framework for reporting that supports the Board and senior management in fulfilling their responsibilities to monitor and address issues relating to safety and quality of care.

An individual should be assigned to coordinate all aspects of quality and accreditation. Resources should be allocated to educate and support staff to fulfil their responsibility to monitor, evaluate and continually improve the services they provide.

COMMUNICATION ACROSS AND WITHIN PROFESSIONS
RMH should further investigate relationships between medical and nursing staff and implement strategies to improve their communication and interaction related to patient care. Managers should continue to monitor nursing relationships to ensure nurses, and particularly junior nurses, feel confident of the respect of their peers.

Shared accountabilities should be defined for communication and a process established for educating staff and monitoring the effectiveness of communication across the organisation. The Hospital should develop strategies for listening actively to staff issues, and should provide improved opportunities for staff feedback. There should be a review of organisational culture and satisfaction levels of non management staff, and strategies developed to address adverse cultural and morale issues.

IMPROVED MANAGEMENT OF MEDICATIONS
RMH should review the design of its individual patient medication storage system to ensure that risks of medication errors are minimised and access to individual patient medication storage containers is appropriately restricted, documented and audited.

RMH should review procedures governing ‘loaning’ of drugs between wards and obtaining non imprest items after hours, medication storage facilities within the Intensive Care Unit and the Emergency Department, ensuring medications are stored appropriately and securely to prevent unauthorised access, auditing of drug stocks to ensure compliance with drug storage. The Director of Pharmacy should be given the responsibility for monitoring and addressing compliance with legislation.

The RMH Medication Risk Committee should develop comprehensive feedback mechanisms to enable staff to learn from errors, and should implement proactive preventative strategies that link to quality programs. The potential should be explored for the introduction of a standardised medication chart for all Victorian hospitals to decrease the incidence of medication errors.

RISK MANAGEMENT AND PATIENT SAFETY
The RMH should develop a hospital wide program for meeting Department of Human Services requirements for reporting sentinel events and limited adverse occurrence screening. The Hospital’s policy and reporting methods should be revised to ensure reporting lines are unambiguous, timelines for all levels of action are clearly stated, there are clear and effective feedback loops, key performance indicators are practical and relevant, and policy changes related to adverse events are captured appropriately and implemented through the quality improvement program.
The RMH should ensure there are appropriate educational programs on clinical risk management for all staff. Education on clinical risk management should be included in orientation programs for all new staff.

COMPLAINTS PROCESSES
There should be improved methods of management of staff complaints and staff feedback, to ensure all complaints are registered and actioned, and feedback is provided. The methods should include provision for further review of serious complaints where the staff member is dissatisfied with the outcome of the initial management of the complaint. The Hospital should make sure all staff are familiar with the provisions of the Whistleblower Protection Act 2001 (Vic) and processes are in place for its implementation.

CLINICAL DOCUMENTATION
The RMH should produce improved standards for the handling of medical records. Nursing leaders should contribute standards for nursing documentation and provide relevant education to all clinical staff. There should be improved standards for documentation of care planning and outcome evaluation.

7.5 Discussion

The Melbourne Hospital Inquiry was notable for the support it received from key stakeholders, including the management and staff of the hospital involved (Health Services Commissioner: 2004). A follow up analysis of the Inquiry produced by the Commissioner’s office in 2004 gave some interesting insights as to why this might be so.

In October of 2004, the Health Services Commissioner’s Office published an analysis into the Royal Melbourne Hospital Inquiry. The analysis documented “… the background and management of a successful, speedy and cost efficient investigation and provides a “road map” which may be useful in assisting any relevant future inquiries into hospital-based incidents” (Health Services Commissioner, 2004:3).

The report identified the need for clear terms of reference for inquiries, drawn up in consultation between Commissioner’s and Minister’s offices so as to avoid (as in the Camden and Campbelltown HCCC Inquiry) confusion over the focus of inquiries. Inquiry teams are to be selected carefully, in order to ensure a combination of appropriate skills, strong commitment to the inquiry process, a clear understanding of the expectations and workload of an inquiry, and in order to promote open and honest communication between team members.

Communication issues made up the bulk of the suggestions for an effective inquiry process. Information to stakeholders should to be handled in a timely manner so as to reduce anxiety and to ensure that information is received by stakeholders before it is released to the media. In the same vein, hospital staff are to be informed of the specific purpose, inquiry and reporting methods of an inquiry, including the principle that quality improvement, and not blame, is the objective of most inquiries. Team members are to be made freely available to staff. Dialogue between inquiries and other parallel investigations, such as those held by Coroners, Medical Councils and Registration Boards amongst others are considered highly important.

The form of evidence to be included (such as written submissions) in inquiries is to be determined and publicised before the commencement of the inquiry process. At the end of the process, copies of the draft of the inquiry reports are to be supplied to anyone subject to adverse
comments, prior to their release. Finally, interested parities at the periphery of the Inquiry are to be encouraged to be involved in inquiries, on the basis that they might provide useful, but unexpected information (Health Services Commissioner, 2004).

7.6 Footnote

7.6.1 The outcome of the legal investigation

The Coroner investigated 80 deaths from the Neurology Ward at the RMH, mainly as a consequence of the claim by a colleague of the two accused nurses that they had planned to kill one patient using insulin and had actually accelerated the death of another patient. The deaths were the subject of an initial Inquiry by hospital authorities when the claims were made in two anonymous notes sent to management in October 2001 (Butcher 2003).

The Police and the Coroner were notified in March 2002, after a private investigator for the Hospital submitted reports on the death of one patient and on allegations of misconduct and unprofessional behaviour. During their investigations into those two deaths, Police were informed that a third patient had died in suspicious circumstances involving the administration of morphine. These three deaths were the focus of the inquest.

The investigations had been rendered more complicated because one of the accused nurses had admitted she was involved in the death of one of the patients. She had been suffering at the time from a “... drug-abuse problem combined with a degree of mental instability”.

The Coroner, in his inquest on the three deaths, concluded that each appeared to be from natural causes. However, he inclined to accept the evidence uncovered during the Police investigation that indicated there were serious deficiencies in the recording nurse activity, lack of supervision and leadership, and little or no accountability of prescription drugs on the ward.

7.7 References and selected bibliography


8 Southland DHB Mental Health Services, New Zealand

8.1 Context

Mr Mark Burton became a client of the Mental Health Service of Southland District Health Board (Southland DHB) in July 1998. The Mental Health Service operated at several sites and included community- and hospital-based facilities. Mr Burton received care from the Queenstown Community
Mental Health Team and had twice been hospitalised as a voluntary patient in Ward 12 of Southland Hospital, Invercargill.

The second inpatient episode lasted for 50 days. He was discharged from Ward 12 on 30 March 2001. One day later, he killed his mother.

In response to publicly expressed concerns, a clinical audit was initiated by Southland DHB. The audit was conducted by a psychiatrist with no connections to Southland – Dr Bridget Taumoepeau from Wellington. Her report, released in September 2001, expressed many concerns about the quality of care that had been provided. The Southland DHB’s Director of Mental Health then commented publicly that the report highlighted problems with Southland DHB’s Mental Health Services that needed to be addressed.

In October 2001, the Health and Disability Commissioner (the Commissioner) initiated an independent inquiry that reported its findings in October 2002. It took account of the Coroner’s inquest into Mrs Burton’s death that reported in December 2001. The report by the Commissioner (Health and Disability Commissioner 2002) is the main source of the summary provided below.

The Commissioner examined clinical practices in great detail as they related to the care of Mr Burton, and concluded there had been many deficiencies. Although each deficit singularly may not have been responsible for the outcome, in total they resulted in poor care. There were inadequate monitoring and control mechanisms to ensure that staff practised safely, that incident and risk management strategies were in place, and that policies and procedures were followed. Communication with Mr Burton’s family were inadequate, discharge planning was ineffective, and there was a notable lack of coordination between the inpatient and the community care teams. The "…overall picture is one of sloppy care that was lax and laissez-faire."

*Inter alia*, the Commissioner recommended that there should be competence reviews of many clinicians, internal auditing and staff training processes should be enhanced, care pathways improved, efforts made to develop a culture of critical appraisal, a quality improvement strategy developed and monitored, and improvements made to communication processes and systems. He referred his findings to the Director of Proceedings for the purpose of deciding whether further action should be taken.

### 8.2 The Inquiries

#### 8.2.1 Dr Taumoepeau’s clinical audit

Dr Taumoepeau’s report outlined the context and summarised the care that Mr Burton had received. She drew conclusions on its appropriateness.

Virtually all of her findings were confirmed during the more detailed investigation conducted by the Health and Disability Commissioner, and there is consequently no need to describe them here. However, she had fewer constraints on the scope of her investigation than the Commissioner. She therefore chose to address the general methods of work of the mental health services team rather than merely those aspects of Mr Burton’s care. This led her to presenting recommendations about improvement of those processes in future. They differ only in minor ways to the recommendations of the Commissioner, but they are worth noting. We will summarise them in a later section of the paper. However, we will first summarise the Commissioner’s report because it presents the background necessary to interpretation of her conclusions.
8.2.2 Terms of Reference of the Commissioner’s Inquiry

The Terms of Reference were influenced by two factors: the high degree of public concern, and the contents of the legislation under which the Commissioner was permitted to act. The focus was the patients’ rights as specified by the legislation. The Commissioner determined to investigate whether those rights had been breached with regard to communication with patients and their families, discharge planning and discharge processes, and coordination between clinical teams. These were the specific indications in the Act with regard to quality of care.

8.2.3 The process of investigation

The Commissioner was required under the Act to notify agencies and individual health care professionals that they were under investigation. Selection of the agencies and individuals was influenced by Dr Taumoepeau’s report, and by a formal letter to the Commissioner from Mr Burton’s father. Among other issues, Mr Burton’s father complained about the standard of care provided to his son by the doctor responsible for his care, and the lack of supervision of that doctor by Southland DHB’s Clinical Director of Mental Health Services. In total, those investigated were either directly involved in Mr Burton’s clinical care or carried management responsibility.

Mr Burton’s father also complained of matters that had caused him and his family further harm, but which the Commissioner judged were outside his jurisdiction. They included comments made by Southland DHB staff (in particular, the General Manager and the Clinical Director) following the release of Dr Taumoepeau’s report.

The Commissioner appointed an investigation team of five independent advisors and a project manager. They began by reviewing the report by Dr Taumoepeau, evidence from the inquest, and additional materials made available by Southland DHB including Mr Burton’s clinical records.

The investigation team visited the locations where care had been provided, and interviewed all staff under investigation. They also interviewed other health care professionals and members of Mr Burton’s family. Interviews were conducted face to face or by telephone, tape recorded, transcribed and returned to the interviewees for checking and signing.

The Commissioner formed a provisional view on the quality of care provided. This was provided to all persons whose performance was under investigation. Their responses were taken into account in forming the final opinion contained in the Inquiry’s official report.

Particular weight was given to the clinical notes that were made while care was being provided. The Commissioner considered this was important because, during the course of the several formal and informal inquiries “…the inpatient staff most directly involved clearly discussed the period of Mr Burton’s hospitalisation and, not surprisingly, developed a common view of what had occurred while Mr Burton was in hospital.”

The health care professionals under investigation made several allegations of unfairness over the inquiry process. One was that they had been criticised with regard to the language they had used, and this reflected an undue emphasis on ‘political correctness’. The Commissioner noted that, during the course of investigation, his advisors had indeed reported the use of language they considered paternalistic and stigmatising. However, he supported his advisors in this regard. “This is an aspect of practice that requires little time to correct, but which can have an important effect on the attitudes and values of staff.” Every patient has the right to be treated with respect and “… use of appropriate language is an essential element of respect and is not merely a matter of semantics or political correctness.”
Another criticism of the Inquiry was that it was affected by ‘hindsight bias’: the inquiry team knew that there had been an adverse outcome (the homicide) and was aware of Dr Taumoepeau’s report; and that this affected their judgement. The Commissioner recognised the risks but argued he had taken appropriate steps to minimise them. *Inter alia,* he attempted to ensure his assessment of the quality of care was not influenced by the death of Mr Burton’s mother.

Some interviewees argued that they found the questions asked by the investigation team confusing. The Commissioner rejected this argument. With one exception, all staff interviewed were accompanied by a lawyer (and the person without a lawyer was accompanied by a support person). During the course of the interviews staff were able to, and did in fact ask for clarification where they did not understand a question. Their lawyers were available to assist, object, and seek clarification if necessary. There was an opportunity during all interviews for staff to speak privately with their lawyer.

**8.3 Conclusions of the Inquiry**

The inquiry report contains a detailed description of the care provided to Mr Burton while he was under the care of Southland DHB’s Mental Health Service between 10 February 2001 and 30 March 2001. All the available clinical records were summarised and augmented with comments from the health care staff concerned, and from other persons including members of Mr Burton’s family where relevant.

On the basis of analysis of documentation and the evidence provided through interviews, the Commissioner concluded that Mr Burton did not receive services of an appropriate standard. There were acts and omissions by individuals and by Southland DHB that breached Mr Burton’s rights under the legislation.

It was concluded that there was no single act or single individual who might be held to carry the primary responsibility for the poor care. The Commissioner’s advisors made reference to the analogy by Reason (2000) that clinical disasters may be considered to be the consequence of a chance alignment of minor errors.

This is “… the Swiss cheese model of system accidents in which successive holes in the layers of defences, barriers and safeguards line up.” There were “… numerous holes in this cheese, so many and some of such proportion that they lined up to create large gaps through the substance of the service. Although each deficit singularly may not have been responsible for the outcome, the substance or quality of the service appears in this case to have been so compromised that the risk of occurrence of adverse events was not managed at all effectively.”

In total, there were inadequate monitoring and control mechanisms to ensure that staff practised safely, that incident and risk management strategies were in place, and that policies and procedures were followed. Care was poor with regard to all of the specific Terms of Reference. Contact and coordination with Mr Burton’s family was infrequent and largely *ad hoc.* When contact took place, the substance of the communication was frequently inappropriate in both style and content. The Commissioner noted that “… much of the time the family was left in the dark about what was going on.”

Discharge planning was careless, imprecise, lacking detail, and poorly coordinated. The inquiry report said “… it is not hard to see why Mr Trevor Burton considers that his son was essentially kicked out into a flat to look after himself”. 
The discharge process itself was of doubtful quality. The Mental Health Service failed to form a clear picture of the patient's condition at discharge, and to consider with care the possible implications for post discharge wellbeing. The process took inadequate account of the available information about Mr Burton's disturbed sleep patterns, alcohol abuse, and psychotic behaviours.

Finally, there was a notable lack of coordination between the Queenstown Community Mental Health Team (which had considerable previous contact with Mr Burton) and the Invercargill Community Mental Health Team. Their involvement was considered essential to ensuring Mr Burton's successful discharge into the community.

