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_____ _____

Heather Gluyas **January 2008**

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List of Abbreviations

ACHS	The Australian Council on Healthcare Standards
ACQSHC	Australian Council for Safety and Quality in Healthcare
AHMC	The Australian Health Ministers' Conference
AMA	Australian Medical Association
CHI	Commission for Health Improvement
CEO	Chief Executive Officer
CTG	Cardiotocograph
DoH	Department of Health (Western Australia)
Douglas Inquiry	Inquiry into obstetric and gynaecological services at King Edward Memorial Hospital 1990-2000
HCCC	Health Care Complaints Commission
IOM	Institute of Medicine
KEMH	King Edward Memorial Hospital
MDA	Medical Defence Association
MHSB	Metropolitan Health Services Board
NHMRC	National Health & Medical Research Council
NHS	National Health Service (England & Wales)
NICE	National Centre for Clinical Excellence
NPSA	National Patient Safety Agency
NSW	New South Wales
NVIVO7	Quantitative data analysis software package
NZ	New Zealand
The Inquiry	Inquiry into obstetric and gynaecological services at King Edward Memorial Hospital 1990-2000
TOR	Terms of Reference
UK	United Kingdom
QAHCS	Quality in Australian Healthcare study
QUIC	Quality Interagency coordination taskforce
RMO	Resident medical officer (junior Dr)
WA	Western Australia
WHA	World Health Assembly
WHO	World Health Organisation

Abstract

Major failures in patient safety often lead to high profile inquiries set up to establish the facts, and to identify areas of improvement to prevent further failures. In order to learn from inquiries, we need to be able to identify if, and how, the inquiry process influences improvements.

Using a case study strategy, this research study examined the perceptions of external stakeholders in regards to the impact or influence of the Douglas Inquiry on KEMH's clinical governance systems. The research focused on two areas that were highlighted in the final Inquiry report as requiring reform. These systems deal with the clinical credentialing and performance review and the involvement of consumers in care.

Several sources of data collection were employed. Firstly, document and archive analysis identified the procedures and processes employed by the Inquiry, and the changes that had occurred at the hospital. Secondly, semi-structured interviews ascertained participants' perceptions of changes in clinical governance systems at KEMH post Inquiry, and the influence of the Inquiry on the changes that have taken place. The document and archives were analysed using an analytic approach described by Neuendorf (2002). The Miles and Huberman (1994) framework was used for the analysis of the interviews. The findings were then compared and with the literature.

The study conclusions identified critical factors within the Inquiry process, which influenced improvement in the clinical governance systems examined. These factors were the Terms of Reference (TOR) and the investigative and inquisitorial processes employed by the Inquiry. Absence of one of these critical factors resulted in the Inquiry reinforcing existing barriers and thus, in those areas there was no change. Lewin's (1951) model of change specifically informed the analytic process, with the outcome resulting in the development of a conceptual model of organisational clinical governance change.

CHAPTER ONE: BACKGROUND

"Quality problems occur typically not because of a failure of good will, knowledge, effort or resources devoted to health care, but rather because of fundamental shortcomings in the way that care is organised" (IOM, 2001:25).

INTRODUCTION

Inquiries into health system failures are highly visible to the community, and can undermine the public's trust in the health system. Inquiries can be seen as being politically motivated in order to apportion responsibility and culpability for errors of commission and omission. The potential personal and professional impact on all those involved in an inquiry can be overwhelming. This personal and professional impact may be justifiable, however, if there is some sustained positive change to the system that balances any negative impact (Walshe & Higgins, 2002). This chapter presents a general background of the topic leading to the research question. This will include an examination of patient safety and clinical governance programs in several other countries, as well as in Australia, the role of inquiries into health system failures, the triggers that lead to an inquiry and, the common characteristics present within organisations that are the focus of an inquiry. As well, the barriers to the implementation of effective clinical governance systems, and organisational change management processes will be explored. The chapter will conclude with a discussion of the significance and purpose of the research, the research questions, the research design and the development of the data collection questions.

BACKGROUND TO RESEARCH TOPIC

Patient Safety and Clinical Governance

Patients are a vulnerable group of people. Current literature estimates that 10% of all patient admissions to an Australian hospital result in the patient experiencing an adverse event, with 1 to 2% of patients suffering serious consequences (Braithwaite, Healy, & Dwan, 2005; Smallwood, 2006;

Wilson & Van der Weyden, 2005). In this climate, patient safety has assumed a large focus for health service providers, the governments that manage and regulate the provision of health services, and the community and consumers (patients and families) who are recipients of the care.

This focus on patient safety within the health industry has led to the widespread adoption of the term clinical governance. This term is used to describe the systems and processes that a health agency has in place that contribute to the maintenance of patient safety, and to detail accountability and responsibility for patient safety. Clinical governance also encompasses the mechanisms used to monitor and measure patient outcomes to ensure optimum quality care (Balding, 2005).

The focus on patient safety is an international phenomenon. Each country in the developed world, while having different health systems, has very similar experiences in terms of patient safety. The following discussion will review the status of patient safety programs internationally as well as in Australia.

Perspectives from Other Countries

United Sates of America

The increase in medical malpractice cases provided the impetus for a study in 1991 that reported a 3.7% rate of injuries to patients in New York State hospitals. Of these errors, 13.6% led to death and 2.6% to permanent disability. Wound infections accounted for 29% and drug complications for 19% of the adverse events (Brennan, Leape, & Laird, 1991). A report by the Institute of Medicine (IOM, 2000), found similar results to the 1991 study, and estimated that between 44,000 and 98,000 patients in the United States (US) were injured each year by adverse events while hospitalised. This report went on to identify the need to focus on system

issues. The identified barriers that prevented the improvement of patient safety included:

- Concerns within a healthcare organisation about health care quality not being discussed openly;
- Health care delivery becoming more complex;
- Patient safety not being built systematically into care delivery processes; and
- A pervading "culture of blame" within healthcare for adverse events or errors (IOM, 2000).

A flurry of activity followed the IOM report (IOM, 2000), with President Clinton initiating the setting up of the Quality Interagency Coordination Task force (QuIC), the funding of research by the Agency for Healthcare Research and Quality, and the introduction of revised patient safety standards of the Joint Commission on Accreditation of Healthcare Organisations (*Clinical governance issues paper*, 2001).

In the years following these initiatives there has been some slow progress in terms of improvement in patient safety, with the areas of medication administration and infection control processes recording measurable improvement (Leape & Berwick, 2005). Ascertaining if there have been major improvements in patient safety is not easy, since the US, like most western countries, is still grappling with the lack of a national monitoring system to provide objective measures (Leape & Berwick, 2005; Longo, Hewett, Ge, & Schubert, 2005; Pronovost, Miller, & Wachter, 2006). A recent study by Longo et al. (2005), comparing patient safety systems between 2002 and 2004 in Missouri and Utah hospitals, concluded that improvement in " patient safety system progress is slow and is a cause for great concern" (2005: 2858). On a more positive note however, there has been an appreciable shift in the awareness of the issue of patient safety within both the health industry and the community. An example of this is the growth of articles within professional journals that focus on patient

safety. This focus has seen the number of articles rise from 240 articles in 1994 to 4836 articles in 2003 (Longo et al., 2005:2863).

United Kingdom

In the United Kingdom (UK) before 1997, the National Health System (NHS) focused on fiscal goals as a measure of performance (Ferlie & Shortell, 2001). It was recognised by the government that this focus was administratively resource intensive and thus resources directed at patient care were diminished (*NHS White Paper. A modern and dependable NHS*, 1997). Recognising the problem, the *NHS White Paper* was released in 1997. This paper directed that the focus should shift to clinical together with fiscal responsibility. This was to be done by implementing a new model of clinical governance (*NHS White Paper. A modern and dependable NHS*, 1997). It was proposed to achieve this by setting up two government agencies. The first was the National Centre for Clinical Excellence (NICE). This agency was given the mandate to provide clear national standards for services and treatments, and to assess new and existing clinical interventions for clinical and cost effectiveness. The second agency was the Commission for Health Improvement (CHI). The role of CHI was to establish a framework for assessing and monitoring clinical performance (Nicholls, Cullen, O'Neill, & Halligan, 2000).

Adverse incident and error rates in the UK are similar to those in other countries (*An organisation with a memory*, 2000). It was however, the high profile investigation, held between 1998 to 2000, into poor outcomes for paediatric cardiac surgery at the Royal Bristol Infirmary that alerted the public to the issue of inadequate care and patient safety (Walshe & Offen, 2001). In the shadow of this investigation but prior to the release of the final report of the Bristol Inquiry team, the UK Government released the report *An organisation with a memory (2000)*. This report acknowledged that in the past there had been little systematic learning from patient safety incidents and service failure in the NHS. The report

also drew attention to the scale of the problem of potentially avoidable events that resulted in unintended harm to patients (Braithwaite, Travaglia, Iedema, & Hindle, 2006; *An organisation with a memory*, 2000). The National Patient Safety Agency (NPSA) was set up in June 2001 with the goal of establishing a national mandatory reporting system for adverse events and coordinating the dissemination of prevention strategies identified in the examination of the adverse event reports.

The NPSA website (www.npsa.nhs.uk) lists the achievements that have been made to systems that improve patient safety, but there has been no evidence to date that indicates a reduction in the overall rate of adverse incidents.

World Health Organisation

In 2002 the World Health Assembly (WHA) passed a resolution calling on the World Health Organisation (WHO) to establish a program on patient safety. The resolution proposed four areas of action. These were:

- The determination of global norms, standards and guidelines for the definition and reporting of adverse events and near misses in healthcare;
- The promotion of the development of evidence based policies that will improve patient care with particular emphasis on product safety and safe clinical practices;
- The development of mechanisms that provide a means to identify the characteristics of health care providers that offer a benchmark for excellence in patient safety; and
- To encourage research into patient safety (Donaldson & Fletcher, 2006).

This resolution was adopted by WHO (Donaldson, 2002; Johnstone & Kanitsaki, 2006). In response to this resolution, WHO launched the World

Alliance for Patient Safety in October 2004. The role of the Alliance is to raise awareness and political commitment to improve the safety of care and facilitate the development of patient safety policy and practice in all WHO Member States. Each year, the Alliance delivers a number of programs covering systemic and technical aspects to improve patient safety around the world (*Summary of the evidence on patient safety: Implications for research*, 2008).

Australian Perspective

The current context of healthcare delivery in Australia is one that emphasises patient safety. The growing awareness of the vulnerability of patients to safety related incidents that lead to poor outcomes, was highlighted in a study in 1995. This research titled the *Quality In Australian Healthcare Study* (QAHCS) estimated that 18,000 deaths and 17,000 permanent disabilities occur each year to patients in Australian hospitals as a result of preventable errors (Wilson et al.1995). As a consequence of this study there was an increase in political attention and pressure on health care agencies to demonstrate processes that protected patients (Johnstone & Kanitsaki, 2006).

Successive Federal and State governments committed resources to build capacity within organisations that supported patient safety and quality. In 2000, the Australian Health Ministers' Conference (AHMC) collectively committed funding of $50 million to establish the Australian Council for Safety and Quality in Health Care (ACSQHC). The ACSQHC was given a five-year term and charged with the mandate of leading national efforts to improve patient safety and the quality of health care in Australia. During that time, ACSQHC was responsible for overseeing an increase in the pool of funding available for research. This group also took a leading role in the development of initiatives in areas such as medication safety, open disclosure of incidents, accident and incident monitoring systems, and consumer education improvements. Continued commitment of

resources by Federal and State Health Ministers has now seen the establishment of The Australian Commission on Safety and Quality in Healthcare, a body replacing the former ACSHQC (Barraclough & Birch, 2006; Wilson & Van der Weyden, 2005).

Considerable progress has been made in terms of clinical governance systems, and patient safety initiatives since the 1995 study into patient safety. Each state and territory now has peak advisory groups charged with monitoring clinical governance within the health sector of their jurisdiction. Most have a requirement that certain sentinel events are reported to this committee (Wilson & Van der Weyden, 2005).

Nationally, healthcare agencies also utilise patient adverse event reporting systems and take part in accreditation programs that involve development of patient safety systems within the agency (Wilson & Van der Weyden, 2005). Both adverse events reporting systems and program accreditation require financial and human resources allocated within the organisation to manage and monitor the administrative requirements, thus organisations making this commitment are demonstrating an awareness of the problem (Wilson & Van der Weyden, 2005).

Despite this activity and the progress that has occurred, there continues to be high profile exposures of health system failures leading to poor patient outcomes. Inquiries into health system failures such as the King Edward Inquiry in Western Australia (WA) (2001), the Campbelltown and Camden Inquiry in New South Wales (2003), and most recently in Queensland the Bundaberg Inquiry (2005), challenge the perception that there has been significant improvement in patient safety.

The final reports from each of these inquiries identified that each of these organisations was collecting information that indicated there were problems with patient safety. This information included recording and monitoring of adverse events, patient complaints, staff dissatisfaction and

litigation threats. There seemed however, to be barriers that prevented the implementation of organisation-wide system and process change to remedy the problems (Davies, 2005; Douglas, Robinson, & Fahy, 2001; *Investigation Report Campbelltown and Camden Hospitals, MacArthur Health Service*, 2003).

This situation is not unique to Australia but is mirrored in other countries such as New Zealand (NZ) and the UK. Recent reports in the UK identified a steady increase from five health inquiries in the 1980s to 52 in the 1990s (Walshe & Higgins, 2002), while in NZ there is an annual increase of the number of health inquiries or investigations into poor care (Cull, 2001).

Inquiries into Healthcare Failures

Inquiries are set up to investigate systemic failures in healthcare delivery. Such major failures are different from a single event failure that may capture media attention or be the focus of a coronial inquest. Health system failures that result in an inquiry are distinguished by the scale and magnitude of the breakdown in care. The timescale of the events may stretch over months or years, and there are a number of different occasions where poor patient outcomes (including patient deaths) have occurred as a result of inadequate or unsafe care (Walshe & Shortell, 2004).

Walshe and Higgins (2002:896-897) identify six main purposes for the instigation of an inquiry. These are to:

- Establish the facts;
- Facilitate catharsis or therapeutic exposure for stakeholders;
- Reassure the public that something is being done to remedy the problem;
- Apportion responsibility;

- Serve the interest of political considerations; and
- Learn from events and thus prevent further failures.

The first five of these purposes are, to some degree, addressed by the establishment of an inquiry that is open to the public, robust and transparent in process. The last purpose, that of 'learning from events to prevent further failures', requires ongoing commitment. Over time, after completion of an inquiry, media and community attention is diverted by other events. Thus, the commitment to improve may be difficult to maintain. As the focus shifts away from the healthcare facility that was the focus of the Inquiry, the external scrutiny, political impetus, and the internal organisational resources and commitment, may not be able to sustain the force required to implement changes that prevent further failures.

Inquiry Triggers

The trigger for an inquiry is often a staff member or a group of staff raising issues of poor care to the administration within the organisation (Walshe & Shortell, 2004). When this fails to address the problem, the staff members often seek outside intervention by raising the issue to external administration, politicians or the media. This was the situation at King Edward Memorial Hospital (KEMH) in Perth, WA, where, it was noted at the inquiry set up to investigate concerns about patient care, that the deficiencies in care had been identified by staff and reported to the management on several occasions. It was not however, until the newly appointed Chief Executive Officer raised these matters externally that the chain of investigation commenced (Douglas et al., 2001). Similarly the investigation into Campbelltown and Camden Hospitals was triggered when a group of nursing staff, frustrated at a lack of action by the organisation's management over their concerns, sought intervention from the New South Wales (NSW) Minister for Health (Faunce & Bolsin, 2004). The Bundaberg Hospital Inquiry (2005) was likewise triggered by a nurse. Once again frustrated by the inaction of management to issues of

poor surgical care, she took her concerns externally, where they were raised in the Queensland Parliament (Van der Weyden, 2005).

Although not as common, there are occasions where a particularly well-informed group may champion a cause, which then results in enough pressure to capture the attention of authorities. This was the situation in New Zealand in the case of the National Women's Hospital failure to treat a cohort of women with cervical cancer (Cartwright, 1988). Regardless of the trigger, once an issue is raised in the public domain, media attention and the resulting consumer reaction often leads to overwhelming pressure for a formal response (Walshe & Shortell, 2004).

Common Characteristics of Health System Failures

Various comparisons in the literature of findings from different health inquiries have identified several common factors that occur repeatedly in health system failures. Firstly, the identified problems within the organisation are longstanding. Many hospital staff members are aware that there is a problem, although they may not know the magnitude of the problem. Secondly, significant harm or damage results for patients affected by the sub-optimal care. As well, the organisations concerned seem to have poor leadership, to be geographically or organisationally isolated, and have an inward-looking culture. These organisations also lack effective management systems such as mechanisms for performance review. Finally, staff and patients of these organisations are disempowered and thus unable to voice their concerns (Braithwaite et al., 2006; Faunce & Bolsin, 2004; Walshe, 2003; Walshe & Higgins, 2002; Walshe & Offen, 2001; Walshe & Shortell, 2004)

Each of the Australian hospitals mentioned previously (KEMH, Campbelltown & Camden and Bundaberg), had systems in place to collect and monitor clinical governance information. This should have alerted management to serious clinical care problems. Unfortunately, the systems in place lacked robust or rigorous review processes or alternatively, the

systems were easily bypassed or ignored (Faunce & Bolsin, 2004; Van der Weyden, 2005). As well, each hospital was taking part in an external accreditation survey process. Part of this survey involved assessing the adequacy of the organisation's clinical governance and clinical risk systems and processes. The final exposés of the major problems within these organisations occurred in spite of these systems, not because of them (Faunce & Bolsin, 2004). Thus, a reliance on patient safety and performance monitoring systems to detect problems and thus provide a trigger for remedial action is misplaced (Van der Weyden, 2005; Walshe & Shortell, 2004).

This situation is not unique to Australia. In their analysis of major healthcare failures in the United States, the United Kingdom, New Zealand and Canada, Walshe and Shortell (2004) found a similar pattern of bypassing the clinical governance systems and accreditation processes that were in place at the time. This was also noted in a study by a team of researchers led by Braithwaite (2006), which examined eight health inquires in six different countries.

With clear evidence that improvements are required, what then are the barriers blocking the required changes to the systems and processes that will improve patient care?

Barriers to Change

Within any organisations it is possible that groups and individuals may resist change. This can be for a variety of reasons including the barriers of organisational inertia, threats to group or individual expertise or power relationships, and fear of the unknown. To some degree this resistance to change provides stability for the organisation, however these barriers can also result in an organisation's inability to adapt and respond to changing circumstances or expectations (Robbins, Millett, & Waters-Marsh, 2004). Health organisations are no different to any other organisation in terms of

these barriers, but the context of health delivery does provide a unique aspect to the barriers to change.

There is no doubt that in the main, hospitals are staffed with competent and caring professional staff (Hewett, 2001). Unlike other industries however, clinical staff providing care are working in a climate where the product (patients and families) they are dealing with is already flawed (patients are sick, families are grieving), or as an acceptable part of their role, they damage the product (surgical intervention, painful procedures) (Walshe & Shortell, 2004). These professionals are accustomed to the outcome of their care not necessarily providing a perfect solution. They work daily in situations where people get sicker from chronic or terminal diseases, or where medication and treatments do not work. They work with patients and families to increase acceptance of suboptimal health status and support people as they learn to live (or die) with the results of traumatic injuries or acute and chronic diseases. Health professionals thus deal constantly with the results of life's adverse events. To function effectively, health professionals must accept that in providing care, even when they are providing the best possible care, this may not result in a positive outcome for the patient. They therefore develop a tolerance for things going wrong or not being perfect.

Contrast this situation to other industries often compared to the health industry. When looking at safety and risk in industries such as the airline, oil or nuclear industries, these industries function in a safety paradigm of low tolerance for near misses, adverse events and poor outcomes (Schulman, 2004). Any flawed or damage product, once identified, acts as a trigger to review and thus reduces or prevents the likelihood of a repeat of the factors that led to the problem. If adverse events and incidents are to trigger the same immediate response within the health care arena, then the challenge is to find a way to increase health professionals awareness to preventable adverse events and errors while not fracturing the coping mechanisms that allow them to accept inevitable poor clinical outcomes (Walshe & Shortell, 2004).

Healthcare is also unique in that even when adverse incidents or even a major failure of healthcare is made public, the customers (patients and families), continue to use the service. This is particularly so when the hospital or health service is the only one available in the community. Contrast this to a major airline failure or nuclear industry failure. In this situation, the customers can boycott the service, or if the risk is extreme, the organisation will be shut down until remedial action is put in place. In health, while people continue to get sick and require health care, a hospital may be the focus of investigation but patients will still present for care (Walshe & Shortell, 2004). Day-to-day care activity within the hospital does not change, and although patients and families may have a heightened anxiety about something going wrong, for most, their individual interactions with health professionals continues to be positive. This creates a different mindset and incentive for both direct care health professionals and health management when business continues as normal. Thus, for health organisations, the need to commit human and financial resources in an environment of scarce resources, does not carry the same organisational imperative as it does for other industries, where failure to fix a problem may result in the organisation having to cease operating the business (Walshe & Shortell, 2004).

When there are problems indicative of a health service's failure of care, a common factor that may act as a barrier to remedial preventative action is the fragmentation of information (Walshe, 2003; Walshe & Shortell, 2004). Many people may know about different parts of the problem without realising the quantum of the problem, or if they have some indication that there is a major problem, they do not have the authority to initiate action to fix the problem (Walshe, 2003). This problem with fragmentation of information was identified in all the final reports of the inquiries mentioned previously. Each of these reports noted that the problems (or some aspects of the problem) were well known to many staff but no remedial action resulted from this knowledge (Davies, 2005; Douglas et al., 2001).

A further area that makes healthcare unique in terms of the barriers to change is the culture of medical professional dominance that prevails within healthcare both in Australia and internationally (Carroll & Quijada, 2004; Ferlie & Shortell, 2001; *Investigation Report Campbelltown and Camden Hospitals, MacArthur Health Service*, 2003; Rubin & Leeder, 2005; Willis, 2006). Willis (2006) describes this culture as one where the medical profession has considerable influence on the content of their own work (autonomy), over the work of other health occupations (authority) and as institutionalised experts in all matter relating to health in wider society (sovereignty). This cultural dominance until very recently has been appropriate in the context of less advanced treatment options and medical technology, and limited access to electronic communication and resources. However, with the current context of healthcare being one of high technology, instant access to electronic resources, job designs that involve multiple competing priorities, and a growing body of well informed consumers, this cultural dominance is acting as a barrier to change (Carroll & Quijada, 2004; Ferlie & Shortell, 2001; Germov, 2002; IOM, 2001; Long, Forsyth, Iedema, & Carroll, 2006; Willis, 2006).

Carroll & Quijada (2004) identify the need for a reframing of this culture of dominance. This reframing will require a shift from individual practitioner autonomy to team autonomy. Decisions about patient care will then be shared between health professionals together with the patient and families. This shift to team autonomy must be accompanied by the shift from the blame and shame individual accountability to one where the focus is on systems and processes. Without this cultural shift, a transparent system where risks and errors are examined openly and individual professionals feel safe to report concerns will be difficult to achieve (Carroll & Quijada, 2004; Ferlie & Shortell, 2001; Willis, 2006).

Germov (2002:300) suggests that the biggest challenge to the culture of medical dominance is the introduction of Australia's clinical governance policies that "... may represent the most effective challenge to medical

dominance to date". The development of clinical governance models across health care may be reducing the impact of the medical dominance culture however, the "...deeply entrenched values, beliefs and practices of medical dominance in Australian hospitals still prevail..." (Long et al., 2006:516) and these beliefs and practices act as a barrier to patient safety reforms.

Stanton (2008:36) asserts that "the medical profession are the most powerful group in the healthcare sector as they make important resource decisions and largely control the production process". Occupying this influential position means that the beliefs and attitudes this group have about the process of care, and the systems and processes that manage this, is pivotal to how the care processes are then delivered. These beliefs and attitudes are influenced by several things including the type of education and training that emphasises doctors need to be self reliant, independent, autonomous and accountable to their profession (Stanton, 2008). As well, these early beliefs are reinforced in the socialisation they receive as they enter practice. This reinforcement occurs from those already in the medical profession and also from other health professionals and the community who, by their own patterned reactions and interactions, reinforce the concept of medical dominance (Allsop, 2006). Finally, these attitudes and beliefs are maintained by what is described by McPherson and colleagues as the homophily principle (McPherson, Smith-Lovin, & Cook, 2001). This phenomenon is described as the situation where people tend to associate with others like themselves in terms of social situation, education, gender and race. West, Barron & Dowsett et al. (1999) assert that this phenomenon is strong in the medical profession with the resulting situation that as professionals they have little contact with differing views. Because of this homophily principle, doctors are not as likely to be exposed to new or differing information from outside their medical professional circles, and they remain unaware of changed trends or expectations that do not impinge immediately on their sphere of practice. This, combined with the medical profession's position of power within health organisations, means that that if this group do not see a need for

change, then they can be extremely resistant to change initiatives (McGrath et al., 2008; West, 2008).

Nursing culture also acts as a barrier to change. This occurs since the nursing culture mirrors and reinforces the medical culture of dominance in several ways: firstly, by accepting and reinforcing the idealistic philosophy of clinical perfection that has the expectation of error free performance for both nurses and doctors (IOM, 2004:299-300). This type of culture inhibits error reporting and thus the opportunity to learn from mistakes is lost (Edmondson, 2004). Secondly, the culture is reinforced by accepting the authority gradient that occurs because of the medical dominant culture. This compromises effective communication and teamwork (Carroll & Quijada, 2004; Chiarella, 2002; IOM, 2004; Wachter, 2008). When these two perspectives are compromised, they have a direct impact on patient safety (IOM, 2004; Reason, Carthey, & de Leval, 2001; Wachter, 2008). This acceptance of a culture of perfection, and the impact of the authority gradient on communication and teamwork, will continue to act as a barrier to change until the nursing profession acknowledges the situation and embraces education and training to manage interactions and expectations in a positive and constructive manner (IOM, 2004; Kramer & Schmalenberg, 2002; Wachter, 2008).

Another significant barrier to change is unique to public healthcare organisations, as opposed to private sector organisations. This is the circumstances and framework in which, by the nature of being public sector organisations, they have to operate (Hurley, Baum, & van Eyk, 2004). Ferlie (1997) suggests that this is because of the difficulty in balancing demand, which usually exceeds resources, and because of the political context within which public sector organisations work. Political leaders, electoral cycles and shifting political focus can all have a significant impact on the ability to implement and manage change. Mechanic (1996) supports this, reporting that the shifting political context impacted negatively on the momentum for change and was one factor that

led to failure of the planned reforms within the health system that was the focus of his study.

It is within this unique context that healthcare organisations seek to identify the change management processes that will overcome barriers that impede improvement in clinical governance processes.

Organisational Change Management

The barriers that exist and the way they operate to inhibit or frustrate change in an organisation can be understood in terms of a number of existing theories or models of change. One such theory is Lewin's (1951:320-322) three step model of change. This model is based on the concept that individuals and groups strive for equilibrium (state of no change or status quo). This state of equilibrium is how the individual or group life is expressed. The forces that change the equilibrium or status quo are driving forces (pushes towards or supports change) or restraining forces (pulls away from or restrains change). To maintain the status quo, the two pressures of the driving force and the restraining force must be in balance. To effect change, the balance of the two forces must be changed. The status quo may be maintained because conditions under which the group exists stays constant, thus this status quo does not arise out of resistance to change. If the conditions or the environment under which the group exists changes (increase in the driving force), and there is no change in the equilibrium, then there must have been an increase in the barriers or resistance (restraining forces). This increase in the resistors to change prevents the drivers of change upsetting the balance and thus the status quo is maintained (See Figure 1 for diagrammatic representation of Lewin's (1951) model).

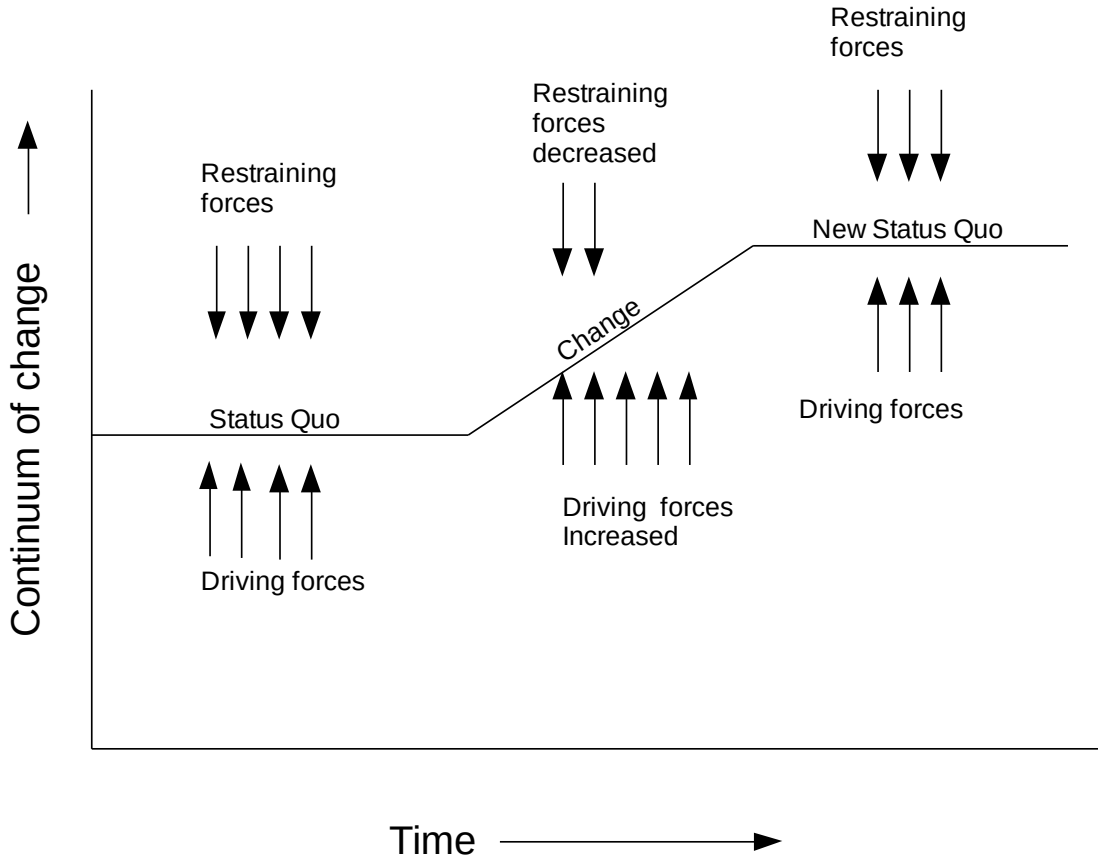


Figure 1: Lewin's (1951) model of change
(adapted from Lewin, 1951:216)

As stated previously, the sources of organisational resistance can be structural inertia, group inertia, and threat to expertise, established power relationships, or to established resource allocations. Upsetting the equilibrium to facilitate change in an organisation, typically requires some form of intervention by a change agent (Daly, Speedy, & Jackson, 2004; Lewin, 1951; Marquis & Huston, 2006; Robbins et al., 2004)

While Lewin (1951) provides a model describing the change process, other factors impinge on organisational change management. Reger, Mullane, Gustafson, & DeMarie, (1994) discuss different types of change process in relation to the environment within which the organisation operates. Incremental change involves minor change and is suitable for

stable environments. Tectonic change involves moderate change and is suitable for turbulent conditions, and revolutionary change involves massive change and is suitable for a crisis situation. Reger et al (1994:33) assert that incremental changes are unsuitable for complex environments since the environmental conditions are shifting faster than the organisation is able to respond. In this situation, incremental change makes it impossible to overcome the internal inertia and the bad habits that have been reinforced by bureaucratic processes.

Dunphy and Stace (1990) as cited in Hurley, Baum, and van Eyk (2004:32), describe tectonic and revolutionary change in terms of transformational change. They describe this as "radical and wide ranging change to a mission, culture and structure in order to meet changing environmental conditions". This type of change can be extremely confrontational to members of an organisation considering that it challenges core beliefs and assumptions about what the organisation stands for and the way the business is transacted on a routine basis (Hurley et al., 2004; Reger et al., 1994; Southon, 1996).

Within the current environment of Australian health care there are many examples of successful implementation of safety and clinical governance initiatives (Barraclough, 2001; Barraclough & Birch, 2006; Southon, 1996). The focus of these reforms has, in the main, been single project implementation (incremental changes) rather than whole system reform (Johnstone & Kanitsaki, 2006). Ferlie and Shortell (2001) also note that clinical governance reforms have mostly been narrow and single level in focus. They go on to assert that any sustained improvements in clinical governance systems need to involve four levels of the organisation. These are the individual, the team, the organisation and the wider environmental context (Ferlie & Shortell, 2001:283-289). It is of note though, that there is very little reported in terms of transformational reform involving organisation-wide clinical governance systems of the type that may have prevented the healthcare failure at KEMH.

Significance of the study

The need to improve patient safety is well documented in the current literature. McLean and Walsh (2003:22), in reviewing the Inquiry into care at KEMH (commonly known as the Douglas Inquiry), identify the lessons that need to be learned are in the areas of "issues of accountability and responsibility, leadership and culture, safety and quality systems, staff support and the development of concern and compassion for families." This is supported by Barraclough (2003) who stated that the issues identified in the Inquiry report are not confined to KEMH, and must be considered to be applicable to all other public and private hospitals in Australia. Duckett (2003), Hindle (2003) and Siddins (2003), all agree with Barraclough's assertions in relation to the same inquiry. These authors identify that the issues raised at the Inquiry that resulted in poor care are applicable across the whole health system.

Inquiries of this type tend to be highly politicised and very visible to the general public (Walshe, 2003; Walshe & Higgins, 2002). The act of the inquiry itself can be viewed by politicians and the community as the remedial action for the problems being investigated. The reality however, is that an Inquiry in itself does not "fix the problem". Rather, it is the actions and changes that occur subsequent to the Inquiry that will improve an unacceptable situation. There is very little examination given to this aspect (Hindle, 2003; Walshe, 2003; Walshe & Shortell, 2004). When changes are examined, the focus is inevitably on reporting changes in policies and procedures, management structure or accountability processes. While structure and process changes are vital, they do not necessarily translate into differences of how care is being delivered at the coalface. For example, a policy can be written in terms of how patients are to be involved in their care (structural change), and conformity with the policy can be measured by auditing compliance (process change). However, unless there is some way of ascertaining from recipients of care that there has been a change in how they are being involved in their care (outcome), then the change has not "fixed the problem". There is very

little reported on the outcome aspect of changes (Edmondson, 2004). So, the question of whether an Inquiry has actually made a difference to patient safety or patients' perception of their care is not addressed.

After an inquiry, there may be some ongoing monitoring of organisations that are at the centre of the investigation. There are however, few mechanisms to ensure formal dissemination of the findings or the institution of actions that should be put in place as a result of the key recommendations arising from an inquiry (Walshe & Offen, 2001). This is evident when reviewing the significant findings from the inquiries into the three Australian hospitals mentioned previously. The time span of the separate investigations covers approximately five years. This time span should be enough to ensure that the problems influencing the lack of effective clinical governance in the first hospital investigated in 2001 (KEMH) would not be repeated in 2003 (Campbelltown and Camden) let alone in 2005 (Bundaberg). This, unfortunately, is not the situation. Although the circumstances in each case were different, there were similarities in the significant findings of all three. These were that there were ineffective or inadequate systems to monitor and report adverse events, absence of transparent systems and support to deal with patients and staff concerns about quality and safety, and a lack of an effective medical credentialing and performance review system (Davies, 2005; Douglas et al., 2001; Faunce & Bolsin, 2004). It is also striking to note that similar findings to those in these three Australian cases above were described in the report of the high profile Bristol Royal Infirmary inquiry into paediatric cardiac surgery, which commenced in 1998 in the United Kingdom (Faunce & Bolsin, 2004; *Investigation Report Campbelltown and Camden Hospitals, MacArthur Health Service*, 2003; Walshe & Offen, 2001). This lack of shared learning across the health system leads to history repeating itself with little evidence of improvement in adverse event rates or patient safety.

In order to learn from inquiries into health system failures, several areas require further investigation. Firstly, there is a need to be able to identify

whether an inquiry process influences the reform of clinical governance systems and processes. Secondly, if inquiry processes do influence change in some way then, there is a need to identify how the conduct or inquiry process influences this (Duckett, 2003; Hindle, 2003; Walshe & Higgins, 2002). These issues are at the heart of this study. The context of identifying and clarifying the research question is explained below.

The Research Purpose

The aim of this research was twofold. Firstly, to ascertain if inquiries into healthcare failures led to changes in the clinical governance systems of the hospital that was the subject of the inquiry. Secondly, to identify factors within the inquiry that may have influenced changes either in a positive or negative way. To do this a study of one inquiry (Douglas Inquiry henceforth referred to in this report as the Inquiry) was undertaken to identify factors that may have influenced changes in the clinical governance systems and processes at the hospital under investigation (KEMH). The specific areas of medical credentialing and clinician performance review, and consumer involvement in care were chosen as the clinical governance processes to be examined.

DEVELOPMENT OF THE RESEARCH QUESTION

The Research Questions

The Development Process

A number of authors (Eisenhardt, 1989; Punch, 2005; Stake, 2000; Yin, 2003) stress the importance of ensuring clarity around the research question. To make sure of this, the following section identifies the general area of study and the particular area of interest. Both Yin (2003) and Punch (2005) declare that in asking the what and why questions and narrowing the focus of the study, the researcher is then able to start posing the question of what data will be required to answer the question, and where the best sources of that data would be. Figure 2 demonstrates this process as applied to the development of the research question for this specific study.

The general area of study is patient safety, with the particular area of interest within the broad area of patient safety being clinical governance systems and processes. The general research questions then are to identify barriers to clinical governance system improvement in healthcare agencies and the strategies that may be useful in overcoming these barriers.

The researcher believed that the general research question still needed to be narrowed to one that focused on a manageable and contained area. Thus, the decision was made to narrow the study to focus on a process of change that would be considered significant and possibly generalisable to other contexts. As an inquiry into a health service failure is a significant event and can be separated from other influences, it was believed that this would provide a unique set of circumstances allowing an identification of barriers pre inquiry and the opportunity to examine changes post inquiry. Whether there were changes to clinical governance processes post inquiry would be irrelevant, since the study focus is to be the effect of the inquiry on the change process either positive or negative.

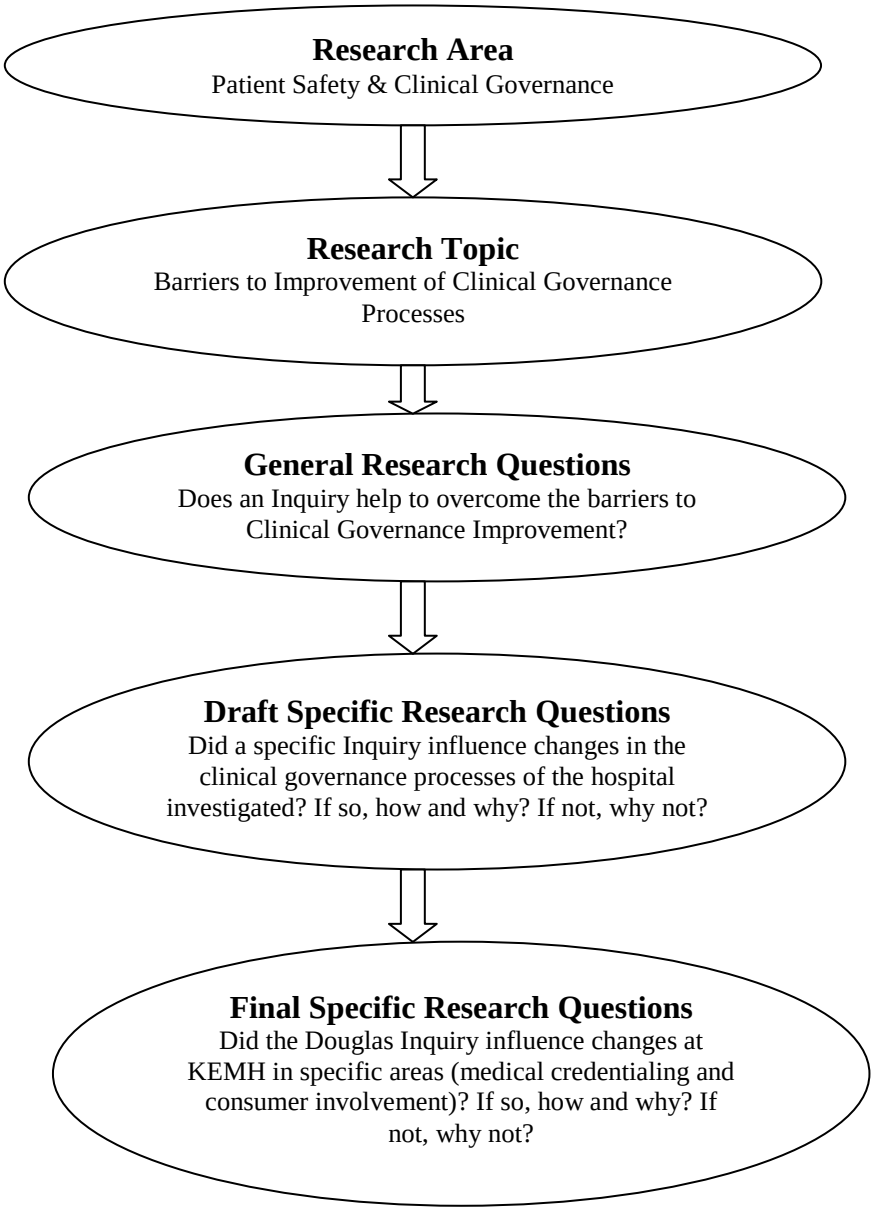


Figure 2: The process of development for the research question

In the first instance, the specific research questions were articulated as the influence of an inquiry on clinical governance systems. As the researcher started to explore the data collection questions for this research question however, the realisation came that the study needed to be narrowed even further due to the availability of resources to undertake the study. The researcher decided therefore, to study one hospital (KEMH) that was the

subject of an inquiry, and to focus on several specific areas within the clinical governance framework identified at the particular inquiry as requiring improvement.

The specific areas that were chosen as the focus of this study are medical credentialing and performance management and, consumer involvement in care. These areas were chosen for several reasons. Firstly, credentialing and performance review processes are excellent examples of administrative functions that are important for patient safety, easily measured in terms of structure, process and outcome, and require cultural change from clinical staff. It is an area highlighted in the final Inquiry report as an area of significant deficiency.

The second area, involvement of consumers in care, is more difficult to measure objectively. Yet, in terms of what is valued by patients and families, it is of great importance. In terms of the Inquiry, it was an area of major focus, and requires significant cultural change from clinical staff. For both of these areas, it was believed that if the Inquiry was shown to have influenced the clinical governance processes, the knowledge could be transferable to similar contexts.

This development process moving from the general to the specific, allowed the central research question and the supporting research questions to be articulated clearly.

The Central Research Question

The central research question then is:

- Did the Douglas Inquiry influence changes in the clinical governance systems at KEMH in specific areas of medical credentialing and clinician performance management, and the involvement of consumers in care?

The Supporting Research Questions

The supporting research questions to answer the central research question are:

- Were there changes in the medical credentialing and clinician performance management systems post Inquiry?
- Were there changes in the involvement of consumers in care post Inquiry?
- If the Inquiry did influence change in the specific areas, how and why?
- If the Inquiry did not influence change in the specific areas, why not?

While the researcher understands that this study focus was very narrow, the original general research question was seeking to understand those factors that may influence clinical governance improvement from a broader perspective. The literature identifies clearly that there is a need to understand this. So, while no two hospitals are the same, the differences are expressed in terms of organisational function and operation, the clinical specialities and caseload, or the community they serve. KEMH as a public sector acute tertiary metropolitan hospital still has many similarities with other public sector hospitals (Hindle, 2003). The areas of similarity are particularly in terms of workforce context, consumer/patient expectations, resource constraints, public sector and community accountability, and the need to work within a political context (Eager, 2004). Findings from this research study therefore, may have transferability to other similar public hospitals.

The Research Design

Concurrent with the process of identifying the questions and the best sources of data, a research design needed to be identified. The researcher identified that case studies typically focus on an event, issue or program. Using multiple sources of evidence and through a detailed investigation, description and analysis, a deep understanding of the object of the study is developed (Creswell, 2007; Hancock & Algozzine, 2006; Punch, 2005; Yin, 2003). For this reason, the researcher believed that a case study strategy was the approach of choice. The case for this study was identified as the Inquiry, the Inquiry process and the Hospital. The choice of case study strategy is discussed in detail in Chapter 2.

Data Collection Questions

Having identified the research questions the next stage of the process was to identify how the research question could be answered and where the best sources of data would be. This then leads on to the development of the data collection questions (Punch, 2005; Yin, 2003). See Table 1 for diagrammatic representation of the process.

To ascertain what changes had taken place the researcher identified that there would need to be access to documentary evidence from KEMH together with data from consumers to corroborate the documentary evidence. To understand the influence of the inquiry on changes at KEMH the researcher believed that external stakeholders who understood and experienced the outcomes of change at KEMH would provide unique and valuable insights into the influence of the inquiry on change at KEMH. This aspect is explored in greater depth in Chapter 2.

Table 1: Process for the development of the data collection questions

Specific Research Questions →	**What Information do I need? →**	**Data Sources →**	**Data collection questions**
Did the inquiry influence changes in the clinical governance processes? →	Identify the contextual conditions of the Inquiry conduct and processes and also KEMH pre Inquiry →	Documents Archives Interviews →	Using documents and archives, what was the profile of KEMH and the background context that led to the Inquiry? What was the stated purpose, terms of reference and the methods and processes adopted by the Inquiry? What were the findings of the Inquiry identified from the document and archive review?
How did the Inquiry influence changes? →	Evaluating if any changes (and the extent) had taken place at KEMH in the areas of interest of this study →	Documents Archives Interviews →	What changes post Inquiry can be identified in documents and archives in regards to: • The involvement of consumers in the maintenance and improvement of performance at KEMH; and • Clinician credentialing and performance review processes at KEMH? To what extent do the participants perceive that the Inquiry contributed or influenced change or reform of : • The involvement of consumers in the maintenance and improvement of performance at KEMH; and • Clinician credentialing and performance review processes? Are the participants' perceptions of reform or change similar to those identified in the document and archive search?
Why did the Inquiry have the influence it did? →	Identifying barriers or drivers of change in pre KEMH context Identifying barriers or drivers of change in Inquiry process →	Interviews →	What factors or elements of the Inquiry do the participants perceive impacted positively or negatively on change or reform of: • The involvement of consumers in the maintenance and improvement of performance at KEMH; and, • Clinician credentialing and performance review processes?

Based on the decisions to this stage, the following data collection questions were developed to form the basis of data collection to answer the research question:

1. Using documents and archives, what was the profile of KEMH and the background context that led to the Inquiry?
2. What was the stated purpose, terms of reference and the methods and processes adopted by the Inquiry?
3. What were the findings of the Inquiry identified from the document and archive review?
4. What changes post Inquiry can be identified in documents and archives with regards to:
    - the involvement of consumers in care at KEMH; and
    - medical credentialing and performance review processes at KEMH?
5. To what extent do the participants perceive that the Inquiry contributed or influenced change or reform of :
    - the involvement of consumers in care at KEMH; and
    - medical credentialing and performance review processes?
6. Are the participants' perceptions of reform or change, similar to those identified in the document and archive search?
7. What factors or elements of the Inquiry do the participants perceive positively or negatively impacted on change or reform of:
    - the involvement of consumers in care at KEMH; and
    - medical credentialing and performance review processes?

CHAPTER SUMMARY

In this chapter, the general background of the topic leading to the research question was introduced. This included a discussion of patient safety and clinical governance programs in Australia and internationally. Following this, a detailed discussion about the different aspects of inquiries into

health system failures was presented. The barriers to the implementation of effective clinical governance systems were then discussed. The chapter concluded with a presentation of the significance of the study, the research purpose, the research questions, the research design, and the process used to develop the data collection questions. The research paradigm and the case study strategy will de discussed in Chapter 2. Subsequently, Chapter 3 will provide a detailed description of the case of interest.

CHAPTER TWO: METHODOLOGY

"...research attempts to isolate some of the most important contributing causes from extraneous causes and provides a major source of hypotheses about what causes events in our world "(Browne & Keeley, 2004:143).

INTRODUCTION

As discussed in Chapter 1, the general research question is to identify barriers to clinical governance system improvement in healthcare agencies and the strategies that may be useful in overcoming these barriers. The specific research question for this study is seeking to understand the impact of one inquiry (the Douglas Inquiry) on changes in the clinical governance processes at the hospital investigated (KEMH). To do this the case study strategy was selected for this study. This chapter details the rationale for choosing this design, and the design reliability and validity tactics. This then leads on to a discussion about the methods employed to conduct the study. These include a description of the sample, data collection, and the analysis methods employed. The process by which the findings were then synthesised and developed using Lewin's (1951) model of change will then be articulated. The chapter will conclude with a discussion on the ethical considerations for this study.

RATIONALE FOR CHOOSING CASE STUDY STRATEGY

Background

There is some debate as to whether case study research is a method or a strategy. Stake (2005) views a case study as the subject or problem being examined, as opposed to Denzin and Lincoln (2005) who consider case study to be a strategy of inquiry. Yin (2003) describes case study as a research strategy, and Creswell (2007) as a research methodology. It is difficult to provide unqualified support for either method or strategy as the descriptor for case study research without lengthy debate with research methodology experts. That discussion however, is beyond the scope of

this study, and thus the researcher will use the terminology 'case study strategy' while noting there is debate as to the acceptable descriptor.

The case study strategy is one type of research that employs the qualitative approach (Creswell, 2007; Hancock & Algozzine, 2006; Stake, 1995; Yin, 2003). Qualitative research seeks to primarily understand and describe social situations. Denzin and Lincoln (2005:3) describe qualitative research as:

> … a set of interpretive, material practices that makes the world visible. These practices... turn the world into a series of representations including field notes, interview, conversations, photographs recordings and memos to self... qualitative researchers study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them.

Case studies are different from other types of qualitative research in that the focus is in developing an in depth description and understanding of the case or cases being studied by using multiple sources of data such as interviews, observations, documents and archives. The data analysis is done through description of the case and the themes of the case (Creswell, 2007).

Yin (2003:13) defines the circumstances for the use of case study strategy as when the research " investigates a contemporary phenomenon within its real-life context especially when the boundaries between phenomenon and context are not clearly evident". The case being studied can be a simple, easily defined unit, or it may be a complex multifaceted entity. Thus, the case could be an individual, a group, an organisation, a particular incident, an event, or there are many other possibilities. A significant feature of a case study strategy however, is that the case is bounded by space and time (Hancock & Algozzine, 2006; Punch, 2005; Yin, 2003).

Case study strategy in the past has not been well accepted as valid or rigorous methodology for scientific study (Hancock & Algozzine, 2006; Platt, 1992; Stake, 2000; Yin, 2003). In recent times however, case study

strategy is gaining acceptance as the benefits of this type of study for illuminating certain situations or events is realised (Hancock & Algozzine, 2006; Platt, 1992; Punch, 2005)

Although there are significant merits in the case study approach there are several criticisms levelled as limitations in using this strategy (Yin, 2003). The first is one that is not particular to case study strategy and is often levelled at the qualitative paradigm in general. Yin (2003) cites detractors that claim the limitation of this type of research is the inability of the researcher to be separate from the issue being studied and thus maintain objectivity. Proponents of qualitative research, on the other hand, claim that without subjective and contextual data, true understanding of social situations can not be obtained (Hancock & Algozzine, 2006; Punch, 2005; Stake, 1995). Yin (2003:36) also rejects this criticism provided the researcher rigorously implements a research design that systematically incorporates tactics designed to ensure validity and reliability in the conduct of the research.

A second potential limitation of case study research concerns the issue of generalisability. The possibility of case study findings being generalisable and thus meeting the requirements for external validity is a vexed one (Eisenhardt, 1989; Kyburz-Graber, 2004; Punch, 1998).

Both Yin (2003:40) and Punch (1998:153-156) argue that there can be case studies where generalisability is both possible and appropriate. For example, when the researcher has developed propositions or concepts from the investigated case and has compared them formally to a broad theory. In such instances, Yin (2003:39) notes the findings would have analytical rather than statistical generalisability. Both authors argue that when case studies are exploratory or descriptive, there is no requirement (or even expectation) that the findings will be generalisable to other cases. This indicates that the perceived limitation is clearly not an inherent weakness of the method at all (Punch, 1998: 153-156; Yin, 2003:38-40).

Stake (2000) argues that focus on generalisability should not be articulated in the same way as for quantitative studies. Rather that it should be that the generalisations about a particular case can be made to a similar case, or the case as a representative case that would give insight into a general question. Stake (1995) labels the latter as an instrumental case study.

Schofield (2000) supports Stake's (2000) position, but describes this as transferability or fit between the case being studied and others to which the findings might apply. Schofield (2000) goes on to stress that if there is going to be transferability, then there is an imperative for well-defined case boundaries and thick descriptions to ensure there is enough information to judge if there is a fit with another situation.

Case Study Strategy Applied to Current Study

Case studies as a research strategy have particular strengths when wishing to examine or explore an issue or phenomenon within the context or setting that it occurs. Punch (2005) describes the holistic, bounded nature of the case study strategy as one that gives the opportunity for an in depth understanding of the complexity and context of the particular case being studied. Neuman (2006) identifies that this strategy provides a comprehensive and in-depth understanding of the case participants' experience. Additionally, the phenomenon of interest and the subjective meanings the participants have attached to their experiences are identified.

Investigating the effect of the Inquiry on changes in processes at KEMH, specifically in relation to medical credentialing and the involvement of consumers in care, lends itself to the case study strategy. This is because the research is seeking a deep understanding of the case of interest, which is bounded by space and time, and is a contemporary phenomenon within a real life context (Punch, 2005).The Inquiry, the Inquiry process and the hospital itself constitute the case of interest for the study. The particular issue for investigation is the Inquiry's impact on change or reform at

KEMH. The hospital then, in the context of the Inquiry and its aftermath, is the unit or focus of analysis.

Stake (1995) identifies two different types of case study that relate to the aim of a research study. If the goal is to seek understanding about a particular case rather than a general problem he labels that type of study as an intrinsic case study. When the goal is to seek general understanding by the study of a particular case, he labels this an instrumental case study.

The current case study is an instrumental case study. In seeking to understand the influence of the Inquiry on clinical governance reform, the findings will be considered in the context of the general research area of patient safety and clinical governance and identifying if an Inquiry influences change. The Inquiry is an extreme case, but at the same time, KEMH is typical or representative. No two hospitals are ever going to be similar in terms of organisational function and operation, the clinical specialities and caseload, or the community they serve. KEMH however, as a public sector acute tertiary metropolitan hospital, will still have many similarities with other public sector hospitals, especially in terms of workforce context, consumer/patient expectations, resource constraints, public sector/community accountability and political environment. Thus, there is opportunity for findings from this research study to have transferability to other similar public hospitals.

Case studies can utilise a single or multiple case design (Yin, 2003:39-53). Yin states that the single case design is suitable if the case:

- can be considered a significant case to test aspects of a particular theory;
- is representative or typical;
- represents an extreme or unique case; or
- is one that provides the opportunity to investigate something previously unavailable for research.

This study meets the parameters Yin identifies as being suitable for a single case design. The Inquiry is an extreme case and provides the opportunity to investigate something previously unavailable for research. This is because it relates to a high profile and public event documenting KEMH's organisational failure. The impact on KEMH and any reform of clinical governance systems can therefore, be isolated and considered independent of other factors. As well, this type of organisational failure is relatively rare and thus provides a unique chance to study the impact of the Inquiry. The use of a single case to gain understanding of a wider issue is considered by Stake (1995:3-4) to be an instrumental case study.

Finally the single case design is appropriate because as well as searching for answers to identify if there has been change in the structure, process and outcome levels of clinical governance, the research question is seeking specifically to identify how and why the Inquiry impacted on change in particular areas (medical credentialing and consumer involvement). Thus, the changes cannot be divorced from the context of the Inquiry itself and the aftermath of the Inquiry. The investigation of the bounded case (the Inquiry, the Inquiry process and KEMH) and the resulting conclusions about change and the drivers or barriers to change, becomes the critical test of a significant theory, that being Lewin's (1951) change management theory. This then meets Yin's (2003) single case suitability criterion that the case of interest can be considered a significant case to test aspects of a particular theory

Yin (2003), in discussing the single case design, describes two types of analysis, either holistic or embedded. With holistic, there is a single unit of analysis, while with the embedded there are multiple units embedded within the single case. This study is searching for evidence of changes in those clinical governance processes related to medical credentialing and consumer involvement together with reasons why those changes occurred. Consequently, this study involves multiple units of analysis embedded

within a single case (see Figure 3 below for diagrammatic representation of this).

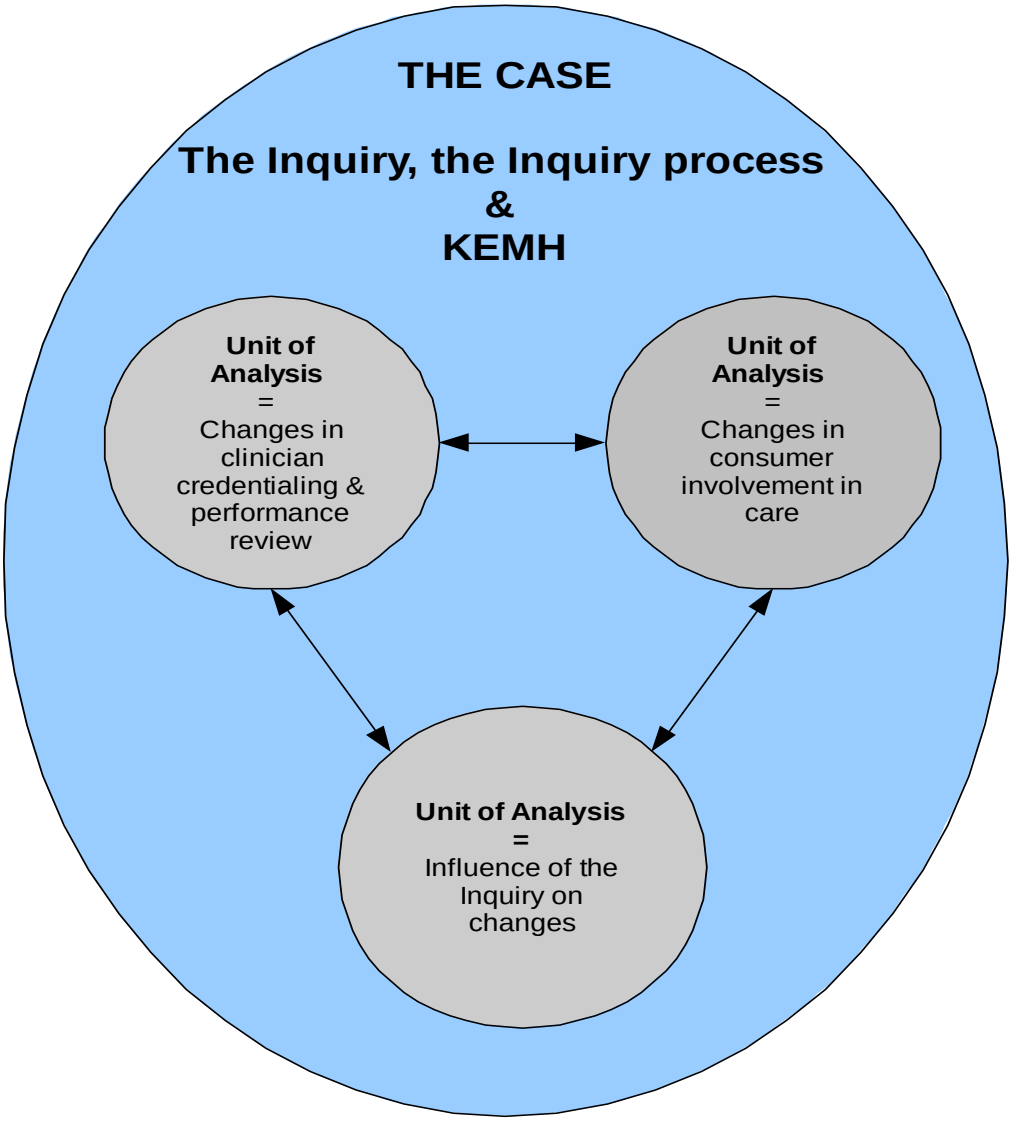


Figure 3: Single case design with multiple units of analysis (adapted from Yin, 2003:40)

The case study strategy then, has a number of pertinent advantages for undertaking this study. The case itself is bounded in time and space. The research question requires an in-depth analysis by using multiple sources of data, with the analysis involving multiple units of analysis as well as the development of themes describing the impact of the Inquiry on changes at KEMH.

DESIGN RELIABILITY AND VALIDITY

Creswell (2007) identifies several perspectives in regards to the terminology used to describe the reliability and validity techniques for qualitative research. One of these perspectives utilises what are traditionally recognised as quantitative terms; for example, construct validity, internal validity, external validity and reliability. Another perspective uses what has come to be recognised as applying to qualitative research, for example, credibility, transferability, dependability and confirmability. A further perspective uses terms such as authenticity, integrity, criticality and congruence. There are various arguments put forward for the different terms. One view states that using quantitative terms in qualitative research promotes its acceptance while another view claims that using terms unique to qualitative research is better in keeping with the naturalistic setting (Creswell, 2007). Creswell's (2007) position asserts that the terminology in itself is not important rather the focus should be on describing and demonstrating accuracy in the research process. He goes on to suggest that researchers should always reference and explain the techniques used. The debate on which terminology should be employed to describe the strategies for reliability and validity are beyond the scope of this study, however, for this study the terminology used is that of Yin (2003). The decision to use Yin's terms was taken in recognition of his acknowledged expertise in techniques and principles of case study research (Creswell, 2007; Hancock & Algozzine, 2006; Neuman, 2006; Pare, 2002; Punch, 2005). Yin (2003) identifies the four tests that have been used to establish the quality of any research design, also applies to case study research. Yin uses terms that have been traditionally applied to quantitative research designs, but claims they are relevant to case studies because of the empirical nature of this type of research. Yin (2003:34) describes these four reliability and validity tests as:

- Construct validity: establishing correct operational measures;
- Internal validity: as establishing a causal relationship…whereby certain conditions lead to other conditions;
- External validity: establishing the domain to which a study's findings can be generalised; and
- Reliability: demonstrating the operations of the study- such as collection procedures.

A wide range of tactics and safeguards were employed that were intended to ensure reliability and validity of this study (see Table 2 below for summary of tactics used throughout study). These tactics were kept under constant review and refinement throughout the study. The tactics employed during the pre-empirical stage where the research topic is identified, the problem described and the research questions articulated were discussed in the previous chapters. The approaches taken to address validity and reliability matters during data collection and analysis will be discussed later in this chapter. The following section will deal with the tactics that were generally applied to the research design to ensure reliability and validity.

Table 2: Tactics employed to ensure design reliability and validity (adapted from (Pare, 2002:13; Yin, 2003:34)

Reliability criterion	**Description**	**Tactics used in this study**	**Stage of research design**
Construct validity	Establishing correct operational procedures	• Multiple sources of evidence to provide cross verification • Developing interview skills pre-interview • Instrument design and trial • Establish chain of evidence • Review by peers and mentors of report	• Data collection • Data collection • Data collection • Data collection • Write up
Internal validity	Establishing a logical link between the research questions, the data collected and the inferences/conclusions made in the analysis	• Multiple sources of evidence to provide cross verification • Consider rival explanations • Double analysis/ reanalysis • Peer review and challenge • Member checking • Journaling & memoing • Explanation building utilising current literature and Lewin's change management theory	• Data analysis • Data analysis • Data analysis • Data analysis • Data analysis • Data analysis • Data analysis
External validity	Establishing the context to which study's findings may be generalised.	• In depth (thick)description of the case	• Write up
Reliability	Detailing the processes so the study can be repeated	• Research protocol • Choosing appropriate data sources to answer the research question • Database • Detailed description of methodology	• Research design • Research design • Data collection and analysis • Write up

Research protocol

For every research study undertaken, the risks and obstacles faced by the researcher are many and varied. To overcome some of the pitfalls and to ensure the completed study stands up to process and methodological scrutiny, the researcher was advised to develop a protocol that would provide guidance at each step (Yin, 2003). In the initial stages of study development, an audit tool (see Appendix 1) was developed by the researcher to provide a mechanism to ensure that the study could be monitored for technical adequacy at each step in the research process.

The overall structure of the audit tool was based on the linear model described by Punch (2000). This breaks the research process into two stages: the pre-empirical stage, in which the research area was identified with reference to the literature, the problem described and then the research questions are articulated; and the empirical stage, where the research design was developed, data collected and analysed and the research questions answered.

The need to identify the data or evidence required to answer the research question spans both the pre-empirical and empirical stages and as such, becomes the question or challenge that maintains focus on the study. For clarity and ease of use, the audit tool followed this model by posing questions for each of the subsections. The tool was extremely useful throughout the study to act as a safeguard to ensure that all aspects were being considered at each stage. Within the tool one of the areas considered concerned data requirements and the best and most suitable sources of data, which would provide information to answer the research questions. For this study, multiple sources of data were required to meet these needs.

Multiple sources of data

The use of multiple sources of data is a tactic for providing some certainty in terms of the validity of a particular research study. In terms of case study strategy, Yin (2003) and Creswell (2007) identify that a fundamental element of case studies is the use of multiple sources. The use of multiple sources of evidence provides a mechanism for viewing the case being studied from different aspects. This can represent different parts of the case or cases being studied which means that when the information is brought together, the wholeness of the research case can be described. As well, the multiple sources can be different perspectives or representations of the same case. Using these separate perspectives of the same case provides a means of verifying or disproving the final description and conclusions, rather than relying on just one perspective of the case to inform the description and conclusions. Yin (2003:98)) describes this as "converging lines of inquiry" or "triangulating the data", while Denzin and Lincoln (2000) talk about this process in terms of measuring the same phenomenon by different methods to get a thorough and more authentic picture.

Yin (2003) goes on to state that it is imperative for the validity of the study when choosing multiple sources to ensure that the sources are appropriate to gather the data for the questions being asked. There are two aspects to this. Firstly, that the methods will provide information to answer the research questions and secondly, that the information gained provides cross-verification.

In this study the research questions were seeking to understand firstly if change had occurred, secondly how the Inquiry influenced the change, and thirdly why the Inquiry impacted on change (accepting the impact could have been positive or negative). It was important therefore, that the data sources were going to provide the information needed to answer these questions. As stated above the data sources chosen were interviews,

documents and archives. In choosing to use interviews, documents and archives as data gathering tools, each set of data would give a different perspective of the case and provides cross-verification.

When dealing with the question of whether or not there had been change after the Inquiry at KEMH, documents and archives obtained from KEMH, the Department of Health West Australia, and Hansard (official parliamentary report), detailed the policies and procedures that had been changed or introduced at KEMH. The types of documents included were organisational charts, accreditation and audit reports (specific to clinical governance area), terms of references and reports for KEMH governance committees and medical credentialing, and performance management tools and reports. These documents and archives in the main provided the structure and process aspect of policies and process change (if there had been any) at KEMH post Inquiry.

The interviews with external stakeholders supplied information about whether the participants had noticed any change in how the clinical governance processes were actually working. This gave information from the aspect of whether any structural and process reform at KEMH was actually translating into outcomes for those interacting with KEMH. Put another way, using the interviews, documents and archives as multiple sources of information was expected to result in a comprehensive understanding of whether there were clinical governance changes post Inquiry in how KEMH was reporting changes and whether this was translating into changes in how the service was being delivered.

When investigating why change occurred, it was anticipated that all three sources would provide data about whether the Inquiry influenced change in either a negative or a positive manner. Nevertheless, it was expected that each source would provide different facets and aspects of the same phenomenon while providing substantiation of the different perspectives.

These multiple sources of information provided a cross-verification and a depth of understanding for understanding the research questions. Using multiple sources of data however, did result in an enormous amount of data, which provided a challenge in terms of managing this efficiently and effectively.

Managing the data

Yin (2003) advocates the necessity of a database. This allows the researcher to manage the volumes of data obtained from the multiple evidence sources. As well, a database enables the researcher to use it as a management tool to enhance the reliability of the research project. By organising all data and evidence into an easily retrievable filing system, the researcher provides the opportunity for the study data to be available for external scrutiny if required. It is also easily accessible for the researcher to analyse data and produce the report, and it ensures that the information is available if there is a requirement for the study results to be duplicated in the future.

For this study the software program *NVIVO 7 (2006-2008)* was used to store, manage the data, and as a tool for analysis. Both Creswell (2007) and Punch (2005) discuss the use of computer programs for qualitative data analysis. These authors identify the positives as providing a tool to organise and manage the data, together with allowing easy retrieval, sorting, comparing and contrasting of codes and categories. They also identify the advantages of being able to easily create and manipulate visual models to help in the process of developing ideas and forming conclusions about the data. Creswell (2007) makes the point that having the ability to manage and store the data easily encourages the researcher to spend more time on examining the data in close detail rather than tending to be more cavalier when there are large amounts of text or transcripts.

Of course, with any tool there are cautions and disadvantages. Creswell (2007) identifies that the time taken to learn to identify a suitable program and then to learn to use it can be substantial. This can act as a considerable disincentive. Moreover, for this study, the time to do this was significant. Overall though, using a software program to manage and analyse the data was found to be extremely advantageous for this study.

To manage the volume of data collected for this study, several functions of the computer software package *NVIVO 7 (2006-2008)* were utilised to categorise and document it. Although this package is primarily a data analysis tool, it also has the functionality to permit a wide variety of materials to be imported into the project folder. The types of sources that can be imported are field notes, memos, audio interviews, transcriptions, and literature reviews. Once imported, the information can be labelled and sorted into folders at the discretion of the researcher.

Those sources unable to be imported, such as newspaper articles and books can be summarised in the same way and then an external link can be established to where the data is sourced. This link can be an actual link if the file is stored electronically or a descriptive link (for example, article stored in the top drawer of the filing cabinet). Thus at anytime, all sources of data can be identified and found.

Once a source is imported, the program allows notes to be written on the record dialogue card in a separate entry or within the source itself. In the program, these are called *LINKS* or *ANNOTATIONS* (see Table 3 below for example). This function was extremely useful when managing the data as the query function of the program enabled searches for data or, depending on how the item had been described, to identify linked data. Maintaining this required discipline when importing documents or creating external links to ensure that the item was fully described. The researcher's skills in undertaking this task improved over time.

Table 3 : Excerpt from NVIVO 7 list of annotations

Shows link to the source (in this case interview 4) and subsequent link to the annotation made during the transcribing of the interview

Annotation List Excerpt

Source	Folder	Created
Interview 4	**Documents/Interviews**	**28/08/2007 2:37:03PM**

Excerpt of Interview transcript

A lot of people thought that in the public/private sector it was quite different in that when you had in the private doctor, they weren't around all the time, and you had to call them in, and then they realised that the same thing was happening in the public sector, not having people around when you needed them ...so that change was good that was for the better…

Linked Annotation

This was said in relation to clinicians thinking that patients were safer in the public sector as there was a perceived structure of RMOs registrars and consultants that were available on site 24 hours a day... with Douglas they realised that this wasn't the case (no1 interviewee said this as well)

To have all the data or, at least a record of the data, stored electronically within the same program being used for data analysis was a tremendous benefit and certainly enabled all data to be utilised fully.

The concern for the researcher with this type of data management system was the potential to lose data because of an electronic failure. This was allayed somewhat by ensuring that the program was regularly backed up to another secure electronic system remote to the working system.

METHODS

INTRODUCTION

The previous section identified those aspects dealing with the design, and organisation of this case study. These aspects are all integral features in preparing for a case study, and in ensuring the quality of the case study conduct. If not carried out thoroughly they can put at risk the whole conduct of the study. The focus of the next section is a detailed discussion of those aspects that follow the design and organising stages. This includes a description of the sample, data collection and data analysis methods employed to conduct the study.

THE SAMPLE

Yin (2003:86) identifies six sources of data that can be utilised for a case study. These are documentation, archival records, interviews, direct observation, participant observation and physical artefacts. Data collection for this study employed three of the six sources identified by Yin. As discussed in the previous section, these sources were documents, archives and semi-structured interviews. A specific description of the sample for each of these data sources is given below.

Documents and Archives

Document and archival reports for the case study were accessed from a variety of sources. These included the following:

- KEMH Inquiry terms of reference, scope and boundaries and the final Inquiry Report;
- Progress reports that were tabled in the WA Parliament by the Implementation Task force set up to implement the recommendations of the report;

- Hansard (WA Legislative Assembly and WA Legislative Council) transcriptions where reference was made to the report or the inquiry;
- Australian Council for Health Standards (ACHS) Reports;
- Department of Health West Australia Annual Reports;
- KEMH policies, procedures and other clinical governance documents;
- Media reports; and
- Conference and journal reports.