According to the Commissioner, the weaknesses in Mr Burton's care were an inevitable consequence of the overall style of work of Southland DHB's Mental Health Service. It was characterised by attitudes of complacency and *laissez-faire*. The care processes were such that the family of Mr Burton had "... every right to feel that the health system failed them." The processes that were deficient were described in detail in the Commissioner's report. The behaviour of each of the main parties was discussed in turn, and is summarised below.

**The attending doctor**

The attending doctor was a Medical Officer Special Scale (or simply MO here). The position was intended to be occupied by a psychiatrist, but this was not the case due to claimed recruitment difficulties. When recruited, he was given to believe he would work under supervision because of his limited knowledge of psychiatry, and that arrangements would be made to ensure it was available when needed. The Commissioner concluded the arrangements were inadequate. The MO reported in the interview that he could obtain a reasonable degree of access to the Clinical Director. Unfortunately, the MO did not consider that he needed to discuss issues relating to Mr Burton's care. The Commissioner concluded that the MO underestimated his need for supervision.

The MO argued that there was the opportunity for adequate discussion of individual patients with both nursing staff and consultant psychiatrists during the weekly review rounds. He argued that this opportunity was in fact taken, and that he was given no indication that the way he was managing Mr Burton might be inappropriate.

However, the inquiry team concluded that the records available did not support the MO's assertion, and did not show that the advice of others contributed in any significant way to Mr Burton's management. At one of the five weekly meetings while Mr Burton was a patient, no consultant psychiatrist was present. The inquiry team's advisors concluded that "... as a forum for supervisory input on a regular basis from a more experienced member of the medical staff, the meetings would have been of limited value."

The MO's work was criticised in almost every respect. He did not record his admission assessment on a standardised assessment form, and what he recorded was incomplete. For example, there was no detail about the nature of threatening behaviour or precipitating factors, the main concerns of the family, or social circumstances. There was no medical history, and no record of quantity or frequency of use of alcohol and cannabis. Some of the deficiencies were resolved later, but many remained unresolved at the time Mr Burton was discharged.

The MO did not develop and document an adequate treatment plan. For example, he did not identify the need for the clinical team to understand the nature of Mr Burton's psychotic experiences, or ensure effective treatment and management of the risks of psychotic phenomena. He did not give systematic and adequate attention to matters he identified as priorities, such as Mr Burton's drug and alcohol use. There were no systematic attempts to find a residential facility that would address
substance abuse. He did not give adequate attention to Mr Burton’s mental state and did not adequately assess whether there was an improvement in Mr Burton’s psychotic symptoms.

He failed to monitor Mr Burton’s medication after the dose of olanzapine was increased on admission. There was no evidence of regular systematic review of the effectiveness of the treatment or the patient’s tolerance of it. He did not sufficiently specify the circumstances in which the ‘as required’ medication (which he prescribed on admission) was to be used.

The MO failed to manage clinical risk. For example, he did not complete an ‘Assessment of risk’ form. He did not review Mr Burton’s assessed level of risk following incidents – such as when the patient returned to the ward apparently intoxicated and behaving in a threatening manner. He did not make a formal assessment of risks before it was decided that Mr Burton would have a week of trial leave, or before discharge.

Similar concerns were expressed by the Commissioner with regard to leave planning and discharge planning. With respect to the latter, the MO prescribed a three month supply of medication but there was no record of his having discussed with the patient the need to adhere to the prescribed dose, or of strategies to monitor adherence or to restrict supply. There was no evidence of a comprehensive review of Mr Burton’s mental state on March 30 2001 (when the plan to discharge was confirmed), a mental state examination, or a review of risk factors. Nor was there any record of discussion of Mr Burton’s substantial use of alcohol in the week of trial leave, or the implications for his mental state.

Further, the MO discharged Mr Burton without the community key worker attending the discharge meeting (after the MO changed the meeting time without advising her). He failed to ensure there were adequate arrangements to monitor Mr Burton in the days following his discharge.

A discharge meeting was planned for 11am on 30 March at which Mr Burton, the MO, and relevant nursing and social work staff were to be present. Mr Burton arrived early at the inpatient unit and did not want to stay until the arranged time, so the MO agreed to bring the meeting forward without advising the key worker or ensuring that she could attend. The meeting was held without her, and the patient was discharged without arrangements in place for follow up care by the key worker, or an opportunity for her to provide input into the appropriateness of discharging Mr Burton at that time.

Finally, the MO did not exercise due care in terms of helping to find appropriate accommodation after discharge. The records did not support the MO’s claim that the issue of accommodation was discussed at length and with care with Mr Burton and his family. The Commissioner concluded that two aspects were inadequately handled: the search for residential programs to address drug and alcohol use; and a more complete needs assessment to address those aspects of support necessary for improving Mr Burton’s ability to cope in the community. Referral was made for needs assessment, but the MO did not subsequently check the outcome – including whether the information required to plan ongoing care had been obtained.

The Commissioner concluded that consideration should have been given to compulsory confinement of Mr Burton. There was evidence of a mental disorder, a history of problems with medication concordance, and reluctant engagement with treatment plans. At least, the MO should have discussed this with a senior colleague but he did not do so.
Finally, the Commissioner was critical of the MO’s efforts to involve the patient’s family, who were loving and interested in being involved in his assessment, care and progress review. The patient’s father reported that he had little information about some aspects of inpatient care. He felt that he had to initiate most of the contact with the clinical team, and even then little information was provided. The MO told the inquiry team that the Mr Burton family (other than the father) gave the impression that they did not want to be involved in the patient’s care any more. In total, the Commissioner concluded that the MO did too little to involve the family, discuss their concerns, outline the likely course of treatment and proposed plans, or ensure appropriate involvement of the family in the treatment process.

The MO also failed to make adequate clinical records. The inquiry report said that his entries in the patient’s notes were ‘scanty’, he failed to document a treatment plan, and did not document the rationale for leave. The MO admitted to the Inquiry that his clinical records did not meet an appropriate standard, and acknowledged that it would be “… hard to justify that amount of documentation”.

**Enrolled Nurse A**

Patients at the hospital were typically assigned two nurses – a primary nurse (usually a staff nurse and an associate nurse (usually an enrolled nurse)). Enrolled Nurse A was Mr Burton’s associate nurse from the day he was admitted. She was also Mr Burton’s *de facto* primary nurse before Staff Nurse A took on the role as described later.

The Commissioner considered it had been inappropriate to allow Enrolled Nurse A to perform the duties of the primary nurse. However, she had provided appropriate care, and could not be held responsible for having been given responsibilities above what was defined by the operating rules.

**Staff Nurse A**

The performance of Staff Nurse A was more strongly criticised. In particular, she performed poorly with regard to planning and evaluating Mr Burton’s care, coordinating his care while on trial leave, discharge planning, directing and supervising Enrolled Nurse A, and ensuring consistency in quality of care.

She did not undertake a comprehensive nursing assessment when she became Mr Burton’s primary nurse, nor did she update his existing care plan. She did little with regard to coordinating care with other members of the clinical team or involving the patient and his family. She failed to ensure there was an adequate discharge plan.

When questioned about her failure to perform a comprehensive nursing assessment, she claimed this was because she considered that such assessments should be instigated by the doctors rather than nurses. She also said that she did not update Mr Burton’s nursing care plan because there had been no change in the level of risk assessed by the doctors.

The Commissioner recognised there were system deficiencies, including limitations of the primary nursing system, which placed Staff Nurse A in a difficult position at times. However, he concluded the problems mainly originated in substandard performance of the particular nurse.

**Social Worker A**

Social Worker A was judged to have provided care of an inadequate standard. For example, he failed to pay sufficient attention to clinical aspects (including failure to read the notes relating to Mr Burton’s past care). He demonstrated a poor understanding of Mr Burton’s mental illness, and this
adversely affected the care he provided. He had no knowledge or skills to assess Mr Burton’s mental state, failed to create effective care plans, and did not give appropriate recommendations to other members of the team.

Social Worker A argued that he was working within a ‘dysfunctional system’. The role he should have played within the team caring for Mr Burton was ill defined and not fully understood by other members of that team. The managers at Southland DHB should therefore accept some responsibility for the fact that he had been placed in a position that he was not professionally equipped to fill, and in a team that could not (or would not) give him appropriate collegial support.

This view was accepted in part by the Commissioner. With regard to supervision of the period of trial leave, for example, Social Worker A was given a task for which he was poorly equipped. He was given no clear guidance by the MO or Staff Nurse A with regard to what he was expected to monitor while Mr Burton was on leave, nor told that Mr Burton presented unusual risks. However, in other respects, the inquiry team concluded there were deficits in Social Worker A’s performance, within the scope of work for which he should have had sufficient experience and training.

**Mental Health Needs Assessor**

The Mental Health Needs Assessor was assigned to undertake an assessment of Mr Burton while he was in the inpatient mental health unit, and this was clearly specified in the operating rules and guidelines to be an essential part of the patient’s discharge planning. The clinical team made a referral for Mr Burton to have a needs assessment but he was discharged before the assessment was completed.

The Needs Assessor documented the partially completed assessment on the approved assessment form and made an effort to involve Mr Burton and his parents in the process. However, she failed to provide all the relevant information to the rest of the team, partly because she was given the impression by others in the clinical team that the assessment was neither urgent nor important. The Commissioner was critical of her lack of assertiveness in her interaction with the clinical team once she had gathered information that she herself considered important to the discharge plan.

**Alcohol and Drug Services Counsellor**

The Alcohol and Drug Services Counsellor worked at Rhanna Clinic, which is part of Southland DHB’s Mental Health Services. Mr Burton was referred to the Clinic by Ward 12 staff almost a month after he was admitted to hospital. The Alcohol and Drug Services Counsellor was assigned the referral and undertook an alcohol and drug assessment.

The Commissioner was critical of only one aspect of the work: the Counsellor failed to document any overall conclusions or recommendations after he completed his assessment. This surprised the Inquiry’s experts, as one purpose of a specialised assessment is to provide a more expert perspective than is available from a general clinician. Such an assessment should be followed by some conclusion in relation to its findings. The experts concluded that the Alcohol and Drug Services Counsellor’s failure to document conclusions or recommendations indicated he did not appreciate the important role of a specialist service in the spectrum of care.

The Counsellor noted in response to the provisional opinion that he did include in his report the client’s expectations and a discharge plan, and thus it should have been apparent that Mr Burton was unwilling to address his alcohol and drug problem. This was not accepted as sufficient
reason: the Commissioner concluded that it represented poor practice to the extent that other members of the clinical team were denied the opportunity to gain a more in-depth insight from the specialised assessment.

Management and leadership

There were three people who had the primary management and leadership responsibilities for Southland DHB’s Mental Health Services: the Clinical Director; the Patient Services Manager; and the Team Leader. According to the Inquiry, they each failed to fulfil their statutory responsibilities.

Clinical Director

The Clinical Director was Southland DHB’s senior psychiatrist, with line management responsibilities for all mental health services medical staff. He or she was expected to provide leadership, ensure clinical services were provided effectively, and facilitate the training and development of medical staff as appropriate. Inter alia, the Clinical Director was required to assess the performance of medical staff, establish and monitor clinical standards of practice (including peer review, clinical audit and quality assurance activities), and ensure that clinical notes were adequately maintained.

The inquiry team concluded the Clinical Director failed to provide adequate clinical leadership. He did not realise that the monitoring and reviewing the standards of practice of medical staff were required by his position description. Moreover, he failed precisely to define the roles and responsibilities of medical staff involved in the provision of mental health services.

His position description clearly assigned to him the responsibility for reviewing the MO’s performance and ensuring that he met recognised standards of clinical practice. However, he regarded the MO as a psychiatrist even though he had no specialist qualification and limited formal training in psychiatry. More importantly, he failed to specify the limits on the MO’s right to provide unsupervised care. The Clinical Director said that he thought it would be ‘ungentlemanly’ to review the MO’s standard of practice and that he was not aware of the necessity to be ‘looking over his shoulder’ or to be checking on him in any way. His assumption was that a qualified and responsible physician would bring his concerns to a colleague if he felt he was not managing.

In response to the Commissioner’s provisional opinion, the Clinical Director argued that the expert advisors seemed unable to distinguish between supervision and oversight and that “… what they seem to deem appropriate would be more accurately described as surveillance”. He stated that comments about the legal requirements for oversight not being met were incorrect and referred the Commissioner to the guidelines for general oversight published by the Medical Council of New Zealand.

The Commissioner concluded that there was indeed a difference between supervision and oversight, but neither oversight (as required by law) nor supervision had been undertaken by the Clinical Director in relation to the MO.

The Commissioner noted that the Clinical Director appeared to have no knowledge of what was in his position description. In defence of his employee, the Chief Executive Officer of Southland DHB argued that the Clinical Director’s “… lack of in-depth familiarity with a generic job description is both trivial and understandable”. The CEO argued further that it was sufficient for staff to be aware only of the general intent of their position descriptions, especially given that practices change over time. The Clinical Director had a moral obligation to address the clinical issues first, regardless of the scope of practice envisaged by his position description.
The Commissioner disputed this view. He noted that the Clinical Director had some key responsibilities in his position description of which he needed to have been aware in order to carry out his responsibilities. In particular, he ought to have been aware that monitoring and reviewing the standards of practice of medical staff was a critical duty.

The Clinical Director argued that complexity and overwork were major factors. The mental health services were seriously under resourced and there was a lack of experienced staff. The inquiry team accepted that there were extreme pressures, but concluded that the Clinical Director failed to take reasonable actions to ensure that the MO was operating within an appropriate scope of practice, and that he was adequately supervised.

**Patient Services Manager**

The Patient Services Manager was a member of Southland DHB’s senior management team and reported directly to the Chief Executive. Her main tasks were “… to develop, provide and monitor the delivery of high quality, patient focused, effective clinical services; develop a style of leadership, and management systems and processes, that reflect Southern Health’s values; and enable the people within mental health services to actively contribute to the continuous improvement of health services and their delivery.”

Her performance was judged to be satisfactory in most respects. However, she performed in an unsatisfactory way with regard to ensuring there were adequate staffing levels. For the most part, understaffing was a corporate error on the part of Southland DHB. However, the Patient Services Manager could have handled some matters more effectively. In particular, she should not have given so large a role to the part time Team Leader.

Nor should she have assigned a social worker who had no prior experience of mental health. She was responsible for his position description, and failed in her duty by not ensuring it specified knowledge of mental illness as a requirement, especially in view of the fact that the position description required him to work autonomously with patients with mental illness. Similarly, she should have seen that the Alcohol and Drug Services Counsellor had insufficient training and support to provide Mr Burton with services of an appropriate standard.