The hierarchy of research questions provided the guide when undertaking document and archive search. Documents and archives that would provide information were identified in several ways. The initial search involved studying the transcript from the final report of the Inquiry with special emphasis on those Inquiry recommendations that focused on the areas pertaining to this study. From this, particular documents, such as reports or reviews held by the Department of Health West Australia, the WA Government Publisher, Hansard, or more generally, documents available either electronically or in print, were identified.

Some documents and archives were also identified in the interviews with participants, who referred to them in relation to supporting their views or as a direction to the researcher that they might yield more information. Mostly, these documents were internal KEMH documents.

The final process for identifying relevant documents and archives involved a review of the pertinent recommendations of the final Inquiry report. For each of these, a list of possible documents that would support implementation was compiled. Following the approval of the FOI application, this list was then sent to an appointed person at KEMH (see Appendix 2 for list of documents). Subsequently a meeting was arranged where the list was reviewed and additional applicable documents

identified. Following final approval, the majority of documents were released to the researcher

Interviews

The researcher selected a purposive sample of five people drawn from senior members or officers of clinical professional, regulatory and consumer representative organisations. Purposive sampling involves deliberately selecting participants, based on the researcher's judgement, whose experience and knowledge will be the most relevant to inform the research (Ingleton, 1998) In order to obtain a diverse range of perceptions there was a limit of one participant per organisation.

The sample was chosen deliberately from organisations that had either direct interactions with clinicians or consumers providing advocacy or policy advice, or those that had a role in the registration, accreditation or credentialing of clinicians (see Appendix 3). Senior members or officers of these organisations are in the unique position of having knowledge and experience of the clinical governance systems and processes in place at KEMH as experienced by patients, families, clinical staff or management of KEMH. This knowledge was gained through their frequent and ongoing interactions with these groups. While having this knowledge of the KEMH, these senior officers are not members of the staff of KEMH involved in the delivery of the service, and thus are less likely to have a vested interest in representing a view of KEMH that would portray only a positive image. As such, it was felt that a more rounded and complete view of changes would be gained from this purposive sample.

The decision to limit the size and sample pool to five senior members from these organisations was made based on the specialised knowledge that this group would have of how organisations function at a system level. In addition, limiting the number to five participants from different professional backgrounds and experiences would provide ample opportunity to identify themes within the data without being overwhelmed

with so much data that it would be difficult to undertake meaningful analysis with the resources available. Thus the size and the experiences and understanding of systems issues of the participants would inform the research by ensuring an in-depth analysis and understanding of the topic being investigated.

Participants from these organisations were identified either by personal knowledge of the researcher or by reference from people within those organisations. Possible participants were contacted by email with an initial brief explanation of the study and an invitation to contact the researcher (see Appendix 4). Contact details for the researcher were supplied. The process continued until five participants were identified. Individuals were sent an information letter about the study and asked to confirm if they were willing to take part in the study (see Appendix 5).

DATA COLLECTION

In this section, the tactics for gathering and ensuring the trustworthiness and reliability for each data sources will be discussed.

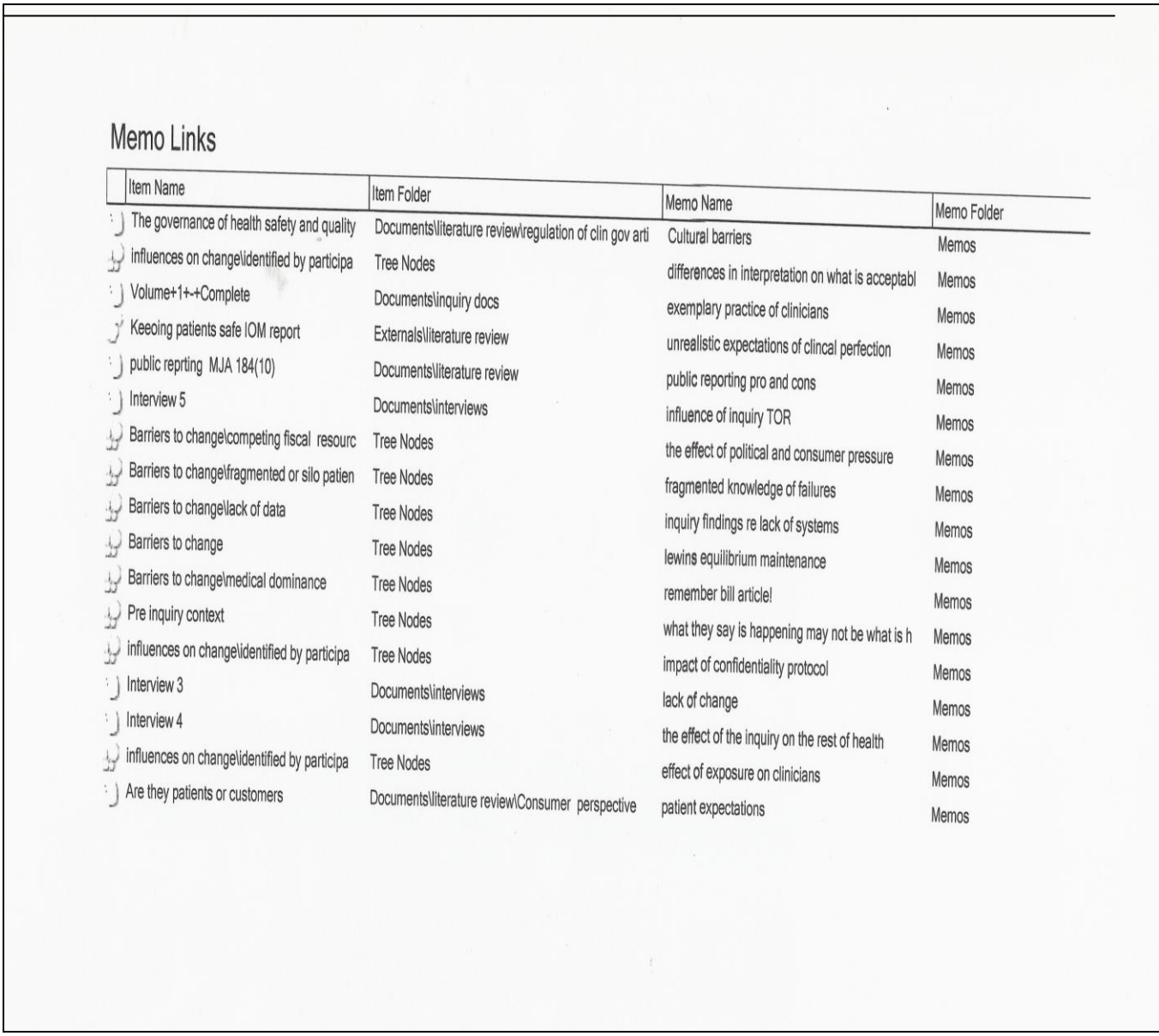
Documents and Archives

Documents can include letters, memoranda, agendas, administrative documents, newspaper articles, journal articles and conference presentations. Archives comprise documents such as organisational records, official papers, or recorded material kept for their historical interest (Stake, 2000; Tellis, 1997; Yin, 2003). For the purpose of this discussion, documents and archives will be considered together, bearing in mind the process used for gathering and assimilating data from these sources was the same.

Document and archival reports were used to identify particular elements of the Inquiry and Inquiry process that may have influenced change. This information provided a different perspective from the views and

perceptions of change gathered from the participant interviews. Data from documents and archives was also used to identify the actual changes in the clinical governance systems at KEMH post Inquiry and to verify information from the participants.

The researcher was cognisant of the need to consider the factors that can influence content, and consequently the analysis of documents and archives. Thus, as each document was obtained, a notation was made about it. This notation identified factors such as the social production and context in which the document was produced, together with, the intended audience and purpose for which the documents was written (Punch, 2005: 226-227). This information was noted in *NVIVO 7 (2006-2008)* when either each document was imported, or an external link was established on the dialogue card attached to each document. The significance, or any other pertinent thoughts about the document, was also noted using the memo and annotation function of *NVIVO 7 (2006-2008).* See Figure 4 below for extract of *NVIVO 7 (2006-2008)* memo links. This identifies the item, where it is stored in *NVIVO 7 (2006-2008)*, the name of the note (memo) and where the note (memo) is stored in *NVIVO 7 (2006-2008)*.



Memo Links

Item Name	Item Folder	Memo Name	Memo Folder
The governance of health safety and quality	Documents\literature review\regulation of clin gov arti	Cultural barriers	Memos
influences on change\identified by participa	Tree Nodes	differences in interpretation on what is acceptabl	Memos
Volume+1+-+Complete	Documents\inquiry docs	exemplary practice of clinicians	Memos
Keeoing patients safe IOM report	Externals\literature review	unrealistic expectations of clincal perfection	Memos
public reprting MJA 184(10)	Documents\literature review	public reporting pro and cons	Memos
Interview 5	Documents\interviews	influence of inquiry TOR	Memos
Barriers to change\competing fiscal resourc	Tree Nodes	the effect of political and consumer pressure	Memos
Barriers to change\fragmented or silo patien	Tree Nodes	fragmented knowledge of failures	Memos
Barriers to change\lack of data	Tree Nodes	inquiry findings re lack of systems	Memos
Barriers to change	Tree Nodes	lewins equilibrium maintenance	Memos
Barriers to change\medical dominance	Tree Nodes	remember bill article!	Memos
Pre inquiry context	Tree Nodes	what they say is happening may not be what is h	Memos
influences on change\identified by participa	Tree Nodes	impact of confidentiality protocol	Memos
Interview 3	Documents\interviews	lack of change	Memos
Interview 4	Documents\interviews	the effect of the inquiry on the rest of health	Memos
influences on change\identified by participa	Tree Nodes	effect of exposure on clinicians	Memos
Are they patients or customers	Documents\literature review\Consumer perspective	patient expectations	Memos

Figure 4: Excerpt from NVIVO 7(2006-2008) memo link list

Electronic searches were carried out of Hansard (Parliamentary record of both Legislative Assembly and the Legislative Council), the Department of Health West Australia and Department of Health and Ageing, various media, KEMH, Quality and Safety websites, and journals and conference reports. As well, more general electronic searches were undertaken using academic and Google scholar search engines for any other resources that might be identified. The search dates were from 1990 onwards, with various terms being used such as KEMH, Inquiry, patient safety, clinical governance, consumer complaints, healthcare failure, clinical risk,

credentialing and accreditation. Documents identified were perused quickly and if they had any reference to anything relevant to the research study questions or background literature review they were then downloaded or obtained in hardcopy and entered into the database on *NVIVO 7 (2006-2008*). This provided an enormous amount of information for data analysis.

Access to the majority of the primary and secondary reports was freely available since documents were accessible within the public domain. Some documents or sections of these documents however, were not. In particular there was a section of the final Inquiry report that had been withheld from the public domain, together with, internal KEMH documents and archival reviews and reports that were not available publically. The researcher was able to access these using the Freedom of Information (FOI) legislative process (see Appendix 6) for copies of request and responses). At all times, those involved in reviewing the FOI applications and providing the documents, once applications were approved, were helpful and responded in a timely manner to the requests for information.

While the document and archival retrieval was underway, simultaneously, the interviews for the study were being undertaken.

Semi-structured Interviews

The decision to utilise semi-structured interviews was twofold. The first purpose was to validate or corroborate the data gathered from the document and archival examination to ascertain if there had been any change in the clinical governance processes post Inquiry.

Secondly, the researcher was also seeking to understand whether the participants perceived if and how the Inquiry may have influenced changes in the clinical governance systems and processes at KEMH. In

describing their perceptions, it was anticipated that the participants would provide insights and additional information that would not be available from other sources to enhance the exploration, description and analysis of the research question.

A single interview was planned for each participant; in the design however, the possibility that participants would be approached for a follow up interview if clarification of information was required was included.

Instrument

In developing the interview schedule, the researcher was cognisant of the issues that needed to be dealt with as part of the process, including researcher interviewing skills, interview and design/content, sampling and data analysis. Each of these points will be discussed in relation to the development of the instrument.

Interviewing Skills

Neuman (2006) identifies the difficulty that new researchers face in terms of being able to create an environment where both the interviewer and the participant are comfortable while, at the same time, maintaining some formality that allows the interviewer to direct the subject matter. The interviewer needs to be able to be listening actively, but at the same time, analysing at a level that ensures that any markers or leads the participant gives during the answer are able to be followed up by probing (Donalek, 2005). The risk in the probing is that the participant may feel interrogated or challenged. From the researcher's point of view, by probing in one direction, information may be lost as the interview moves away from the subject matter of the original question (Price, 2002). The luxury of reflection, post interview, identified lost opportunities to explore certain

issues. This helped in future interviews but did not plug the gaps of an interview already concluded. In planning for the interview, the researcher identified the need for pre interview practice. Several sessions were undertaken with colleagues that resulted in the development of techniques such as notes on the interview sheet to prompt areas to be probed (see Appendix 7). This proved invaluable in terms of being able to maintain the flow of the interview, but at the same time providing an unobtrusive tool for the researcher to think on her feet and maintain composure.

Reflection, post interview, with colleagues was also valuable in terms of identifying alternative means of asking questions and the impact of the researcher's language on the participant during the interview.

There is much is written in the literature about the different types of questions or the way questions can be framed to draw out information in an interview. Price (2002) identifies three levels of questions that he labels laddered questions. The first level constitutes action questions, which are the least invasive and are used to set the context or scene. Second level questions are knowledge questions. These are more invasive since they focus on "what do you know?" and "what do you think?" type of questions. The final level and most invasive according to Price's laddered questions are the personal philosophy questions. These types of questions are concerned with the beliefs, values and deep-seated feelings of the participants.

Patton (cited in Minichiello, Fulton, & Sullivan, 1999:401) describes the different types of questions as, experience/behaviour; opinion/values; knowledge; sensory; demographic and timeframe. Berg (cited in Minichiello et al., 1999:402) describes the different types as:

- Essential questions which are used to elicit specific information; extra questions that are similar to essential questions but are used to cross check or clarify;

- Throw away questions, which are those designed to obtain the demographic information; and
- The probing questions, which are those used to bring out the detail and depth of information from the participant.

While each of the authors cited uses different terminology, each has identified the need for different types of questions depending on the type of information being sought. They have also identified the need to be cognisant of the opportunity to use the different types of questions at different times in the interview to build rapport and trust. The hierarchy or sequencing of questions as proposed by each of the authors has provided a framework for the researcher to explore the issues being investigated in a systematic way. The interviews began with questions about the participants' backgrounds. This gave them the opportunity to relax and become familiar to the tape recorder. As each interview progressed, the researcher would ask the participant their experience with a particular element and then probe from there. By maintaining the flow of less specific to more specific the chances of missing vital information or insights that the participants could contribute to the understanding of the topic was minimised.

Interview design/content

In deciding the areas needed to form the basis of an interview Minichiello et al. (1999:400) proposed that the researcher needed to be thoroughly familiar with the background and the issues needed to be investigated. This provides the researcher with the information and data that will inform the research question.

Berg (cited in Minichiello et al., 1999:400) proposed that the researcher should identify the categories and then develop questions for each category questions that would ensure the topic was explored in depth.

In this study, the specific areas of focus were the involvement of consumers in care at KEMH, and the systems and processes that dealt with medical credentialing and performance review. Thus, the interviews were concentrated around those themes and formed the basis of the interview guide as it was developed.

An interview guide was developed listing the topics as identified above, with possible questions for the interviewer (refer Appendix 7). The questions were developed keeping in mind the need to build rapport and move from the general to the particular and onto probing the different areas (Minichiello et al., 1999). The guide formed a basis for the interview, however it was not prescriptive. Within the interview other questions arose that allowed the researcher to probe the subject area to a greater depth. The question cues were modified several times in response to interview trials.

Field notes were made both during and immediately after the interview to capture the researcher's impressions of the participant's actions and reactions, together with other thoughts about the interview or the interview content (see Appendix 8 for example).

The Interview

Each participant was contacted to organise a time and venue for the interview that suited the particular person. During this initial contact the purpose of the study, the need to record the interview and the issues of confidentiality and informed consent were discussed briefly by the researcher. The participants were then sent an introductory letter and a consent form for consenting to be a part of the study.

At the interview, the preliminary information, as noted above, was once again discussed before the interview commenced. The participants were asked if they were willing to sign the consent form. Each of the

participants indicated their willingness to do so. Several of the participants sought clarification that the views being sought for the study were from them as individuals and that they were not representing their particular organisation's views. This was confirmed with them before the interview recording began and again, once the recording of the interview commenced. The issue of consent was also repeated once the recording began with each participant being asked to confirm that they were willing to take part in the interview, and that they understood the purpose of the interview. It was also confirmed on the recording that the participants understood that they could withdraw at any time during the study.

The participants had been told that the interview was anticipated to be of about one hour duration. The range of actual interview time lengths ranged from 51.12 mins to 1hr 11.58 mins. My impression for each of the interviews was that this was a comfortable length and that towards the end the participants were beginning to get restless and display signs that they were ready to conclude the interview.

Each of the interviewees chose to be interviewed within their work settings during work hours. Although the settings were within a private office, background noise external to the offices was evident on the recording. My impression however, was that even though I was aware of people and movement outside the office we were using, this did not appear to inhibit the participants in their dialogue. Several of the participants when discussing their perceptions of the vulnerability and powerlessness (participants' words) of patients and families became quite emotional. At this stage, the researcher offered to conclude the interview, but the participants concerned chose to continue.

At the conclusion of the interview, the participants were once again told they would be free to withdraw at anytime from the study, and were told they would be sent a transcript of the interview on which they could make comment. After reviewing the transcripts, only one participant asked for

changes. These changes were minor grammatical alterations rather than substantive content changes.

The interviews were downloaded onto *NVIVO 7 (2006-2008).* They were then transcribed into a text document in draft form. The researcher then edited and corrected the draft transcription using the recorded interview. This process was particularly helpful since repeated listening to the recording by the researcher to revise and correct the draft transcription led to an immersion in to the interview. During this process, impressions and gestures, which had been observed by the interviewer, were noted as annotations or memos. These added depth and meaning to the interview and would have been lost if the researcher was not involved intimately in the transcription.

The interviews, which were conducted over several months, and the collection of documents and archives, occurred concurrently.

Journaling and Memoing

From the inception of this study, the researcher used a journal to record thoughts and ideas. This was a useful tool in the formative stages of the study, when the research questions were developed to clarify concepts and ideas. Journaling also added value to the process of data collection as observations and salient points were noted. The use of the journal to record ideas, thoughts and possible resources to follow up really came into its own during the data analysis stage.

During the evolution of the study, the journal was ever present so that as deliberations, considerations and reflections occurred they could be noted. The trigger for these was often a conversation or literature unrelated to the study, but something contained within these would initiate some clarifying or new thought, which if not captured straight away would be lost (see Appendix 9). Although journaling is a type of memoing (Creswell, 2007;

Miles & Huberman, 1994; Punch, 2005), in most instances for this study the entries were used in a very informal way to capture random ideas, reflective ramblings, observations about participants or documents, and also to write notes on administrative conversations and procedures. These thoughts were not only about data analysis but also covered the other aspects of the study such as concepts and theories related to the development of the research questions and methodological theories, processes and procedures. The journal entries were reviewed regularly, with the review itself then initiating a process of further development and inspiration in terms of the data analysis.

Miles and Huberman describe the process of memoing and the value of this to inform data analysis. They state "... they tie together different pieces of data into a recognisable structure...and they are one of the most useful and powerful sense-making tools to hand" (1994:72). They go onto discuss the different uses for memos including capturing random thoughts (place holding memos), the pulling together of ideas or clarifying thoughts (integrative or barometric memos), and general notes about a piece of data or source (marginal notes). All of these types of memos were part of the journaling process for this study (see Table 4 below for examples). On the other hand, the process of memoing was also very much a part of the data analysis in *NVIVO 7 (2006-2008).* On occasions, the thought noted in the journal was transcribed directly into *NVIVO 7 (2006-2008)* as a memo, if it related directly to a particular code or category, or if it was perceived to be an emerging theme. In the main however, memos and annotations were made directly into *NVIVO 7 (2006-2008)* when the data was actually being analysed. Thus, these memos were much more associated with, and connected to, the tangible physical and mental processes of actually working with the data. For this study therefore, journaling and memoing served a similar purpose and involved a similar cognitive process that at times overlapped but they were definitely viewed as two separate but equally valuable processes.

Table 4: Examples of different types of memos

(adapted from Miles & Huberman 1994:72)

Types of Memos	**Example**
Place holding memo	*it is all about perception and paradigms in terms of how view events...* *is a Douglas necessary when the two viewpoints and paradigms are so far apart that there is no middle meeting ground....* *is it a deafness to each others view* (written on plane returning from a conference)
Integrative or barometric memos	*For the public it made the stories real as they were about real people having an awful experience when it should have been a good experience. But most importantly having children has resonance with a wide cross section of the public whether they are of stage in family where Consumers are having children or grandchildren, or have had children themselves or they know someone who they care about who is or has had children. So it is very personal to a lot of people, they can relate to the joy or they can relate to the fear of something going wrong. Because this is an experience that people relate to and is commonplace, the general public can not protect themselves by saying 'that won't...can't happen to me because randomness or not fitting the profile' They understand that it could have been them or someone they know or care about. When there is a suggestion that something may have happened because of poor process, and that the adverse event could have, or might have been prevented then there is a strong movement/ push for change.* (written when trying to clarify the effects of media exposure on general public)
Marginal notes	*Is this indicative of the blindness of the medical fraternity of the barriers that had prevented reform... maybe you don't see that there is a problem when you are the problem?* (written as an electronic margin note while reading an article by several medicos criticising KEMH whistleblower)

As data from both the interviews and the archive and document retrieval progressed, data analysis commenced.

DATA ANALYSIS

Documents and Archives: The Analytic Process

There are several methods identified in the literature that can be used to analyse documentary evidence (Atkinson & Coffey, 2004; Hodder, 2003; Neuendorf, 2002; Punch, 2005). These are summarised by Neuendorf (2002:5-8) as including rhetorical analysis, narrative analysis, discourse analysis, structuralist analysis, conversation analysis, critical analysis and normative analysis. Each has a place depending on the purpose of the analysis. For this study, the documents and archives are not being used to understand, describe and give meaning to the social context, group or individuals, interactions or other sociological perspectives. Rather, it is to establish if policies, procedures and guidelines have been described as per the recommendations of the Inquiry and then to identify if there is documentary evidence that any post Inquiry changes in the policies procedures and guidelines has translated into actions. Thus, the documents and archives have been examined using a normative analytic approach as described by Neuendorf (2002:8) that uses a set of criteria developed to identify if the documents reflect either the changes required by the Inquiry or evidence of implementation. This set of criteria acts as a checklist when reviewing the documents and archives.

The checklist comprised the following criteria:

- Policy procedure or guideline described the process or expected behaviour as per the Inquiry recommendation. The term used for this criterion is **specific;**
- Policy, procedure or guideline describes the process or expected behaviour in detail but not exactly as per Inquiry recommendation or with a required element omitted. The term used for this criterion is **implied;**
- A KEMH organisational or KEMH staff member produced document claiming that a policy, procedure or process was in

place, or an outcome described that would indicate implementation. The term used for this criterion is **self- reported evidence;** and

- An external report produced by an external agency following examination of KEMH processes stating that policy, procedure or guideline had been implemented. The term used for this criterion is **external evidence.**

Each document was reviewed using the criteria above seeking evidence that demonstrated compliance with the specific recommendations relating to both medical credentialing and performance management (25 recommendations), and consumer involvement in care (15 recommendations). The results for each area of focus were compiled using an excel spreadsheet, demonstrated in Chapter 4, where the findings for this analysis are reported.

The researcher was mindful during this process of document and archive analysis that, as Atkinson and Coffey (2004:58) state, "...they are not ...transparent representations of organisational routines (and) decision-making processes...". These authors go onto state "we cannot treat records... as firm evidence of what they report." The researcher however, was reassured by Hodder's (2003:156) assertion that "...texts can be used alongside other evidence...". In this study therefore, the evidence being gathered from documents was being tested against the information that was gained from the interviews, with each set of data providing a different aspect of the whole picture about the status of the clinical governance structures post Inquiry at KEMH.

Interviews: The Analytic Process

The Miles and Huberman (1994) framework was used for data analysis. This framework involves procedures for data collection, data display, and drawing and verifying conclusions. A detailed description of the analytic strategy utilised follows in the next section.

The software program *NVIVO 7 (2006-2008) was* used for the analysis. This program uses a system of coding to nodes. These nodes are used to store data about the specific theme or category. They were created by the researcher as required and were established in a hierarchical structure from a general category (parent node) to more specific categories (child node). An example of this hierarchical structure is demonstrated in Figure 5.

Before analysis commenced several parent nodes were established that provided initial organisation for the coding. These parent nodes included categories such as barriers to change, changes in credentialing, changes in consumer involvement, influences on change, and Inquiry findings. These categories were those that reflected the major research questions and the literature reviewed as part of the development of the study. Beneath these parent nodes, child nodes were created. The initial child nodes provided a separation of source and so were labelled *identified in documents* and *identified by participant*. These preliminary nodes provided the early framework for beginning the data analysis. Very quickly however, as themes emerged in the source data, new parent and child nodes were added. Figure 5 provides an example of a developing coding node hierarchy. As each new parent or child node was added, the previous sources that had been coded were rechecked to identify if that theme had not been identified on first coding. Codes were established, merged, re-established and linked throughout the process of data analysis.

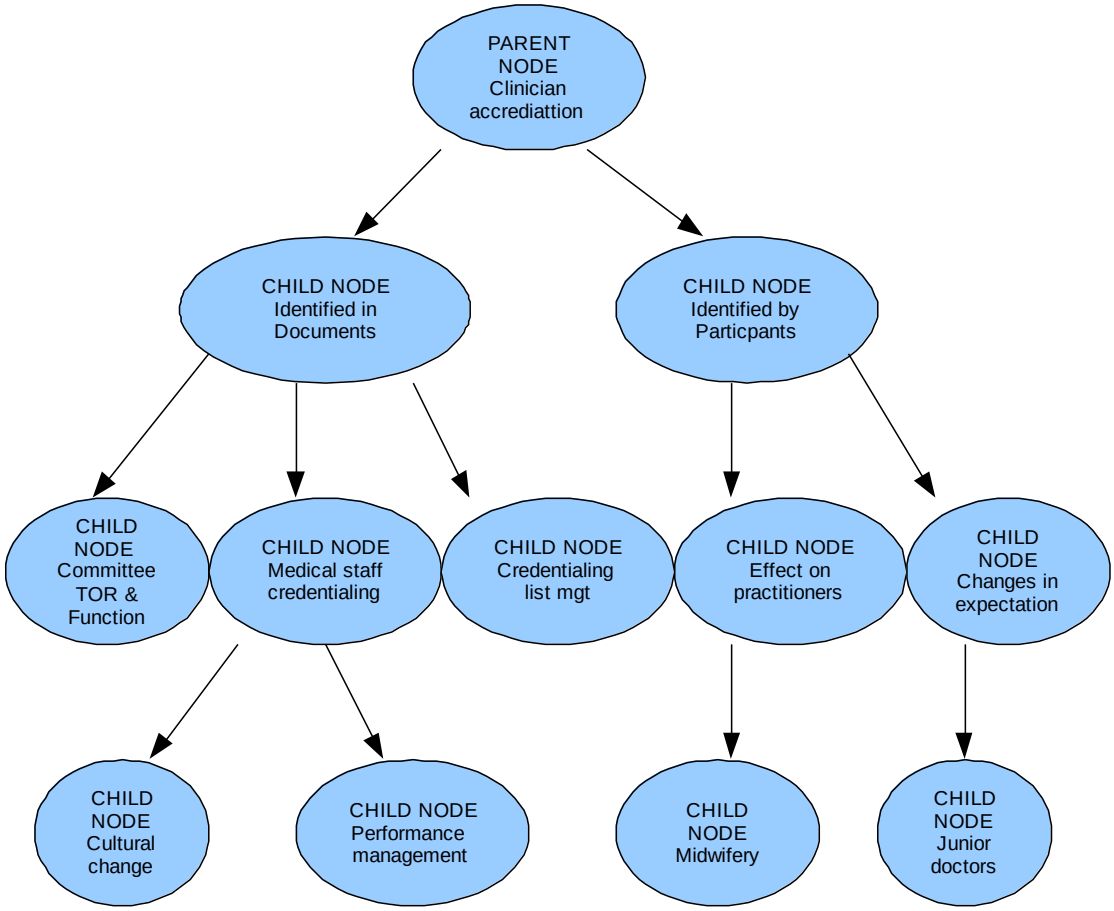


Figure 5: Example of development of a coding hierarchy

NVIVO 7 (2006-2008) provided the opportunity to build models throughout the process of analysing the data. This function was particularly helpful in developing ideas by permitting the researcher to begin to cluster data and explore how one code may relate to another (see Figure 6). Eventually this led to the aggregating of data to identify the emerging themes. Stake (1995:74-77) and Creswell (2007:163-164) describe this as categorical aggregation and discuss the role of intuition, researcher knowledge of the context and case, together with, the actions of searching for corroborating or disconfirming information in the sources that leads to this sorting and combining of the data into themes.

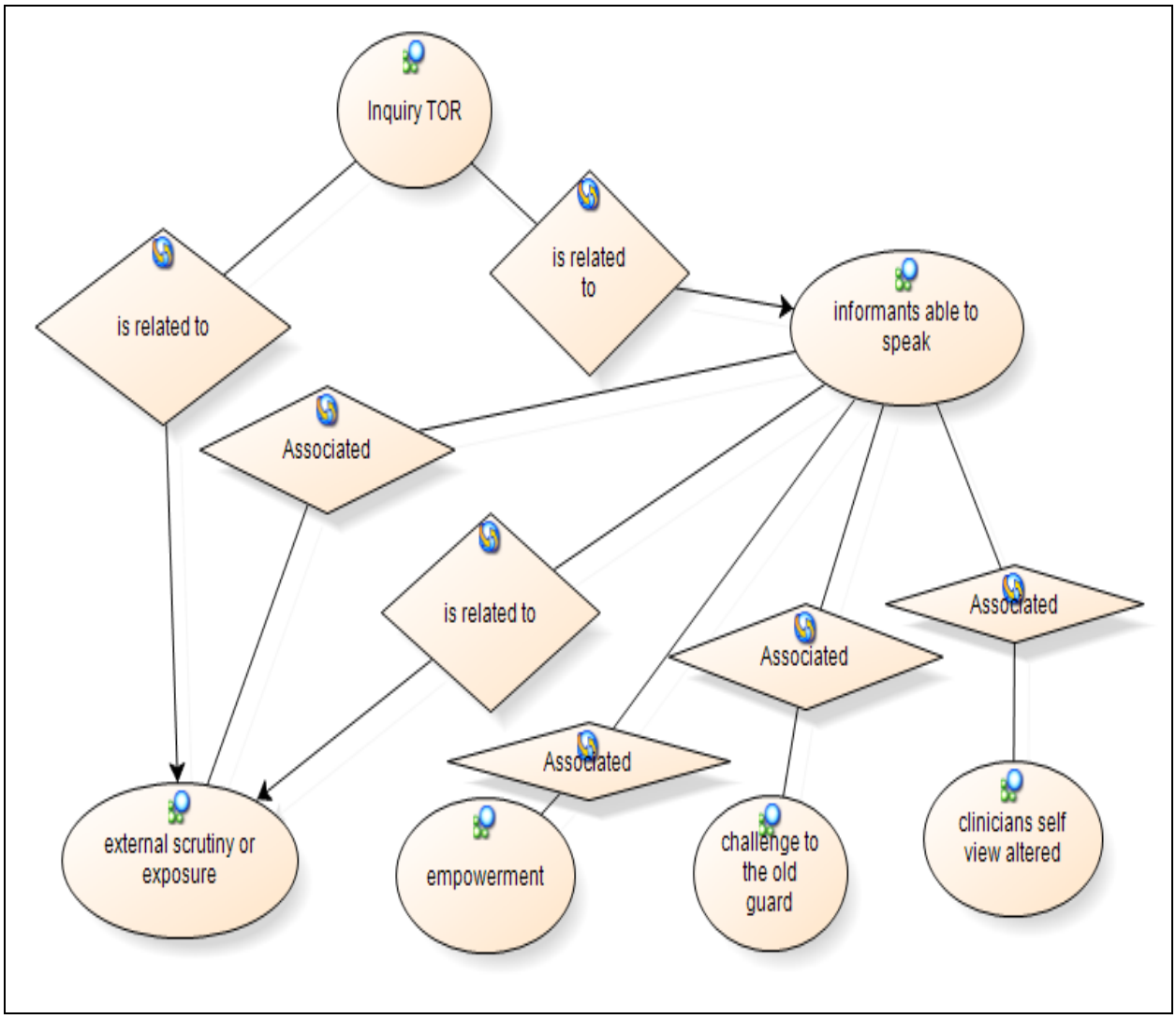


Figure 6: Example of NVIVO 7 model
This model demonstrates developing ideas concerning relationships between the Inquiry TOR and other coded data.

Slowly, this iterative process resulted in a gradual development of what Yin (2003) and Miles and Huberman (1994) describe as a logical chain of evidence, that is, an identification of a specific factor that provides some clarification or illumination of the research questions with a demonstration of how the data codes or themes have been built up to support this. The *NVIVO 7(2006-2008)* modelling function was used to develop these as they provided a graphic and easily understood method for the researcher to ensure that the relationships between the data made

sense and led from one to other until the wholeness of the data codes and themes and relationships was understood.

The final stages of the data analysis involved comparing and contrasting the themes from the data analysis with the literature to answer the research questions. Lewin's (1951) model of change specifically informed this process, with the final outcome resulting in the development of a conceptual model of organisational clinical governance reform. Lewin's model of change was considered appropriate to provide a framework in which to consider the findings of this study. This was because Lewin's work on change theory has provided the base for the development of a large body of work, and subsequent development of models of change and change theories, over the past fifty years. As well, his work is still considered to be contemporary, and is utilised in many studies examining change processes (Bamford & Daniel, 2005; Burke, 2008; Robbins et al., 2004).

Analytic Strategy

Yin (2003:116-120) recommends that in building propositions from the data to answer the research questions and develop conceptual models, a general analytic strategy is required. He identifies four strategies that can be used for single case studies. These are pattern matching, explanation building, time-series analysis and logic models. An explanation building strategy was used for this research. The reason for this was that the objective of the study was to identify if factors from the Inquiry influenced change, and if they did, how and why this impact occurred. Miles and Huberman (1994:90-91) describe this explanatory process as an analytic progression of building a framework where the researcher begins by describing what happened or what the context is, then moves through stages to describe how variables are connected and then how they influence each other (see Figure 7 below for summary of overall analytic strategy)

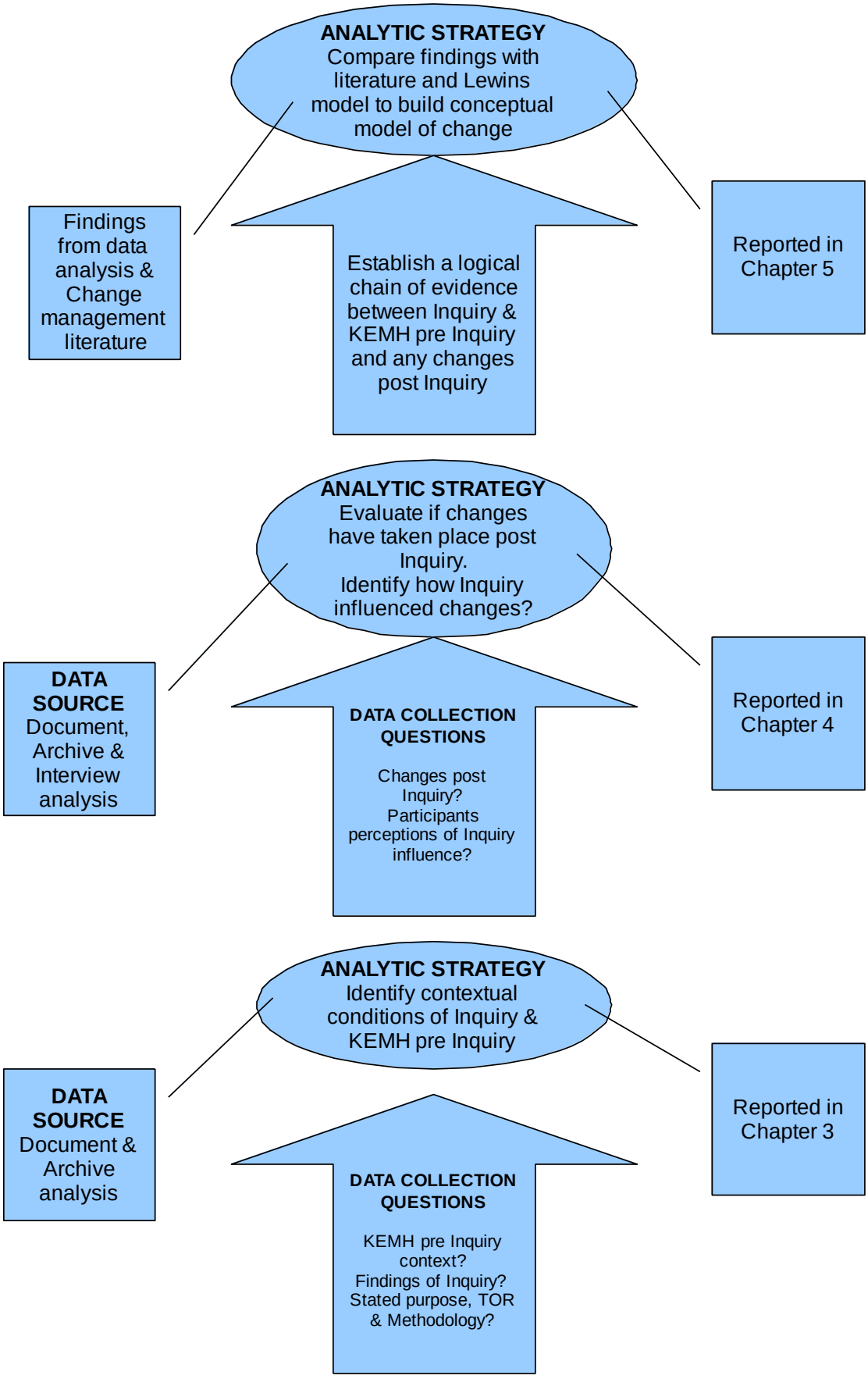


Figure 7: Summary of overall analytic process

It was essential that the researcher ensured constant reference to the tactics and strategies utilised to ensure credibility and reliability of the final propositions resulting from the analysis. A discussion of these strategies follows in the next section.

Tactics for ensuring reliability of data analysis

Yin (2003:137-139), identifies several principles that should be kept in mind to ensure that data analysis is robust and reliable when undertaking a case study. These are firstly, that all information acquired must be as extensive as possible, related to the research question, and all of the data obtained must be reviewed and examined in the analysis. Secondly, the analysis must show that negative or alternative explanations were considered. The final principle is that the analysis cannot be done in a vacuum of knowledge about the issues being investigated. Rather the researcher needs to be guided by the current discussion and thoughts about the case being which, underpins and promotes recognition of significant information during the data analysis.

The first strategy identified above, ensuring that all pertinent data is collected and that this data is related to the research questions is discussed in detail in previous sections. To reiterate briefly, the researcher employed multiple sources of data to provide a different viewing frame for the research questions. The number, breadth and depth of data sources was developed by examining each of the research questions to identify what sorts or type of data would be required to answer the questions. As the data was obtained, it was entered onto a database, which ensured that each piece was examined during the data analysis process.

To manage the process of considering alternative suppositions the researcher used several strategies. Firstly, throughout the study, several clinicians familiar with the study context and subject matter, as well as the

research study academic supervisors, were accessed to discuss and take on the role of devil's advocate. Many times during this process, different or alternative ideas were raised and developing ideas from the data analysis were challenged. An example of this process was in the early stages of data analysis when one clinician mentor challenged the validity of using the Inquiry report as a source of information to describe the situation at KEMH pre Inquiry. This clinician believed that the information might be biased. Lengthy discussions with the supervisor and the clinician led to the decision to use the report as an important source for the information but only if the information used from the report was validated by more than one source. An explanation of this is included in Chapter 3 of this report. These discussions also added a dimension to the developing thoughts, in that, while the dialogue did not result in an idea or concept being completely discarded the outcome would be that the dimensions of the concept or conclusion would be developed and expanded. This process while at times confronting, added depth and trustworthiness to the analysis and the conclusions.

A further strategy to ensure rival theories were considered involved contacting participants at the final stages of data analysis seeking their feedback in regards to the interpretation of the data. This was particularly valuable, and although was not recorded as a formal interview, field notes were made concerning the discussions. These were used to review the propositions.

Another approach to ensure reliability of data analysis is identified by Miles and Huberman (1994). They highlight that when identifying a particular theme for coding or sorting into themes, it can be considered more powerful if it is then found in other sources of data. For this study, the researcher was mindful of these issues when undertaking the data analysis. When undertaking the coding if several participants made the same comment or observation then some weighting was given to this evidence. If the same thing was then emphasised in the documents or archives then this theme was strengthened further. An example of this was

the theme of the impact of medical culture on change. The majority of the participants mentioned this in their interviews, unprompted by the interviewer. A review of the documents identified medical culture as a dominant topic in relation to change management. Thus, this particular theme was identified as being a dominant one when considering change management.

As the researcher was working alone on the data analysis, double analysis and reanalysis were employed by the researcher to ensure reliability of the analysis. This involved coding a segment of data and then recoding the same data after a time interval. The target was a 90% congruence between initial analysis and reanalysis (Miles & Huberman, 1994). This process was undertaken after the researcher had taken an eight-week break from data analysis. The interview reanalysed was the first interview and since this had been coded four months previously and not viewed since that time, it was believed that this was a good test of congruency. No new themes or codes were identified, and sources that were coded to the themes were the same, although the second coding identified several further comments to be coded to existing coding nodes.

ETHICAL ISSUES

The guiding principles that underpin the execution of ethical research are integrity, respect for persons, beneficence and justice (NHMRC, 1999). The particular ethical issues that arose for this research study can be divided into those that impacted on the participants, (including internal and external stakeholders), and those concerned with the research process and methodology. Each will be dealt with in the following discussion.

Researcher Bias

A strategy for dealing with potential researcher bias is required. Yin (2003) proposes several strategies to deal with this potential problem including being open to contrary findings. Denscombe (2002:157-172) describes the aspects of which a researcher needs to be aware in terms of maintaining objectivity. These include being aware of the researcher's background and experience and the need to consider the impact of personal assumptions and meanings, and the imperative to consider alternate explanations. The strategies the researcher used for this study to ameliorate the potential for bias were discussed in the previous section. These strategies included:

- Conducting and recording self interviews before attempting to interview participants;
- Offering interview participants the opportunity to review the transcripts of their interview; and
- The supervisors and mentors being asked to review and provide feedback, and challenge with alternate viewpoints throughout the study.

The Participants

The issues that arose in relation to the participants involved in the interview were those concerning informed consent, maintenance of confidentiality and assessment of the need for strategies to minimise harm or risk (Neuman, 2006).

To deal appropriately with the issue of consent the cohort of possible participants was sent a letter (refer Appendix 5) inviting participation in a

semi-structured interview. A description of the purpose of the study, and the process were included in the introductory letter. The letter also contained a detailed explanation that if the participant chose to take part in the study they would be free to withdraw at any stage without penalty and that any information that they have given prior to this would be destroyed. Contact details for both the principal researcher and the supervisors, and the details of a representative of the University who is independent of the research study were also detailed in the letter.

The introductory letter also contained a description of the process that would be involved in the collection and storage of the data. The processes to be used to maintain confidentiality was also detailed. This involved all data in the form of audiotapes, transcripts and computer disks being stored in a locked cabinet within the University for a period of five years. Access was only available to the researcher and supervisors. In accordance with the National Health and Medical Research Council (NHMRC) guideline (1999), these will be destroyed after five years.

Prior to commencement of the interview, the participants were asked if they had any further questions and concerns about their participation. The details of the research and the measures that would be in place to protect confidentiality such as data storage and maintenance of security of the data were reiterated. The opportunity to withdraw at any stage without penalty was restated. Permission to use a recording device to record the interviews was also confirmed at the interview. The participants were then asked to sign a consent form to take part in the research (see Appendix 10). A copy of the consent form was given to the participants

The researcher must also anticipate possible harm or risk to participants (Neuman, 2006). In the proposed study the possibility of harm or risk could exist in relation to the interview participant's career and professional standing within the organisation. The Inquiry was a significant and very public event within Western Australia. The issues raised were and continue to be highly emotive to patients, consumers and

to those people involved in the delivery of care. As time has passed the negativity and angst that arose because of the Inquiry seems to have lessened. To be raising the issues five years on with the possibility that there may be some criticism again of the thoroughness of the clinical governance processes at KEMH has the potential to be viewed as unconstructive and harmful. Anybody who may be identified as being involved in the process is at risk of being perceived by peers or health system managers as either unhelpful or in the worst case destructive. To negate this risk, stringent strategies to maintain anonymity were used, such as coding and the destroying of all identifying data and not reporting demographic data that potentially may identify the individuals who were interviewed.

The study has been framed deliberately so that the focus is on system and process barriers and enablers of change rather than a focus on any individual's role in the process of change. The organisational theories that are used to explore the impact of the Inquiry on changes to clinical governance systems and processes are system theories rather than those that focus on individuals' potential impact on the change process. Any reference to individuals or individual actions implicated in the barriers or enablers have not been included in any data analysis or the final research report.

Stakeholders

The NHMRC position statement identifies research participants as anyone on whom the research may impact (NHMRC, 1999). For this study the other stakeholders included KEMH staff, the community of patients and consumers, organisations involved in health delivery and the University of Notre Dame Australia (UNDA). The researcher utilised several strategies to ensure the integrity of the study and disseminate information about the project to the other stakeholders. These included:

- Gaining ethics approval from the UNDA School of Nursing Research and Ethics committee together with the UNDA Human Research Ethics Committee (see Appendix 11);
- Application under Freedom of Information legislation as required to the various government departments to access primary and secondary reports not freely available within the public domain; and
- Dissemination of the research by way of academic journals and conference presentations of the research process and findings.

CHAPTER SUMMARY

The case study strategy was used for this study. This chapter described the case study strategy and the reasons why this design was considered most applicable to the research questions. The data collection and data analysis processes were discussed. The strategies to ensure validity and reliability employed for the study were specified. The methods by which the findings were then synthesised and developed using Lewin's (1951) model of change were detailed.. This chapter concluded with a discussion on the ethical considerations for this study. The following three chapters will report the results of the data analysis to answer the data collection questions. Chapter 3 will describe the case being studied for this research. That is, the context of KEMH pre Inquiry, and the conduct and processes of the Inquiry. The findings from the data analysis for the first three data collection questions provided the information for this description. Chapter 4 will report the results of the analysis of the information from data collection questions 4 to 6. This will provide the answer to the research question seeking to identify if changes have occurred post Inquiry in the clinical governance processes at KEMH, specifically in the area of interest for this study. Chapter 5 will present a discussion of the findings with reference to relevant research literature. The primary research question will then be answered using Lewin's (1951) model of change. A conceptual model of clinical governance change is also presented in

Chapter 5. The final chapter will identify the limitations of this research and discuss some implications for the future.

CHAPTER THREE: THE CASE

THE CONDUCT AND PROCESSES OF THE INQUIRY AND THE CONTEXT OF KEMH PRE INQUIRY

"Sometimes it is tempting to avert your gaze from a problem - particularly if it involves confronting deep-seated issues within the organisation. To look away is almost always a mistake. The courageous route is to face up to it and resolve it despite difficulties" (Donaldson, 2003).

INTRODUCTION

Stake (1995) and Yin (2003) identify that fundamental to a case study report is the need for an extensive description of the context and setting of the case being examined. This provides the framework for understanding the research question and the findings from the research. In the situation of an instrumental case study, as this is, the intent is to use a significant case to provide insight into the general research interest focus of the barriers to clinical governance system improvement and the strategies that may be useful in overcoming these barriers. The Inquiry, the Inquiry process, and the hospital itself constitute the case of interest for this study. The particular issue for investigation is the Inquiry's impact on change of clinical governance processes at KEMH. This chapter will provide an in-depth description of the case and its context. The findings from the data analysis for the first three data collection questions detailed in the previous chapter provided the information for this description. To begin with, a narrative picture of KEMH pre Inquiry will be presented. This will provide an accurate understanding of the context in which the issues that triggered the Inquiry took place. The Inquiry, including the Terms of Reference (TOR) and the methods and processes used, will then be reviewed. Finally, this chapter will summarise the specific recommendations from the Inquiry that dealt with the particular areas of focus of this study. These recommendations are those that dealt with the

issues of involvement of consumers in care at KEMH, and medical credentialing and performance management of clinicians.

A significant amount of the information used in this chapter to describe the Case (the Inquiry, the Inquiry process and the hospital) is sourced from the Inquiry Report (Douglas et al., 2001). Consideration has been given to the possibility that there may be criticism in using the report as a source of information for this description. While size and scale of an inquiry is no assurance of data quality or integrity, Walshe and Higgins (2002) suggest that inquiries of this type can be viewed as case studies in organisational failures. As such, a framework for evaluating the quality of a case study can provide guidance in assessing the integrity and validity of the methodology that leads to an inquiry's findings. Yin (2003) and Stake (2005) identify the characteristics of this framework. This framework is discussed in detail in the Chapter 2 (Methodology). The key points from the framework are that there needs to be multiple sources of evidence that provide a method of cross-validation of claims, and a clear and logical chain between the evidence and the conclusions. A full and formal evaluation of the investigations and documentation of the evidence and conclusions of the Inquiry report is beyond the scope of this Chapter, and is not the purpose of this study. Nevertheless, information used to describe the case of interest for this study obtained from the Inquiry report is only utilised if there is clear link between the evidence and the conclusions and information is validated by multiple sources of evidence.

KEMH PRE INQUIRY

Background

KEMH is the only tertiary maternity service referral centre for the State of Western Australia (WA). This means that patients requiring specialist and complex maternity care from anywhere in WA are transferred for care to KEMH (see Figure 8 for a map of the geographical catchment area). Established in 1916, by the year 2000 approximately 5000 babies were

born at KEMH each year. KEMH's other roles and functions included providing tertiary service gynaecology and neonatal care as well as being a teaching hospital for medical and midwifery students (Douglas et al., 2001:105).

Figure 8: Map of Australia - Unshaded area indicates catchment area for KEMH tertiary services

When the Inquiry was established in the year 2000, the service at KEMH comprised:

- 250 inpatients beds;
- 60 neonatal cots;
- A range of maternity, gynaecological and other reproductive outpatients' services;
- 5000 gynaecological operations per annum;
- 5000 births per annum; and

- 8000 to10,000 emergency presentations per annum (Douglas et al., 2001; McLean & Walsh, 2003)

The profile of patients attending for treatment reflected the role of the hospital as a tertiary centre (deals with high acuity complex cases), with a significant number of patients being of a higher risk clinical profile, for example, multiple births, early and late pregnancy complications, and complex gynaecological surgery. There were also a large number of patients with social problems relating to substance abuse, obesity, and poor living and domestic conditions. This particular cohort of social circumstances has a significant impact on the risk of complications during the ante and postnatal period. Together with this complex clinical profile, many of the patients were presenting late in pregnancy as unbooked patients. The clinical implications of this are that there is an increase in pressure in terms of having adequate time for a thorough assessment and planning process pre-delivery. This situation has a significant impact on the ability of staff to be prepared and able to manage any untoward event that may result, in a timely manner.

Organisational Structure

The period examined by the Inquiry was the decade from 1990 to the year 2000. During this time, the hospital was subjected to a series of management changes that affected the continuity and stability of the leadership and management climate. The first of these changes was the amalgamation of the KEMH with the WA State tertiary paediatric service the Princess Margaret Hospital (PMH). Although each hospital operated on separate sites, their management and administrative structures were merged. This process caused uncertainty for all staff including the clinical staff, and raised suspicion that it was the beginning of an attempt to close

KEMH on the current site and move it, in some merged form, to another site (Douglas et al., 2001).

There was little continuity in senior leadership roles during this period. There were three different Boards of Management, three different Chief Executives, four different Directors of Medical Services, and two different Directors of Nursing and Midwifery (see Appendix 12 for details). Together with the insecurity created by multiple incumbents in the leadership positions, the establishment of a devolved management structure in 1996 created a further area of uncertainty. This devolvement of accountability and responsibility was driven by the rationale of placing " ... greater decision making authority on the clinical staff providing patient care services" (Douglas et al., 2001:128). The devolved structure involved the establishment of clinical care units under the joint direction and management of a Doctor and a Nurse or Midwife. The personnel in these roles reported directly to the Chief Executive.

This restructure had several marked effects on the overall effectiveness and efficiency of the hospital's role as a tertiary provider of care. Firstly, the clinicians in the Clinical Care Unit Director positions undertook the roles with very little managerial and administrative training. Secondly, the responsibilities of the managerial role resulted in them having less time to spend on clinical work. This was especially significant considering that there was a medical workforce shortage within KEMH. Finally, silos between clinical care units developed as each became protective of their resources. Consequently, the needs of their unit assumed primacy over the overall needs of the hospital system. The positions of Director of Medicine and Director of Nursing, which were responsible for overall clinical standards and the professional workforce, could have had a unifying effect on the silo mentality. Unfortunately, as the key decision-makers for each clinical unit (the Directors) reported directly to the Chief Executive, the capacity for the Directors of Medicine and Nursing to influence the operational management decisions of each unit was limited (Douglas et al., 2001:126-135).

Workforce Environment

Throughout the period investigated by the Inquiry, there were significant workforce shortages noted. There had been repeated requests for an increase of staff throughout the period by medical staff, with little impact. The reasons cited for the lack of action included budgetary constraints and the inability to attract staff. A further barrier to action was the influence of Visiting Medical Officers, who are contracted sessional consultants as opposed to permanent employees. This group did not support an increase in permanent staff because of the perceived threat that they would experience a decrease in influence and a loss of positions at the hospital (Douglas et al., 2001:678-884).

The number and availability of medical consultants affected the effectiveness of the supervision of the junior doctor's practice. This was demonstrated in the clinical file review undertaken by the Inquiry. In this review, it was identified that junior doctors delivered most of the care in 70% of high risk cases. Junior doctors also reported that they were not encouraged to contact senior staff for advice in the management of complex cases. It was also noted that nursing and midwifery staff were relied on to provide support for the junior medical staff (Douglas et al., 2001:586-587; McLean & Walsh, 2003:16-17).

The chronic staffing situation and a lack of supervision and availability of medical staff, led to an environment that was extremely frustrating and stressful for clinical staff. Furthermore, this state of affairs contributed to the inability to recruit and retain staff (Braithwaite et al., 2006)

Clinical Care

It was noted by the Inquiry that there was evidence of " ... exemplary conduct and practices, in both clinical and administrative areas, that reflect credit on both the individuals concerned and the hospital itself " (Douglas et al., 2001: pg. x). Despite noting these areas of excellence however, there was, on the other hand, also extensive evidence given at the Inquiry of significant problems in the clinical care that was being delivered at KEMH (Braithwaite et al., 2006; Douglas et al.2001; McLean & Walsh, 2003). McLean and Walsh summarise the conclusions about the standard of clinical care as:

> ... non existent or sub-standard care planning, coordination of care and documentation... [and] poor management of high risk cases and medical emergencies, and non-existent systems to review and respond to adverse events. Documentation was often incomplete [and] lacking important clinical information for continuity of care. Outcomes of discussions with senior staff were rarely noted and in most cases it was impossible to determine the extent of a consultant's involvement in decisions about care (McLean & Walsh, 2003:14).

KEMH did not have a process for the development and maintenance of currency of clinical policies and guidelines (Douglas et al., 2001:1062-1200). Because of the lack of process, many of the policies and procedures were not based on the best available evidence of the time. Implementation and adherence to policies and procedures was also not well managed. There were many incidences cited at the Inquiry where a policy was generally not followed or was ignored by different clinicians if they chose to do so (Douglas et al., 2001:1062-1200). Specific examples of repeated non- compliance with guidelines or policy that was noted at the Inquiry included:

- Cord blood testing where following a change in protocol in September 1997 it took approximately 22 months for effective action to be taken to prevent continual breeches of the protocol (Douglas et al., 2001:1167-1181); and

- Oxytocic policy (Douglas et al., 2001:1182-1184); unnecessary cardiotocographs (CTGs) on low- risk patients (Douglas et al., 2001:1184-1185).

Employment Issues

Employment of professional staff in any industry is governed by the need to ensure that the correct staff members are appointed to perform duties for which they have the qualifications, knowledge and training. There is also an expectation that once appointed a professional person would continue to maintain and/or update their skills and knowledge. This general expectation for all professionals applies equally to medical staff. It is, therefore, anticipated that they will:

- Have the appropriate qualifications for the positions to which they are appointed;
- Have the skills to perform the clinical interventions and procedures they are undertaking; and,
- Maintain currency in terms of skills and knowledge (*National Guidelines for Credentials and Clinical Privileges*, 2002).

To manage this expectation there needs to be systems and processes in place to assess qualifications and competency (termed appointment or accreditation and credentialing). There should also be a method of monitoring the ongoing performance of the professional, in a fair, equitable and transparent manner (termed performance management) (*National Guidelines for Credentials and Clinical Privileges*, 2002).

The situation at KEMH in the period under review was that there was an *ad hoc* process of medical appointment, medical credentialing and monitoring of performance. Despite several recommendations being made by the Australian Council for Healthcare Standards (ACHS) in their

survey reports of 1991 and 1994 identifying deficiencies in this area (Douglas et al., 2001:1023), significant inadequacies in processes were still noted in the Child and Glover review undertaken in 2000 (Child & Glover, 2000:16; Douglas et al.2001:1023-1024).

In terms of credentialing, the Inquiry report details that there was clear evidence that administrators and clinicians were aware that there were deficiencies in this process. Documents tabled at the Inquiry, including memos, letters and minutes of the Medical Advisory Committee (MAC) from the period 1990 to 1999, illustrate that clinicians and administrators had major concerns in regards to lack of formal credentialing for current, new and developing surgical interventions (Douglas et al., 2001: 955-1026). Comments noted in the report that are illustrative of the depth of many doctors and midwives' concerns included the following:

> Junior staff were often left to perform operations for which they had little supervision previously and are often inadequately prepared to operate without supervision (pg.1025)
>
> Names of those clinicians who were accredited to do these procedures needed to be made public (within the organisation) and not left to the Nurse manager in Charge of Theatre to have to make decisions as to who and who could not operate (pg.1023)
>
> I don't think that it is a good idea to allow the registrars to decide for themselves whether they are competent to do cases or not...(pg.965)
>
> I don't believe that (Dr)... should have been allowed to operate on Friday without being accredited... (pg.975)

These comments and many others that are similar, demonstrate an awareness of the lack of formal processes to manage credentialing. This knowledge did not translate into action, since there appeared to be some barrier that prevented anything being done to address the problem.

In terms of appointment, the Inquiry report noted that in general, the process for the appointment of junior doctors and midwives was accomplished fairly well. On the other hand, there were significant flaws in the process for the appointment of consultants. These included a lack of

documentation and a lack of a consistent process for contacting referees or establishing that the applicant was the best person for the job (Douglas et al., 2001:1679-1687)

In the area of performance management of the senior medical clinical staff at KEMH the situation was also substandard. The Inquiry report identified that for Consultants working between 1990 and 2000 there were very few performance reviews. The situation was slightly better for the junior medical staff and, midwifery and nursing staff, but there was significant room for improvement even for these groups of clinicians (Douglas et al., 2001-1782) .

Involvement of Consumers

The Inquiry gathered considerable evidence from former patients and families (consumers) about their perceptions of the care that they received. Many of these people reported positive experiences, both in relation to the care they received and their interactions with staff. On the other hand, many people also identified negative experiences. The report written for the Australian Health Ministers in July 2002 summarised the consumer issues as:

- Inadequate information about their treatment and little or no involvement in decisions about care;
- Inadequate or no information about things that went wrong and what was being done about the situation;
- Poor treatment and disrespect when making complaint;
- Lack of support when they experienced poor outcomes or adverse events; and
- Poor or no communication from Hospital staff during potential medical negligence case reviews (*Lessons from the Inquiry into Obstetrics and Gynaecological Services at King Edward Memorial Hospital 1990- 2000*, 2002:23).

KEMH did have a comprehensive complaints policy in place yet the policy did not translate into an effective and appropriate process involving the patient and their family if they wished to make a complaint. Complaints were also not considered within a quality improvement framework, rather, they were managed from an organisational defensive and self protective stance (Braithwaite et al., 2006; McLean & Walsh, 2003)

Safety and Quality

The Australian Council on Healthcare Standards (ACHS) is an organisation that provides an independent in-depth assessment of a healthcare organisation's quality of care and programs for quality improvement. The assessment is based on a survey of the facility by external surveyors and the comparison of organisational self-reported data against national standards and benchmarks. ACHS awards an organisation accreditation if they believe the organisation meets a required standard of care (*ACHS National Report on Health Services Accreditation Performance: 2003 - 2004*, 2005).

ACHS accreditation is perceived by many involved in healthcare as confirmation that an organisation is functioning at an acceptable level of safety and quality. Organisations that receive accreditation usually display their accreditation certificate in a place that is prominent for public viewing. This is seen as a proclamation to the public that the organisation provides safe and quality care (*ACHS National Report on Health Services Accreditation Performance: 2003 - 2004*, 2005)

KEMH received accreditation from ACHS in 1991, 1994 and 1997. At each survey, there were recommendations about areas that required improvement. However, there was no evidence of follow up by either KEMH or the ACHS to ensure that the recommendations were actioned (Douglas et al., 2001:1823).

Cultural Climate

Organisational culture is defined simply by Robbins et al., (2004:489) as " a system of shared meaning held by members [of the organisation]". There is some debate in the literature about whether culture is something an organisation *has* or something an organisation *is* (Kirk, Parker, Claridge, Esmail, & Marshall, 2006; Parker, Lawrie, & Hudson, 2006; Robbins et al., 2004; Scott, Mannion, Davies, & Marshall, 2003; Westrum, 2004). For the purpose of this study however, the importance of organisational culture is the effect it has on an organisation's performance, in particular, the influence of culture on an organisation's response to difficult situations. An organisation's culture is expressed by the members of that organisation in their behaviours and attitudes and the effects this has on their actions (Robbins et al., 2004; Scott et al., 2003; Westrum, 2004). Throughout the Inquiry, evidence was given that demonstrated clearly the dominant organisational culture at KEMH pre Inquiry was not one that supported and embraced change (Douglas et al., 2001). Douglas et al. (2001) note in their executive summation of the situation at KEMH between 1990 and 2000 that:

> For the most part, the problems were long-standing, recurrent and widely known ... the issue has been failure of the Hospital's leaders and managers to do something effective ... responses from those in a position to do something about a particular problem commonly included: ignoring the problem; denying there was any problem ;criticising those who suggested there was a problem; referring the matter to one or more committees... with little subsequent action and no resolution; and, reiterating the mantra that KEMH is unique and therefore can not be compared to any other institution ... (2001:xv1-xv11)

The description thus far of the situation within KEMH pre Inquiry has identified that there were significant barriers to the improvement of problems and issues. Table 5 below summarises the barriers present, with examples demonstrating the behaviours and attitudes. These factors served as powerful barriers to change in the systems and processes at KEMH. KEMH was therefore unable to respond adequately to changing clinical, consumer and public sector accountability expectations.

While the barriers to change may have been dominant within the culture at KEMH during this time, it should be recognised that there were also factors both within the culture at KEMH and in the external environment that, if given support, could have acted as drivers of change. As noted above there was certainly a plethora of evidence presented at the Inquiry that identified that many staff were striving to overcome clinical care issues. As well, much evidence was identified demonstrating that medical and midwifery staff repeatedly raised issues of poor staffing, inadequate communication and poor clinical care processes that were not addressed (Douglas et al., 2001). There is also a political and consumer expectation that as a Public Sector organisation there are professional, clinical and fiscal accountability and monitoring systems in place monitoring, reviewing and identifying systems and processes to ensure a high quality of care (Ferlie, Ashburner, Fitzgerald, & Pettigrew, 1996; Hilgartner, 2007; Lipsky, 1980). If these systems were in place for the West Australian Public Health sector, then they failed to identify and remedy the problems at KEMH. Finally, as part of a professional responsibility, the expectation is that the clinical care provided will be based on the best evidence available. This requires that the organisations and the professionals within it have systems to maintain currency and awareness of new trends and research in care. All of the elements that could act as drivers for change were present within the culture at KEMH, however, the barriers that were also present dominated. Thus, the resultant climate was one where changes and improvements in the clinical governance systems were very difficult to initiate let alone sustain.

Table 5: Barriers to Clinical Governance Improvement at KEMH 1990-2000

Barriers	Examples
Lack of leadership	Lack of action re issues raised in regards to: inadequate staffing; inadequate supervision of junior staff; lack of credentialing and performance management; clinical care issues; patient concerns and complaints Director of Medical Services and Director of Nursing- no line management authority post 1996.
Lack of continuity of leadership	Three Boards; three CEOs; four Directors of Medical Services; two Directors of Nursing between 1990-2000 Devolved management structure introduced 1996.
Medical dominance (3 aspects: content of work, authority over others and authority over society)	Inadequate information provided to patients about care and care management options; Acceptance or lack of accountability for substandard care planning, poor management of high risk cases and poor documentation of care; Junior medical staff & Midwives reluctant to contact Senior staff for assistance; Poor compliance with policies and procedures e.g. cord blood testing policy; Direct and indirect intimidation of Inquiry informants; Efforts by AMA to discredit Inquiry; MDA challenge to scope and legitimacy of Inquiry.
Powerless staff	Issues in regard to clinical care and staffing not addressed by management; Issues in regards to non-compliance with credentialing processes, and care policies and procedures not addressed; Junior staff discouraged from contacting Senior staff for advice.
Inward looking culture	Policies and procedures not up to date or based on best available evidence; Rhetoric and belief of KEMH as world class facility with little external benchmarking to validate; Non- acceptance of complaints or criticism.
Lack of alternate hospital options for patients	Only public tertiary maternity hospital in Western Australia.
Powerless patients	Inadequate information provided about care and care options; Inadequate communication & lack of support when there was a poor outcome; Disrespect and poor treatment when making a complaint.
Pubic Sector/political focus on fiscal & efficiency outcomes	Budgetary constraints cited as reason for lack of staff and other resources; Financial performance indicators closely monitored.
Lack of public sector/political focus on clinical governance issues	ACHS improvement recommendations ignored and not followed u; Non existent systems to monitor, review or respond to clinical care issues, credentialing issues or patient complaints.

Lead-up to the Inquiry

In December of 1999 the recently appointed Chief Executive Officer (CEO) of KEMH reported to the Metropolitan Health Services Board

(MHSB) CEO that he had major concerns about the quality and safety of patient care. He summarised his concerns as:

- Lack of an overall clinical quality management system;
- Problems identifying and rectifying clinical issues by senior management;
- Inadequate systems to monitor and report adverse events;
- Absence of a proper and transparent system to deal with patient complaints and claims;
- Shortage of qualified clinical specialists particularly after hours;
- Inadequate supervision of junior medical staff; and
- Possibility of substandard patient care (Braithwaite et al.2006:80)

After consultation with an independent senior clinician, the CEO of the MHSB commissioned an independent assessment. This review was carried out by Dr Andrew Childs and Ms. Pauline Glover in the short time frame of two weeks. The report of the review (Child and Glover report) identified serious system and performance issues (see Appendix 13 for review summary). The Child and Glover report resulted in a great deal of debate in the media with both individual clinicians and the Australian Medical Association (AMA) being extremely critical of the findings. The general public was subjected to ongoing headlines in the local media in regards to the situation at KEMH (Braithwaite et al.2006:81). In response to this situation, on 23rd May 2000, the Minister for Health established an inquiry into the obstetric and gynaecological services at KEMH. The Inquiry was established under the *Hospitals and Health Services Act 1927* and the *Public Sector Management Act 1994.*

THE INQUIRY

Background

A statutory public inquiry is an instrument of Government that can be established to investigate issues of public interest (Lindall, 2002). The purpose of an inquiry may be for all or one of the following reasons:

- To investigate a major disaster or event and establish the facts of what happened;
- To establish accountability and responsibility;
- To research and review an issue of public interest and provide policy advice and recommendations to government;
- To reassure and build public confidence; and/or
- To serve a political agenda such as mobilising public support or to show concern without actually doing anything (Hilgartner, 2007; Smith & Weller, 1978; Walshe & Higgins, 2002).

A statutory inquiry is established within a legal framework, which gives it certain legal powers of inquiry and protection for those involved. Proceedings may be conducted in public or private. The findings are reported to the Parliament through the Minister/s who established the inquiry (Hilgartner, 2007; Lindall, 2002; Smith & Weller, 1978; Walshe & Higgins, 2002).

The role of an inquiry is to investigate fully and identify the factors, influences and issues that have led to the inquiry's formation. Several crucial factors influence an inquiry's effectiveness in meeting its role. These are the legal powers of investigation and protection, and the directions given to an inquiry, which describe the extent, boundaries and/ limitations of issues to be considered as part of the inquiry. The Legislative Act(s) under which an inquiry is established and the terms of reference (TOR), are the implements that specify both the legal powers of investigation and protection, and the depth and scope of an inquiry's examination (Hallett, 1982; Walshe & Higgins, 2002).

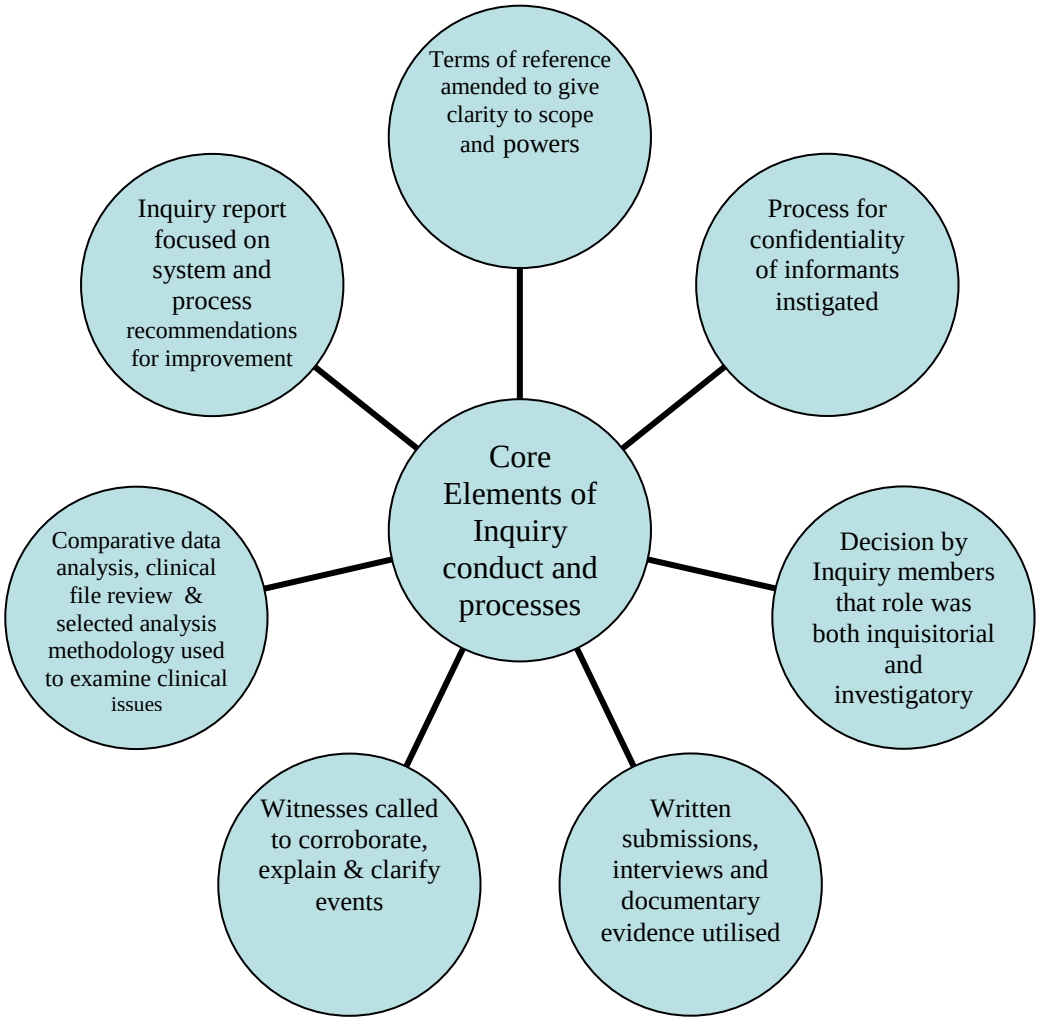


Figure 9 : Core elements of the conduct and processes of Douglas Inquiry

Inquiry Establishment

The Inquiry into obstetric and gynaecological services at KEMH 1990-2000 was established on May 23, 2000. The Premier and the Minister for Health, using Section 11 of the *Public Sector Management Act 1994* and section 9 of the *Hospitals and Health Services Act 1927*, created the Inquiry. The initial appointees to the membership of the Inquiry were Mr Neil Douglas (Chairman), Professor William Walters, and Associate Professor Kathleen Fahy. Professor Walters indicated that he was unable

to act as a member and so he was replaced by Professor Jeffrey Robinson in June 2000 (Douglas et al., 2001).