**Team Leader**

The Team Leader had overall responsibility for the management and leadership of the inpatient mental health unit. This included responsibility for the budget. It also included responsibility for aspects of the team’s clinical practice.

In particular, she was responsible for ensuring that policies and procedures were established and implemented, including ensuring that individual treatment and discharge plans were developed in consultation with patients, families, and other caregivers. The nursing staff, Recreation Coordinator, Social Worker and Occupational Therapist reported to the Team Leader. The medical staff did not. In spite of the wide range of responsibilities, she was only employed for 30 hours per week.

We note as an aside that the exclusion of medical staff from the requirement to report to the Team Leader might have been problematic in terms of ensuring cohesion. This aspect is not, however, raised in the Commissioner’s report.

The Commissioner concluded that, in general, the Team Leader ran a cohesive team with a high degree of loyalty and commitment to the work. Her management of the ward resulted in a relatively stable nursing workforce in the face of national mental health staff shortages.
However, aspects of her work were criticised. First, there was no evidence of a consistent method of allocation of primary nurses to patients. Nor were there reliable and permanent records of the assignments of a primary nurse. The Team Leader admitted there were weaknesses, most of which derived from existing practices when she took over the job. In particular, assignments were largely a matter decided by negotiation among groups of nurses. Inadequate rules were in place to cover problem areas, such as nurse absences on leave. Steps were being taken to overcome the problems.

Second, the inquiry team was critical of the Team Leader’s failure to ensure enrolled nurses were not given (or took) an inappropriate level of responsibility for planning, implementing and coordinating care. This was related to the issue of allocation of primary nurses. While the Commissioner accepted that the inadequate processes were already in place when the Team Leader was appointed, he considered there should have been time to address them before Mr Burton became a victim.

Third, the Team Leader was responsible for ensuring patients had clinically sound care plans that took account of the views of patients and their families. The hospital used a computerised care planning application. However, it was not useful for care planning in the mental health setting, and there were low levels of compliance among the nursing staff. The Commissioner accepted that the Team Leader was addressing the need for improved nursing care plans. However, he was critical of the fact that Mr Burton’s care plan was made by an enrolled nurse, and that it was never checked and updated or amended as necessary by a registered nurse.

Finally, the inquiry team concluded that the Team Leader failed to realise that nursing staff should be actively involved in the process of risk assessment, rather than simply following the doctor’s lead. The Commissioner considered it was a mistake to encourage or allow nurses to play a passive role.

**Corporate responsibility: Southland DHB**

The inquiry team concluded that the standards for the mental health service that were specified in position descriptions, policy statements, and procedural documentation were generally adequate. However, some staff were not aware of the standards. At best, they had only a general idea of their contents. In this and other ways, the standards were not satisfactorily implemented.

A widespread failure to follow the standards contributed to and facilitated mistakes by individual clinicians. As noted, the Commissioner concluded that the Team Leader and the Clinical Director did not exert sufficient leadership to ensure compliance. Moreover, the Patient Services Manager did not apply adequate processes to monitor compliance and its effects on the quality of clinical practice.

The inquiry team concluded that the inadequate performance of these and other staff responsible for the care of Mr Burton was a consequence of systemic weaknesses in the monitoring and control mechanisms in Southland DHB’s Mental Health Service. The concerned staff carried personal responsibilities for aspects of poor care, but they were also victims of inappropriate cultures.

The example was given of the maintenance of clinical records. The MO’s failure to keep adequate records was noted earlier. However, many of the other staff involved in Mr Burton’s care did not generate good records. The Commissioner referred to frequent use of the term ‘settled’ to describe Mr Burton’s mental state. He considered this term to have little meaning. “It conveys a sense that there were no behavioural problems observed, but gives no idea as to whether clinical phenomena such as delusions, hallucinations, or even negative symptoms of schizophrenia (such as anergia, amotivation, withdrawal) or of mood disorder were evident, or sought after and unable to be assessed. These details are the essential criteria against which clinical progress can be measured.”
In total, documentation of Mr Burton’s symptoms was so inadequate that “… an observer uninvolved in his care would not be able to determine accurately whether Burton was really ill in any way, or what progress he had made.”

Patient documentation was of poor quality in spite of several attempts to improve. In 1999, for example, Southland DHB introduced integrated clinical notes. All clinical records for a patient were required to be stored together to promote continuity of care throughout the mental health service. All members of the multidisciplinary team were required to document patient care, variances, progress and treatment in the integrated notes.

These requirements were not met in Mr Burton’s clinical records. For example, needs assessors kept their records separately in the social work department until the needs assessment was completed. Copies of incident forms were not kept in the clinical records.

The Mental Health Needs Assessor, Recreation Coordinator and the Alcohol and Drug Services Counsellor involved in Mr Burton’s care did not make any entries in Mr Burton’s clinical records – and did not realise they were expected to do so.

Southland DHB was considered to be responsible for several other hospital wide weaknesses. One was inadequate compliance with incident reporting rules. With respect to Mr Burton’s care, the Commissioner concluded there were at least two occasions on which an incident form should have been completed but was not. Where an incident was in fact reported, there was no evidence to show it was investigated in accordance with the rules.

Particular concern was expressed by the Commissioner regarding weekly team reviews, which provided the only opportunity for clinical staff to review the practice of colleagues and to offer support and guidance. The documentation from the reviews undertaken in relation to Mr Burton suggested that significant information was not discussed – such as his persisting psychotic symptoms, various incidents that occurred during his inpatient care, and the possible use of compulsory assessment and treatment.

Another hospital wide weakness concerned the roles and functions of the clinical directors. The Commissioner argued that clinicians who are given responsibilities such as those that applied at Southland DHB must be given training and the time and support to develop their skills. In the case of mental health services, this was not the case. For example, there was no reduction in the Clinical Director’s clinical workload when he was appointed as Clinical Director. The General Manager of Hospital Services at Southland DHB admitted there was no formal guidance or direction given to clinical directors about how to manage, including how to set their priorities.

Indeed, Southland DHB had allowed the view to be formed that clinical leadership should take a back seat relative to the provision of clinical care. It appeared that no consideration was given to the possibility that a focus on the immediate care of individual patients might mean they (and future patients) might suffer from unresolved systemic problems. At least, managers of all types seem to have been reluctant to face this dilemma.

Several references are made to failures to communicate and collaborate. For example, it is noted that the Patient Services Manager wanted to work in partnership with the Clinical Director, and initially said that she felt she did. However, she subsequently admitted that the relationship to one of ‘cooperative endeavour’. The evidence showed that the Patient Services Manager and the Clinical Director did not in fact always work together effectively. The Commissioner noted that “…a successful partnership requires a willingness to build a partnership on both sides based on common goals, and a commitment to clinical and financial accountability and to better
health outcomes for patients. Developing a partnership between clinical leaders and management is a key factor in building a quality culture within the New Zealand health system (Malcolm and Wright 2002).".

Many other examples of poor team work were provided. The Patient Services Manager considered that the Clinical Director had an important role in the monitoring of standards but this view was not shared by the Clinical Director. They identified different training priorities for the service, and there was no evidence to suggest they had discussed training issues. They agreed to disagree on such matters as internal clinical review and incident reporting.

In total, the Commissioner concluded that Southland DHB’s Mental Health Service was poorly managed. There were so many organisational shortcomings that quality of care for mental health patients was inevitably compromised. The risk of adverse events was not managed effectively. Southland DHB must accept corporate responsibility for this state of affairs.

8.4 Recommendations of the Inquiry

The Commissioner gave precedence to a simple corrective measure: letters of apology, signed by the Clinical Director, the MO, the Patient Services Manager, the Team Leader, Staff Nurse A, the Mental Health Needs Assessor, Social Worker A, and the Alcohol and Drug Services Counsellor should be dispatched to Mr Burton and to his family. Southland DHB should also offer letters of apology.

The remainder of the recommendations fall under eight main headings. First, the two doctors whose performance was most criticised (the MO and the Clinical Director) should have their competence reviewed by the Medical Council of New Zealand.

Second, self assessment was called for. All the staff whose performance was reviewed and criticised were asked to review their own practices in light of this report.

Third, Southland DHB was advised to review and improve the performance of those health care professionals whose performance was deficient. For example, the training and supervisory needs of the Clinical Director and the Patient Services Manager should be addressed. Performance criteria for the Team Leader’s practice should be defined. The qualifications, skills and experience of the Mental Health Needs Assessor should be reviewed. The competence of the Social Worker and the Alcohol and Drug Services Counsellor should be assessed.

Fourth, Southland DHB was advised to take a large number of specific actions to address the underlying causes of poor care. They can be taken from the conclusions summarised above.

Of particular importance, the hospital should develop internal audit and monitoring processes directed at compliance with policies and procedure documents. Immediate attention should be given to patient assessment, patient record and documentation, incident reporting, risk assessment and management, quality care and treatment, discharge, supervision, and family and carer participation. This should include the review of policy and procedure implementation mechanisms to ensure adequate attention to these documents in orientation of new staff.

Fifth, attention should be given to developing a culture of continuous quality improvement. This should include establishing a culture of critical appraisal and reflection by all inpatient staff and by senior medical staff. The initial priority should be to review the impact of changes in inpatient team weekly review processes (attendance and active participation of all senior medical staff, presentation of cases, documentation of outcomes, communication of decisions).
Sixth, efforts should be made to improve nursing standards for mental health nursing. This should include the identification of specific skills that need to be improved.

Seventh, staffing structures and employment conditions should be reviewed. This should include consideration of the establishment of processes to provide professional support for nurses, a comprehensive mental health nursing clinical career pathway, and an improved model of nursing assignment to patients.

Finally, steps should be taken to improve communication and coordination. This should include better integration of support services such as needs assessment and drug and alcohol services.

8.4.1 General recommendations of Dr Taumoepaeu’s clinical audit

We noted earlier that Dr Taumoepaeu’s report presented an almost identical picture of the quality of Mr Burton’s care to that presented by the Commissioner. However, she made more general recommendations about care processes. These are summarised below.

First, the minimum requirement is that each patient must have a full mental status examination recorded at admission and a full review of that mental status examination close to the time of discharge. This is primarily the responsibility of the medical staff. The alcohol and drug history taken by the medical staff in the mental health services should be detailed, regardless of whether or not the patient will subsequently be referred to the drug and alcohol services.

Second, the medical staff must outline at least the basic treatment plan and ensure which individuals will carry out that plan. This must occur immediately after assessment.

Third, documentation should be improved. Documentation must be completed on admission and discharge and at other key times (such as when there is a marked change in the patient’s situation or referral to a different part of the service).

Fourth, the inpatient weekly review form is inadequate in that it does not assist staff in assessing treatment goals and tasks to be undertaken. The review report form is better and could be adapted for both inpatient and outpatient use. It should include such issues as barriers to discharge, and indicate tasks to be undertaken, by whom and in what time frame. If the patient is being reviewed as an inpatient on a weekly basis the form should be sent as a matter of course to the patient’s community team.

Fifth, it is the responsibility of medical staff to ensure they adequately read the notes when they review a patient. However, there should also be a process whereby staff of other clinical professions (and especially nursing staff) can highlight patients of concern who need review by the medical staff.

Sixth, incident reports should be filed in the clinical notes in chronological order alongside progress notes. Staff should be clear about the threshold for filing in an incident report and there should be a list available to staff as to which incidents require a report to be written. A note of the incidents should be included in the weekly review.

Seventh, medical officers need to have formal and regular supervision by a consultant psychiatrist. The Terms of Reference of supervision should be recorded and should include frequency, length of supervision sessions and content. The content should include a requirement for the medical officer to present all new patients to the psychiatrist and to follow up on recommendations made by the psychiatrist. In other words, the medical officer should be treated as a registrar in terms of supervision and accountability.
Eighth, training should be provided in certain areas including risk assessment and mental status examination. Competencies should be identified if these are not already in place for all disciplines. There should be regular training sessions for the multidisciplinary team, and all multidisciplinary team members should be encouraged to present at those sessions. Medical staff should be required to attend peer review and clinical review educational sessions.

8.5 Discussion

While the Southland Inquiry is distinguishable, amongst the other inquiries in this report, in dealing with a single incident, the process, findings and outcomes of this inquiry are remarkably similar to those other inquiries. As with other inquiries, additional investigations were also conducted. The Commissioner’s expert panel produced a separate report, which is outlined in section 8.6 below. A coronial investigation into the death of the client’s mother was also held.

The Southland Inquiry painstakingly sifted through the roles, responsibilities and failures of each of the clinicians and managers involved in the case. Its ultimate finding was that the incident involved arose from a combination of individual and broader systems factors, rather than a single cause. The Commissioner was careful to ensure that this conclusion did not result in a dilution of responsibility for what occurred. Indeed he argued that both individual and corporate responsibility needed to be taken for the death of Mrs Burton, and the impact on the Burton family as a whole. To this end, and unlike other inquiries in this instance, the Commissioner ordered all the staff involved, and the Board, to write formal letters of apology to the family.

In the aftermath of the Inquiry, the Health and Disability Commissioner’s Office issued disciplinary proceedings against three registered health professionals involved in the case. Disciplinary charges were filed before the Medical Practitioners Disciplinary Tribunal against the Medical Officer and the Clinical Director of the service. In 2003 the MO was found guilty of 17 charges of professional misconduct. He was banned from practising medicine for six months, and received a fine. A disciplinary charge was also filed with the Nursing Council against one of the staff nurses (identified as ‘A’ in the Inquiry). The coronial inquiry found that Mark Burton should not have been released. It did not, however, single out clinicians for comment, referring rather to the shortage of psychiatrists and the need for better staff training.

8.6 Footnote

8.6.1 The Review Panel’s report

The Commissioner’s expert group (the review panel, RP) produced a separate report in 2002. This is appended to the inquiry report. For the most part, it is identical in content to the main body of the Commissioner’s report. However, there is one element that is discussed in greater detail and given greater emphasis – the idea of quality improvement. The RP also used the terms total quality management and continuous quality improvement as if they had identical meanings.

The RP noted that quality improvement was the theme of a report commissioned in 1992 by the Canterbury Area Health Board (Bonner et al 1992). The RP argued that the framework presented in the report applied as much now as it did then. The authors’ framework for good quality care comprised optimal outcomes, minimal risks to patients, clients and staff, patient satisfaction and the efficient use of resources.
According to the RP, "... total quality management seeks continuous improvement, involving everyone with an emphasis on quality in all processes. The role of management is to provide leadership, communicate a clear vision, and provide the support and education to create the required cultural change within the organisation. Teams should be empowered to continuously improve the process and build quality into the system."