Figure 9 above summarises the core elements of the Douglas Inquiry in terms of the conduct and processes utilised. Each of these elements is discussed in the following section.

Terms of Reference (TOR)

As stated above, the TOR for an inquiry are crucial in determining the scope and boundaries of an inquiry's investigation. The TOR also have a critical impact on an inquiry's ability to examine and investigate an issue in an effective and efficient manner. The initial terms of reference (TOR) for this Inquiry detailed, as part of the instrument of appointment, the scope and issues that were to be investigated. It was believed by the members of the Inquiry however, that there were two essential problems with the original TOR. The first issue identified was that the TOR required that the Inquiry examine whether "... the incidence of adverse events is acceptable and appropriate ..." (Douglas et al., 2001:27). The Inquiry members believed that this was not achievable due to the difficulties in:

- Identifying and classifying all such events that may have happened in the period of time 1990-2000;
- Proving that the adverse events were directly attributable to the care provided; and/or
- Comparing adverse event rates with other hospitals' rates due to the problem of ensuring that definitions and classifications of adverse events were the same from hospital to hospital.

The second issue with the original TOR centred on the requirement for the Inquiry to examine representative cases. The Inquiry members believed

that this terminology provided an option for potential challengers in the future to claim that the cases chosen were not representative.

These issues with the TOR were raised in an Interim Report. As a result in August, 2000, the TOR were amended by the Premier and the Minister for Health.

The amendments gave the Inquiry the capacity to use clinical performance indicators as benchmarks. These would provide a comparison of care delivered at KEMH against what should be expected. The changes to the TOR also allowed the Inquiry to select cases to be examined that would or might be illustrative of deficiencies in policies, procedures or care outcomes. The full amended TOR with definitions is reproduced in Appendix 14 (Douglas et al., 2001:31-34). In summary, the Inquiry TOR specified the Inquiry was to:

- investigate specific obstetric and gynaecological services that had been provided;
- assess whether the services provided were appropriate and adequate;
- identify the nature, extent and causes of any deficiencies; and
- recommend changes (Douglas et al., 2001:3).

The Inquiry members believed that the amended TOR allowed the Inquiry to meet the purpose of the investigation. The Inquiry purpose as directed in the amended TOR was summarised succinctly by McLean and Walsh (2003:13) as " ... to inquire into the provision of obstetric and gynaecological services at KEMH" over the period 1990-2000".

Statutory Powers and Protection

The second area crucial in contributing to an effective inquiry process are the statutory powers and protection afforded to an inquiry when it is established (Hallett, 1982; Walshe & Higgins, 2002). AS stated above, the legislative framework under which this Inquiry was established involved two different Legislative Acts. The first was Section 9 of the *Hospitals and Health Services Act*. This section states that:

> Holding of inquiries
>
> > (1) The Minister may, from time to time, hold such inquiries or investigations as he may deem necessary in relation to any matter concerning the public hospitals or any public hospital, or the administration of this in relation to public hospitals, and may appoint one or more persons to conduct such inquiries or investigations as he may deem fit.
> >
> > (2) When an inquiry is being held the Minister or any such person shall have free access to all books, plans, maps, documents, and other things belonging to any board, and shall have in relation to witnesses and their examination, and the production of documents, the powers conferred upon a Royal Commission or the chairman thereof by the Royal Commissions Act 1968, and may enter and inspect any building, premises, or place, the entry or inspection whereof appears to be requisite for the purpose of such inquiry.
> >
> > *(Hospitals Act 1927)*

The Minister for Health requested the Crown Solicitor's office to provide advice about the capacity of Section 9 of the *Hospital and Health Services Act* to provide legal protection for inquiry members, witnesses and those involved in the work of an inquiry. This advice identified the possible limitations on legal protection under this Act. To overcome this, both the Inquiry was established under the legislative framework of both *Hospitals and Health Services Act* and the *Public Sector Management Act*. The Public Sector Management Act gives the same protection to a "special inquirer" as a person conducting a Royal Commission and to an inquiry

witness as to a witness at a Royal Commission (Douglas et al., 2001:34-37).

The Inquiry members believed strongly however, that these two Acts did not give adequate protection to counsel involved or, other staff working for the Inquiry. A strategy to address this issue was never proposed by the Government. This was a cause of dissatisfaction to the Inquiry's members. A further issue identified in regards to the establishment of the Inquiry under these two Acts was that the members of the Inquiry believed that the power of the Inquiry to ensure confidentiality for informants was not articulated clearly.

The issue of confidentiality for informants was believed to be of particular importance in regards to this inquiry. For KEMH staff, the hospital was a relatively small and closed community that had not demonstrated support in the past for staff members who had raised concerns about clinical care and poor processes. The relatively small size compared to other major tertiary hospitals in other states also impacted on the possibility that an informant would be identified, even if their name was withheld, by factors that provided clues to their identity within the information that they gave. The Inquiry members believed that this put staff informants at risk of possible civil or criminal liability claims or identification as a whistle blower with all the personal and professional negative implications that arise from being labelled as such. A further consideration for staff who could face negative consequences from giving information to the Inquiry was that with KEMH being the only tertiary maternity service in the State there were few alternative local employment opportunities particular to this type of specialist service (Douglas et al., 2001:41-45).

The members of the Inquiry were aware that there were groups and individuals opposed to the Inquiry and who were directly and indirectly intimidating possible informants by suggesting that their confidentiality was not assured if they chose to give information to the Inquiry (Douglas et al., 2001:64). This negativity towards external scrutiny of KEMH was

also highlighted by a concerted effort by the West Australian Branch of Australian Medical Association (AMA), which utilised the media to undertake a campaign of criticism of the role and requirement of the Inquiry (see Appendix 15 for examples of AMA statements). To add to this general uncertainty, the Medical Defence Association (MDA) submitted an early submission to the Inquiry challenging the power and scope of the Inquiry to investigate an individual public sector body and therefore, disputing that the legislative framework under which the Inquiry was established provided any powers of investigation or protection. This submission was never pursued before the Inquiry, but throughout the Inquiry and subsequent to the publication of the report a challenge remained a possibility (Douglas et al., 2001:44-46).

In their preliminary report to the Government in August 2000 the Inquiry members presented a submission seeking the reconstitution of the Inquiry as a Royal Commission under the *Royal Commissions Act*. It was believed that this would provide protection to both staff and counsel involved in the Inquiry, together with, protection for informants to the Inquiry (Douglas et al., 2001:A49). The Minister for Health rejected the Inquiry's request. The basis for this rejection was that the Solicitor General did not support the Inquiry members' concerns about the lack of legislative protection of confidentiality for informants and staff working for the Inquiry (Douglas et al., 2001:A53- A75). In order to deal with the concerns of the Inquiry members in regards to confidentiality the Inquiry developed protocols that they believed would protect informants' statements and also other Inquiry records and materials (including confidential records and materials) from publication and unauthorised access (Douglas et al., 2001:58-62).

The ability of an inquiry to research and investigate issues relies on the inquiry employing thorough and meticulous methods and processes to obtain accurate and relevant information and data.

Inquiry conduct

An inquiry can have an investigatory or inquisitorial role depending on the issues to be examined and the aims and purpose of the inquiry. An investigatory inquiry gathers and analyses information and data to provide advice and recommendations. An inquisitorial inquiry considers and probes events and occurrences to identify and report (and sometimes make recommendations) about them (Hallett, 1982). Depending on whether the role is investigatory or inquisitorial affects the conduct and methods of an inquiry.

The members of this Inquiry determined that in order to meet the requirements of the TOR the role would be both investigatory and inquisitorial. Thus, documents, submissions from informants, case notes, and information from a variety of external sources were utilised as part of the investigatory role. In terms of the inquisitorial role, witnesses were called to give evidence to provide corroboration, explanation or further clarification about information, or to describe and explain their actions and decisions in relation to events that had occurred in the period that was being investigated (Douglas et al., 2001:A101-107).

Written Submissions

Members of the public were invited to make submissions to the Inquiry through a series of advertisements in the *West Australian* and *Australian* newspapers. The Australian Medical Association also published an advertisement encouraging supporters of KEMH to make submissions to the Inquiry. The call centre, Health Direct, which is a consumer health advice service, also made a hotline available to take calls in regards to the Inquiry. In all the Inquiry received 293 submissions. Of these over 200 appeared to have been former patients of KEMH; the remainder were from other individuals or organisations. In total 56 of the 293 submissions were complimentary of the care received at KEMH. (Douglas et al., 2001:73-74).

Document Sources

The Inquiry obtained documentation from a variety of sources. The full list is available in Appendix 16, including documents and information from various Clinician Professional Colleges, Patient Safety organisations, WA Universities, the Department of Health West Australia, the Coroners Court, Regulatory Authorities and the National Health Medical Research Council (Douglas et al., 2001:78). The largest amount of documentation however, was obtained from KEMH. Also included were copies of 55,000 emails (which covered the period 1990-2000), and electronic and hard copies of the following:

- Over 1600 patients' clinical files;
- Ward documents;
- Accident/incident files;
- Statistical data;
- Quality assurance documentation;
- General correspondence files;
- Rosters and diaries;
- Personnel files;
- Patient complaints;
- Operational procedures;
- Organisational charts;
- Policies and guidelines;
- Recruitment and performance management documentation; and
- Committee minutes (Douglas et al., 2001:75-78)

Some of this documentation was readily available and submitted to the Inquiry in a timely manner when requested. On the other hand, the Inquiry found that even with repeated requests to KEMH for other information and documents, there seemed to be some impediment to their production. Thus, the Inquiry staff, following formal notification of their intentions to

do so, attended KEMH and removed the documents they required that had not been forthcoming.

The Inquiry used a document management system that allowed full text electronic searches and retrieval of documents once they were scanned into the system. This involved 2.3 million pages of scanned documents. Patient clinical files were not scanned into the document management system (Douglas et al., 2001).

The information collected in the documents for examination and analysis was substantial, but this was not the only source of evidence gathered. The Inquiry also utilised the information obtained through interviews with former patients, and current and former staff of KEMH.

Interviews

There were two different types of interviews used to gather information. The first were informal interviews conducted by an Inquiry lawyer. In informal interviews, the witnesses were not compelled to answer questions, they were able to attend the interview with legal representation, and their evidence was provided back to them as a written statement they were able to amend if they so chose. To protect confidentiality the original written statement remained the property of the witness. The copy, held by the Inquiry, was destroyed at the conclusion of the Inquiry (Douglas et al., 2001:46).

The Inquiry informally interviewed 70 former patients in person and, a number by telephone interview. The Inquiry requested 122 staff members to attend the Inquiry for an informal interview. Of the number requested to attend, 106 staff attended of which 36 of these were considered as confidential witnesses. The interviews varied in length from 1.5 hours to several days (Douglas et al., 2001:80-82).

The informal interviews were conducted over a period of five months. During this period, it came to the attention of the Inquiry members that staff at KEMH were being told by others that their confidentiality would not be protected if they chose to take part in the informal interviews. Thus the Inquiry felt it necessary to circulate a letter to all staff within the hospital disputing this claim (Douglas et al., 2001:80-82).

The second type of interview was a formal interview. For this, the witness gave their evidence under oath (or affirmation) before the members of the Inquiry. The evidence was recorded and transcribed to become part of the formal transcript of the Inquiry's hearings. The Inquiry, by virtue of the legislation under which it was established, had the power (which was invoked) to order non-publication of the transcripts of the formal interviews (Douglas et al., 2001:47)

Although the Inquiry had these powers of preventing publication of the transcripts, the members of the Inquiry were acutely aware of the risks of inadvertent identification of witnesses if the taking of evidence was held in public. Consequently, the issue of whether the Inquiry was closed or open to the public was one that needed to be considered.

Public or Private Hearings

The Inquiry received two submissions that supported public hearings and three that opposed public hearings. After consideration of these the Inquiry ruled that the hearings would be in private. This decision was based largely on the Inquiry's view that unless there was some measure of comfort for prospective witnesses (either informal or formal) and that the Inquiry could assure their anonymity, then there was a likelihood that vital information would not be presented to the Inquiry (Douglas et al., 2001:83-84).

Having identified the important aspects of how the Inquiry would be conducted the next area to which the Inquiry members turned their attention was the methodologies that would be employed to consider and analyse the information.

Inquiry Methods

Investigation Boundaries

As stated above the Inquiry members interpreted the objectives of the TOR as requiring them to:

- investigate specific obstetric and gynaecological services that had been provided;
- assess whether the services provided were appropriate and adequate;
- identify the nature, extent and causes of any deficiencies; and
- recommend changes (Douglas et al., 2001:3).

In broadly defining these objectives, the Inquiry members determined that assessment of adequacy and appropriateness of care would be evaluated against a relevant standard for patient care and safety. In their discussions describing this standpoint, the Inquiry members articulated clearly that although conduct and practices at other hospitals were relevant, they would not be the principal comparators. The rationale for this was that in some cases, practices at other hospital might also be deficient in terms of patient care and safety. If this was the situation, then using another hospital's deficiencies as a comparison of KEMH deficiencies would serve no purpose except as a justifier of poor and substandard performance (Douglas et al., 2001:3-5).

Another important point identified by the Inquiry was that with the focus on problems and shortcomings at KEMH, care and practices of an acceptable and high standard would not receive the attention they

deserved. The Inquiry highlighted in their report the "... many instances of exemplary conduct and practices that reflect credit both on the individuals concerned and on KEMH itself' (Douglas et al., 2001:5)

Having identified the limits and boundaries of the Inquiry investigations, an efficient and effective process on undertaking the analysis of the information gained in the investigations had to be identified. The Inquiry used three main processes to analyse the information. These were:

- A comparative data analysis;
- A clinical file review; and
- A selected issues analysis (Douglas et al., 2001:6).

Comparative data analysis

The comparative data analysis was undertaken for the Inquiry by a consortium of experts in perinatal epidemiology statistics, and clinicians in the field of obstetrics and gynaecology.

The aim of the comparative data analysis was to undertake a quantitative comparative analysis of clinical practices and outcomes at KEMH with 13 similar hospitals in Australia. The comparisons utilised routinely collected data from three sources:

- The State perinatal data collections;
- The State hospital inpatient statistics collections; and
- The Australian and New Zealand Neonatal Network data collection.

It was recognised that the limitation of this data was the possibility of human error in the collection, coding and retrieval of data (Douglas et al., 2001:645-664).

Clinical File Review

The clinical file review involved qualitative and quantitative review, and analysis of selected clinical patient files. The sample of files was a purposive sample, selected on the basis that the case was representative of a group or types that were at increased risk of poor clinical management and / or the circumstances increased the risk of adverse outcome, or both.

The review comprised a retrospective analysis of events recorded in the clinical files. This analysis was in several stages. The first involved summarising the patient admission events and assessing the quality of care. The second stage involved applying a rating scale to each summarised admission in regards to both the type, frequency and seriousness of errors and contributing factors (Douglas et al., 2001:177-179).

The rating scale for errors included five types. These were:

- Failure to recognise a serious, unstable situation (not including CTGs (cardiotocographs));
- Failure by senior staff to assess a woman/baby in a serious and unstable situation;
- Inappropriate intervention;
- Inappropriate omission (not including CTG); and
- Incorrect action in relation to CTG (Douglas et al., 2001:193-194).

The five factors that comprised the rating scale for contributing factors were:

- Delay in providing clinical care;
- Lack of an adequate clinical policy;
- Lack of an adequate clinical care plan;

- Lack of coordination of care; and
- Unsupervised junior staff assessing patients and providing complex clinical care (Douglas et al., 2001:195-196)

The clinical file review process was undertaken by expert clinicians including midwives, nurses, medical specialists and experts in statistics and epidemiology (Douglas et al., 2001:179).

The TOR of the Inquiry stated that the Inquiry was to refer "…any allegations of gross carelessness, incompetence or improper conduct ... which may warrant further investigation ... to the appropriate professional or other bodies" (Douglas et al., 2001:34) The Inquiry however, was very clear that the focus was on the examination of systems and organisational factors that contributed to patient safety and quality care. From the total of 605 clinical files reviewed, the Inquiry referred only nine cases to the Medical Board for further investigation. In other cases where care had been graded as unsafe, systemic or organisational factors were perceived to be the biggest contributing factor to the unsafe care (Douglas et al., 2001:20).

Selected Issues Analysis

The issues selected for closer analysis were determined by the Inquiry's view that the issue would impact on the quality and safety of patient care. The issues identified were:

- Clinical practice;
- Clinical guidelines and policies;
- Incident reporting and management;
- Education and training of clinical staff;
- Employment issues affecting clinical staff; and
- Quality improvement (Douglas et al., 2001:15).

Each of these issues was examined utilising information gained from the comparative analysis, the clinical file review, submissions to the inquiry, witness statements taken at informal and formal interviews, transcripts on evidence and the documents from KEMH and other sources described in the section above on Inquiry conduct (Douglas et al., 2001:670).

The Inquiry was established on the 23rd May, 2000. Eighteen months later, following investigation and examination of documents, witness statements and other evidence, the information was synthesised and compiled into a report on the issues as described in the Inquiry TOR. The final report of the Inquiry was presented to the Premier and the Minister for Health on 30 November 2001.

THE INQUIRY REPORT

An Inquiry is established to conduct research for the purpose of reporting facts, describing what happened and why and, to make recommendations for the future (Hallett, 1982).

The Inquiry report comprised five volumes. The report states that there are 237 recommendations (Douglas et al., 2001:xxv), however manual counting for this study identifies 236 recommendations.

The Leader of the House tabled the report in the Legislative Council on the 20th December 2001. Once tabled the majority of the report was available for the public to access. There were several sections (approx 300 pages) however, that the Minister for Health directed be withheld from the final Inquiry report. These sections were those that dealt with the review of the management and outcomes of specific patient cases and also patients' testimony describing their views and experiences. In denying free access to these sections of the report, both clinicians and consumers were not given the opportunity to understand the extent of the clinical care problems and also the impact of adverse events, poor outcomes and

inadequate communication experienced by patients and their families. Also removed from the appendices of the Inquiry report was a copy of the Child & Glover report and the response report by KEMH management to the Child and Glover findings. Both the Child and Glover report, and the KEMH response to this report, are referred to in detail within the final Inquiry report, thus a general understanding of the content can be inferred. However, without access to the original documents the full import of these documents which describe the organisational context pre Inquiry and also demonstrate KEMH management's attitude of defensiveness and denial in responding to the criticisms in the Child and Glover report, is lost. The act of withholding sections of the final Inquiry report resulted in a significant amount of evidence from the testimony, and comments from the Inquiry panel, being unavailable in the public domain for either consumers or KEMH staff to access and then use as justification and a driver for change.

In summary, the final Inquiry report that was tabled in the Legislative Council of the West Australian Parliament "identified problems with the delivery of services at KEMH. The problems covered clinical, administrative and management issues. They ranged in seriousness, with some being very serious" (Douglas et al., 2001:x).

Problems that influenced care were identified in the following areas:

- Care planning, care delivery and documentation;
- Inter-hospital performance;
- Clinical policies and guidelines;
- Incident reporting and management;
- Staffing problems;
- Education and Training;
- Consultant accountability and cover;
- Junior doctor supervision and training;
- Credentialing of doctors;

- Performance management of clinicians;
- Involving women and families in care;
- Managing complaints; and
- Quality improvement and accreditation (Douglas et al., 2001).

As is common in many inquiries into health care failures, the report identified that the problems were well known but had not been dealt with (Walshe & Shortell, 2004). Also, as has been noted at other inquiries, the report identified a failure in leadership, and fundamental cultural, management and accountability problems (Braithwaite et al., 2006; Cartwright, 1988; Davies, 2005; Douglas et al., 2001; Edmondson, 2004; Walshe & Offen, 2001).

The Inquiry report notes that if changes and improvements were to occur, there would need to be an acknowledgement and acceptance of the magnitude of the problems by the leadership and staff at KEMH, and those professional bodies that supported staff at KEMH. Additionally, the report points out that change to policies and procedures alone would not achieve the radical change in attitudes and culture of some of the medical community, and the KEMH management group, who were acting as barriers to change. The report goes on to identify that without strong leadership and commitment any changes made would not overcome the problems, and that care at KEMH would continue to be compromised (Douglas et al., 2001:x-xxx111) .

Specific recommendations were made for each matter the Inquiry examined and reported. Since the breadth and range of these is beyond the scope of this study however, the following discussion will focus on the recommendations that pertain to this study. These dealt with medical credentialing and clinician performance review, and the involvement of women and their families (consumers) in care at KEMH. These issues were chosen for several reasons discussed in previous chapters. Briefly though, the area of medical credentialing and performance review was

chosen as being representative of an important clinical governance administrative function. Consumer involvement in care was chosen because of its featured prominence at the Inquiry as an area of dissatisfaction for patients and families. Both of these areas were highlighted in the final Inquiry report as requiring significant improvement. Thus, it was believed if the inquiry influenced changes in these processes at KEMH, then, as representative examples in this instrumental case study of a clinical governance process, it would have wider application to similar contexts.

INQUIRY RECOMMENDATIONS SPECIFIC TO THIS STUDY

Medical Credentialing & Clinician Performance Management

Credentialing involves having a system in place within a hospital to ensure that staff have the appropriate qualifications and skills, knowledge and training to undertake the procedures, required to provide care to the patients for whom they are caring. Performance management is a term used to describe the process whereby there is regular review of a person's work to make certain that person is maintaining their skills and knowledge to continue to perform the procedures and care provision they are undertaking. Performance management also involves providing the opportunities for staff to develop and enhance their knowledge and skills (*National Guidelines for Credentials and Clinical Privileges*, 2002)

The Inquiry report found that there were significant deficiencies in these processes at KEMH. It was identified that there was no formal credentialing process before June 2000 (McLean & Walsh, 2003:17). In regards to performance management of clinical staff, the hospital had no formal performance management system in place until 1997. It was noted however, that the midwifery staff did have their own system in place during the period of review, although this was not as robust as it should

have been and there were noteworthy gaps in some clinical areas. The lack of a formal hospital-wide system resulted in very few medical staff participating in a performance review process (McLean & Walsh, 2003:18).

The deficiencies in credentialing and performance management resulted in 25 recommendations. Of these, 14 concerned credentialing and 11 concerned performance review (Douglas et al., 2001). A full list of the recommendations in this area is available in Appendix 17.

In terms of credentialing, the theme of the recommendations covered the need for a credentialing process and a committee system to oversee this. The credentialing process was to cover all levels of medical practitioners at KEMH from the senior to junior doctors. The report stressed the need for a process to ensure there was a credentialing list that maintained currency and was readily available to all staff who needed access to it (Douglas et al., 2001).

The recommendations concerning performance management were broken down into each clinical staff category. These groups were detailed as consultants and directors, registrars, residents, and midwives and nurses. The recommendation requirements for each group were similar with a focus on the need to develop and implement a rigorous hospital wide system.

Involvement of Consumers in Care

As part of the clinical file review, the Inquiry examined the perceptions of women and their families in regards to the care they received. As well, former patients were interviewed and patient submissions reviewed, to determine their views on their involvement in their treatment and their interactions with staff (Braithwaite et al., 2006: 94).

The perceptions of many women and their families were that they had not received adequate information about their treatment options, or been involved in their care choices. They reported lack of support when they experienced poor outcomes or adverse events, and poor treatment and disrespect when making complaints about care and treatment (McLean & Walsh, 2003). Specifically the Inquiry report noted the major psychosocial concerns as:

- Failure to provide adequate explanation of poor outcome;
- Failure to include a woman and her partner in decision making (in terms of consent, discussion, information sharing, listening to woman's plan/thoughts/concerns;
- Lack of sensitivity, respect, dignity and support (generally and when emotionally distressed); and
- Failure to listen or respond appropriately to the woman expressing her subjective symptoms (Douglas et al., 2001:442-444).

The Inquiry made sixteen recommendations in regards to involvement of women and their families in care (see Appendix 18 for full text of these recommendations). Fifteen of these recommendations are included in this study. The sixteenth recommendation (No.47) is not included as it relates to the appointment of an extra staff member, including the details of the role requirements. This recommendation is important in terms of enhancing involvement of women in care however, evaluation of this role would require assessment of an individual's performance. This is beyond the scope of this study for two reasons. Firstly, the focus of the study is on system improvement rather than on an individual in the system, and secondly, because the resources required undertaking this sort of assessment, exceeds those available. The recommendations were broken down into four broad categories (see Figure 10 for summary of categories). The first category was communication with women and their families. In this section, there were five recommendations. The key points covered were ensuring that discussions were undertaken with women and that these discussions were documented in the clinical file. In addition,

that there should be access to interpreters 24 hours per day, and that when a baby dies, there should be a plain English post mortem report that is discussed with the woman and her family.

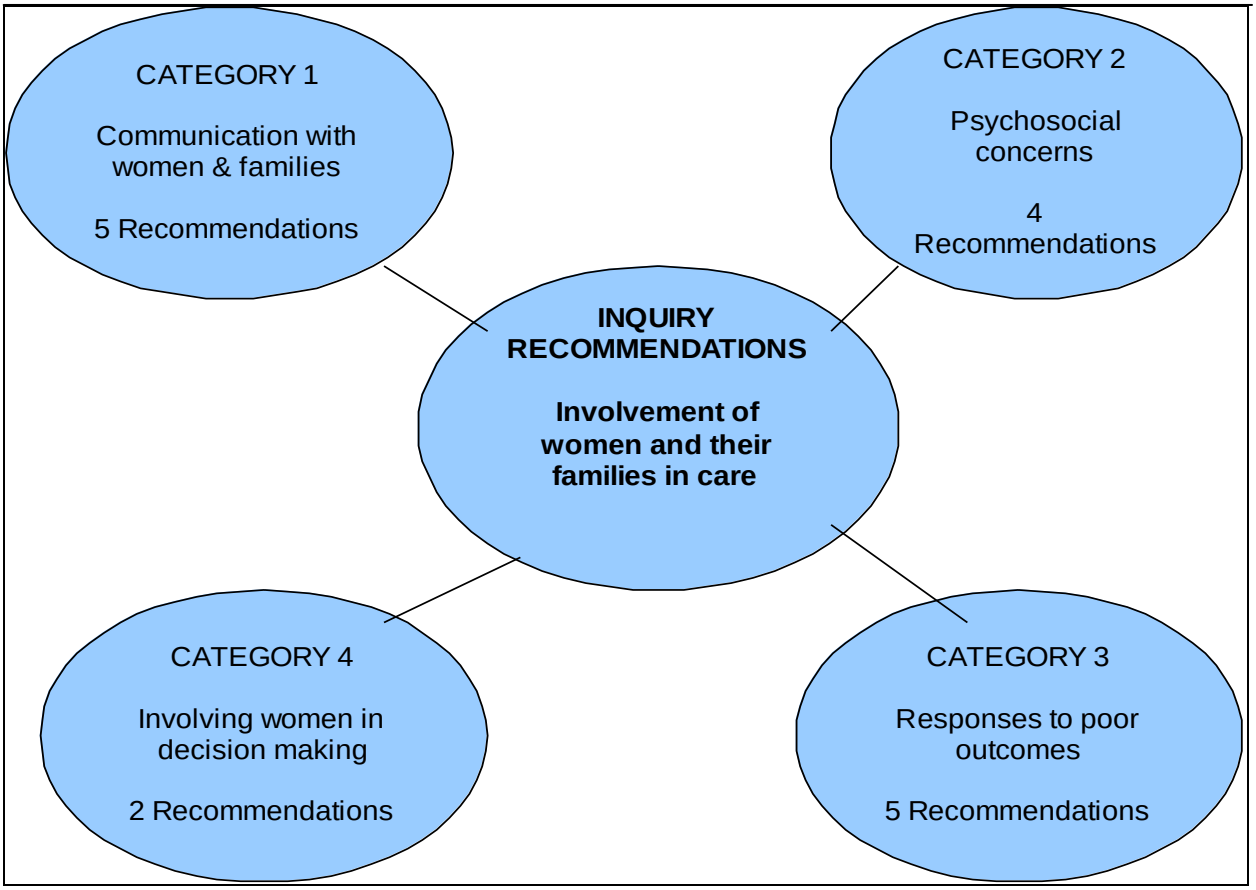


Figure 10: Inquiry Recommendations – The four categories for involving women and their families in care

The second category was one that dealt broadly with psychosocial concerns. There were four recommendations in this section. The main areas covered in these recommendations concerned ensuring continuity of care for women, and scheduling regular workshops for all clinical staff to develop and maintain skills in communication with women and their families about all aspects of their care.

The third category of recommendations concerned responses to poor outcomes. There were five recommendations in this section. In the main, these continued the theme of the previous recommendations but with a

specific focus on workshops for all clinical staff, focusing on communication and empathy skills when dealing with women and families who have experienced death of a baby or a poor outcome of care.

The fourth and final category concerned involving women in decision-making. There were two recommendations in this section. Once again, the focus of these was on strategies to build the skills of the clinical staff to ensure that women were involved in any decisions being made about the care of the woman or her baby.

To achieve a high standard of patient care it is necessary to focus not only on the obvious areas of direct care processes and on other less obvious areas that comprise the totality of the systems and processes that contribute to a patient episode of care. The recommendations discussed above dealing with women and families' involvement in care is one of those aspects that may be less obvious at the outset of a discussion of quality care. Another aspect is one that deals with the credentialing of medical staff and the performance management of all clinical staff involved in providing care.

CHAPTER SUMMARY

This chapter has provided an in-depth description of the case of interest for this study. Firstly, a description of the circumstances and working environment of KEMH during the period 1990-2000 was presented. This provided both an appreciation of the context in which the issues that triggered the Inquiry took place, and identified the barriers to any improvement initiatives. Secondly, a description of the establishment of the Inquiry and the processes and procedures employed by the Inquiry were detailed. Finally, the specific recommendations from the Inquiry that dealt with the particular areas of focus of this study were discussed. The following chapter will report the findings from the analysis of the data to answer the research questions. Firstly, the investigation into whether there were changes in the processes for medical credentialing and clinician

performance review, and consumer involvement in care at KEMH post Inquiry will be reported. This will be followed by an account of the perceptions of the participants in regards to the influence of the Inquiry on any change processes involved.

CHAPTER FOUR:

FINDINGS FROM DATA ANALYSIS

"We must ensure that we learn the lessons from KEMH and improve the whole system's performance on safety and quality' (Duckett, 2003)

INTRODUCTION

Chapter 1 described the development of the specific research question for this study and the relationship of the research topic to the current literature. Chapter 2 specified the methods by which the research question was investigated. Chapter 3 presented a detailed description of the case being examined in this case study, that is, the pre Inquiry context of KEMH, together with, the conduct and outcome of the Inquiry processes. This chapter presents an analysis of the data gathered from document/ archive and interview analyses to identify several components that are required to answer the research questions as detailed in Chapter 1. To reiterate, these four research questions are:

- Were there changes in the medical credentialing and clinician performance management systems post Inquiry?
- Were there changes in the involvement of consumers in care post Inquiry?
- If the Inquiry did influence change in the specific areas, how did it and why?
- If the Inquiry did not influence change in the specific areas, why not?

The analysis of the document, archive and interview findings is presented in several sections. The first section analyses the data as applied to medical credentialing and performance review. The second section examines the data investigating if there were changes post Inquiry in the clinical governance processes that deal with the involvement of consumers in care. Using the findings to the first two sections, the third

section provides a conclusion to the question of whether there were changes in the clinical governance systems being studied. This is be followed by a presentation of the findings, examining the perceptions of the participants in regards to the influence of the Inquiry, (if any), on clinical governance change processes at KEMH post Inquiry.

REVIEW OF THE DOCUMENT, ARCHIVE AND INTERVIEW ANALYTIC PROCESS

The documents and archives were examined for evidence of policy, procedure or guideline change using an analytic approach as described by Neuendorf (2002:8). A full description of this is given in Chapter 2; in brief, this uses a set of criteria as a checklist to identify if there have been changes in policies, procedures or guidelines.

As stated above, the Miles and Huberman (1994) framework was used for data analysis of the interviews. This involves building an explanatory framework by identifying the component parts of the case being studied and describing how the features are connected and how they influence each other. Miles and Huberman describe this analytic progression as being necessary as "... it is hard to explain something satisfactorily until you understand just what something is..." (1994:91). A detailed description of how this analytic progression was achieved is given in Chapter 2. In brief however, this was accomplished by the researcher coding categories from the document, archival and interview texts, identifying themes or trends, developing propositions to answer the research questions, and finally building a conceptual model to explain the influence of the Inquiry on KEMH's clinical governance processes (review Figure 7 in Chapter 2 for summary of overall analytic strategy). The software program *NVIVO 7 (2006-2008)* was used for data analysis.

The first area reported here is that which deals with medical credentialing and clinician performance management. Document and archive findings will be presented first followed by findings from the interviews. This same format will then be followed for the next section where the findings for the involvement of consumers in their care will be reported.

MEDICAL CREDENTIALING AND CLINICIAN PERFORMANCE MANAGEMENT POST INQUIRY

The findings presented here are related to the data collection questions that investigated changes in the documents and archives in regards to medical credentialing and clinician performance review processes.

Document Analysis

The Inquiry recommendations for this section of the report were based on evidence presented to the Inquiry that there had been a lack of formal credentialing and performance management systems in place in the years 1990 to 2000 (Douglas et al., 2001). The Inquiry recommendations centred on the establishment of credentialing and performance review processes to address the deficiencies identified. This also involved developing processes for ongoing maintenance and monitoring of compliance with the requirements for credentialing and performance review. In total, the Inquiry made 25 recommendations in this section, 14 concerning credentialing and 11 concerning performance management.

Documents and archives are considered together here and referred to generally using the term ‘documents’. In the main, documents for this section were sourced from KEMH utilising the Freedom of Information Act to obtain the required information. Some documents were sourced from the Department of Health West Australia, the KEMH website, Quality and Safety websites and, academic journals and conference

reports. From the initial review of all documents obtained, 30 revealed information about policies procedures or outcomes concerning medical accreditation and clinician performance review.

Each document was examined for references or evidence to support any changes made post Inquiry, specifically in regards to medical credentialing or clinician performance review as per the recommendations of the Inquiry report (refer Appendix 17 for the full text of recommendations related to medical credentialing and performance review). For the document analysis, the recommendations were summarised into the following groups:

- Credentialing committee scope and function (terms of reference, meeting frequency, administrative functions);
- Credentialing list management (in terms of currency maintenance and distribution);
- Medical staff credentialing requirements (process of notification, monitoring and currency maintenance); and
- Performance management for each clinical group (initial process in place, ongoing development and review processes).

As each document was examined, the code *specific, implied, external evidence or, self-reported evidence* was used to note reference to a process or outcome that related to the recommendations. Table 6 details the results of this document analysis.

The discussion of the results in Table 6 is reported below in two sections. The first covers those aspects concerned with medical credentialing as described above to include credentialing committee scope and function, credentialing list management and medical staff credentialing requirements. The second section reports on the performance management processes for the clinical groups of medical and nursing combined.

Table 6: Document analysis for evidence of compliance with Inquiry recommendations-medical credentialing and clinician performance review

	Policies/ Guidelines	Clinical Guidelines	External reviews/reports	Journal/conference reports	KEMH reports/reviews
Medical Credentialing Recommendations					
Committee scope and function	Specific		External Evidence	Self-report Evidence	
Credentialing list management	Specific		External Evidence		Self-report Evidence
Monitoring medical staff credentialing requirements	Specific		External Evidence	Self-report Evidence	Self-report Evidence
Clinician Performance Management					
Consultants					
Process	Specific	Specific	External Evidence		
Regular review	Specific	Specific	External Evidence		
Registrars					
Process	Specific	Specific	External Evidence		
Regular reviews	Specific	Specific	External Evidence		
Residents					
Process	Specific	Specific	External Evidence		
Regular reviews	Specific	Specific	External Evidence		
Midwives					
Process	Specific		Implied		Self-report Evidence
Regular reviews	Specific		Implied		Self-report Evidence

KEY: Specific= Policy or procedure as per Inquiry recommendation; Implied= process described in detail but not as per Inquiry recommendation; Self-reported Evidence = KEMH self-reported evidence indicating implementation of policy or procedure; External evidence=external review indicating implementation of policy or procedure

Medical Credentialing

To meet the requirements of the Inquiry recommendations, documents reviewed for this section needed to demonstrate that there was a process describing the credentialing committee's scope and function. The credentialing process was to cover all levels of medical practitioners, there was to be a robust process ensuring that the list was updated as required, and updated lists were to be distributed appropriately to all clinical areas. Figure 11 demonstrates the sources coded to this section.

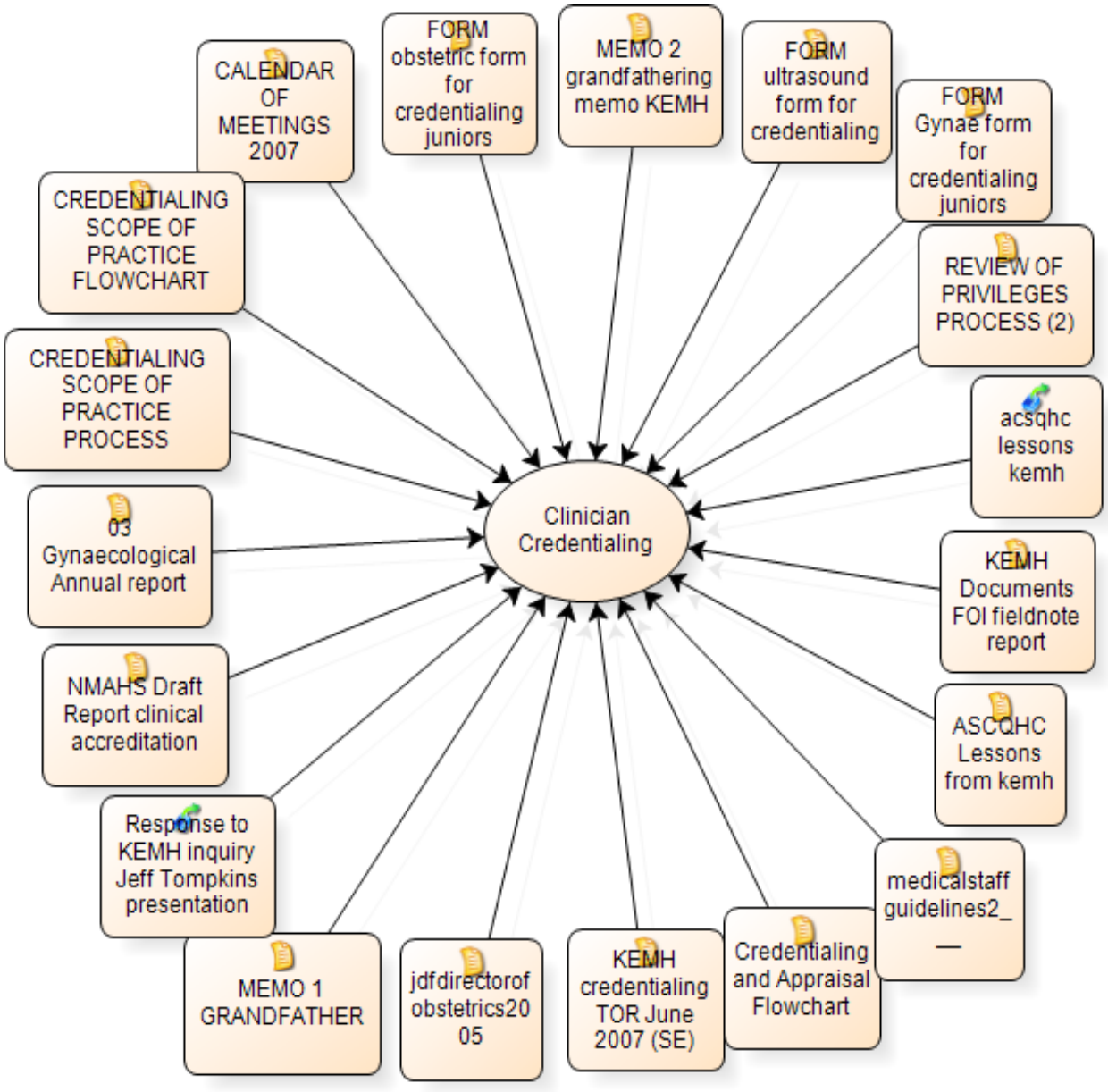


Figure 11*: *Documents demonstrating references or evidence of improvement for clinician credentialing

The documents analysed clearly demonstrated compliance with the requirements of the recommendations of the Inquiry. The documents ranged from policies, procedures and guidelines to KEMH self-reported data in Annual reports. Of particular note however, was the recent audit report by the corporate governance unit of the Department of Health West Australia that examined credentialing within the North Metropolitan Area Health Service (NMAHS). KEMH is one hospital within the NMAHS. Although overall compliance with DoH requirements by all hospitals was

not high, it was noted that "*... KEMH particularly has made much headway in the credentialling [sic] of its Medical Practitioners...*" (*Review of Clinical Credentialling [sic]: North Metropolitan Area Health Service*, 2007).

Having established that the documentation demonstrated compliance with the Inquiry credentialing recommendations, the second area examined in this section is that which deals with clinician performance management.

Clinician Performance Management

The recommendations concerning performance management were detailed in the final Inquiry report for each clinical group. The groups consisted of consultants, registrars, residents, and midwives and nurses. The Inquiry recommendations articulated similar expectations in that there was to be a process described and implemented for each group that ensured performance management was undertaken on an ongoing and regular basis. Once again, the document analysis demonstrated compliance with the Inquiry recommendations (refer again to Table 6 above). This documentation included specific policies for each group in regards to performance management together with guidelines with precise descriptions of requirements. The audit report undertaken by the DoH describes in detail the process for medical staff credentialing and performance management as:

> *... [at] KEMH... the re-credentialling [sic] process is ongoing, via performance review (consultants are reviewed every 1.7 years) and training conducted through a comprehensive training program and learning sessions. For performance reviews, the head of department reviews doctors to ensure that they are still meeting their defined scope of practice and this is updated on the database. A letter is then sent by Medical Administration to the department for sign off to indicate that the doctor has gone through this performance appraisal process. In the case of clinical privileges, a list is produced that informs heads of departments which doctor's clinical privileges are due to expire. The heads of department then respond as to whether they recommend the privileges to continue and are happy with the doctor's performance. Medical Administration would reissue their privileges for another 3 years or for a*

> *specified time ... (Review of Clinical Credentialling [sic]: North Metropolitan Area Health Service, 2007)*

In terms of the changes made, the documents examined are articulating the processes as stipulated in the Inquiry recommendations. Other reports and reviews undertaken by external agencies indicate that the processes as described are actually occurring in the hospital. The data from the interviews will now be reported to identify if the findings from the document analysis are corroborated by the participants.

Interview Analysis

In this section, the perceptions of the participants about changes that may or may not have occurred at KEMH in regards to credentialing and performance management are reported. The participants commented on their experience with staff currently working at KEMH. All participants who made comments in this section were positive there had been changes in the processes of clinical credentialing and clinician performance management.

Three coding themes emerged in the coding analysis of the interview transcripts for this category (see Figure 12). These were: medical credentialing and performance management; midwifery credentialing and performance management; and the effect that medical credentialing and performance management had on clinicians.

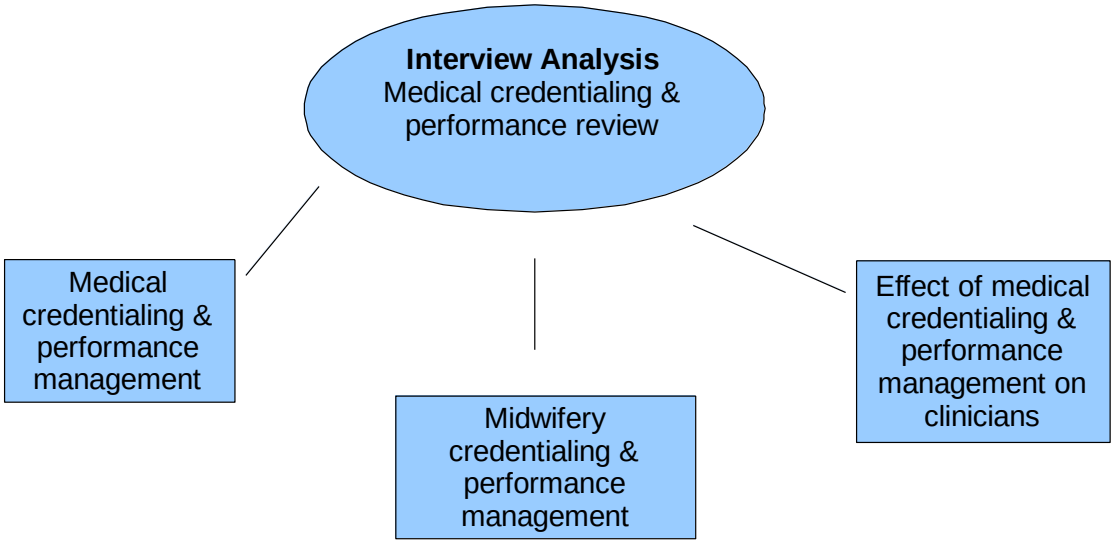


Figure 12: Interview analysis coding themes for changes in medical credentialing and clinician performance review

The researcher noted that in the coding of the interviews for this category participants did not always separate credentialing and performance management but rather, spoke of them as part of a whole entity. The comments presented as part of the discussion (below) reflect this. The researcher focused on the content meaning of the comments rather than on the semantics of the word label the participant gave to the process when coding to the different coding themes of this category. A fuller discussion for each of the coding themes is presented below.

Coding Theme: Medical credentialing and clinician performance management

Participants were very clear that there had been substantial changes and improvements in this area. The comment by these participants are typical of all those who made comments on this category.

> *... (KEMH) have certification and privileging policies in place to clarify scope of practice within the service which is connected to safety and quality care ...*
>
> *... the credentialing documents that were being produced were very comprehensive ... before in the past it was "did you have that qualification?" and then you had a job ..."*

Of particular note, was how impressed participants were with the breadth and scope of the credentialing process especially in comparison to other sites within Western Australia. They commented on the processes being applied to all levels of medical staff as well as to specific procedures. Some examples of these comments are:

> *... the difference of course is that King Edward has a procedures specific credentialing system that most other sites don't have comprehensively … and the other thing about King Edward is that their credentialing system starts from junior staff level and not just at consultant level and I think all the other site … are consultant only ...*
>
> *... formal structures now in place for, particularly for the junior staff but also flowing through to consultant level ...*

Although no participants commented explicitly about the performance management process as described in the policies and procedures, all who made comments noted the opportunities and processes in place in terms of performance development. One participant remarked that:

> *... accreditation has occurred so the Drs acknowledge what is required And it's been good because there are education opportunities and skill updates available... and that has been provided to them by the Public Health System. So that's been good for them but it is also been good for patients …*

And another comment in relation to performance review:

> *... there is a half-way peer revision that now agreed to and acknowledged by the those servicing the area ... and it comes from their College... and so their College actually identifies what the practice has been, reviews the practice and, makes recommendations and they are encouraged to comply ...*

The next coding theme identified dealt with midwifery credentialing and performance management.

Coding Theme: Midwifery performance management

Only two of the five participants commented on this area. Both of these participants had a midwifery background. Specific comments were made within similar areas to the coding theme above. These were in the areas noting general improvement, the requirement for regular ongoing and specific competency assessment and finally, the opportunities for ongoing performance development. The following comment captures the essence of views concerning this section:

> *... Midwives, a similar process but not as involved...all midwives must undergo annual emergency management competency and there, that process is very clear when you articulate it now, that all midwives must do it ... staff not being able to work in the labour ward for instance if they hadn't achieved those competencies ...*

In the final coding theme within this category of clinician credentialing and performance, participants discussed the effect this process had had on clinicians. These comments will be presented in the next section.

Coding Theme: Effect on clinicians

Four participants made comments that were coded to this coding theme. Several talked in very definite terms of the initial reaction of medical and midwifery staff to the changed processes and expectations in terms of credentialing and performance management. These are encapsulated by the following comments:

> *... for I would say the majority it did change their behaviour ... eventually… initially it was an aggressive ... yes I suppose aggression describes the type of behaviour because they were being asked to comply with policies they felt that they had no ownership of or that they didn't develop ...*

> *... and there were a lot of midwives who were fearful and, there were a lot of midwives that were anal retentive about it and, there were a lot of midwives that didn't care because ... they felt it didn't apply to them ...*

Participants went on to comment on reactions as the processes have become the norm. The comment by this participant describes the changed viewpoint:

> *... and midwives were more ready to listen to aspects of care that they might need to change, legal aspects that would cover them and enabled them to provide appropriate care ...*

It is very clear that the participants believed that there had been significant changes within the area of medical credentialing and performance management. There were no negative comments at all in this section, with several participants commenting on the positive model that KEMH was demonstrating to other hospitals.

Having examined the area of medical credentialing and clinician performance review, the next section will move on to the examining whether there have been changes in the involvement of consumers in care at KEMH post Inquiry.

CHANGES IN CONSUMER INVOLVEMENT POST INQUIRY

Document/Archive Analysis

For the purpose of this section, documents and archives are considered together and referred to generally using the term documents. Documents were obtained from a variety of sources including Hansard (the official record of the WA Parliament for the Legislative Assembly and the Legislative Council), the Department of Health West Australia, the Department of Health and Ageing, various media, KEMH and the KEMH website, Quality and Safety websites, and academic journals and conference reports. Each document was examined for references or evidence to support any changes that had been made post Inquiry,

specifically in regards to consumer involvement as per the recommendations of the Inquiry report (refer Appendix 18 for recommendations). From the initial review of all documents obtained, 52 documents were identified that could potentially provide information (refer Appendix 2 for list of potential sources of evidence of changes). Of these documents, 32 revealed information about policies procedures or outcomes concerning consumer involvement (see Appendix 19).

The final Inquiry report identified 15 consumer improvement recommendations pertaining to changes that had to be made by KEMH to improve its processes to do with consumer involvement. The consumer improvement recommendations within the Inquiry report were divided into the subcategories of:

- Communication with women and families;
- Psychosocial concerns;
- Responses to poor outcomes; and'
- Involving women in decision-making

Each document obtained for this section of the study was reviewed for either a description of a process or policy, or a description of an outcome that indicated implementation of a policy or process as specified within any of the 15 consumer improvement Inquiry recommendations. The code *specific, implied, external evidence or self- reported evidence* was used to note reference to a process or outcome that related to the recommendations.

The following discussion will present an overview of the findings for the document analysis. This is followed by a detailed discussion for each of the categories.

Overview of findings: Documents analysis - changes in consumer involvement post Inquiry.

Table 7 below displays the results of the document analysis against each of the recommendations within the four categories. For the purpose of the document review two Inquiry recommendations (44 and 46), within the category of responses to poor outcomes, have been combined since both recommendations dealt with similar aspects of the same element.

As illustrated in Table 7, of the 15 Inquiry consumer improvement recommendations, evidence was identified in the analysis of documents that 12 of the Inquiry recommendations dealing with consumer improvement have been met. The researcher also noted that for the recommendations for which evidence of implementation was identified, there were multiple sources of documentary evidence articulating the detail of the policy, procedure or guideline. Table 7 also demonstrates that there were three consumer improvement Inquiry recommendations for which no evidence was clearly identified in the document analysis. These were the areas concerned with the provision of regular communication training and workshops for all clinical staff. In order to ensure that documentary evidence had not been overlooked, further clarification was sought from KEMH, using the FOI process, explicitly seeking information on workshops or training for clinical staff that would cover the aspect of communication with women and families. The full response to this FOI request is revealed in Appendix 20. In summarising this response, different workshops are listed for corporate, nursing and midwifery staff. These focus, in the main, on communicating with colleagues and do not specifically target specifically empathetic communication skills with patients and families. Furthermore, the document states that for medical staff there are "no specific sessions run by this hospital department which deal specifically with communication".

Table 7: Document analysis for evidence of compliance with Inquiry recommendations- consumer involvement in care

Inquiry Recommendation	Policies/ Guidelines	Clinical Guidelines	External reports/reviews	Journal/ conference Reports	KEMH reports/reviews
Communication with women and families					
Treatment discussed & noted in pt. file	**Specific**	**Specific**			
Written Information to be given	**Specific**	**Specific**	**External Evidence**	**Self-report Evidence**	**Self-report Evidence**
Interpreter services	**Specific**	**Specific**		**Self-report Evidence**	**Self-report Evidence**
Consent withheld discussion	**Implied**	**Implied**	**External Evidence**		**Self-report Evidence**
Plain English post mortem results	**Implied**	**Implied**			
Psychosocial concerns					
Enhance continuity of care		**Specific**			
Regular communication workshops					
Women to be included in conversation	**Specific**	**Specific**			
Method for eliciting experiences & feedback to staff	**Specific**		**External Evidence**	**Self-report Evidence**	**Self-report Evidence**
Responses to poor outcomes					
Staff trained for sensitive discussions					
Guidelines for sensitive discussions	**Specific**	**Specific**	**External Evidence**	**Self report Evidence**	**Self-report Evidence**
Poor outcome discussion & care					
Involving women in decision- making					
Policy re involvement in clinical decision making	**Specific**	**Specific**	**External Evidence**	**Self-report Evidence**	**Self-report Evidence**
Communication skills re subjective experiences & assessment strategies					

KEY: Specific= Policy or procedure as per Inquiry recommendation; Implied= process described in detail but not as per Inquiry recommendation; Self-report Evidence = KEMH self reported evidence indicating implementation of policy or procedure; External evidence= external review indicates implementation of policy or procedure.

A detailed discussion for each of the four sections as categorised within the Inquiry report dealing with consumer involvement will now be presented.

Communication with women and their families

There were four areas within this category where compliance with the Inquiry recommendations is described. These areas were those dealing with the Inquiry recommendations describing the requirements for treatment to be discussed with patients and that discussion to be noted in the patient file, written information to be given to patients, the availability of translator services and, the requirement for plain English post mortem results. Figure 13 identifies the documents that demonstrated references or evidence that specifically dealt with the recommendations in this category.

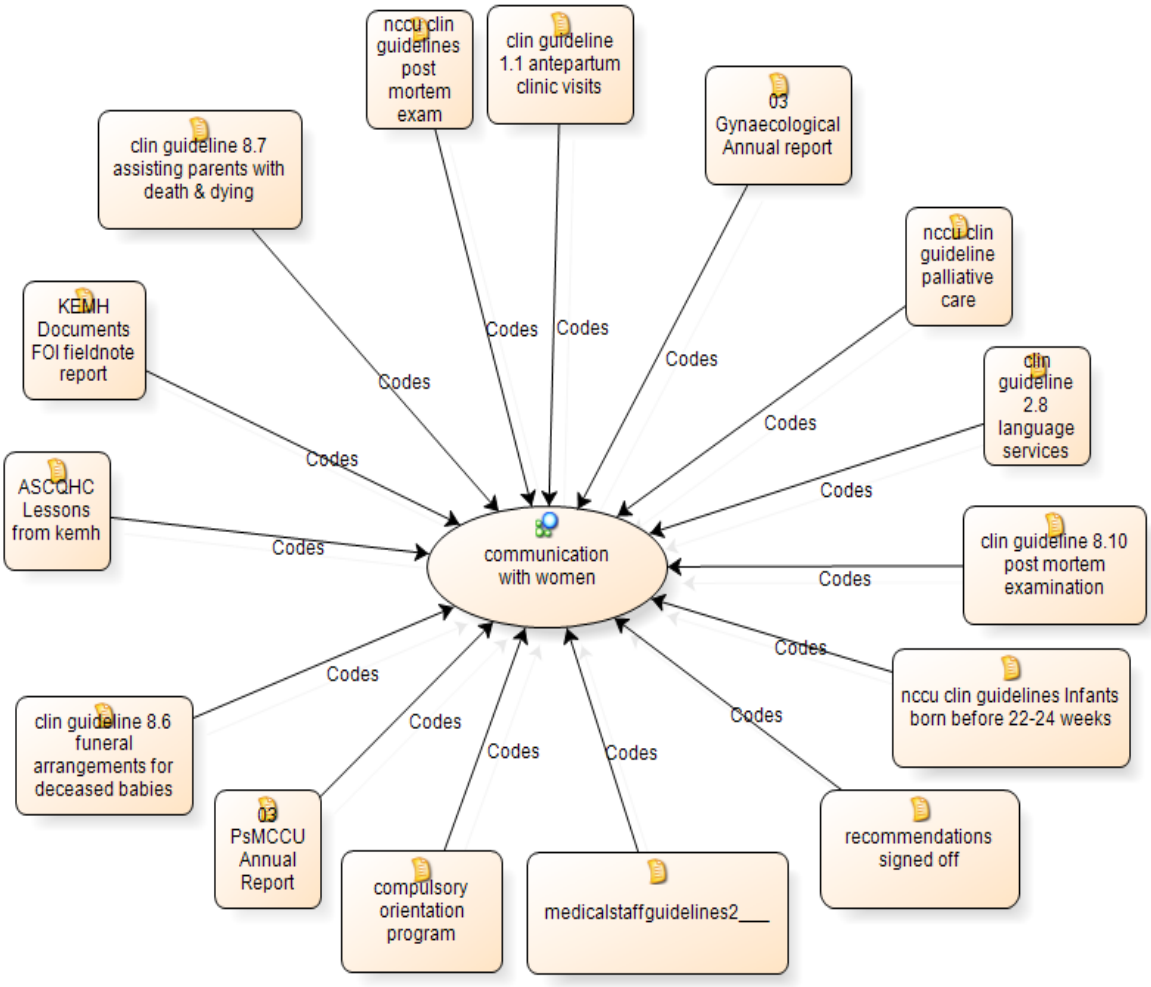


Figure 13: Documents demonstrating references or evidence of improvement for the category of improvements in communication with women

It must also be noted that the public website for KEMH has a comprehensive section that provides information about different

procedures and conditions together with the services available. This provides a source of information for those consumers who are both cognisant of this resource and able to access the internet.

The fifth recommendation in this category required that if a woman withheld consent for an important and medically indicated treatment, the consultant was to be informed, and he or she was to review the circumstances with the woman and her family. This recommendation was justified within the Inquiry report because it was believed that refusing to give consent for a procedure may represent a communication breakdown rather than a true decision to refuse treatment. This opinion was formed from substantial testimony from patients and also from the review of clinical files where consent had been withheld. Subsequently, it was evident that patients had not understood the information or been given adequate explanation on which to base the decision to refuse treatment. In these circumstances, it was identified that a consultant needed to be involved to ensure that the refusal was an informed refusal rather than being based on a misunderstanding of the information or an interpersonal issue with other staff involved in seeking the consent originally (Douglas et al., 2001:227-500). In the analysis of the documents and archives for this section of the study, the process of consent was described in great detail in policies and guidelines developed post Inquiry. None of the documents analysed however, indicated the requirement for the consultant to review the circumstances of the refusal for consent with the women and her family. Thus for this particular category of the Inquiry recommendation, only part of the requirements had been met.

The next category within the recommendations concerning involvement of consumers in care is those dealing with psychosocial concerns,

Psychological Concerns

There were four recommendations in the Inquiry report concerning this category. The focus of these concerned ensuring continuity of care, including women in conversations about their care, scheduling regular communication and empathy skills workshops for all clinical staff and ensuring there were feedback mechanisms for consumers (Douglas et al., 2001:501). The documentary evidence sources for this particular category are shown in Figure 14.

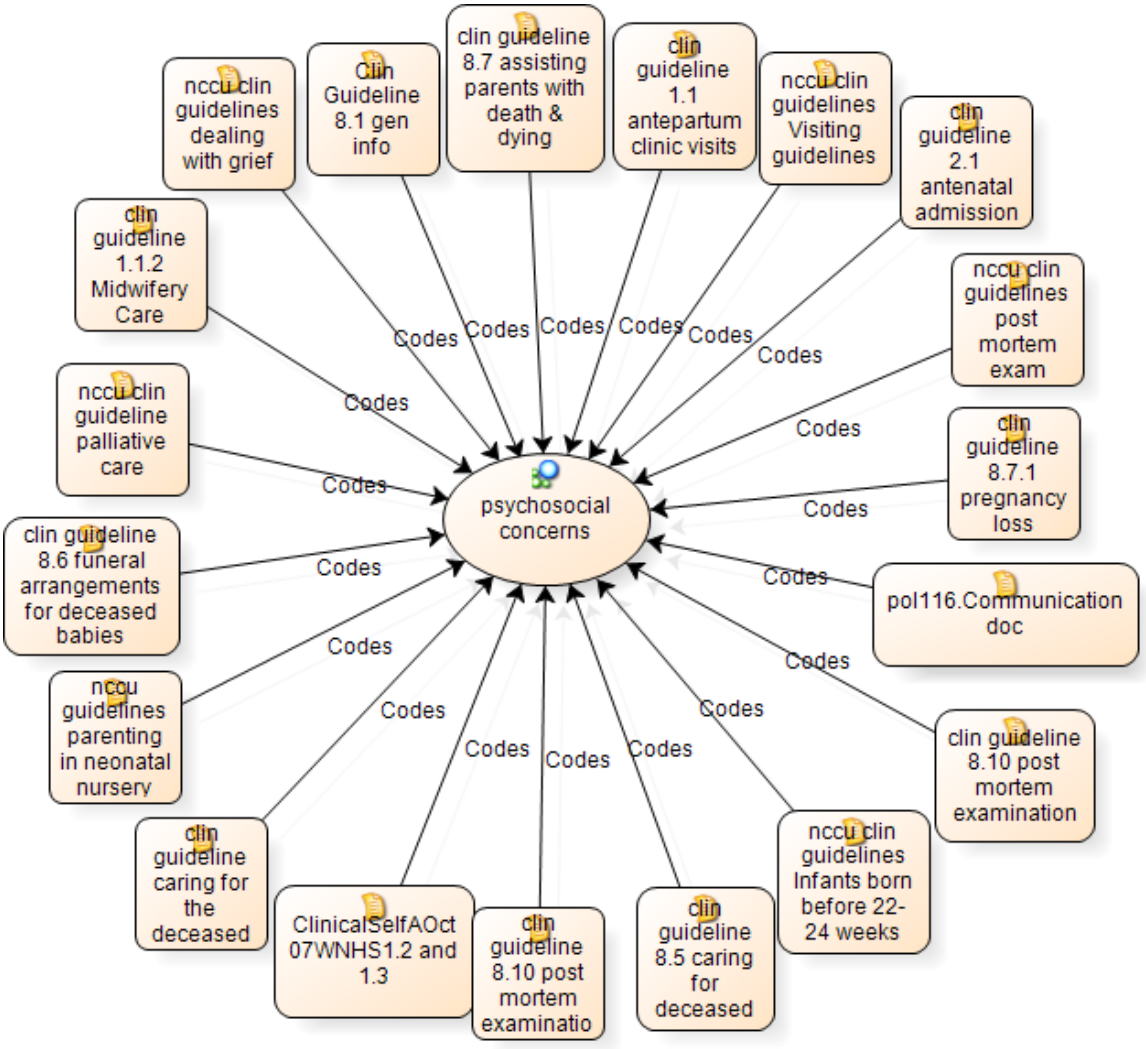


Figure 14*: *Documents demonstrating references or evidence of improvement for the category of improvements in psychosocial concerns

Within this category, three of the four recommendations had policies and procedures or evidence described as per the Inquiry recommendations. These were those that dealt with enhancing the continuity of care, including women in conversation and ensuring there was method for eliciting feedback from women. As well, it is identified that there are suggestion boxes throughout the hospital that patients, families or visitors can use for anonymous feedback. Self-reported evidence also noted that a customer liaison person had been appointed. The role of this person is to visit the wards each day and to approach patients and seek their feedback. As well, any patient who is identified by staff as possibly having concerns, is approached specifically by the customer liaison person and their feedback sought. The issues identified by the customer liaison person are investigated and resolved and the feedback information collated and reported to the wards on a regular basis. A complaints/compliments process is in place with forms available at ward and unit level, together with, the forms being available on the internet. All complaints are investigated, with a report being submitted to the North Metropolitan Area Health Service Executive on a quarterly basis.

The fourth recommendation in this section required that KEMH conduct regular communication workshops for medical, midwifery, nursing and allied health staff, specifically emphasising how to respond sensitively to women, how to involve women in decision-making and how to respond to women who had poor outcomes. Extensive document review, discussions with the KEMH Director of Quality and Safety, and a specific FOI request, failed to identify any evidence demonstrating compliance with this recommendation. One policy did state " ... Staff are encouraged to attend Department of Nursing and Midwifery Education and Research Perinatal Loss Study-day ... or other health related Communication Skills Workshops to refresh and improve their knowledge and skills (*Policy No.116: Effective communication with patients and their families* 2006) An examination of the program content of the study day identifies that topics *may* include the role of the grief counsellor and the handling of different emotions. There is no indication that the focus of the study day is

providing a communication skills workshop emphasising how to respond sensitively to women, how to involve women in decision-making and how to respond to poor outcomes. While Policy No. 116 acknowledges the need for communication workshops, the researcher did not believe that this conclusively met the requirements of the recommendation, which required a more active role on the part of KEMH in ensuring that workshops were *regularly conducted* for all staff. Consequently, it is clear that KEMH have not implemented all the requirements of the Inquiry recommendations concerning improving the psychological care of women and families.

The next category within the Inquiry recommendations dealing with the need to involve consumers in care was concerning responses to poor outcomes.

Responses to poor outcomes

The Inquiry report made four recommendations under this category that were reviewed for this study. Two of these continued the theme of communication skills identified in the previous category. These required that midwives and other health professionals be trained to deal sensitively with the woman and her family. As well, guidelines were to be developed and implemented in regards to discussions of poor outcomes with women and their families. The other two recommendations concerned continuity of care and sensitivity when dealing with a woman after a poor outcome. These required that the woman should be offered at least one appointment with the consultant or senior registrar to discuss a poor outcome. As well, the post natal visit was not to occur in the antenatal clinic, but was to be conducted by someone who had had contact with the woman previously and knew the woman and the circumstances of her case (Douglas et al., 2001:502). For the purpose of this review these last two recommendations were combined. The documentary sources for this category are revealed in Figure 15.

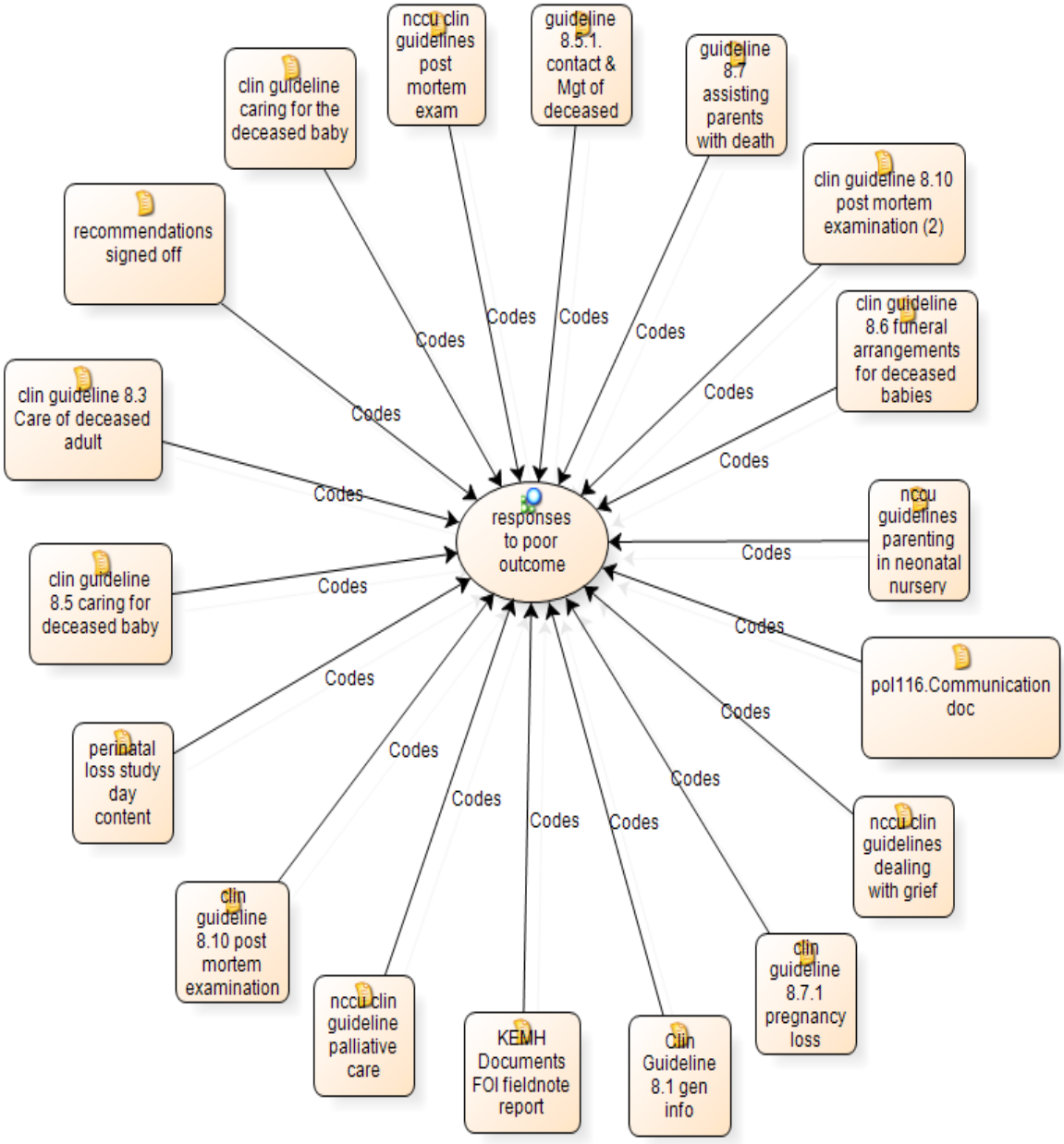


Figure 15: Documents demonstrating references or evidence of improvement for the category of responses to poor outcomes

Within this category documentary evidence was identified that demonstrated compliance with the requirements of three of the Inquiry recommendations. There was extensive evidence located in multiple KEMH policies and clinical guidelines in regards to discussing poor outcomes. There was more information coded from sources to this particular recommendation than to any other. The documents analysed for this section of the study, described in detail the rationale of the need for

sensitive discussions, the processes that should be utilised, and the supports available. Thus, there was widespread documentation describing the process of dealing with patients and families sensitively. There was self-reported evidence that this process was in place. In regards to the Inquiry's fourth recommendation, the researcher was unable to identify any evidence to support the KEMH self-reported data that the hospital had, in fact, put in place regular training and skills workshops for staff that would demonstrate compliance with this recommendation.

The documents analysis therefore identified that KEMH was only partially meeting the requirements of the recommendations for the section concerning psychological support for poor outcomes.

The final category in the recommendations concerning consumer involvement in care is those involving women in decision-making

Involving women in decision-making

There are two Inquiry recommendations in this category. They are firstly, the requirement for KEMH to develop a policy to ensure that a woman and her family are included in clinical decision-making. Secondly that KEMH is to ensure that staff have the necessary skills with regards to including the subjective experiences of women as part of the assessment and care planning strategies (Douglas et al., 2001). The documentary sources for this category are revealed in Figure 16 below.

As in the previous categories, the Inquiry recommendation that identified the need for policy and process development was well demonstrated in the documents obtained for analysis. As per the previous categories, no evidence was found in the documents obtained that demonstrated compliance with Inquiry recommendations requiring communication skill development. It must be noted that within one policy there was a clear statement describing the need to consider a woman's subjective experience (*Policy No.116: Effective communication with patients and*

their families 2006). Nevertheless, the researcher did not believe that this met the recommendation requirements. The rationale for this decision is that descriptions of required behaviour do not necessarily translate into the action of the behaviour. Thus, this does not meet the requirement of the particular recommendation.