The Ministry of Health had incorporated these ideas into its 1997 publication titled ‘National Mental Health Standards’. One of the themes was that mental health service organisations should "... promote continuous quality improvement" in order to "... ensure that services offer the highest level of care to those who use these services. They thus provide some useful direction for clinical and operational leaders within an organisation."

Southland DHB had taken some steps to incorporate standards into its mental health services operating rules and guidelines. The RP concluded that those rules and guidelines had been well designed and subsequently subjected to regular review and updating to take account of changes in practice standards and recommendations from incident reviews.

The main problem, according to the RP, was that many of the rules and guidelines had simply not been put into practice in day to day care provision. There were deficiencies in terms of both the establishment of a culture of quality improvement, and in the processes of care that should have been the subject of continuous improvement.

Particular attention was given to deficits in leadership at the level of the hospital and at the level of the mental health services team. The deficits included a lack of mutual understanding, ineffective communication, and failure to establish forums in which problems could be openly discussed.

The RP noted several symptoms of these problems. For example, "... the Clinical Director reported that he does not find a specified reporting relationship to the organisation’s medical advisors to be useful, and he largely does not use it.” The General Manager simply accepted standards of practice were satisfactory "... without evidence of clear systems for review of performance for medical staff.”

Individuals raised concerns. But there was seldom any willingness to have them discussed in team meetings.

For example, one member of the team noted a change in Mr Burton’s behaviour that might have been due to alcohol use and was concerned to document it but "... there appears to have been no follow up by other staff.” The Mental Health Needs Assessor noticed a change in Burton. "She was concerned enough to discuss it with the nurse present at the time, but the nurse made no record of this.” Social Worker A, when conducting the drug and alcohol assessment, obtained information not gathered by any member of the inpatient team. He documented this but the team overlooked it. Finally, a new graduate nurse was concerned that Mr Burton had contacted his father and was expressing paranoid ideas. She felt that the concerns in the letter had to be taken seriously, but they were not.
8.7 References and selected bibliography


9 Winnipeg Health Sciences Centre, Canada

This section concerns care that was provided at the Winnipeg Health Sciences Centre (the Centre) in 1994. Twelve children died between 14 March and 21 December during or shortly after having undergone cardiac surgery at the Centre. There was a high degree of concern in the mass media, mainly as a consequence of actions by the parents of the children who died.

The Inquest that was subsequently conducted found that care had been seriously deficient. The following is taken mainly from the Inquest Report.
9.1 Context

The Centre had been operating a small but apparently satisfactory paediatric cardiac surgery program (the Program) for several years. However, it was suspended for a short time in 1993 due to the loss of key staff including three cardiologists.

In early 1994, the Program was reactivated following the recruitment of a new surgeon (Dr Odim) as head of the team, and a new director of paediatric cardiology. Concerns were expressed at the time as to whether the restart was premature, but there were some centre wide financial pressures that may have influenced the decision. The Inquest was later to conclude that there were significant problems including inadequate recruitment processes that failed to take account of a lack of experience among the new recruits, and unclear lines of authority. In total, the inquiry team was to conclude that “… the Program continually undertook cases that were beyond the skill and experience of the surgeon and the team.”

Child deaths in 1994

Inadequately explained deaths began to occur almost immediately after the Program was reactivated. The first of 12 deaths occurred on 15 March 1994 and the last on 21 December 1994 – after which the Program’s operation was suspended. Moreover, there was a variety of other events including unusually high levels of post-operative complications that gave rise to concern. Only the deaths were subsequently subjected to rigorous investigation.

The Inquest was to conclude that, of the 12 deaths, five were preventable and four were possibly preventable. The evidence was insufficient to reach a conclusion on two deaths, and one was judged not to have been preventable. The youngest child was two days of age, and the oldest child was just over four years of age.

Concerns inside the Centre

Two groups of staff were concerned about the performance of the new surgeon almost immediately after he began work. Nurses (and particularly those in operating rooms and intensive care units) made a variety of attempts to intervene, but were largely ignored as described below.

Perhaps more important in some respects, anaesthetists began to express concerns. In May 1994 (following the death of the fifth of the 12 children), the members of the Section of Paediatric Cardiac Anaesthesia unanimously agreed to refuse to participate in any further paediatric open-heart cases until a review had been undertaken. It is a rare event in most health systems for any doctor to express formal concerns about another doctor, and the fact that there was concerted action by the anaesthetists should have been an event that no one could reasonably ignore.

Formal internal and external reviews

The reaction of the Centre was to do only what was necessary to reduce the level of concern. The anaesthetists’ minimum demands were accepted: an internal review committee would be appointed and the Program would restrict itself to low risk cases during the review period. Cases that could not await the outcome of the review were therefore transferred to paediatric cardiac surgical facilities in other provinces. However, during this period of reduced services, two more children died following surgery at the Centre.
In spite of the evidence that was subsequently shown to be overwhelming, the review committee concluded the problems were a normal consequence of having a relatively new team, and that the team had resolved the causes. It therefore recommended that the Program return to full service in September 1994. From that point until 21 December 1994, five more children died.

After the death of the twelfth child, the Centre determined that no further paediatric cardiac patients be referred for surgery to the Paediatric Cardiac Surgical Program until a review could be completed by an external team. The team presented its report to the Centre in early February 1995. It expressed serious concerns that needed to be addressed and advised that the Centre should suspend the Program for a further six months.

A relatively neutral press release was issued as a compromise between the review team and the Centre’s management. It might not have resulted in any significant public interest if it had not stimulated some of the parents into action. They might have been less angry if there had been any kind of admission of possible error on the part of the Centre, or even a sympathetic expression of regret. As it was, the parents had been treated poorly (involving little more than statements that ‘surgery is always risky’ and ‘the Centre has an enviable reputation’) and were determined to be heard. With the assistance of the mass media, they mounted a high profile campaign for a public inquiry – and more or less achieved what they demanded.

9.2 The Inquiry


On 5 March 1995, the Chief Medical Examiner for the Province of Manitoba ordered an Inquest into the deaths of the 12 children. He directed that one Inquest be convened to investigate all the 1994 deaths. The Minister of Justice declined to appoint a public inquiry, indicating that the matter might be reconsidered once the Inquest had reported.

Inquests in Manitoba are governed by statute, and to a certain extent by common law. They are presided over by judges of the Provincial Court of Manitoba. Their primary role is to determine the identity of the deceased, the facts surrounding the death, how the deceased came to die, and whether the death was preventable. Additionally, an Inquest is mandated to inquire into whether any of the policies or programs of an institution or government should be changed in order to prevent a repeat of such a death.

The Inquest commenced hearings in December 1995 and completed them in September 1998. Its final report was issued nearly four years after the decision was announced to undertake the Inquest. Some 83 witnesses testified during more than 285 days of hearings. Nearly 50,000 pages of transcript evidence were produced, and 10,000 pages of material were filed as exhibits in these proceedings. The volume of evidence was similar to the combined total for the two main Inquiries over Bristol, and far exceeded the volumes of the Macarthur Health Service and Celje Inquiries.

9.2.2 Conclusions of the Inquiry

The Judge said in his preamble that each child had died under different circumstances, but there were common causes for the most part. This led him to the general conclusion that a combination of many serious organisational and personnel problems experienced by the Centre’s Paediatric Cardiac Surgery Program during 1993 and 1994 had contributed to the deaths of most of the children. In short, the Program “… did not provide the standard of health care that it was mandated to provide and which parents believed, and had a right to expect, that their children would receive.”
The central finding: systemic problems leading to poor care

It was concluded that some of the problems that the Program faced related to the abilities and conduct of specific individuals. However, the more important conclusion was that most of the problems “… were largely systemic in nature.” They related to the structure of the Centre and, in particular, to hospital policies and procedures governing staffing, leadership, team work, communication, decision making and quality assurance. “Weaknesses in all of these areas led to problems in the procedures and outcomes of the program. As a further result of systemic failures, the issues surrounding the abilities and conduct of certain team members, and the performance of the surgical team itself, were not dealt with in a timely or effective manner.”

Replacement of Program staff

The evidence suggests that the loss of and failure to replace professional medical staff meant that the Centre could not continue to provide the level of service that it had previously provided. The impact on the Program of the loss of medical staff was not appreciated by the heads of the responsible departments.

The Centre’s process of recruitment of new staff was flawed in many ways. First, those responsible for staff replacements in 1993 and 1994 were slow to begin the process of recruitment, took too long to find capable replacements once they did begin, relied on inadequate professional staff recruitment processes, and failed to take appropriate steps to address case load and other Program issues when positions were left vacant for extended periods of time.

Second, there was confusion as to who was on the formal search committee established to find replacements. Several senior staff claimed they believed others were responsible.

Third, there were no documents establishing a formal search committee, no minutes were kept of any formal committee meetings, and no criteria existed for the candidates that were sought. There were no formal ratings of candidates against specific criteria.

Fourth, no serious attempts were made to assess the competence of candidates in an objective way. In the case of the new surgical team leader, Dr Odim, the Centre relied almost exclusively on his curriculum vitae and brief and informal interviews. No one at the Centre actually saw him perform a surgical procedure or spoke with anyone at his previous place of employment (and where he had most recently trained). The assessment of Dr Odim’s operating room skills appears to have been made largely on the basis of what he told them, where he had trained, what his curriculum vitae stated, and comments from people who had not observed him in surgery or had had no involvement with him for three years or more. No consideration was given to assessing his ability to develop and work with a surgical team like that at the Centre.

The Inquest Report emphasised the importance of surgical ability. “It seems logical to think that when hiring a surgeon, one of the most important areas to investigate is that of the individual’s surgical skills and ability. One can properly assume that any trained surgeon has been certified as being capable of performing the surgical procedures associated with the field of specialty for which he or she is being hired. However, such certification does not provide information on the level of skill and ability that the person brings to the position. That can best be determined by observing the candidate while he or she actually performs surgery and by interviewing those who have recently observed the candidate in surgery and have the capabilities themselves to make judgements about the level of skill of the candidate. Those at the Centre responsible for recruiting Dr Odim did none of those things.”
It was further pointed out that, had the Centre consulted with the surgeon who had supervised Dr Odim during his most recent medical training, they would have learned from him that Dr Odim was not ready for the position he undertook at the Centre. The Inquest team believed this should have led to reconsideration of his suitability. At least, the Centre would have been able “...to put into place measures to monitor and assist Odim, as well as ensure that his lack of experience and need for assistance in some technical areas did not compromise patient care.”

Unclear lines of authority

The Inquest established that the ultimate responsibility for paediatric cardiac surgery at the Centre was jointly held by the heads of the Departments of Surgery and Paediatrics. The responsibility of the two departmental heads was in fact demonstrated when it was necessary to obtain their joint agreement to a reduction in services in May 1994 and a suspension of the services in December 2004.

However, the lines of authority and consequently the responsibility were unclear and confusing to virtually all Centre staff during 1994. The confusion was in part due to the fact that the Paediatric Cardiac Surgery Program was multidisciplinary in that it required clinicians from a variety of departments (nursing, perfusion, surgery, cardiology, anaesthesia, paediatrics, intensive care, neonatology and pathology) to work together. Thus there were many opportunities to claim someone else was in charge. Moreover, the distinction was unclear between responsibility for services and responsibility for the work of specific clinicians. This was the case with regard to determining who was responsible for monitoring the performance of the surgeon.

The problems were exacerbated by previous (and largely ad hoc) arrangements regarding supervision. For example, the medical director of the Centre had provided day to day management and monitoring of the surgical aspects of the Program. This was despite the fact that the surgeon was formally responsible to the section head of Cardiovascular Thoracic Surgery. In addition, many Centre staff believed that the head of Paediatric Surgery had some responsibility for monitoring the Paediatric Cardiac Surgery Program by virtue of his title. He did, in fact, have very little such authority. The confusion was compounded with the recruitment of new staff who were seldom told precisely about their responsibilities. One new member of staff was assumed to have taken over the responsibilities for monitoring surgical outcomes of his predecessor but was in fact never asked to do this.

The Inquest recommended that any future program must have clear written lines of authority and responsibility. Efforts must be made to ensure that program members understand these lines of authority. This is of particular importance in a multidisciplinary program.

Individuals’ responsibilities

Two of the doctors – the head of the surgical team (Dr Odim) and the acting medical director (Dr Giddins) were concluded to have failed in their duties with regard to monitoring and responding suitably to the poor surgical results in the Program.

In addition, Dr Odim failed to be honest about his experience, attempted procedures that were not supported by the evidence, and failed to listen to and take note of advice from other members of the surgical team. Dr Giddins not only referred patients to Dr Odim but also reassured parents of those patients that Dr Odim was capable of performing any and all of the procedures required for his patients. Therefore he had a responsibility to ensure that the assurances he was giving were justified.
Misusing the concept of the ‘learning curve’

The evidence suggests that poor performance was recognised and then justified on the grounds that all surgeons must go through a learning process. No action was considered necessary because Dr Odim was on a learning curve that would ensure better performance in future.

The Inquest conceded that there are learning curves in surgery. However, this should have been recognised by providing additional supervision at the start rather than used as an excuse for poor care or optimism unfounded in performance monitoring. The Inquest was particularly critical of the tendency on the part of some staff of the Centre to justify inaction on the grounds that there had been ‘similar results’ at the start of Dr Odim’s predecessor: that there had been a sharp learning curve before and therefore it could be expected again.

The Inquest stressed the need to take three steps before the start up of the Program in 1994. First, an effort should have been made to ensure an experienced person was in a position of authority in the Program to provide guidance. Second, those in charge of the Program ought to have been careful to ensure that the new surgeon and the restarted Program were closely monitored at least throughout the first year. Third, initial patient selection ought to have been restricted to those cases that promised the best results while individual and team experience was gained.

The evidence suggests that these steps were not taken. It was clear that “… those in charge of the Program acted on the basis that poor surgical results would simply improve over time. That was simply not appropriate.”

Management and supervision

The heads of the Departments of Paediatrics and Surgery failed to manage staffing matters adequately. They did not address the underlying issues that led to the departure of previous staff, but rather simply replaced them with less experienced staff. This was in spite of the fact that the departing staff had repeatedly complained of a lack of support from the Centre, and the consequent inadequate standards of the work being undertaken.

It was accepted that the departmental heads might have distracted to some extent by budgetary and administrative changes undertaken at the Centre during 1993-1994. However, if this were true it should have been recognised, and the departmental heads should consequently have considered delaying the Program’s restart.

The departmental heads were also judged to have failed to ensure there was a proper orientation for the new staff. Nor did they ensure there was either formal or informal mentoring of new staff. “In the case of a young surgeon in his first appointment following his residency, more careful consideration ought to have been given to the fact that he was facing an entirely different experience from what he had faced as a surgical resident.”

Inadequate attention was paid to building and mentoring the Paediatric Cardiac Surgery team as a whole. Without leadership, the problems that arose in the early operations rapidly led to unresolved – and in the end unresolvable – conflicts. The operating room and ICU staff were not properly prepared for Dr Odim’s particular approach to surgery and post-operative care, while Dr Odim often made assumptions based on his limited experience at other institutions. This led to increased friction and mistrust.
The lack of supervision meant that the Program was characterised by poor case selection in 1994. The Program undertook cases that were beyond the skill and experience of the surgeon and the team.

**Poor team work**

The Inquest concluded that poor team work was a feature of much of the Centre’s operations. The two doctors most involved, Dr Odim and Dr Giddins, were both responsible for a portion of the poor team work. The report said that they “… did not take appropriate steps to establish and maintain open and ongoing lines of communication with other related medical services in the hospital, such as nursing and anaesthesia.”

Dr Odim was particularly at fault. He used techniques and approaches with which other team members were not familiar and for which the surgeon did not prepare them. He erroneously assumed that everyone knew what he was talking about. In some cases, there was a lack of consultation and briefing before the team undertook complicated procedures. One example was Norwood procedures, where Dr Odim failed to give sufficient advice to the neonatal intensive care unit.

Among their recommendations, the Inquest team emphasised the need for protocols to be developed that involved all involved clinicians. They should specifically address the needs of new or temporary staff. The purposes should be both provision of information, and building the trust and the open communication on which all teams depend.

In an addendum, the Report provides more details about team building processes. In the specific context of surgery, a description is provided of processes that must include all players. There should be pre-operative briefing sessions that focus on the plan for the operation, and discussion of contingencies.

There should be more use of standard operating procedures, the development of leadership skills, the provision for team development and maintenance processes that emphasise team communication, clarity in the decision making process, a process of conflict resolution, post-operative debriefing sessions for all operations regardless of outcomes, and a stress management component.

Emphasis is given to training that focuses on the development of behavioural strategies to manage error. It should be specifically designed to decrease or reduce the probability of errors occurring, correct errors before they have an impact, and contain or decrease the severity of the consequences of those errors that have been made.

Teams should learn to address day to day issues, and particularly those relating to communication and decision making that arise between different members of the team (such as between doctor and nurse or surgeon and anaesthetist). There should be training in crisis management that includes the use of simulations of critical incidents, in order to provide participants with predetermined responses.

It is noted, however, that health workers not only need to learn how to work together during crises. It is more important to work as a team under normal circumstances, when nothing goes wrong. Teams that normally work well together will probably make fewer errors and encounter fewer problems. When serious problems arise, the team will have already dealt with any interpersonal and organisational difficulties.

Training to manage error must be included in the earliest training of doctors, nurses and other health care workers. If this is not the case, it will continue to be difficult to move from doctor-dominated to team-based care. To be effective, the value of quality assurance, risk management and team
performance must become embedded in the culture of each health care organisation. This will require active promotion by senior staff responsible for training and evaluation, and they themselves will consequently need additional training. No matter how training is delivered, it must be an ongoing process: repetition and reinforcement are vital if the desired outcomes are to be achieved. There must be continuing programs, both formal and informal.

Finally, the Inquest stressed that team work is the key to improvement, and that the focus must be on changing the culture of health care organisations. It is particularly important that medical professionals deal in more appropriate ways with patients and their families, and that doctors and lay managers “… should cease to treat nurses as under-trained subordinates whose concerns can be readily dismissed as emotional responses to tragic outcomes.”

Inappropriate staffing levels

It was noted that all small surgical units like that at the Centre are likely to have problems of staffing from time to time. This is yet another reason for avoiding low volume procedures where there are significant complexities. A balance has to be struck between excessive workloads, and ensuring each team member is involved in a sufficient number of cases to maintain an appropriate skill level. Steps should therefore have been taken to limit the number of patients and select the mix more carefully.

The departmental heads responsible for the Program failed fully to recognise the implications of only one cardiologist being at the Centre for most of 1994. Another error was creating the situation where there was only one surgeon who was on constant call. Staff shortages in the Department of Pathology also contributed to the fact that autopsy reports were not completed in a timely manner.

The evidence suggested that an appropriate balance had not been struck between the number of anaesthetists providing anaesthetic care to the Program and the number of cases in which each anaesthetist participated. Put another way, too many different anaesthetists were involved given the low total volume. The need to have enough cases to develop and maintain skill levels is the same for an anaesthetist as for a surgeon. The Inquest recommended several obvious steps that needed to be taken in future to ensure an adequate level and mix of staff at all times.

Poor treatment of nurses

It was concluded that, because nursing occupied a subservient position within the Centre, issues raised by nurses were not always treated appropriately. Throughout 1994, the experiences and observations of the nursing staff involved in the Program led them to voice serious and legitimate concerns. They made both informal complaints, and “… made proper and appropriate use of existing channels to voice their concerns.” For a variety of reasons, their concerns were not addressed. Indeed, the reception they were given led some nurses to silence themselves. It also left them frustrated and distraught, and many paid a heavy emotional price. By the time the Program ended, at least one nurse was on the verge of taking her concerns outside the Centre, at great risk to her position and career.

The nurses were never treated as full and equal members of the surgical program, despite the fact that this was the stated intent of the administrative changes that the Program underwent in June 1994. Intensive care unit nurses, for example, were never properly involved in the review team that assessed the Program during 1994, and nurses in general were not properly involved in the external review that preceded the Inquest.
One of the stated goals of the Centre’s reorganisation in 1994 was to strengthen the nurses’ roles. However, it implicitly devalued nurses: the reorganisation was actually driven by a concern to cut costs primarily by reducing staff, and the majority of the reductions were in nursing.

The concerns expressed by some of the cardiac surgical nurses were dismissed on the grounds that they reflected “… an inability to deal emotionally with the deaths of some of the patients.” Furthermore, any concerns over medical issues that the nurses expressed were rejected on the grounds that they did not have “… any proper basis, clearly stemming from the view that the nurses did not have the proper training and experience to hold or express such a view.”

In addition, while the Centre’s doctors had a representative on the Centre’s Board of Directors, nurses did not. This reflected the implication that the nurses “… lacked a vision of the larger picture”.

We note in passing that this is inconsistent with most of the available evidence. It suggests nurses tend to have much broader views of the patient in relation to family and community, and a greater appreciation of the need to see both the clinical and the financial dimensions of care.

The Inquest Report argued that the role of nurses has traditionally been subordinate to that of doctors. “While they are no longer explicitly told to be silent, it is clear that legitimate warnings and concerns raised by nurses were not always treated with the same respect or seriousness as those raised by doctors.” The attempted silencing of members of the nursing profession, and failure to accept their legitimate concerns, meant that serious problems were not recognised or addressed in a timely manner.

The Inquest made several recommendations. First, it was necessary to put in place structures that ensure that staff can make their concerns known without fear of reprisal. This applied particularly to nursing.

Second, the structure of the Centre should be adjusted to ensure that the position of nursing did not continue to be a subservient one. The Nursing Council of the Centre should contain members selected by the nurses themselves. It should have representation on the Centre’s governing body and be responsible for monitoring, evaluating, and making recommendations pertaining to the nursing care. It should also serve as a vehicle through which nurses could report incidents, issues, and concerns without risk of professional reprisal.

Third, the Centre should establish a clear policy on how staff should report concerns about risks for patients. This policy must ensure that there is no risk to the person who is making the report. It should be clear to every staff member to whom they are to present such reports. The Province of Manitoba should consider passing whistleblowing legislation to protect nurses and other professionals from reprisals stemming from their disclosure of information arising from a legitimately and reasonably held concern over the medical treatment of patients.

Poor treatment of the families

The most important problem for parents was that their children were given poor care as noted above. However, the Inquest noted other aspects in which they were treated poorly.

In particular, there were weaknesses in the process of informed consent. Parents were not as fully informed as they were entitled to be when asked to give consent to surgery on their children. Most witnesses accepted that patients and family members granting consent on behalf of a patient are entitled to know the risks before they give their consent to surgery. However, there was clear disagreement over the methods and content of information to be shared.
Several medical witnesses argued that declaring one’s medical experience is not a requirement for informed consent. On the other hand, most parents felt strongly that they should have been provided with more information about the Program and about the surgeon’s experience.

Many Centre staff seemed to believe it was sufficient to describe the surgeon as highly trained, or ‘one of the best’, and to state that the Centre’s program was ‘as capable as anywhere else’. They argued that it would have been inappropriate to tell the families that Dr Odim had not performed any of the procedures he proposed in 1994 without supervision. The Inquest said they were concerned as to the logic of doing the former while not feeling obligated to do the latter.

Some witnesses felt that the patient or parent is owed the truth if a question about previous experience is asked, but that a doctor can remain silent on the same point if the patient or parent does not ask. The Inquest argued that, while the obligation to tell the truth is obvious, it seems illogical that some would see the obligation to be truthful as not encompassing an obligation to disclose a relevant fact. While it might not be necessary to disclose a surgeon’s abundant experience at performing a particular procedure, a surgeon’s lack of experience is clearly a fact that is relevant to the question of whether or not someone would be willing to entrust his life, or the life of his or her child, to that surgeon. For that reason alone, such information ought to have been disclosed without prompting.

A related concern was that information provided about surgical risk was misleading. The risk factors that were cited to parents for the procedures undertaken by Dr Odim in 1994 were not based on the reality of the Centre’s situation at the time. In many cases the indications that were given to the parents were reflective of profession wide risk, rather than the level of risk for the procedure at the Centre.

Information such as the relative inexperience of the surgeon, and the fact that he would be performing the procedure in an unsupervised setting for the first time in his career, was not factored into the risk assessment shared with the families. This information should have been included when determining what to say to parents regarding the risk level associated with the operation on their child. The Inquest Report argued that all the available data clearly suggested a risk factor attached to a surgeon’s experience. The fact that it is clearly higher with inexperience ought to have been disclosed to the parents, along with an indication as to what was applicable with Dr Odim. The state of experience and level of functioning of the surgical team should also have also been taken into account.

Furthermore, all parents whose children underwent operations after 17 May 1994 should have been informed about the anaesthetists’ withdrawal of service on that date. Parents were entitled to be informed of the decision to perform only low risk procedures thereafter. They should also have been made aware of the external review and allowed to read its report. They should have been contacted and informed of the decision to suspend the Program in February 1995, before that decision was made public.

The Inquest recommended that the Department of Health of Manitoba should prepare and distribute widely a patients’ rights handbook that includes detailed advice on informed consent. The handbook should clearly indicate patients’ rights including those of being fully informed before giving consent to medical treatment, of a surgeon’s experience in performing a particular procedure (and the experience of the Centre and the surgical team), a second opinion, and out of province referral in certain circumstances.
The Centre was further advised to review all its policies on communication with families. There should be a requirement for medical staff to be forthright and truthful in disclosing all relevant information to the patient or representative before the procedure in question.

Inadequate support for the families’ legal costs

The families involved in the Inquest experienced serious problems in meeting the costs associated with having legal counsel. All families had good reasons to participate in the proceedings but its length meant that the less wealthy could not afford to do so.

The Inquest team argued that the families were entitled to have all their legal costs paid. In the event, some families obtained reimbursement from the government. However, it was unfair for families to have to take steps to persuade the government to provide them with financial assistance for legal costs on a case by case basis. Families that were best able to develop and marshal private or public support stood in a potentially more favourable position than did those whose political contacts or influence were less. The Report consequently recommended that the government should establish a policy for the routine payment for counsel for families granted standing at inquests.

Monitoring within the Centre

The formal and informal monitoring of issues at the Centre failed to identify the problems with the Paediatric Cardiac Surgery Program in a timely fashion. As noted elsewhere, the responsible departmental heads, the cardiologist and the surgeon did not adequately monitor surgical performance either on a case by case or collective basis. Nor did these doctors appreciate the significance of the poor level of communication and the poor interpersonal relationships between the surgeon and others. The departmental heads were also slow to respond effectively to concerns that were raised by program staff.

Like many other managers, they ignored pertinent information that was brought to their attention and, at best, simply tolerated the bearers of bad news. The responsibility for dealing with this information was never clearly delineated.

There was no tracking of common indicators that might point to matters of concern, such as the duration of cardiopulmonary bypass times, the duration of total circulatory arrest times, the volume of blood loss, the number of units of blood and blood components transfused. There were no plans to develop such a database at the time that the Program was suspended. Nor was there any attempt to collect data from the Program and compare the results of the Centre’s program with any others, as one basis for evaluation of the Program’s performance.

There was no debriefing setting in which members of the surgical team could debate and discuss pre-operative issues, intra-operative care (including surgical procedures and post-operative care) and outcomes. Routine rounds were mentioned as a possible setting for such discussions, but they were clearly intended as teaching and learning opportunities for staff in the Centre generally and were open to individuals not involved in the case, such as medical students. The rounds were not intended as a forum for a full and frank discussion of the details of each procedure. In the medical culture of the time, the rounds did not provide an appropriate forum for discussion of related concerns, such as communication between various clinical professions.

The medical culture of the Centre reflected the concept of the surgeon as the supreme and infallible captain of the ship. This meant that what should have been the collective concern about the team’s ability to handle certain cases turned into highly charged conflicts centring on the surgeon. Once framed in that manner, it became difficult to have open discussions or successfully resolve the issues.
Despite formal policies, the use of incident reports was not an engrained element of the Centre's culture. Centre staff observed many serious and alarming events in 1994. Indeed, many staff members began keeping private accounts of these events. However, only one incident report was filed for the cases under review during the entire year.

Problems and complications during operations were often not charted, recorded or reported to the Standards Committee. The Committee structure was simply not capable of addressing and evaluating important questions in a timely fashion. The process did not, in most instances, begin to review a death until an autopsy had been completed.

Finally, Dr Odim's membership on the panel of surgeons that reviewed each surgical death for the Centre had the potential for a serious conflict of interest. This was yet another manifestation of a 'club culture' where members should never be questioned and non members had no standing at all.

**Monitoring outside the Centre**

In Manitoba, the Office of the Chief Medical Examiner (CME) has a primary responsibility for investigation of patient harm. It failed to identify the problems with the Program, mainly because of over reliance on information provided by the surgeon alone.

In most cases, the CME investigation team waited for the final autopsy report – which was not available to the CME in a timely manner. It did not track surgical deaths by program, and consequently was unable to identify trends in the Program.

Moreover, many relevant matters were never communicated to the CME – such as the anaesthetists' withdrawal of service. In most cases, the CME simply read the medical records and spoke with the surgeon concerned. Even a cursory discussion with the nurses and the anaesthetists would have revealed significant underlying concerns.