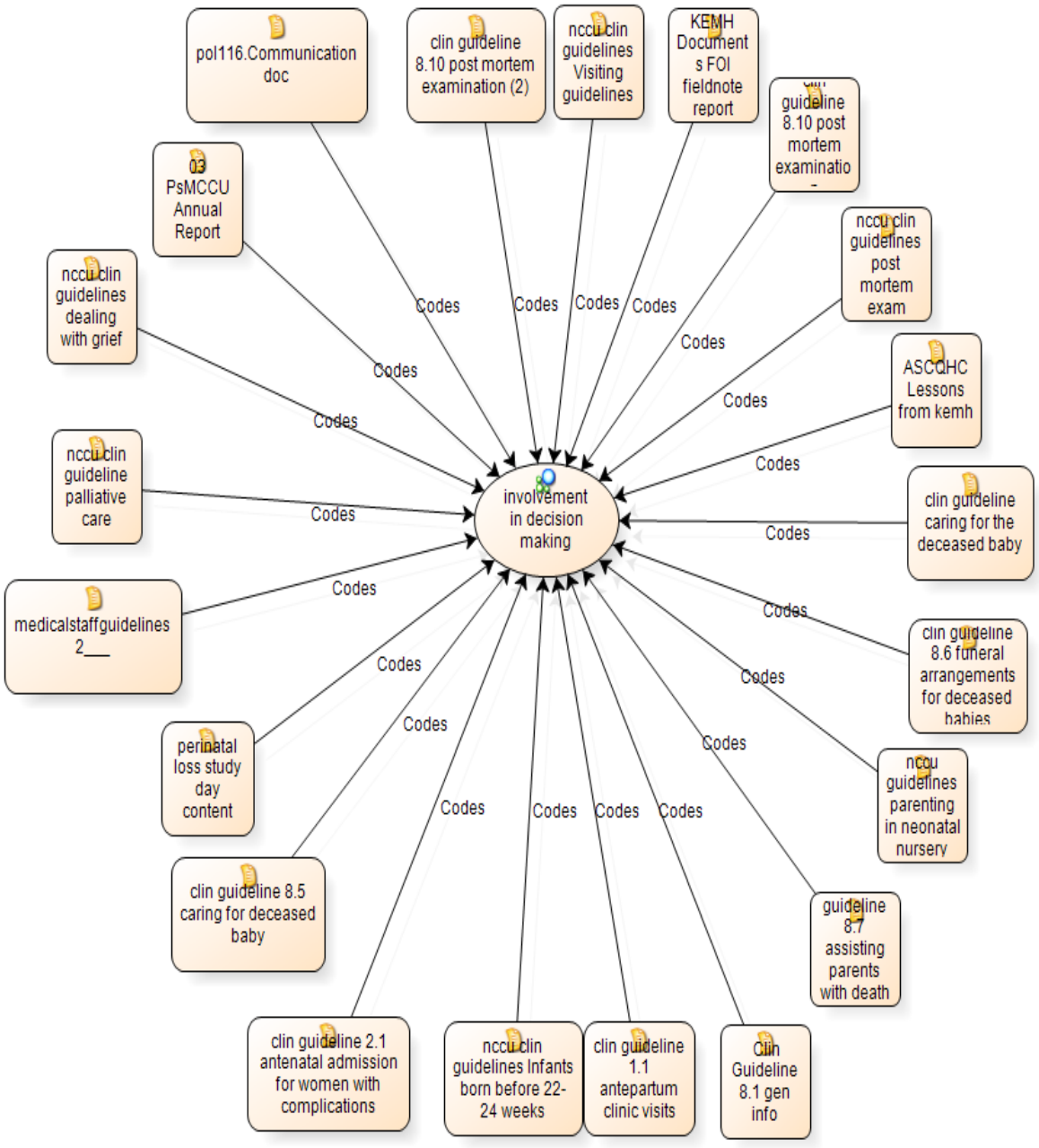


Figure 16: Documents demonstrating references or evidence of improvement for the category of involvement in decision-making

Summary

In this section dealing with involving consumers in care, documents were analysed for evidence of meeting the requirements of the Inquiry consumer improvement recommendations. Of the 15 Inquiry consumer improvement recommendations, evidence was identified in the analysis of documents that indicates that the requirements of 12 of the Inquiry consumer improvement recommendations have been met. The three consumer improvement Inquiry recommendations for which no evidence was clearly identified in the document analysis concerned the provision of training and regular workshops for all clinical staff in regards to communication.

The following section of this chapter will discuss the participants' perceptions of changes that have taken place at KEMH following the Inquiry in regards to the involvement of consumers in care.

Interview Analysis

Five participants were interviewed for this study. A full discussion of the rationale for the sample size and background is provided in Chapter 2. An interview schedule was developed that focused on the areas of interest for this study. In this section, the perceptions of the participants about changes that may or may not have occurred at KEMH in regards to involvement of consumers are reported. The information from the interviews was used to validate the information gained from the document and archive review.

Overview of findings: Interview Analysis - changes in consumer involvement post Inquiry

Six coding themes emerged in the coding analysis of the interview transcripts for the category of changes in consumer involvement (see Figure 17). Four of the themes positively identified there had been an improvement in the processes that involved consumers in care. The first theme was one of *general improvement*. Three other themes identified specific improvements. These were labelled: *involvement in clinical care decisions; the management of critical incidents; and continuity of care*. The fifth theme, labelled *needs improvement*, identified that participants believed that changes in the processes of involving consumers in their care still needed to happen. The final theme in this area, the sixth theme labelled *clinician deafness*, identified specifically where clinicians do not hear or understand what it is that patients want from their therapeutic interactions with clinicians.

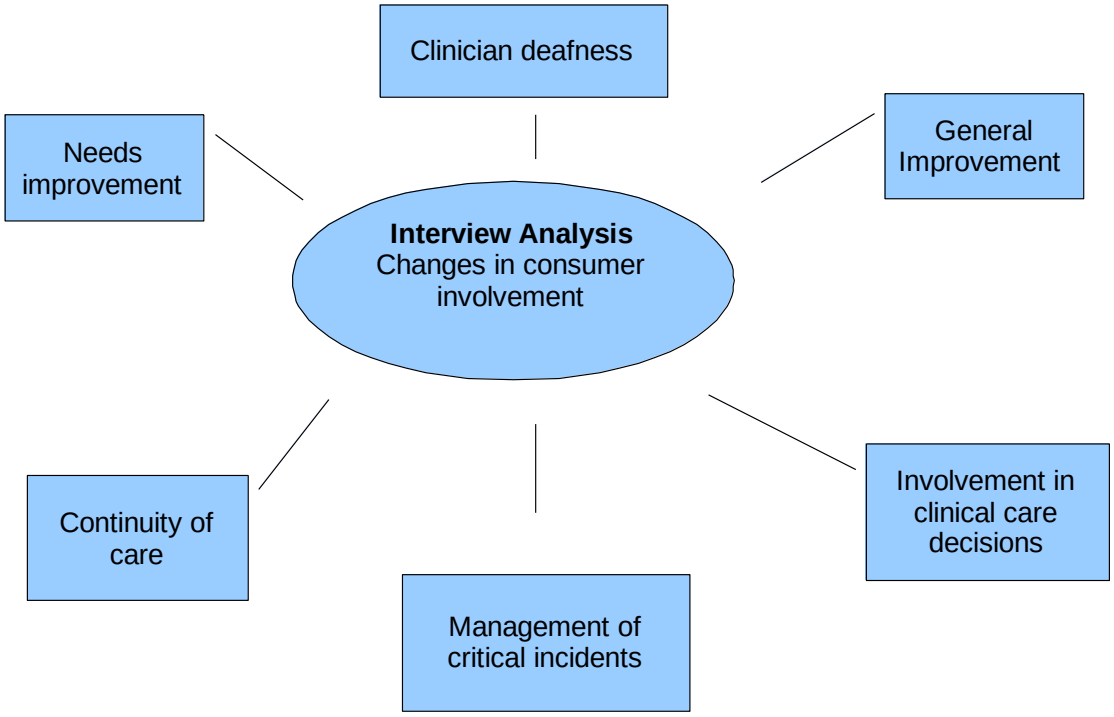


Figure 17: Interview analysis coding themes for changes in consumer involvement

In some areas, the comments made by participants were remarkably similar; in others, very different perspectives on the same theme were noted. A fuller discussion for each of the themes is presented below.

Coding Theme: General improvement

Four of the five participants commented on this area. All of those who commented in this theme had a primary role as clinicians and secondary roles as consumer advocates, either in an operational or strategic context. They spoke from the perspective of their observations and interactions with patients as external stakeholders in the system. Their comments were broad with no specific examples, but were very definite and positive. As one participant commented:

> *... I mean ... from that consumer perspective ... the general feel would be that it had improved ...*

Another participant stated:

> *... what I can say is I don't hear patients talk about King Edward in terms of the Douglas Inquiry or the failures anymore ...*

With another remarking:

> *... I must say that of all the people I've seen that have had interactions with King Edward the.., by far…, the vast majority have been positive. The vast majority have been positive in how they have experienced the health care ...*

Several participants went on to comment with more specific observations in relation to the other themes. Examples are given for the different themes below.

Coding Theme: Involvement in clinical care decisions

This theme focused on patients and families feeling comfortable enough to be able to ask questions, be involved in making decisions about their care, and having access to information that gave them the tools to be involved more actively in the care provided. The participants who commented in this area had primary roles as clinicians. One participant stated:

> *… that what I hear from clinical staff and from what I've seen on the website that there are more mechanisms for consumers to air their preferences or concerns, or to ask questions ...*

And as well that:

> *... so there are so many parties that people can rightly go to now and they explain to them what, they find out what it is they want and what their concerns are ...*

Another participant commented that:

> *... generally feeling more comfortable at being able to ask questions... feeling that people were accessible to ask questions...*

This was reiterated later in the interview with the participant stating that:

> *... going on a number of women I know who have made comments to me there is much better access, and there are people available for them to ask and they are encouraged to ask questions ...*

Together with:

> *... I do know that women are able to access the medical staff if they have any queries whereas before they may not have been able to ...*

This was reinforced by this comment:

> *... I think that women are given a little bit more information once they get access to King Edward on what is available to them and what sort of care and the time frame they might be looking at spending in hospital and that they can access care the first few days post discharge ...*

Coding Theme: Management of critical incidents

Several participants made comments in this area. All participants who commented in this section were primarily clinicians. This coding theme dealt with the support and services available when a patient had a poor outcome. Comments from participants included the following:

> *... I'm aware that there has been a large change in how people are supported in those extreme circumstances and I guess there a number of layers that now offer support ...*

> *... there also seems to be genuine multi-disciplinary formal structured processes that people are given access to so that they can have their questions answered and so that they can grieve and make choices about arrangements for, in the case of neonatal death or stillbirth, cremation or burial, or what have you. Whereas before decisions were often made for people and information was often withheld ...*

> *... the service for supporting people through grief has improved immensely in the last few years ...*

Coding Theme: Continuity of care

This theme focused on an area identified as a major area of dissatisfaction for patients in evidence presented at the Inquiry. It was identified that patients wish for some continuity in care from caregivers they recognise. They also wanted the treatment and care they received in one place to be communicated to their other caregivers. Comments that illustrated perceptions of improvements included the following:

> *... and the team midwifery [a model of care which aims to provide continuity of care] means they are seeing the same people again ...*

... there is a King Edward Hospital GP Liaison Office so therefore I see that that person sits at the interface looking to improve the patient journey from the Community into the Hospital and from the Hospital out into the Community and that's the main thing that I hear as a Clinician outside. … I can't really say about other things except perhaps the Patient Held Record that has been more extensive than before and thirdly, the discharge summary of the Clinicians receiving the patient back into the Community is certainly more comprehensive than it has been before …

Of note is that the participants who commented positively all had primary roles as clinicians. The negative themes in this section of involving consumers in care will now be presented.

Coding Theme: Needs improvement

The second general coding theme was one that focused negatively on consumer involvement at KEMH post Inquiry. In this coding theme, participants identified improvements were still required in the processes that involved consumers in care. The types of negative experiences that participants identified related to patients believing that they had been treated dismissively, or they had felt uncomfortable, and therefore unable, to ask questions or seek more information about their care options. All participants who commented in this area had either primary or secondary roles involving consumer advocacy. The following comments capture the perceptions expressed by participants when describing their experiences or observations with regard to consumer involvement in care post Inquiry:

... but I've been involved in a few reviews of obstetric cases and practitioners ... and they have been concerned …[with] problems with communication, or accessing information or accessing practitioners for information …. other people ... have come out and have tried to access different hospitals because they have not been happy with what was going on. I think the numbers … the few numbers going through … felt they weren't getting the information they needed ... Yet ... I see that with all the policies that have been put in place from the recommendations that were suggested that this has been followed up and things have been put in place but...

...could have said to the consumers that its a caring organisation….instead they get tromped on by a staff member that is

soooo..' important, indeed more important than the reason (for patients) that they are there. So what you have.. is a service ethos cultural issue, that's possibly unshakeable… no matter what you do at a high level ...

... some of the aboriginal consumers we now talk to through our aboriginal workers, they felt they were treated like (expletive) at King Edward ...

Coding Theme: Clinician deafness

In describing the perceptions that improvement was still required, one other specific coding theme emerged. This was that clinicians were deaf to what the patient really wanted and valued in their interactions with clinicians. Several examples of comments about this are revealed below:

... the deafness to the patient reports … [long pause] ... the deafness language, fleeing from your distressed patient … it's the other, the mentality of the other … it's … you can only do that to a person if you are not seeing them as similar to yourself …

... [it] was fine, the birth wasn't bad but (expletive)… I hate that hospital. There are the ones you worry about … the people who still had a good outcome but don't like the hospital because there's something about the cultural dynamic of the service they got ...

… you know (that you have) the safety and quality problems...when they say oh they couldn't be having pain from that operation ..... and then you later find a nick or they're bleeding or whatever… because they (the clinicians) haven't heard..."

It is noted by the researcher that all of those participants who reported negative perceptions about improvements in consumer involvement in care, had consumer advocacy that formed a part of either their primary or secondary roles.

Summary: Changes in consumer involvement

The document and archive review and the interviews provided three sources of data for examining whether changes had taken place in the area of consumer involvement in care. The document and archive analysis showed clearly that changes had been implemented for all but three of the Inquiry report recommendations. The Inquiry report recommendations for which documents and archives did not identify changes were those that dealt with ensuring regular and formal opportunities for clinicians to improve their communication skills with patients and families. The interview analysis confirmed these findings with participants giving examples of where improvements had been made structurally in terms of policies and procedures, but also noting that in terms of the transacting communication with patients and families, there were still improvements that needed to be made.

Findings from the data analysis will now be presented to answer the research questions:

- Were there changes in medical credentialing and clinician performance management systems post Inquiry? and

- Were there changes in the involvement of consumers in care post Inquiry?

WERE THERE CHANGES IN THE CLINICAL GOVERNANCE PROCESSES AT KEMH POST INQUIRY?

This section presents an analysis of the findings from the data analysis investigating if changes occurred post Inquiry in the clinical governance processes at KEMH, specifically in the area of interest for this study. Findings for medical credentialing and performance review will be presented first. This will be followed by the findings for consumer involvement in care.

Medical credentialing and clinician performance management

Figure 18 presents the summary of findings for changes in medical credentialing and clinician performance review post Inquiry. In total, the Inquiry made 25 recommendations in this section. Fourteen concerned with credentialing and 11 concerning performance management Compliance with the requirements of these recommendations was very well demonstrated in the documents and archives. Participant interviews strongly supported these findings. The results from this analysis demonstrate the following outcomes in regards to the research question investigating if there have been changes in the clinical governance systems post Inquiry concerning medical credentialing and clinician performance review at KEMH:

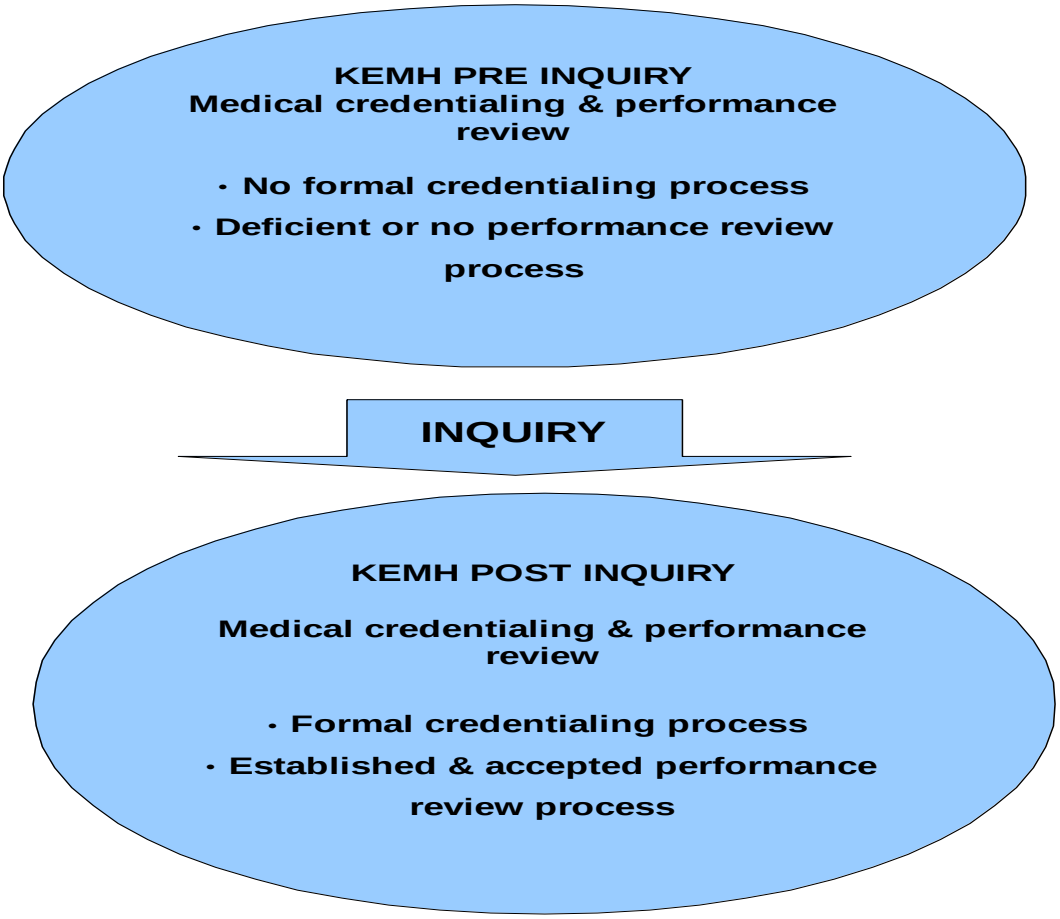


Figure 18 : Summary of findings for changes in medical credentialing and clinician performance review

Results from these findings are:

- Participants' perceptions support that structural changes (policies procedures and guidelines) have occurred post Inquiry in relation to medical credentialing and clinician performance management; and

- Participants' perceptions support that the policies, procedures and guidelines that have been developed in response to the Inquiry recommendations have translated into action.

Consumer involvement in care

The Inquiry report made 15 recommendations in regards to involving women and families in their care. Compliance with those recommendations that required policies, procedures or guidelines to be written were well demonstrated in the document analysis (see Figure 19 below). This compliance was in the main supported by KEMH self-reported evidence in documentation reviewed. This adds support to the evidence identified in the document search. It is striking however, that the majority of comments (all but one coded comment) supporting this were made by participants whose primary role was as a clinician.

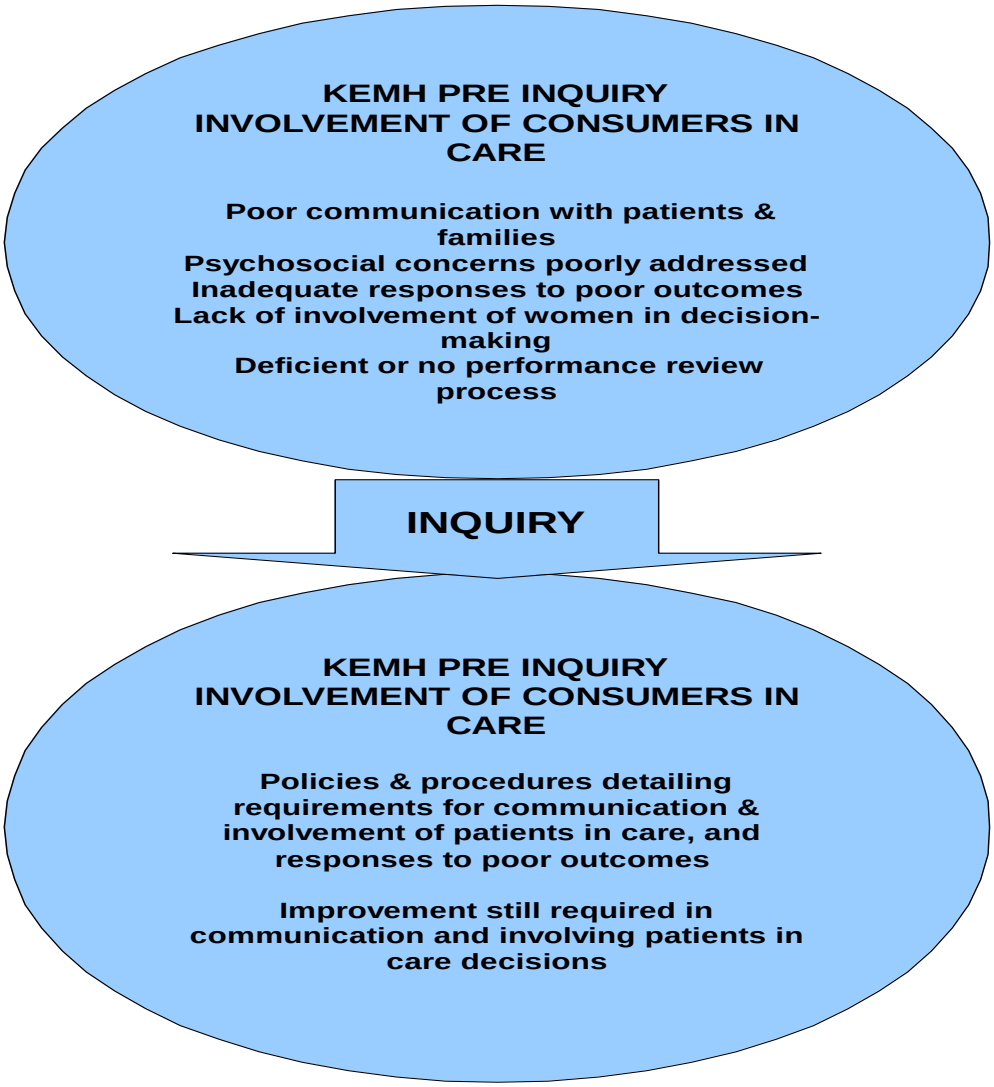


Figure 19: Summary of findings for changes in involvement of consumers in care

The area not demonstrated in the document review was evidence that communication training and workshops for all clinical staff were being conducted. This is of significance in that many of the patients who gave evidence at the inquiry identified that communication between clinical staff and patients was an area of weakness in the care they received. Although some participants identified that there had been improvements in structures and processes for patients being able to ask questions and be involved in care, these comments were made by those participants who were principally clinicians. Participants for whom advocacy was a major role reported negatively about improvements in processes that involved communication and access to information. Thus, although the policies and procedures have definitely been put in place, there is still a deficiency in the widespread adoption of the practices detailed in the policies. Improvement in communication skills will not occur merely because they are mandated in policy and guidelines. Changes in something as fundamental as how one communicates with someone else requires insights and reflective consideration of communication styles, together with a comprehension of the effect of power relationships on communication interactions, especially when one group of the interaction is emotionally or physically compromised (Reason et al., 2001; Wachter, 2008). The three recommendations for which there was no evidence in the documents as being addressed concerned communication upskilling and training. The comments noting the need for improvements were around the communication and interactions with patients. This would appear to be two aspects of the same phenomenon.

The results from this analysis demonstrate the following outcomes in regards to the research question investigating if changes have been made in the clinical governance systems post Inquiry at KEMH regarding involvement of consumers in care:

- Participants' perceptions support that structural changes (policies procedures and guidelines) have occurred post Inquiry in relation to involving consumers in care; and

- Participants' perceptions do not support that the changed policies and procedures have translated into improvement of clinician behaviours, in terms of responding to poor outcomes and involving women in care.

Summary: Changes in Clinical governance processes at KEMH Post Inquiry

Multiple sources of data were used to examine the two issues that were the focus of this study relating to Inquiry recommendations. These sources included documents, archives, and interviews. The document, archive and interview analysis all identified that policies, procedures and guideline had been developed post Inquiry, and these have translated into improved practices as described in the recommendation of the Inquiry.

In terms of consumer involvement in care, the document, archive and interviews all identified that there had been significant changes in the policies, procedures and guidelines. The area where improvements were still required was in the area of communications skills. This was correlated in the documents, archives and interviews.

THE INFLUENCE OF THE INQUIRY ON CLINICAL GOVERNANCE PROCESSES AT KEMH

Analytic Process

Interviews were the sole data source for this particular section. Using the Miles and Huberman (1994) framework each interview was coded using *NVIVO 7 (2006-2008)*. The functionality of *NVIVO 7 (2006-2008)* provided the opportunity to cluster data and explore how one code related to another by building models. The building of models occurred throughout the process of analysis. Through this iterative model building process, an aggregation of data, led to the identification of emerging themes. This then resulted in a gradual development of what Yin (2003:127-133) and Miles and Huberman (1994:143-171) call a logic chain. This logic chain is an explanation or interpretation of events

demonstrating the relationship of the themes to the endpoint of the event. For this section of the study, three explanatory pathways were identified from the analysis of the participants' interviews regarding the influence of the Inquiry on the development of the clinical governance systems being examined for this study. An overview of the findings describing the pathways is presented below. This is followed by a more specific discussion of each theme.

Overview of findings: Participants' perceptions of influence of the Inquiry on change.

The model below in Figure 20 provides a graphic illustration of the themes that emerged from the participant interviews in regards to their perceptions of the Inquiry's influence on change. Within the model there are three different pathways of influence. In the first pathway, the scope and parameters of the TOR provided the mechanism and process that enabled informants to provide information to the extent that they did. Because the Inquiry informants were able to tell their stories (not only by direct evidence but also through the examination of records and the clinical file review), three things emerged. Firstly, an empowerment of staff and consumers; secondly, an alteration in how medical staff viewed their care delivery practices; and thirdly, a challenge to the established powerbrokers or medically dominant culture within the organisation (the old guard). As a result of these three findings, leadership supporting and driving change developed in the organisation, with this resulting in improvement in the clinical governance processes of medical credentialing and performance review, and consumer involvement in care.

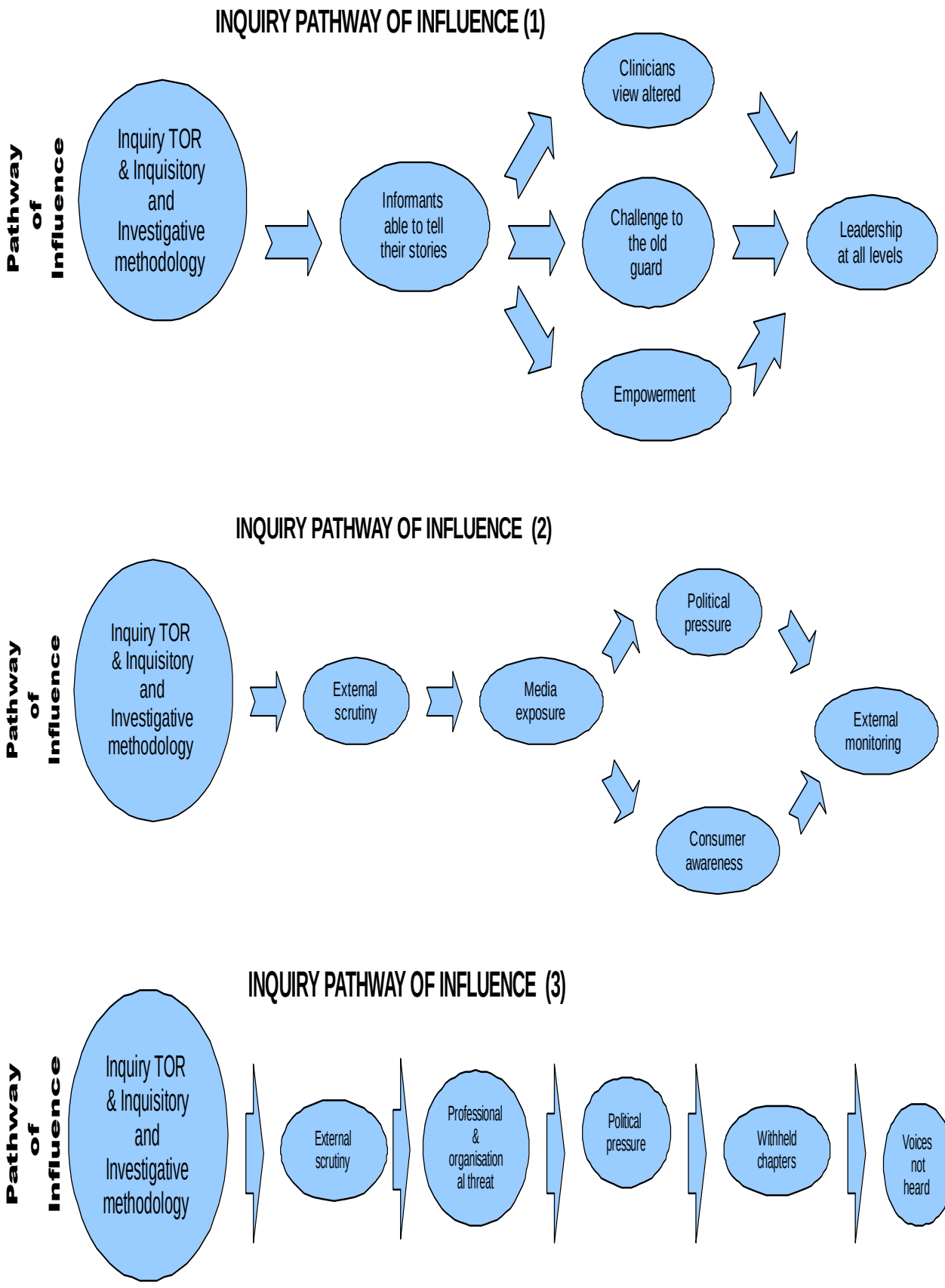


Figure 20: Three pathways of Inquiry influence identified by participants

The second pathway in the model also commences with the theme that the Inquiry was necessary for change. This then leads to external scrutiny and as a result, three themes emerge. Firstly, and similar to the previous pathway, a challenge to the 'old guard' resulted from the scrutiny and exposure. Secondly, there was increased media attention and finally, increased awareness of consumers to the reality of the failures at KEMH. These three themes resulted in political pressure to improve, which therefore, led to pressure on leadership within KEMH to provide evidence of change. The outcome then was changes to medical credentialing and performance review processes, and improvement in processes to ensure consumer involvement in care.

Analysis of the interviews identified a third pathway in regards to the influence of the Inquiry on change. This pathway differs from the previous pathways, since in this case, the Inquiry did not positively influence change but rather reinforced existing barriers. The pathway begins with the theme of the Inquiry TOR being significant to the scope and conduct of the Inquiry, which in turns leads to the theme of external scrutiny. This pathway then differs from the previous pathways in that analysis of participants' interviews identified that the external scrutiny led to a perception of threat by both professional bodies and the KEMH management. This theme is labelled as professional and organisational threat. As a result, there was political pressure to limit the fallout from this perceived threat. This led to the decision to withhold several sections (approx 300 pages) of the final Inquiry report from the public domain. These sections were those where the detailed review of the management and outcomes of specific patient cases was reported. These sections also included the patients' testimony describing their views and experiences. Consequently, although the Inquiry TOR ensured the informants were able to speak, withholding the particular sections that gave voice to their testimony resulted in considerable sections of very graphic detail of the poor clinical care and subjective patients' experiences being unavailable. Thus, generally clinicians within KEMH and consumer and media external to KEMH, were denied the opportunity to gain an understanding

of the scope and extent of the problem and the impact on patients and families. Because clinicians were denied the opportunity to hear and gain a much deeper understanding of the patients and families' perspective, the current paradigm of a power differential between medical staff and patients was not challenged. The power differential, where clinicians think they know what it is that patients want from therapeutic interaction and consumers in these interactions are powerless to influence the interactions, is a significant barrier to change. This was played out in the area that involved the need to develop communication skills in dealing with patients and families, especially in circumstances where there had been a poor outcome. Although in terms of communication, as detailed in the previous chapter, there were certainly significant changes made to the structural elements (policies and procedures), participants believed that this has not translated into recognition that the way these communications are transacted is generally not meeting the needs of the patients and families involved. This pathway therefore, concludes with the theme changes still required. This theme was discussed fully in Chapter 3 but essentially participants described that in terms of changes in consumer involvement, there were areas that still required improvements.

Having provided an overview of findings, details for each theme within the pathways will now be provided.

Pathways of influence

Pathway One

The theme of the Inquiry being necessary for change was the initial premise identified by all participants. Each participant was very positive in their views that the Inquiry was an instrument of change, with several participants making comments on more than one occasion.

The following comments illustrate the strong views held by the participants:

... I mean Douglas came out of many things really, didn't it, and it wasn't just one particular incident that occurred it was a prolonged period of time that was identified there was an issue there and eventually led to that. So I guess, if you look at it, if you articulate it that way, then yeah … you do need it, you do need something like a Douglas …

... Put it on a global perspective, … are royal commissions into police corruption a waste of time ….they're all in the same league, what they're doing is they are taking an institutional system and shake the ... [expletive] ... out of it to see what they find and what's brought them to the point of the Inquiry is some phenomenal evidence that nobody can ignore that's what [we] have inquiries for…

... I don't think people actually understood ... in Western Australia in the metro area [nobody] acknowledged that there were any problems and I think [the]patriarchal culture that occurs in medicine and occurs in areas of midwifery as well ... no … without the Inquiry I don't think anything would have made a difference ...

.. .therefore only a non-institutional approach arising out of a consumer lobby group and altruistic clinicians, through a number of inquiries, would generate sufficient momentum to generate change...

The comments from this participant provide an excellent summary that encapsulates all participants' views for this theme. The participants posed the rhetorical question to the interviewer, paused, and then answered the question.

... The question for you is: what if we hadn't had the Douglas Inquiry? ... Yes ... the Inquiry [was] needed … as painful as it was…

All participants identified that the Inquiry TOR were crucial in identifying the information that would act as a catalyst for change. Participants typically talked in generalities about their understanding that the breadth and scope of any inquiry's TOR impacts on the ability to investigate an issue thoroughly. Based on this understanding, they recognised that the Douglas TOR was structured in a way that did allow a thorough investigation. The following comments illustrate this perspective:

... Well the agent of change is the breadth and scope of the inquiry, you know, this will inform one of the necessary elements for systemic change. So, if we reduce the scope of the inquiry and exclude those things which are necessary to change then any inquiry will fail ...

... Because they have designed [the] Inquiry to take into account what is necessary information and for generating the system change after…

… Look, if I wanted to an inquiry in which either one of any issues were not identified ... [and] ... in which there would be no recommendations that would be "far reaching"... then that can be done ...

The process whereby the Inquiry was able to gather evidence was through written and personal testimony, together with, a review of documents and patient notes of specific cases, and benchmarking of clinical performance. Hence, informants' stories were by the informants themselves, and also by others when reviewing their cases. The TOR provided for confidentiality and anonymity protection, if these were required by informants. In the interviews, none of participants specified knowledge of the details of the TOR that provided the mechanisms for informants to be able to tell their story. All participants recognised however, that the methods employed, and how the Inquiry was conducted, as a result of the TOR, were vital in allowing informants to tell their story. The following comments illustrate this:

... think it was a significant step forward because all of the midwives who were interviewed came away feeling that they had finally been listened to in terms of issues that they had been trying to raise for some considerable time...

… I think it gave those people the opportunity to be heard …

… Gave them the opportunity to speak out .., I suppose they thought in speaking out they might be able to change some of the cultural problems within their section because it means they were going to get some help as well …

… You know... I think the younger people felt they could talk as the ... [the Inquiry investigators]… were a little bit more senior ... and the people that were investigating were external ... they were from out of the Stat , so they [the informants] could actually speak …

Because the informants were able to tell their stories in one format or another (oral, written or through review of their case), this led to the themes of empowerment, clinicians' views being altered, and a challenge to the old guard. The following comments typify those made in regards to empowerment of medical staff:

> *... junior medical staff through that era and post that era, they feel more empowered now to go beyond that immediate clinician, so if they feel that the clinical decision they have reached is the appropriate one and the best clinical outcome for that patient, but that they don't necessarily get that support they feel more empowered to go to someone else for a second opinion whereas in the past they never felt they could do that ...*

In terms of midwives empowerment:

> *... inquest has given the Midwives greater strength in terms of their role ...*

With the following comments are illustrative as applying in general:

> *... Well I think people are just told now that if they want to say something they can say it and they should say it and my perception is that they do ...*

> *... People ask things like, why do you want that, why do you do that and actually have a discussion about that in that they ask for what the policy is and do we follow King Edward guidelines here or don't we and who's decided that, who are the people in charge and who do I communicate with, because I need to communicate ...*

Not only were clinicians empowered by the Inquiry, but several participants believed that when clinicians heard the informants' stories it challenged their current thinking. They gained a new understanding of the extent of the problem and the effect on staff and patients. This resulted in many clinicians reflecting on the system failure and their own practice within that system.