In the autopsies, over reliance was placed on the information that was obtained from the surgeon. The Inquest Report argued that, since information as to what happened during surgery is vital to the conclusions to be drawn by the pathologist, a greater attempt must be made to gather such information from as many of the people involved in the proceeding as possible. To rely exclusively on the one party who might be most responsible for the fatal outcome seemed unwise. It was also inappropriate to have the autopsies in CME cases involving surgical deaths performed by the staff of the Centre in which the operation took place. The better practice would be to have autopsies in CME cases performed by a pathologist not affiliated with the Centre in order to overcome any appearance of a potential conflict of interest.

The Inquest Report recommended many changes in the methods of operation of the CME Office. They included development of a protocol requiring hospitals to inform it of significant changes in the delivery of medical services, maintenance of a database of hospital deaths to track in hospital deaths and causes of death on a weekly and monthly basis, and the conduct of interviews of nursing and medical staff involved in the patient's care.

**9.3 Recommendations of the Inquiry**

Overall, the Inquest made 36 recommendations pertaining to key areas of the Centre's operations. The recommendations relate to: the loss and recruitment of staff; unclear lines of authority; the misuse of the concept of a 'learning curve'; in appropriate staffing levels; the treatment of nurses and of families; monitoring of issues and problems; human and medical error; and the future of Pediatric Cardiac Surgery in Manitoba.
Most of the Inquest's recommendations were addressed, in situ, in the previous sections. The issue of how health services can respond to human and medical error is taken up in the discussion section below.

9.4 Discussion

This final inquiry reflects many of the same concerns, and indeed the same patient group, as the first inquiry, Bristol, reviewed in this monograph. The similarity does not end with the type of operation, or the risk factors involved. In both Manitoba and Bristol (and many of the other inquiries considered) the length of time during which concerns were raised within the hospital, the combination of internal and external formal and informal reviews, along with the outside pressure of families and the role of the media in pushing for a formal inquiry, all form a familiar pattern.

In discussing the Manitoba Inquiry, we would like to consider in detail the implications of the section of the Inquest Report which contains a detailed review of the management of errors. Reflection on the cause and management of errors is a fundamental thread in all the inquiries reviewed. The section in the Manitoba report appears as a consequence of the general rules on inquests. Judges are required to assess responsibility but are not allowed to make final decisions on culpability. They have no choice but to determine if changes are needed in the way that institutions and organisations go about their activities, so as to prevent such deaths from recurring.

Much of the text of the Report is adapted from standard sources of error management, and therefore only a brief summary is needed here. Firstly it is noted, the health care system, like many other systems, is driven largely by humans, and humans make errors of many kinds: in the design and construction of a system; the design and construction of technologies used in the system; the maintenance of technologies; planning and execution; and so on.

Error is a human reality. It is appropriate to strive to reduce the frequency at which errors are made, but unrealistic to believe they can be eliminated. It is impossible to design a system that is error free, and unwise to assume everyone will follow the rules.

It is therefore necessary to manage error from the start, and this can involve two main types of approaches. First, we can seek to identify the person who committed the error in order to hold him or her responsible (to assign blame). The other way is analyse the error in order to learn from it and to improve things so as to reduce the probability that the error will not be made again.

Blaming people for their actions, such as those types of error that involve violations of existing standards or rules, is a major focus of the court system. Legal blaming is a normal and necessary way of addressing errors that violate rules or standards. However, because inquests are not able to make findings of culpability, the obligation of an inquest ought therefore to be to focus on discussing error in the context of what can be learned from it. For the same reason, hospitals need to approach the issue of error from a learning perspective.

Therefore a process must be put into place that emphasises the need to gather and consider all of the relevant facts in an honest and candid manner, without regard to any individual or institutional consequences that might flow from the errors. For that to happen, consideration must obviously be given to balancing the issue of confidentiality and protection of informants from liability for describing what happened, with the equally strong need for patients and their families to be informed as to what really happened.
Unfortunately, the identification of errors is often difficult in complicated systems like health care. The Inquest Report says that error finding “…is often hindered by forces that exist within the medical community. These forces seek to minimise the appearance of errors when they occur. This may arise from the fact that the current culture of medicine reinforces the belief that medical personnel must perform without error. All too often, the making of an error in medicine is equated with a moral failing or is regarded as a sign of ignorance or incompetence. To admit to error, or to imply that a colleague’s actions were in error, is to raise serious questions about someone’s competence, and hence legitimacy and authority within the health-care system. One of the aims of this Report is to contribute to increasing openness about the existence of human error in the medical community.”

Errors are unplanned events that could or do lead to negative consequences. Humans commit errors, not because of any moral failing, but because humans are flawed beings, working in flawed systems that together contribute to the commission of errors. There is a hierarchy of errors: those that give rise to simple incidents; those that evolve into more serious events with the potential for harm to a patient (critical incidents); and those that evolve into events that cause actual harm (adverse outcomes in the words of the Report, and in patient safety parlance).

It is essential to have an error management process that identifies all three types of errors. However, simple and critical incidents are in fact seldom managed. This might be because they did not produce negative results. However, they are important because they are evidence of the potential for harm. The Inquest concluded that there were no processes in place that took account of the many simple and critical errors that, if noted and addressed, would have reduced the actual harm. There was no early warning system.

A fundamental reason for absence of such a system was because there was a reluctance to discuss errors in a setting where everyone might contribute in an open way. The Report says there was no process “…that allowed team members to comfortably and collectively assess and evaluate the events that occurred in the operating room in a manner that contributed to improvements in the way that the patients were treated.” Every hospital needs to ensure there is a process whereby members of surgical teams and programs can learn from the mistakes that they will inevitably make.

The Inquest proposed elements of such a process, with particular reference to human factors analysis as it originated in the aviation industry. “Studies of air disasters suggested that the majority of accidents did not result from technological faults or a lack of technical skills. Instead, the studies suggested that in addition to an underlying flawed system, the contributing factors or triggers for the disaster lay within the area termed human factors. This is the scientific discipline concerned with interactions among humans and other parts of a system in carrying out a purposeful activity. Human factors include leadership, team work, communication and decision making.” It is equally relevant to health care. “Leadership, team work, communication and decision making are recurring themes in this Report. They are not side issues, not matters of mere personality difference, but central issues. Where these issues were not resolved, they often led to tragic results.”

Human factor analysts suggest that the errors, incidents, critical incidents and accidents that arise from human behaviour can best be addressed in a systematic fashion through programs of quality assurance and error and risk management. These programs need to address the behaviour of people who might appear to perform at less than an optimal level. More importantly, the programs must address what are termed ‘systemic issues’ – that is, problems that lie within the whole of the hospital or even the health care system itself.
9.5 A footnote: implementation of recommendations

A Review and Implementation Committee was established in 2000 by the Minister of Health, Manitoba, to ensure changes recommended by the Inquest and other review processes were actually implemented. The first annual report of the Committee made the following points.

First, the Committee reiterated a key feature of the context: that the health care system is highly complicated. Although there are large numbers of highly knowledgeable and committed health professionals, it is far from easy to make some kinds of changes.

Second, the main improvements had been made in a few areas. They included an improved policy on informed consent that could become a model for other hospitals, the establishment of a Nursing Practice Council at the Centre, and the establishment of a new critical incident reporting policy at the Centre. Minor improvements had also been made with regard to accountability, risk management, quality assurance and the handling of patient complaints.

Third, ideas had been developed but implementation had not yet begun in several other areas. They included collaboration between Manitoba Health and the College of Physicians and Surgeons to develop methods of profiling of doctors, development of a policy framework for internal disclosure policies as a guide for individual health care facilities, and development of a guide to health services in Manitoba for the general public.

Finally, the Committee recommended additional actions be taken in other areas. They included increasing the public profile of the College of Physicians and Surgeons (with emphasis on increasing the awareness of the College’s complaint processes), acknowledging (formally, culturally and operationally) the role and skills of nurses, and changing cultures within health care systems. The Committee said that the most important aspects of culture were “… to be more open and accepting of processes that catch mistakes early, and in dealing with mistakes as learning experiences.” However, it noted that “… changes in culture and attitudes take years, not months, and are the responsibility of health care professionals and the general public.”

9.6 References and selected bibliography


In this final section, we provide a list of pertinent papers on three related areas to the inquiries we have covered here. These are: culture, systems change and systems approaches; general papers on inquiries; and inquiries into pre-mediated injury to patients. Copies of these are widely available in the literature, and those from staff of the Centre for Clinical Governance Research can be obtained by contacting us.

**Culture, systems change and systems approaches**


**General papers on inquiries**


**Inquiries into pre-meditated injury to patients**


### Appendix 1: Summary of inquiries

What follows are summaries of the eight inquiries into patient safety we deal with in this report. Each table provides a summary of the context within which the patient safety issues emerged, the findings of each Inquiry team and some of the most relevant recommendations.

The selection of these inquiries was pragmatic: it was partly on the basis of their prominence, and partly on the accessibility of the inquiry reports. A choice was also made to include inquiries into a range of service types and countries. Inquiries into health professionals who caused deliberate harm, such those of Shipman and Allitt, were excluded. While they can teach us about systemic flaws, they were outside the scope of the study.

#### 11.1 Bristol Royal Infirmary, United Kingdom

The Inquiry into the Bristol Royal Infirmary and the Bristol Royal Hospital for Sick Children has one of the highest profiles of inquiries into patient safety. Table 3 outlines the context, findings and recommendations of the case, which relates to the outcomes of paediatric heart surgery at the Bristol. One of the most important systemic issues arising from the Bristol case is that concerns about the safety of the patients were raised by both staff and patients for a period of almost ten years before a comprehensive review was undertaken.
Table 3: The Bristol Inquiry, United Kingdom

<table>
<thead>
<tr>
<th>THE BRISTOL ROYAL INFIRMARY/THE BRISTOL ROYAL HOSPITAL FOR SICK CHILDREN, INQUIRY 2001</th>
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<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>- In 1984 the Bristol Royal Infirmary (BRI) was a designated service for open-heart surgery, and Bristol Royal Hospital for Sick Children for closed-heart surgery for babies aged under one year.</td>
</tr>
<tr>
<td>- While from the early 1980s it was recognised both in Bristol and in the Department of Health that the circumstances under which paediatric cardiac surgery was carried out at the Bristol could be improved, these improvements were not implemented until 1995.</td>
</tr>
<tr>
<td>- Concerns about the performance of the Bristol continued to be expressed both internally (within the hospitals and health system) and externally (in the press) throughout the 1980s.</td>
</tr>
<tr>
<td>- In 1988 a consultant anaesthetist, Dr Bolsin, joined the BRI and began collecting and analysing the mortality data of the paediatric cardiac surgery program, which he continued to do over the next six years. His conclusion was that death rates were much higher than to be expected, and he expressed his concerns repeatedly to managers and colleagues.</td>
</tr>
<tr>
<td>- The catalyst for action was the death on the operating table of the infant Joshua Loveday, on 12 January 1995, on whom a switch operation was performed.</td>
</tr>
<tr>
<td>- BRI announced in April 1995 that it had halted a pioneering technique for open-heart surgery for babies, after nine out of 13 babies operated on in an 18 month period prior to 1993, died.</td>
</tr>
<tr>
<td>- In 1995 the first external review of Bristol, the Hunter/de Leval Review, was instituted. The Review described confusion, miscommunication and the need for a monthly morbidity and mortality meeting. Paediatric cardiac surgery at Bristol was all but halted until a new surgeon was appointed.</td>
</tr>
<tr>
<td>- In 1997 the General Medical Council (GMC) held a disciplinary tribunal on the professional conduct of two cardiac surgeons and the Chief Executive (CE) of the Trust.</td>
</tr>
<tr>
<td>- The Tribunal conducted a review which was limited in scope, considering only 53 of the operations conducted at BRI, in which 29 patients died and four were left with brain injuries. They only considered one type of cardiac operation conducted by these doctors. Nonetheless, the Review found that three doctors were guilty of serious professional misconduct, that they conducted the operations ‘without regard to their safety’ and that the CE failed to respond to warnings about the doctors. The GMC removed two (a surgeon and the CE) doctors from the Medical Register and restricted the other surgeon’s practice for three years.</td>
</tr>
<tr>
<td>- A group of parents of children who had undergone cardiac surgery at BRI organised themselves to provide mutual support. The group had first called for a public inquiry in 1996 and continued to pressure the Government during and after the GMC review.</td>
</tr>
<tr>
<td>- Following the report of the GMC in June 1998, the Secretary of State for Health announced to the English Parliament the establishment of a public inquiry into “… what went wrong …” The Inquiry investigated the care and management of infants undergoing complex cardiac surgery at the BRI in the 12 years preceding 1995.</td>
</tr>
</tbody>
</table>
Findings

- The Inquiry found that the story of the paediatric cardiac surgical service in Bristol was “not an account of bad people … people who did not care, nor of people who wilfully harmed patients”
- The Inquiry concluded that the reasons for the problems were, for the most part, systemic “… products of a system that had fundamental weaknesses”
- Key findings included:
  - While there were constant shortages in the supply of staff, under-funding of the service was not the cause of poor care
  - The National Health Service (NHS) had made an error in approving the paediatric cardiac service, given that the aspirations of the service were not matched by its capabilities
  - The service at Bristol was poorly organised and the physical environment was dangerous, with surgeons in one hospital and paediatric cardiologists in another
  - There was inequitable treatment of various staff, with strong links between senior management and the ‘old guard’ of clinicians
  - The surgeons lacked insight to see that they were failing in their duties
  - There were inadequacies at every point of the care process from referral through to diagnosis, surgery, and intensive care
  - There was an absence of defined standards of care for paediatric cardiac surgery and for any other specialty at Bristol
  - There was a failure to share information with parents, and what they received was often partial, confusing and unclear
  - There was no structure for the monitoring of the clinical performance of health care professionals or of hospitals
  - There was poor teamwork between professionals, attributed in part to the lack of effective clinical leadership, which was found to have affected both the performance, and outcomes, of care
  - Clinicians were actively involved in collecting and discussing data about adverse events, but denied any adverse inferences drawn from that data
  - The management culture included a punitive element, which had resulted in an organisational environment where speaking out was neither acceptable nor safe
  - The NHS management was considered to be poor; having devolved responsibility to Health Care Trusts, it had not subsequently monitored the impact of this process on the quality of health care
  - The Board of Management were either part of the ‘club’ or treated as outsiders, and were unaware of, or uninvolved in, the daily operation of the service
  - There were poor ways of dealing with patients, who were often given inadequate or incomplete information, resulting in their inability to give informed consent
- The central problem was defined as being ‘destructive organisational cultures’

Recommendations

- Children and their health care needs were to be given higher priority in the NHS
  - According to the Inquiry’s recommendations, this would require: better coordination and integration of services; the location of children’s acute hospital services in a children’s hospital; clear standards for the care of children; the publication of information about the quality and performance of children’s health care services; and specialist training of all health care staff working with children
Recommendations (continued)

- Patients in their journey through the health care system were entitled to be treated with respect and honesty and to be involved, wherever possible, in decisions about their care
  - This was to be achieved through the: training of health care professionals in communication skills; free and honest exchange of information between parents and professionals; establishment of an integrated system of support and counselling for patients and carers; and upholding of the right of parents, rather than health care staff, to decide what information they require

- Patients were entitled to expect that both the NHS and the hospital in which they are cared for were well led
  - In order to achieve this, the Inquiry recommended that the: government establish effective systems to regulate the quality of health care; chief executives of health care organisations be supported in their tasks; management boards of health care organisations were to be selected and trained for leadership of health care at the local level; and quality of health care was to be regulated through bodies such as the National Institute for Clinical Excellence and the Commission for Health Improvement

- Patients were entitled to be cared for by health care professionals with relevant and up to date skills and expertise
  - This would require: health care professionals to undertake training in communication, organisational and teamwork skills; medical, nursing and management schools to develop joint, multidisciplinary, courses; medical schools to review their criteria for applicants to ensure greater diversity; a system of regulation covering the education, registration, revalidation and discipline of health care professionals; compulsory continuing professional development, periodic appraisal and revalidation for health care professionals; positive incentives and training for senior clinicians to take on senior managerial roles; proper training and direct supervision for surgeons and other clinicians; permission to be sought from local ethics committee before new or untried procedures were to be attempted on patients; patients to be informed about the experience of surgeons or other clinicians before giving consent; and the employer to carry the primary responsibility for dealing with poor performance and misconduct

- Patients were entitled to care that was safe
  - The components of safe care were considered to be much more than the actions or competence of health care professionals, and included the physical environment, equipment, working arrangements, teamwork and good communication. The recommendations associated with safe care related to the: establishment of a safety culture and the removal of the existing culture of blame; creation of a National Patient Safety Agency for the reporting, analysis and dissemination of information about adverse events, including the analysis of persistent causes of unsafe practices; replacement of the system of clinical negligence with systems for identifying, analysing, learning from and preventing errors; and introduction of incentives for the reporting of sentinel events

- Patients were to be entitled to care and treatment of an appropriate standard informed by current knowledge
  - There were to be agreed and published standards of clinical care for health care professionals to follow, so that patients and the public knew what to expect, and there were to be standards for hospitals as a whole, with hospitals not meeting these standards unable to offer services within the NHS

- Generic standards were to be met by health care institutions
  - All NHS services were to meet a minimum set of capabilities relating to the state of the buildings and equipment, the quality of leadership, and the organisation’s policies and procedures for ensuring that care is safe and of good quality. The services were to periodically undergo a process of revalidation by the Commission for Health, which would also monitor clinical performance at a national level
The public was entitled to expect that means existed for them to become involved in the planning of services

- The NHS was to: take account of, and respond to the interests and needs of the public on a daily basis; involve patients in those processes designed to secure the competence of health care professionals; and embed the interest of patients into all their organisations and institutions. The Inquiry provided principles to facilitate this process.

### 11.2 Campbelltown and Camden Hospitals, Australia

Table 4 summarises the outcomes of inquiries into Campbelltown and Camden Hospitals in south west Sydney. Following the reports in the media of whistleblower nurses, the hospitals were the subject of two inquiries.

The first was conducted by the NSW Health Care Complaints Commission (HCCC) between 2002 and 2003. After political, media and public reactions to the findings of that report, a Special Commission of Inquiry was instigated by the Minister for Health. This Commission reported in 2004. Table 4 highlights recommendations from the second Inquiry.

#### Table 4: The Campbelltown and Camden Inquiry, Australia

<table>
<thead>
<tr>
<th>THE SPECIAL COMMISSION OF INQUIRY INTO CAMDEN AND CAMPBELLTOWN HOSPITALS, 2004</th>
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<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>The Campbelltown and Camden Hospitals are the main health care organisations in the Macarthur Health Service in south west Sydney</td>
</tr>
<tr>
<td>Prior to 2001 there were four years of informal and formal complaints made about medical care, mainly from nurses, at the Campbelltown and Camden Hospitals</td>
</tr>
<tr>
<td>By 2002 the rumours about inadequate care had been picked up by the media, and were front page news</td>
</tr>
<tr>
<td>During November 2002 the Minister for Health heard formal complaints from nurses and directed the Health Care Complaints Commission (HCCC) to investigate them</td>
</tr>
<tr>
<td>The HCCC investigation lasted from November 2002 to December 2003. A significant degree of concern was expressed about the effectiveness of this investigation by a number of the parties involved</td>
</tr>
<tr>
<td>A Special Commission of Inquiry was initiated in December 2003. An Interim Report was published on 31 March 2004 and a final report in July 2004</td>
</tr>
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</table>

| **Findings** |
| The HCCC should have investigated all the allegations in relation to the individual professional conduct of the relevant practitioners and so the stakeholders’ misgivings about the HCCC process were, in broad terms, vindicated |
| Many of the adverse events could have been more appropriately handled through better internal hospital procedures, more open discussion between professional colleagues, and fuller disclosures to patients and families |
| The statutory patient care complaints system in NSW was considered to be well designed, and did not require any changes, but statutory procedures must be followed |
Findings (continued)

- The administrators at the hospitals did not deliberately attempt to cover up adverse events, clinical incidents, or to stifle investigation of allegations
- The complaints system needed to look at both systemic and individual issues, but a systems approach did not exclude orthodox professional discipline procedures
- After the commencement of the Inquiry improvements had been made at various levels of the health service. These included the establishment of the Clinical Excellence Commission and the use of root cause analyses (RCAs) across the health system

Recommendations

- Seventeen suggested changes to the statutory system including issues such as definitions of unsatisfactory professional conduct, changes to the Nurses Act, changes to the Health Care Complaints Act, and changes to the HCCC’s power, procedures and processes
- It was recommended that Area Health Services create policies consistent with the principles in outlined in the Report: open disclosure standards; best practice complaints handling; and a model for managing concerns about clinicians
- All teams conducting root cause analyses (RCA) were to use the Model for Managing Concerns about a Clinician to determine if an individual was to be referred to senior managers for review
- All teams were to conduct RCAs of incidents with a severity assessment code (SAC) of 1 or 2 were to have the same protection as provided in the Health Administration Act
- A review of RCA process was recommended after three years to ensure a balance of usefulness of the information, with the protection provided to participants in RCA teams
- Documents generated by RCAs were to be made available to the HCCC, when a relevant complaint was made – but these documents were not to be made admissible in a statutory disciplinary proceeding or elsewhere

11.3 Celje Hospital, Slovenia

The Celje Hospital Inquiry provides insights into the impact on patient safety of clinical support services, in this case, pathology. It also allows for reflection on a hospital system outside those of English speaking countries. As with Bristol, Celje Hospital had a history of a decade of formal and informal complaints and multiple reviews before any direct action was taken. Table 5 provides the details.

Table 5: The Celje Hospital Inquiry, Slovenia

<table>
<thead>
<tr>
<th>THE CELJE HOSPITAL INQUIRY, 2003</th>
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</thead>
<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>Significant errors made in the Morphology and Cytology Department at Celje Hospital regarding the examination of tissue specimens and reporting of the results</td>
</tr>
<tr>
<td>The hospital conducted its own inquiry in 1994, but the errors continued</td>
</tr>
<tr>
<td>In January 2002, the Medical Director of the Hospital determined that a formal internal inquiry should take place and wrote to the Slovenian Medical Chamber requesting that this occur</td>
</tr>
<tr>
<td>In October 2002 a Committee of Inquiry was convened, with the collaboration of the Medical Chamber and the Slovenian Police</td>
</tr>
<tr>
<td>The final report was presented to the Minister for Health in May 2003</td>
</tr>
</tbody>
</table>
Findings

- There were little hospital data available by which to monitor performance
- The Hospital’s lack of resources was used to rationalise the limited monitoring and management of staff
- Patient empowerment was considered to be unsatisfactory; patients who complained about the quality of the service often had their pathology samples returned with the suggestion that they have them analysed elsewhere
- No one ever apologised to patients, even those who had been found to have been seriously harmed
- While there had been no intentional intent to harm patients there were major systemic and cultural problems. These included:
  - Staff members who felt that it was neither their duty nor responsibility to manage the patient from admission to discharge
  - Doctors who believed that their work should not be subject to oversight by others, and nurses who felt they did not have the responsibility to comment on errors made by senior doctors
  - An organisational culture which discouraged both the admission of errors and acceptance of complaints
  - A medical culture that supported the practice of not writing down rules and guidelines, so that changes to procedures were transmitted almost entirely orally
  - Almost a complete absence of recognition that clinical work required collective management on the part of clinicians

Recommendations

- Significant improvements in clinical team work were needed
- An increased understanding and respect of differences between clinical professions was required
- Forums were to be developed where multidisciplinary teams were able to discuss multidisciplinary problems
- Admission of errors were to be seen as a sign of strength on the part of clinicians and staff
- The patient was to be placed at the centre of care process, rather than the profession or the organisation
- The blaming of individuals and the practice of passing blame downwards was to be avoided in place of a systems approach
- More trust and communication was required between management and staff
- Greater use was to be made of clinical practice guidelines and clinical pathways
- Changes were required at all levels from the government to health care agencies in order to improve the quality of services provided, with patients to be the key players in the process of reform
11.4 Glasgow’s, Victoria Infirmary, Scotland

The Victoria Infirmary, Glasgow, provides an example of threats to patient safety that emanate from the wider hospital environment. The health care associated infection (HAI) in this case was salmonella, but the organisational issues reflect those that occur in response to all types of HAIs.

Table 6: The Victoria Infirmary Inquiry, Scotland

<table>
<thead>
<tr>
<th>THE VICTORIA INFIRMARY INQUIRY, 2003</th>
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</thead>
<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>- There were outbreaks of health care associated infection (HAI) that occurred over several years across Scotland</td>
</tr>
<tr>
<td>- Actions were deemed necessary in the case of the Victoria Infirmary because of widespread public concern and mass media interest</td>
</tr>
<tr>
<td>- There were outbreaks of salmonella infection at the Victoria Infirmary, Glasgow, in December 2001 and January 2002</td>
</tr>
<tr>
<td>- Three people died and a large number were injured or placed at risk</td>
</tr>
<tr>
<td>- An inquiry team was established by NHS Scotland under the chairmanship of Dr Brian Watt in 2002</td>
</tr>
<tr>
<td>- As a consequence of that Inquiry’s report, the Minister for Health and Community Care called a convention of experts and interested people from across Scotland and internationally, in June 2002</td>
</tr>
</tbody>
</table>

| **Findings**                         |
| - One of the patients in the Infirmary was the likely source of the infection, having acquired salmonella enteritidis in the community before admission to hospital |
| - There was no evidence that hospital food caused the outbreak |
| - The exact route or routes of cross-infection could not be identified |
| - The main finding was that while the outbreak of salmonella infection was unfortunate there was no evidence that the deaths could have been avoided |
| - The Inquiry argued that while it was possible to reduce the chances of hospital acquired infection, they could not be eliminated entirely |
| - The Inquiry also found that the Victoria Infirmary (built in 1893) was “… no longer fit for purpose as a busy general hospital.” |
| - It had suffered from a prolonged period of uncertainty about its future with consequent serious underinvestment in the fabric of the building |
| - The Hospital had also faced a longstanding series of difficulties, which had been well publicised, in often hostile media coverage. The above factors were seen to have had two consequences: |
| - difficulties in recruitment (30% shortfall of the nursing establishment in the medical unit where the outbreaks occurred) with reliance on bank and agency staff to fill the gaps, and |
| - a lowering of morale and the development of a ‘siege’ mentality in some Trust staff |
Recommendations

- Increased compliance with existing infection control rules and guidelines was required from all staff.
- Regular auditing of staff compliance with hand washing and food handling was to be conducted.
- Operating procedures centred on issues such as cleaning specifications, dealing with contamination and decontamination of staff, staff uniforms, and the movement of patients were to be refined.
- All staff and managers were to be made responsible and accountable for hygiene issues.
- In order to deal with serious HAI outbreaks as soon as they occurred, each health care organisation was to have:
  - a designated, trained, infection control doctor
  - an Infection Control Team (ICT)
  - an infection ‘issue manager’
- Each National Health Trust was to have a lead Infection Control Nurse (ICN).
- A more systematic approach to reporting of infection control threats was needed, including documentation of:
  - contact and incidents with infectious materials
  - advice given and received about infection control from ICTs
  - the screening of relevant staff in case of outbreaks
  - the classification of incident outbreaks
- The levels of basic ward equipment were to be maintained at a level to reduce the communal use of such equipment.
- The number of infection control staff were to be sufficient to allow them to have daily contact with wards.
- Team work and leadership on infection control issues needed to be improved.
- A culture of openness between the Scottish Executive, the NHS and relevant agencies needed to be developed.
11.5 King Edward Memorial Hospital, Perth, Australia

Prior to the Campbelltown and Camden Hospitals Inquiry, the King Edward Memorial Hospital was the most prominent patient safety inquiry in Australia. This Hospital was subject to multiple formal and informal reviews and two major external inquiries. The report of the last major Inquiry, presented in 2001, resulted in 237 individual recommendations for systemic, organisational and professional change. Table 7 summarises the details of this case.

Table 7: King Edward Memorial Hospital Inquiry, Australia

| KING EDWARD MEMORIAL (OBSTETRIC AND GYNAECOLOGICAL) HOSPITAL INQUIRY, 2001 |
|-----------------------------|-----------------------------|
| **Context**                 |                             |
| ■ In 1990 a report commissioned by the Health Department of Western Australia recommended changes at King Edward Memorial Hospital (KEMH), including revision of obstetric staffing levels. These recommendations were not implemented by the Hospital                             |
| ■ There was a progressively increasing number of concerns raised by staff and patients about the obstetric and gynaecology services at the KEMH during the 1990s                                         |
| ■ In 1999 a new Chief Executive Officer was appointed and he became immediately concerned about several aspects of the Hospital’s processes and performance. These included:                          |
| – the absence of an overall clinical quality management system                                                  |
| – problems in identifying and rectifying clinical issues by senior management                                      |
| – inadequate systems to monitor and report adverse clinical incidents                                               |
| – the absence of a proper and transparent system to deal with patient complaints and claims                           |
| – a shortage of qualified clinical specialists (particularly after hours)                                            |
| – inadequate supervision of junior medical staff, and                                                                 |
| – the possibility of substandard patient care                                                                         |
| ■ In consultation with the Commissioner of Health and the Minister, the Chief Medical Officer and the Metropolitan Health Service Board commissioned the Child and Glover Review in 2000                       |
| ■ In 2001, the Minister for Health established the Douglas Inquiry                                                  |
| ■ This Inquiry reviewed 1,600 patient clinical files over an 18 month period, as well as analysing written submissions, interviews with patients, consultants’ reports, past and present employees’ transcripts, organisational and related documents, and clinical performance data |
| **Findings**                                                           |                             |
| ■ The Child and Glover Review found that there were many serious problems with the Hospital’s clinical and administrative practices. Inadequate processes of care and of responses to problems had “… resulted in serious adverse events and poor clinical outcomes for women and their families.” |
| ■ The Douglas Inquiry found similar issues. These included:                                                          |
| – Care planning and coordination was either non existent or substandard                                                   |
| – There was poor management of high risk cases with junior doctors delivering most of the care                        |
| – There were significant problems identified with the management of medical and obstetrics emergencies                 |
| – The Hospital had substandard documentation, including incomplete or missing clinical information                       |
| – Clinical errors, including failures to recognise a serious and unstable condition, were common                           |
Findings (continued)

- Policy and guideline development, deployment, compliance monitoring and review, were found to be lacking
- There were no formal systems or accountabilities for identifying, reviewing and responding to incidents and adverse events
- Where incidents were reported, there were significant delays between the time of a critical incident and the lodging of a report
- At times there was a complete lack of response to critical incidents and adverse events on the part of the Hospital management and clinicians
- The Hospital had failed to report several reportable deaths to the Coroner
- The Hospital had long term problems with staffing
- Patients’ complaints of the poor treatment and poor communication by staff were poorly handled
- There was no hospital wide quality improvement program

Recommendations

- An evaluation of the structure, role and management of the Hospital was to be conducted
- Junior doctors were to be supervised more effectively, and after hours coverage of senior staff and the availability of back up consultants was to be increased
- Clinical guidelines and guidelines for clinical care planning were to be established
- A policy on how the hospital developed, deployed, monitored and reviewed clinical policies and guidelines was to be developed
- Training on a range of issues was to be conducted and monitored and postgraduate medical education improved
- The gynaecology service and the Adult Special Care Unit were to be reviewed
- Care coordination and follow up responses were to be enhanced
- Patients were to be actively involved in decision making
- Communication with patients was to be improved
- Documentation was to be strengthened and comparative data analysis was to be undertaken and published
- Clinical accountability was to be increased
- An incident reporting system was to be established, along with relevant policies and procedures
- Policies and procedures were also to be established for the appointment, reappointment, supervision and performance management of all clinicians and staff
- The Hospital was to be reaccredited by an external body
- The Clinical Governance Committee of the Hospital was to be held responsible for its decisions and actions
11.6 Royal Melbourne Hospital, Australia

The Inquiry into Royal Melbourne Hospital, summarised in Table 8, offers insights into an organisation in some degree of turmoil. The Hospital had faced constant systemic and organisational change, ongoing shortages of experienced staff, and a lack of managerial and clinical leadership. The Royal Melbourne Hospital Inquiry provides a supporting rationale for systemic approaches to patient safety.

Table 8: The Royal Melbourne Hospital Inquiry, Australia

<table>
<thead>
<tr>
<th>Context</th>
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<tbody>
<tr>
<td>In 2002, serious allegations were made public concerning the conduct of nursing staff at the Royal Melbourne Hospital (RMH)</td>
</tr>
<tr>
<td>The allegations became the subject of separate investigations by the Victorian Coroner and the Victorian Police</td>
</tr>
<tr>
<td>The Nurses Board of Victoria suspended the registration of two nurses but postponed its investigations until the Coroner’s investigation had been completed</td>
</tr>
<tr>
<td>The Executive and Board of Melbourne Health conducted separate investigations into the allegations</td>
</tr>
<tr>
<td>In view of the high level of public concern, the Minister for Health immediately requested the Health Services Commissioner to conduct an independent inquiry</td>
</tr>
<tr>
<td>It was to address general issues, rather than the particular complaints that were the subject of legal proceedings. This Inquiry reported in 2002</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>The inquiry team concluded that the systemic, organisational and leadership changes that occurred between 1995 and 2000 in hospitals across Victoria had had an adverse impact on staff morale and standards</td>
</tr>
<tr>
<td>The resultant leadership instability during this period had resulted in: a lack of accountability; a failure to include staff in decision making; a lack of vision; and too much focus on fiscal matters</td>
</tr>
<tr>
<td>The Hospital was marked by: a culture of elitism; an attitude of complacency; confusion over responsibilities; fragmentation; and a lack of accountability</td>
</tr>
<tr>
<td>Operating rules and guidelines had been inadequate in the past, and where they existed they had low levels of compliance</td>
</tr>
<tr>
<td>The Hospital’s quality assurance and improvement programs were not effectively integrated</td>
</tr>
<tr>
<td>Some relationships between health professionals had deteriorated over the years, to the detriment of patient care</td>
</tr>
<tr>
<td>There had been a decline in the rigour of medication control and clinical document in the recent past</td>
</tr>
<tr>
<td>There were no established systems for collecting data on sentinel events or adverse occurrence screening</td>
</tr>
<tr>
<td>The organisational culture did not value or respond to complaints by staff</td>
</tr>
<tr>
<td>Resource constraints in the 1990s had had led to a combination of factors which affected nurses’ work including: high workloads; exposure to stressful situations; poor roster and shiftwork arrangements; and reduction in staff support positions</td>
</tr>
</tbody>
</table>
Recommendations

- Consistent and transparent management practices were to be maintained
- Leadership decisions were to be documented, communicated and evaluated
- Nurses were to be involved in a range of Hospital committees
- Standards, policies and procedures were to be developed according to best practice approaches
- Strategies to improve the communication and interaction between, and culture and morale of, medical and nursing staff were to be implemented
- The design of individual patient medical storage systems were to be reviewed, and access to medications by staff was to be restricted, documented and audited
- A comprehensive feedback mechanism was to be established so that staff could learn from errors and implement proactive preventative strategies
- A hospital wide program for reporting sentinel events and limited adverse occurrence screening was to be developed
- Improved methods of management of staff complaints and feedback were to be established
- Standards for the handling of medical records were to be improved

11.7 Southland DHB Mental Health Service, Southland, New Zealand

The New Zealand Inquiry into Southland Mental Health Service, summarised in Table 9, underlines the breadth of potential patient safety issues. In this case, the person injured was the patient’s mother, killed by her son after his release from care. Systemic issues, including coordination, communication, quality control, and professional competence, were noted by the Inquiry.

Table 9: The Mental Health Service of Southland District Health Board Inquiry, New Zealand

<table>
<thead>
<tr>
<th>MENTAL HEALTH SERVICE OF SOUTHLAND DISTRICT HEALTH BOARD INQUIRY, 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>- Mr Mark Burton became a client of the Mental Health Service of Southland District Health Board (Southland DHB) in July 1998</td>
</tr>
<tr>
<td>- Mr Burton received care from the Queenstown Community Mental Health Team and had twice been hospitalised as a voluntary patient</td>
</tr>
<tr>
<td>- The second inpatient episode lasted for 50 days. He was discharged from Ward 12 on 30 March 2001. One day later, he killed his mother</td>
</tr>
<tr>
<td>- There was also a Coroner’s inquest into Mrs Burton’s death that reported in December 2001</td>
</tr>
<tr>
<td>- In October 2001, the Health and Disability Commissioner (the Commissioner) initiated an independent inquiry which took account of the Coroner’s findings, and which reported its own findings in October 2002</td>
</tr>
</tbody>
</table>
Findings

- The Commissioner concluded that no single act or single individual could be held to carry the primary responsibility for the poor care but that the “… overall picture [was] one of sloppy care that was lax and laissez-faire.”
- There had been many deficiencies in the clinical care of the patient and that while each deficit singularly may not have been responsible for the outcome in total they resulted in poor care
- There were inadequate monitoring and control mechanisms to ensure that staff practised safely, that incident and risk management strategies were put in place, and that policies and procedures were followed
- Communication with the client’s family had been inadequate
- Discharge planning had been careless, imprecise, lacking detail and poorly coordinated
- The lack of coordination between the inpatient and community care teams was considered notable
- The policy and procedural standards for the mental health service were considered to be inadequate
- Compliance with incident reporting rules was also inadequate
- The staff were found to have failed to work as a team and had been unable to communicate and collaborate adequately
- There were individual findings in relation to each of the staff involved in the case (doctors, nurses, social workers, mental health needs assessor, alcohol and drug services counsellor, patient service manager, clinical director and team leader), as well as to the corporate responsibility of the Southland DHB

Recommendations

- All staff associated with the case, as well as the DHB, were required to apologise in writing to the patient’s family
- The two doctors associated with the case were to have their competence reviewed by the Medical Council of New Zealand
- All other staff were required to review their practice in light of the findings of the Inquiry
- Competence reviews of key personnel were to be conducted and performance criteria established for each of their positions
- Specific recommendations were made to address the underlying, systemic causes of poor care, including the establishment of internal auditing and monitoring processes
- Immediate attention was to be given to patient assessment, patient records and documentation, incident reporting, risk assessment and management, quality care and treatment, discharge, supervision, and family and carer participation in the care of patients
- A culture of continuous quality improvement was to be established, including continuous critical appraisal and reflection by all staff on their own and joint practice
- Nursing standards and skills for mental health nursing were to be improved
- Staffing structures and employment conditions were to be reviewed, including professional support and pathways
- Improvements were to be made to the communication and coordination processes and systems
11.8 Winnipeg Health Services Centre, Canada

The final study, that of Winnipeg Health Services Centre, also relates to a paediatric cardiac service. Like Bristol, doctors, nurses and parents had all raised concerns about patient safety over an extended period of time before an inquiry was finally held. The summary is provided in Table 10.

Table 10: The Winnipeg Health Sciences Centre Inquiry, Canada

<table>
<thead>
<tr>
<th>THE WINNIPEG HEALTH SCIENCES CENTRE INQUIRY, 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>- In 1994, subsequent to a short suspension due to changes in key personnel, the paediatric cardiac surgery program at the Winnipeg Health Services Centre was re-established after the employment of a new surgeon as head of the team, and a new director of paediatric cardiology</td>
</tr>
<tr>
<td>- Inadequately explained deaths began to occur almost immediately after the Program was reactivated. The deaths continued from 15 March to 21 December, 1994</td>
</tr>
<tr>
<td>- In total, 12 children died during or shortly after having undergone cardiac surgery at the Centre. The children were aged from two days to four years old</td>
</tr>
<tr>
<td>- Two groups of staff (anaesthetists and nurses) from the operating rooms and intensive care, had begun to express concerns about the performance of the new surgeon, almost immediately after his arrival at the Centre</td>
</tr>
<tr>
<td>- In May 1994 (following the death of the fifth of the 12 children), the members of the Section of Paediatric Cardiac Anaesthesia at the Centre unanimously refused to take part in any further paediatric open-heart cases until a review of the cases was undertaken</td>
</tr>
<tr>
<td>- An internal review committee was appointed, and the program was asked to reduce its program to low risk cases. During the period of review, two more children died</td>
</tr>
<tr>
<td>- The review concluded the problems were a normal consequence of having a relatively new team and that the team had resolved the causes. It recommended that the program return to full service in September 1994</td>
</tr>
<tr>
<td>- From that time until 21 December 1994, five more children died</td>
</tr>
<tr>
<td>- That review presented its report to the hospital in early February 1995 and advised that the Centre should suspend the program for a further six months</td>
</tr>
<tr>
<td>- The high degree of concern in the mass media continued, mainly as a consequence of actions by the parents of the children who died, who mounted a high profile campaign for a public inquiry</td>
</tr>
<tr>
<td>- On 5 March 1995, the Chief Medical Examiner for the Province of Manitoba ordered an inquest into the deaths of the 12 children, and the Inquest continued hearings until September 1998. It released its report four years after it had commenced hearings</td>
</tr>
</tbody>
</table>

| **Findings**                                    |
| - The Inquest found that care had been seriously deficient; of the 12 deaths, five were preventable and four were possibly preventable. The evidence was insufficient to reach a conclusion on two deaths, and one was judged not to have been preventable |
| - The Inquest also found that while some of the problems in the cardiac surgery program were considered attributable to the abilities and conduct of specific individuals, most of the problems were considered to be systemic in nature |
Findings (continued)

- Systems issues which had been found to effect the outcomes of the program included the hospital policies and procedures governing: staffing; leadership; team work; communication; decision making; and quality assurance

- The recruitment process for new surgical staff was seen to be flawed, with no serious attempts having been made to assess the competence of the candidates

- The lines of authority and responsibility for the program were felt to have been unclear and confusing, resulting in opportunities for blame shifting between staff and management

- There had been inadequate, ad hoc supervision of clinical staff

- Two doctors, the head of the surgical team and the acting medical director, were considered to have failed in their duties

- The surgeons’ poor performance had been identified by the Centre, but had subsequently been justified on the basis of their (the surgeons’) learning curve

- The heads of departments had failed to manage staffing adequately and had not addressed underlying issues which ultimately led to the loss of the program’s previous staff. They subsequently hired less experienced, but available, clinicians

- Poor teamwork had marked the Centre’s operations, with inadequate communication between staff about what where complicated procedures

- Nurses had occupied subservient positions within the Centre, and as a result their concerns were not treated appropriately

- There had been serious weaknesses in the process of obtaining informed consent from parents, including parents not being fully informed either about the risks of the procedures, or the skills of the surgeons

- The Office of the Chief Medical Examiner, which was responsible for the investigation of patient harm, had: failed to identify the problems with the program; waited too long for the final autopsy reports; not tracked the surgical deaths of the program; and relied too heavily on the information obtained from the surgeons involved in the case, rather than seeking advice from a range of experts

Recommendations

- The Centre was to establish a timely recruitment process, overseen by a formal search committee (including input from nursing and related staff) which allowed for the observation of applicants’ skills prior to hiring

- Standard operating procedures and protocols were to be developed

- A range of development programs and processes were recommended including those for: leadership skills; team development; team communication; conflict resolution; and post-operative debriefing sessions

- Structures were to be put in place which ensured that all staff, but in particular nurses, could voice their concerns without fear of reprisal

- A clear policy was to be established on how staff could report concerns about risks for patients

- The Government was to establish a policy for the routine payment of legal counsel for families granted standing at inquests

- Changes to the operation of the Office of the Chief Medical Examiner were also recommended, including the: development of a protocol requiring hospitals to inform it of significant changes in the delivery of service; maintenance of a database on numbers and causes of hospital deaths; and conduct of interviews with nursing and medical staff involved in patient care.