> *... it, it shook a few people up and made them look at their own individual practice ...*

> *... some of the stuff was individual related, in terms of individual clinicians and their willingness to listen ...*

> *... It made them acknowledge that there was a problem because it was already out in the open ... [that is] that things had gone wrong ...*

A third theme resulting from informants having the opportunity to speak was that there was a challenge to the establishment within the hospital. All

participants identified that this was important in that it facilitated change Therefore, the challenge of the old guard from within the organisation, when combined with empowerment and clinician self-reflection, provided a powerful effect in driving the process of change. The comments indicative of this are:

> *… there had been a lot of people of a certain age group who had been the guard in a system that had a very strong culture of the old guard so the younger people coming through didn't have the power ... they were powerless … they could speak up but they weren't heard ... the people who should have been listening didn't want to hear that because part of the problem was that these people, the old guard were the gatekeepers and probably some of the people who were causing the problem in the first place …*
>
> *... suppose they thought in speaking out they might be able to change some of the cultural problems within their section because it means they were going to get some help as well. The younger people weren't getting the support and help with the clinical expertise and the clinical exposure because the old guard simply were not there and they would not show them ... and they would say you do it and let me know when you've done it …*
>
> *... really, everything [now] seems to be on the table to be commented on. It is not always a positive experience mind you and not always constructive, you don't find junior staff just doing as they're told and talking to the consultant you know and no one else ...*

The result of all of these is that leadership arose at all levels in the organisation. This leadership became the driver for changes in the clinical governance systems and processes. One participant's comment catches the essence of this view with the following comment:

> *… these things do not happen de novo. What is evident is strong clinician leadership and clinicians who have an understanding of organisational structure and value-driven clinicians committed to collaborative and transparency, with respect for the human context in which clinicians work in and to be truly supportive of people who can support them ...*

Other comments reflected the changed leadership role of medical clinicians:

> *… I think one of the things I didn't entirely understand at first … but did come clear to me is that there are a lot more people, I'm still talking doctors*

and nurses but more senior doctors, there are a lot more people, who are undertaking a clinical managerial roll than in the past …

… I think that the Senior Consultant staff now have accepted their role, if you like, in those system processes …

… it [the Inquiry] is insufficient in itself, because it requires more … good supervision at unit level, team climate and leadership at all level …

This theme of leadership then leads onto the final themes that were identified in Chapter 4, which identified that changes had taken place in medical credentialing and performance review systems as well as involvement of consumers in care.

The second pathway within the model one will now be discussed.

Pathway Two

As with the previous pathway, participants identified that there was an overarching theme of the Inquiry being necessary for change. In this second pathway, the theme of external scrutiny or exposure was identified as a next key element in the pathway. All participants commented on this factor. The following comments are illustrative of those made:

… Douglas was very public and I think...once you've got it [into the] very open,, very public arena there are far greater pressures to do something …

… it [the Inquiry] was very public and I think that helped in many ways bringing peoples attention to the issues that were there …

… until Douglas came, it really didn't, as you say, didn't blow up and get right out there for everybody to see …

… there was a public discussion of the culture of what was going on within King Edward and that it was probably was an eye opener... and [it was] informing to the public in that there are things that do go wrong …

Analysis of the participants' interviews identified two themes arising from the exposure and external scrutiny that occurred from the Inquiry. These were consumer awareness and media pressure. In the first of these, consumers became aware of their vulnerability when they are patients and that things can, and do, go wrong. All participants believed that this was a significant change for the consumers, who generally do not have the awareness that the care delivered may not be of the standard and quality that would expected. One participant described this as:

> *… the public may have gained some insight to the fact that things didn't go well all of the time … and that there needed to be some way of finding out whether or not things could have been done better for them, and at last I guess it let everyone know that it doesn't always go well …*

Another participant stated:

> *… I think the community thinks a lot more realistically now, I think they still would like every birth to be … can I use the term "Earth Mother"…, but I think on another level, people think well, I'm not sick and I went into hospital, and I wasn't sick and I was expecting to have a baby, and I got sick or my baby got sick. And so if something has gone wrong, they want to know why and they ask why …*

Integral to this increased consumer awareness was the role of the media. This was the second theme identified by participants, although none of the participants viewed the media's role very positively. Several of the comments demonstrating this are:

> *… [the media was saying] ... that King Edward was a dangerous hospital and … some of the statistics of workflows at various sites would suggest that the market place believed that, and decided to go elsewhere ...*

> *... I think it made public that things were not ok. That there was the acknowledgement that "trust me I am the Minister" was not how it should be and there was the engagement through the media at the time...not always good media … and there was a fair bit of media outrage and also what was going to sell a paper and so there was a fair bit of hype …*

Arising from these two themes, there was considerable political pressure to fix the problems identified by the Inquiry. This theme of political

pressure is demonstrated by the following comments from the participant interviews:

> *... I guess the consumers... if you like...wanted to know that something had changed and I guess part of that could well be the political agenda ...*
>
> *... [the] Consumer's Council it was very high on their agenda that the ball didn't get dropped this time ...*
>
> *... we [the health system] come in the name of god and the name of the patient because there is a rise of consumer power now. Because consumer power is consumer lobby group power ... and they are a key player in the political economy of change ...*

This comment from one participant provides a succinct summary of the effect on the politicians for change because of the external scrutiny and exposure:

> *... if you're a politician and mounted the curb and you didn't act you'd be committing political suicide ...*

Participants were clear that pressure on politicians led to the need to be seen to be doing something. None of the participants discussed the detail of the political process that saw the recommendations of the Inquiry accepted by the Minister for Health. They noted however, that as part of the political process of needing to be seen to do something, that external checking systems were put in place to monitor the implementation of the recommendations of the report. It was also noted by participants that the checking and monitoring systems involved consumers. Participants commented thus:

> *... Their risk areas are being monitored now at a unit level and those numbers are analysed by clinical biostatisticians and interpreted by people with clinical expertise and understanding of the clinical context in the area and then risks and performance can be interpreted by the appropriate body ... maybe the MAC. So, what I see is the confluence of using numbers ... quantitative means ... together with the soft knowledge which is important in terms of people who understand the clinical context, which then relates to what is necessary for good health administration, which is an explicit structure in which accountability sits which is then related to the Chief Executive of the service. So within the context we have all our moons lining up about what should be done, which I think is the biggest achievement ...*
>
> *... Well certainly I knew [about the implementation group] . I knew that there was some consumer involvement, whether that's changed, right now I*

couldn't honestly say whether they've actually altered it to this point...there was consumer participation on that group... that was a specific group that was set up to implement the recommendations from the Inquiry …

… Yes, it [the implementation group] was just overseeing it. Getting reports back, progress on recommendations … what had been implemented in direct response to any evaluation that had been undertaken, etc..."

… it's almost a Big Brother thing... actually being watched now, we really need to be more accountable for what we are doing and I think that's been a very positive thing out of Douglas …

Because of the external scrutiny arising out of the Inquiry led by the media and consumers there was pressure on the politicians that then resulted in monitoring and reporting systems being put in place to scrutinise KEMH's performance in implementing the Inquiry recommendations. This pathway influenced the structural changes in the clinical governance systems that are the focus of this study. Thus similar to pathway one, this pathway terminates with the themes identified in Chapter 4 that identified that changes had taken place in medical credentialing and performance review systems together with involvement of consumers in care.

The third pathway revealed in the model, reports participants' perceptions of the influence of the Inquiry where the Inquiry, rather than providing mechanisms that are drivers of change, instead reinforced existing barriers to change. This pathway is described in the following section.

Pathway three

This model commences with the theme that the Inquiry TOR are critical to how the Inquiry was conducted. The Inquiry processes then led to external scrutiny. Participants' comments that illustrate these themes are revealed in the section above and since they remain relevant to this pathway they are not repeated. In this pathway, the results of the exposure arising from the external scrutiny led to what participants identified as a perception of threat by clinicians and the organisation. This theme is labelled as professional and organisational threat. The following comments by participants illustrate this theme:

> *… there was also the public backlash ... so you had the very strong and powerful AMA trying to talk down the problems as well and trying to support the colleagues who might have been caught up in I ... trying to support the colleagues who might have been caught up in it ... so I think it actively engaged the public …*

> *… people tell me that senior people who are in responsible positions ... were a touch concerned about that [the exposure that was occurring as a result of the media focus on the Inquiry] and it forced King Edward to go into a 'we have got out spin and respond type mode' … for hospitals to be involved in marketing as distinct public relations … we've never seen that before ...*

> *… all of the medical factions, and those related factions all got together to support their own, and it is a closed shop …*

One of the reactions to this perceived threat was the withholding of several sections of the Inquiry report. The withheld sections have recently been released under FOI legislation. Several of the study participants have had the opportunity to read the withheld sections that had previously been inaccessible. The following participants' comments were expressed within the context that they have now had the opportunity to read the comments of the patients and families in regards to the lack of involvement in care and poor communication on the part of the treating clinicians. One participant described the effect of having access to the withheld sections this way:

> *… We now read the missing pages … if we'd known that ... we could have understood the recommendations that were before us and understood the human experiences that came from that. You read everyone of those pages and you know it's going to have a bad ending. Ninety cases ... you read everyone and know it has a bad ending... gynaecological and obstetric ... its not just obstetrics… its stupid utter failure on core business of the medical profession in that hospital!!*

With another stating:

> *... none of those poor people that were subject to the Inquiry and who gave evidence ever saw their stories in the public arena. They've got no idea, like I've got no idea whether their story made any difference at all ... it was a gross injustice that [was] committed by withholding those pages... a gross injustice was done to all people involved with the King Edward Inquiry …"*

The specific effect of not hearing the patients' voices and therefore not understanding the patients' perspective and the patient experience of care was illustrated by the following comments:

> *... I think there is still a lot of people out there that are just sitting on the fence, they actually haven't got it yet ... hopefully we don't need to have another crisis ... like a Douglas style type crisis, arriving from an adverse, horrible, unnecessary adverse event or serious problem ...*

> *... so they listen to their own propaganda machine that says they are centres of excellence ... and they set themselves up as sacred cows which can't be touched ...*

This pathway ends with the theme still requires change identified and explained in Chapter 4. The result of this pathway is that the Inquiry did not influence major changes in the some of the processes dealing with the involvement of consumers in care. Instead the dominant model of interaction and communication between clinicians and consumers where the care is directed primarily by clinicians with minimal involvement or input from consumers prevails. This dominant model was not challenged but rather was reinforced by the actions resulted from a perception of threat by major stakeholders. Thus, the Inquiry did not reduce the restraining forces or barriers that hindered training and education initiatives to develop clinical governance processes aimed at improving communication and involvement of patients in their care.

Summary: Participants perceptions of the influence of the Inquiry on change in clinical governance processes

This section has described the findings from the analysis of the participants' interviews, specifically in relation to the influence of the Inquiry on changes that have and have not taken place in the involvement of consumers in care and, medical credentialing and performance review. The findings were presented as pathways of influence commencing with

the Inquiry and building in a logical chain of relationships to the endpoint of whether changes have or have not taken place.

CHAPTER SUMMARY

This chapter has presented the findings from the data analysis undertaken to identify if there were changes in the clinical governance processes at KEMH, specifically in the areas of medical credentialing and performance review and consumer involvement in care. As well, the findings from the analysis of the participant interviews in regards to their perceptions about the influence of the Inquiry on change were detailed.

In regards to medical credentialing and clinician performance review, the document, archive and interview analysis demonstrated that the recommendations from the Inquiry report had been implemented. Thus, there had been significant changes in the clinical governance processes in this area.

In terms of involvement of consumers in care, analysis of the data demonstrated that in terms of policies, procedures and guidelines the changes identified in the recommendations of the Inquiry report had been implemented. However, in terms of training, education and upskilling for clinicians to do with involving consumers in care, both the document and archive analysis, and the interviews identified deficiencies.

The analysis of the interviews in relation to participants' perceptions of the influence of the Inquiry on change, concluded that all participants identified the Inquiry was crucial to change. Three pathways of influence were identified. In two of these pathways, there was a positive influence and in one pathway, the Inquiry process influenced change negatively.

Having identified that there were changes in the processes in some areas and not in others, and that the participants perceive that the Inquiry was

instrumental in the changes, the following chapter will discuss these findings with reference to current literature. Using Lewin's (1951) model of change as a framework, a conceptual model of change demonstrating the influence of the Douglas Inquiry on changes in the clinical governance processes at KEMH, will then be presented. Finally a conceptual model of clinical governance change will be presented.

CHAPTER FIVE

DISCUSSION OF FINDINGS

"...organisations have great difficulty forgetting, or letting go of, precepts and standard operating procedures which are no longer serving them well. They go on dong things the same way, although the environment around then may have radically changed." (Pollitt, 2000:6)

INTRODUCTION

The previous two chapters have described the pre Inquiry context of KEMH and the processes and conduct of the Inquiry. Data analyses of both documents and participant interviews were reported. These analyses identified that changes have occurred in the processes of involvement of consumers in care, and medical credentialing and performance review. There were still areas concerning involvement of consumers in care however, where improvements were required, particularly in terms of clinician/patient communication. The examination of the case as described in Chapter 3, and analysis of the interviews reported in Chapter 4, identified that there were significant barriers to clinical governance improvement at KEMH pre Inquiry. Participants strongly identified that the Inquiry was the instrument of change for the improvements that had occurred. In recognising that the Inquiry was the agent of change, two significant factors emerged as pivotal in terms of influencing the barriers and drivers of change. These were, firstly, the TOR & inquisitorial and investigative methodology employed by the Inquiry and secondly, the external exposure of the status of clinical governance systems at KEMH pre Inquiry that occurred because of the public nature of the Inquiry.

The focus of this chapter is a discussion of the findings with reference to relevant research literature. Lewin's (1951) model of change and its relevancy to change processes at KEMH post Inquiry will then be discussed to answer the primary research question: Did the Douglas

Inquiry influence changes in the clinical governance processes at KEMH? Finally, a conceptual model of change will be presented. This model is based on Lewin's (1951) model, but expanded to specify the detail of the mechanisms of change that increase driving forces and decrease restraining forces to bring about change in clinical governance systems.

COMPARISON OF FINDINGS WITH LITERATURE

In introducing the background to this case study at the beginning of this report, it was identified that both within Australia and internationally it has been clearly identified that there is a need to improve patient safety within the health industry (Braithwaite et al., 2006; Duckett, 2003; Dunbar, Reddy, Beresford, Ramsay, & Lord, 2007; Edmondson, 2004; IOM, 2000; McGlynn et al., 2003; Wachter, 2008; Wilson & Van der Weyden, 2005). What was also clear was that this has been recognised for well over 10 years and even though there have been many initiatives to improve patient safety, there has been minimal progress. This need is especially highlighted with the ongoing very public inquiries into health care failures. In Australia alone, in the intervening eight years since the KEMH Inquiry, which is the focus of this case study, there have been at least another four across the country. (Davies, 2005; Douglas et al., 2001; Faunce & Bolsin, 2004; *Investigation Report Campbelltown and Camden Hospitals, MacArthur Health Service*, 2003; Joseph & Hunyor, 2008). The challenge identified in much of literature reviewing inquiries is that the cultural change required to improve patient safety is enormous (Braithwaite et al., 2006). Thus for those striving to implement improvement changes there is a need to identify a process that overcomes the barriers that block change initiatives.

There is a considerable body of literature that deals with the study of change within health care organisations. In a study undertaken by Hurley et al., (2004) the researchers examined a failed change process that was attempting to implement a regionally-based health care service in

Australia. Hurley et al., concluded that the factors that led to the unsuccessful implementation of this new service were a change in political policy direction, weak leadership support for change, and that staff involved were not informed of the rationale for change. Scott, Mannion, Davies & Marshall (2003), in their literature review of theoretical viewpoints and published studies about clinical change implementation, concluded that there were common impediments to change implementation. These impediments included inadequate leadership and lack of ownership by those being directed to change. Fitzgerald et al., (2007) identified similar findings in their study of 11 healthcare sites in the UK investigating the features that impact on healthcare organisations' ability to change. In this study they found that in those organisations where the change process was inactive, struggling or there was limited or slow progress, the senior leadership team's focus was not on the project and there was fragmented leadership. There was also resistance from clinicians to the change or poor team relations or cohesiveness. Fitzgerald et al., (2007) also found that in organisations where there had been some improvement but the projects were unable to achieve their goals, managerial bureaucracy or organisational re-structuring had intervened to become a barrier. The similarities of the findings of these studies to the current study are obvious. Analysis of the data in the current study clearly identified that the barriers to the implementation of improvements pre Inquiry were a lack of leadership for clinical governance change throughout the organisation and a lack senior leadership focus on clinical governance improvement. Additionally, the dominant culture did not perceive the need for change and the organisation had undergone several restructures throughout the period investigated by the Inquiry.

In identifying those factors that support change, McGrath et al., (2008) reported on the evaluation of clinical process redesign projects in a hospital in South Australia. In this study, the authors identified several factors that are important elements leading to successful implementation and sustainability of such projects. These factors included leadership at

executive, middle management and clinical team levels, and accurate and credible data that supports the need for change. These findings confirmed an earlier case study by Bamford and Daniel (2005) that examined the creation of a new clinical Service Health Authority in the UK. In this study the researchers also identified the key elements to success were providing information to stakeholders about not only what the change involved but also why the change was necessary. Wang, Hyun, Harrison et al., (2006) using data from interviews of service providers involved in clinical system redesign within the US, found several factors were important for successful change. These included involving leaders at the executive and middle level management and developing what they termed 'champions' at the work interface. The key factor for these champions was that they had ownership of the process and were convinced of the need for change. Fitzgerald et al., (2007) identified that in those areas where changes were actively being implemented and accepted by staff leadership and localised support for change were dominant elements. Adding weight to these findings is a review and analysis of clinical governance literature undertaken by Braithwaite and Travaglia (2008). In this analysis elements were identified that are the key to effective clinical governance. These included positive attitudes and values about safety and quality, organisational systems to support safety and quality, accessible and credible data and evidence, and the involvement of patients in care process planning. The common elements then, identified in all of these studies, are the need for leadership, and that those involved in the change need to be convinced of the need to change so there is some ownership of the change process. In the current case study, similar factors of leadership and ownership of the change were identified as keys to the clinical governance improvements that have occurred in medical credentialing and involvement of consumers in care. Where changes have not occurred in the involvement of consumers in care the analysis in this case study identified that the lack of convincing evidence of the need to change resulted in a lack of recognition for the need to improve communication skills.

The studies discussed thus far identify key factors that need to be present if change is to be successful. The conclusions of these also support the findings of the current study. These studies however, do not deal with the underlying cultural norms and behaviours that underpin the organisational climate that impinge on the change process

Findings of the current case study identified that the dominant culture pre Inquiry was a medically dominant culture in which there was a perception that there was no need for change. This acted as a significant barrier to change at KEMH pre Inquiry and contributed to the relative powerlessness of staff and patients, who had identified deficiencies in clinical governance processes, but were unable to effect change. This finding is similar to those of other studies. Braithwaite (2005) in his examination of two health inquiries (KEMH and Bristol) described the impact of culture on group behaviours as the phenomenon of 'tribalism'. He asserts that tribalism is the group behaviours that reinforce the wholeness and entirety of the group (the tribe) by turf protectionism and actively excludes those who are perceived as different and do not belong. This striving for preservation of the tribe, whether it be the professional tribe or the organisational tribe leads to a 'them and us' mentality, especially when a threat is perceived as in the instance of criticism (perceived or real) of the tribe, or attempts to challenge the performance of the tribe. This observation of tribal behaviour is not new, with Lewin (1951) in his extensive studies on organisations and change identifying that the majority of individuals within the organisation will display behaviours and conduct that reflect closely the dominant cultural norms and expectations. If an individual rejects the dominant cultural norms and does not conform to group behaviours, this results in an individual being ostracised and rebuffed by the group. Schein (1985) concurred with Lewin's work and concluded that groups or individuals will only embrace change, even if shown the need for change, if they believe they are psychologically safe and there will not be a loss of self esteem. More recently, Walshe and Shortell (2004:107) in their study examining health care failures in six countries identify that a common theme in these

failures was the existence of what they termed a 'club culture'. They describe this culture as having an enormous impact as a barrier to improvement, and declare that "a culture of secrecy and protectionism" (pg 107) is endemic and results in a defensive reaction to any threat.

A contributory explanation for this type of group or tribal behaviour can be found in the sociological principle of homophily. This is the sociological principle that people tend to group together with those similar to each other (Brashears, 2008). In the comprehensive review of research across the 20th and 21st centuries of this sociological principle, McPherson et al., (2001) identify that the effect of homophily is that it "…limits people's social worlds in a way that has powerful implications for the information they receive, the attitudes they form, and the interactions they experience" (pg. 415). McPherson et al., while acknowledging and describing the impact of family, race and religion on attitudes and values, also identify the powerful influence of organisational and occupational context on the values and attitudes of individuals as part of the group socialisation. Confirmation of a specific dominant culture in healthcare is provided in the study undertaken by Braithwaite et al., (2006). In their summary of the analysis of eight Inquiries in six countries, they suggest that " the aspects of the way of thinking and behaving are common to healthcare (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" (2006:8). The results of the current study identified that the medical dominant culture at KEMH pre Inquiry had a profound effect on the powerlessness of staff. The effect of this was that staff found they were unable to challenge the concept interview participants identified as *the old guard.* This effect of the medical dominant model was also identified in an ethnographic study undertaken by Long et al.,(2006). This study, in an Australian hospital, examined a multidisciplinary team committed to communication and decision-making strategies that was designed to be non-hierarchical. All team members, including the medical voice, were committed to challenging the medical dominant model. What was evident, was that the

team struggled with putting this into practice and that the medical voice had more authority and autonomy than the non-medical team members. The context of the study undertaken by Long at al. is different to the current case study because the staff involved in their study was committed to challenging the dominant model. It does however, serve to illustrate that in a context where there is no recognition that the medical dominant model exists, let alone that it should be challenged (as in KEMH pre Inquiry), the difficulties in challenging the status quo would be even greater.

The medical dominant culture also contributed to patient powerlessness at KEMH pre Inquiry. This phenomenon was studied in a cross sectional survey undertaken by Davis, Koutantji & Vincent (2008). This study, which examined patients' control of communication in a therapeutic relationship, identified the unequal communication relationship between patients and clinicians. This study assessed the willingness of patients to question healthcare staff about their treatment. The researchers found, that when encouraged to do so, some patients will ask questions but only those questions that do not challenge the clinical skills and abilities of the healthcare team. Findings from the current case study were similar to this. Evidence given at the Inquiry and the analysis of participant interviews identified that in the main, patients and families did not feel able to challenge the dominant clinical cultural paradigm. This paradigm was one of exclusion of patients in care decisions, particularly in circumstances where there had been a poor outcome.

So far, this discussion has identified a considerable body of research that concurs with the findings of the current study in identifying the barriers to change and the influence of dominant culture on group behaviour and views. These studies also identified several key factors in overcoming resistance to change. These included providing data or evidence that demonstrated the need to change, creating a climate that supported the development of leadership for change at all levels of the organisation and generating the expectation of demonstration of improvement in processes.

The current study adds to this body of research by identifying specifically the factors in the conduct and processes of the Inquiry that provided the agency for the conditions necessary for change to be achieved. As well, the results of this study provide an explanation for the lack of improvement in the area of clinician and patient interaction. The reason identified for this was that the dominant view was unchallenged because the evidence that could have provided the impetus for change was withheld from the public domain. There is a further area where the current study provides a contribution to the understanding of those processes that can influence change. This area is one which deals with the examination of outcomes following an inquiry into a health system failure.

There have been many studies undertaken that deal with the examination and analysis of health system inquiries. These include: the study scrutinising the Bristol Inquiry undertaken by Walshe & Offen (2001); similar research by Walshe & Shortell (2004) which studied six different inquiries in six different countries; a study undertaken by McLean & Walsh (2003) that examined the KEMH Inquiry; and finally the Braithwaite et al. (2006) comparative analysis discussed above, which looked as eight different inquiries in six different countries. These studies identified similar aspects of health care contexts present when there is a failure. These were poor leadership, lack of effective clinical governance systems, disempowered staff and patients, geographical or clinical isolation, inward looking cultures and the failures of care were significant. All of these studies identified the need for cultural change and acknowledged the difficulty in achieving this. These findings mirror the conclusions of the case study being reported here. Given these findings and other literature identifying the need to monitor outcomes of inquiries the expectation would be that there would be literature reporting on health agencies post inquiry to identify any improvements. Extensive literature searches utilising academic electronic search engines including Supersearch and Ebscohost however, have failed to identify any empirical studies examining changes as a result of health inquiries. The current case

study makes an important contribution to this deficit in knowledge about the impact of inquiries on change, not only in evaluating if there has been change but also in identifying the key elements of the Inquiry that have impacted positively and negatively on the change process.

Having identified the elements of this study that further understanding of clinical governance change management, this Chapter continues with a discussion of the changes with reference to Lewin's (1951) change model and the introduction of a conceptual model of change for improvement of clinical governance systems.

LEWIN'S (1951) MODEL SUMMARISED

In seeking to answer the principal research question, the researcher is not seeking to find if clinical governance change happened post Inquiry, but also if so, why this occurred, and if not, why not. The previous discussions have identified the following: the changes that have and have not taken place within the area of study focus; that there were factors within the Inquiry that influenced changes either positively or negatively; and, how these influential factors influenced specifically the barriers that were inhibiting clinical governance improvement pre Inquiry. These conclusions will now be examined within the framework of Lewin's (1951) theory of change in order to gain a greater depth of understanding of the process of change that has taken place at KEMH.

Lewin's (1951) model of change has been used to illuminate the investigation of changes at KEMH because although Lewin's research work was undertaken in the 1940s, it is still considered to be contemporary (Burke, 2008; Robbins et al., 2004). His work is utilised extensively to provide understanding of the processes of change and as a model on which to base the planning to implement change (Burke, 2008; Cherry & Jacob, 2005; Daly et al., 2004; Robbins et al., 2004). Essentially, the elements of Lewin's work that provide insights to the

current study are those concerned with individual and group behaviour in relation to change, and his work which describes the change processes.

Lewin identifies that when investigating group behaviour in the context of change, the subjective and objective contextual conditions in which the group is functioning, must be taken into consideration. Lewin highlights that these contextual conditions include the cultural norms of the group that dictate behaviour, values and attitudes, and the environmental context within which the group operate. Lewin asserts that "... it is impossible to predict group behaviour without taking into account group goals, group standards and group values, and the way a group sees itself and that of other groups ..." (pg.308). In explaining the environmental context, Lewin describes this as the social field, stating that "... [the social field] is viewed as occurring in and, being the result of, a totality of coexisting social entities, such as groups, subgroups, members, barriers and channels of communication ..." (pg 308). Change in group behaviour is influenced by this social field and the impact this has on group norms and values. In understanding change processes, Lewin maintains that individuals and groups strive to maintain their context (social field) in a state of no change or status quo. The forces that can change the equilibrium or status quo are driving forces (pushes towards or supports change) or restraining forces (pulls away from or restrains change). To maintain the status quo driving forces and the restraining forces must be in balance. Lewin goes onto describe that if the social field remains constant and there is no change to any factors within it, then the group processes or behaviour will remain constant. However, if the environmental conditions (social field) changes and the group processes and behaviour remain the same, then there must be factors that are providing resistance to change (see Figure 21 below).

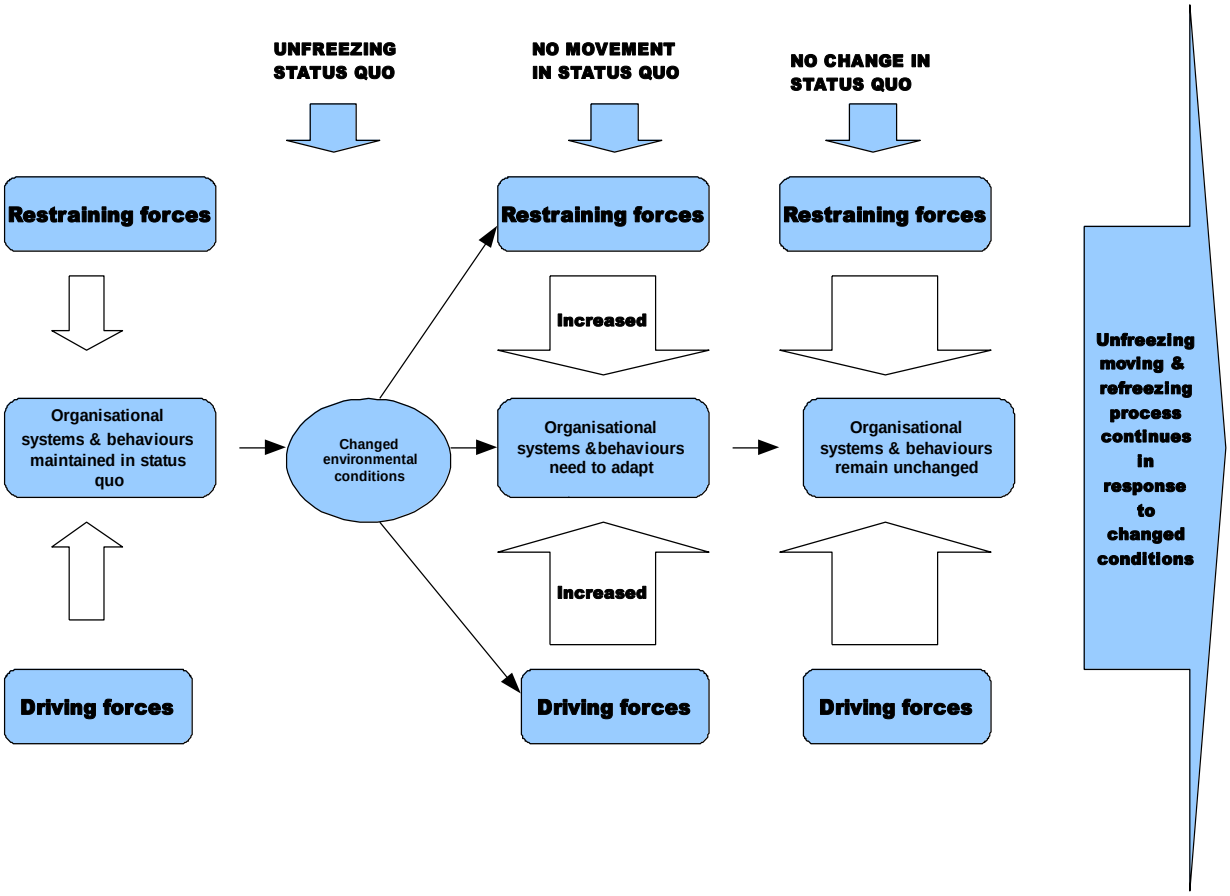


Figure 21: Model of change demonstrating 'no change' in status quo. Changing environmental conditions increase driving forces however there is a resulting increase in restraining forces (based on Lewin, 1951)

Simplistically then, if change is required, all that is needed is to identify driving forces and restraining forces (barriers) and then increase or decrease them to reach the desired change state. Lewin identified however, that increasing the driving forces is not without cost. This is because, generally any increase in driving forces impacts on group tensions. Increasing group tensions results in higher group fatigue, aggressiveness, emotion, and lower constructiveness. If this tension is increased beyond a certain point the group becomes dysfunctional. He asserts that to achieve a desired change state, it is better to diminish the restraining forces rather than just increasing the driving forces (Lewin, 1951:320-322). Further to this, Lewin (1951) also identified that the forces that drive or resist change have the added characteristics of being either induced or owned. Induced forces are those imposed on the group

or individual and are more likely to be resisted by the group, whereas those forces for change that are owned by the group are more likely to be embraced and thus are more likely to overcome barriers to change (see Figure 22)

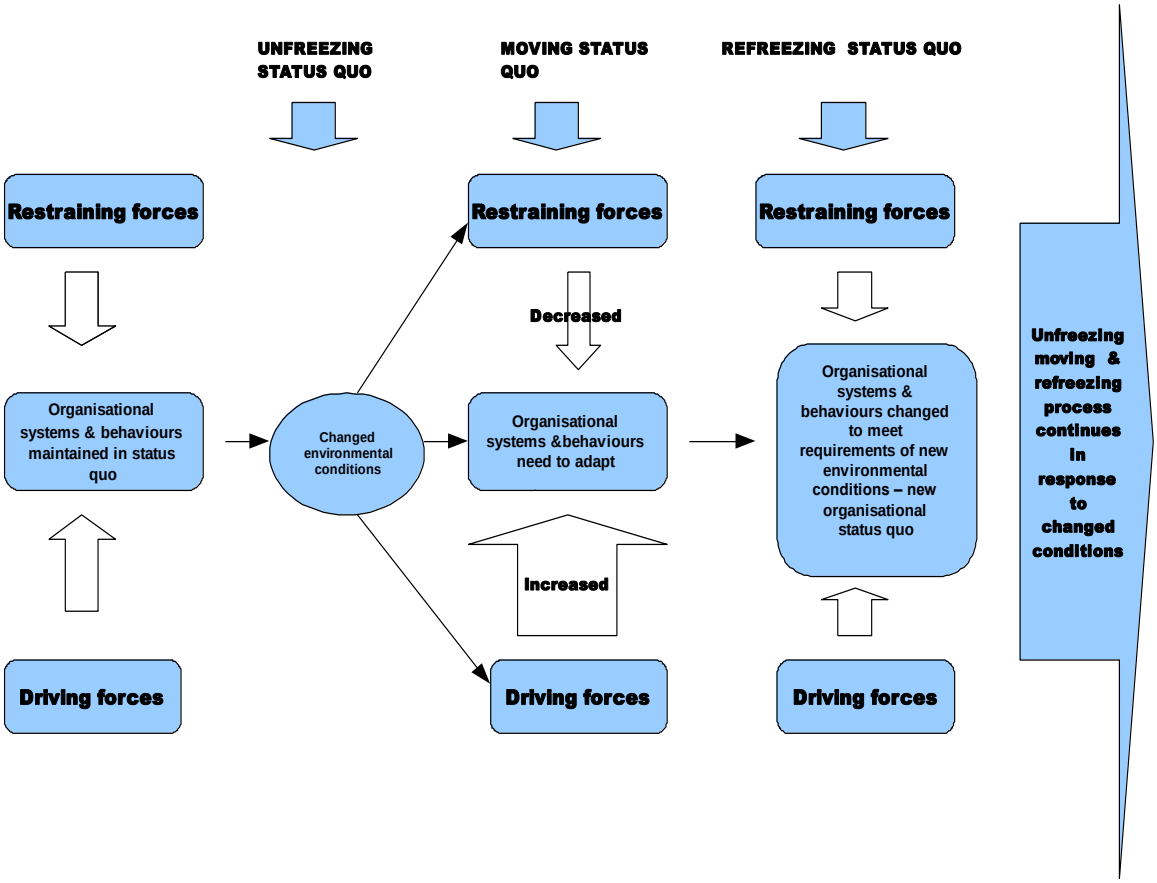


Figure 22: Model of change demonstrating change in status quo. Changing environmental conditions increase driving forces decrease restraining forces (based on Lewin, 1951)

In terms of achieving permanency of the desired change state, Lewin identifies three stages (refer to Figure 22 above). These are unfreezing, moving and refreezing. Without these three stages, the change will be short-lived and the group processes and behaviour will return to the previous unchanged state. He describes unfreezing as "... [the need to] break open the shell of complacency and self-righteousness ..." and to do this it "... is sometimes necessary to bring about deliberately an emotional stir up" (Lewin, 1951:330). This unfreezing creates within the organisation a climate and willingness to change. It may be accomplished

in many ways and should be adapted to suit the particular circumstances. It can include demonstrating the need for change with data showing suboptimal performance or a threat to the organisation of an external force. However, even if the need for change is identified, the group is unlikely to support change unless the conditions are present that allow the group to feel safe to support the change without losing face. Thus unfreezing has two components, demonstrating the need for change convincingly so that the group is prepared to own the change in group views or norms required to make a change, and providing a climate where the group feels safe to embrace the changes (Burke, 2008; Lewin, 1951; Robbins et al., 2004; Schein, 1985).

The second stage in Lewin's (1951) model is described as moving. This stage involves working towards the new changed state or status quo by carrying out the desired change in processes or behaviours. This may involve training and education for the new behaviours or planning and designing new work processes.

The final stage is refreezing. This component requires rebalancing the driving and restraining forces. This is can be achieved by a change in the group goals, standards and values, and the way a group sees itself and that of other groups within in the social field. It may involve putting in place systems to reinforce the changed behaviour such as new ways to measure performance, or organisational structural changes (Lewin, 1951:308).

Having summarised Lewin's (1951) model of change, the discussion will now move to identifying the relevance of Lewin's (1951) model to the changes that have occurred at KEMH post Inquiry.

LEWIN'S (1951) MODEL APPLIED TO CLINICAL GOVERNANCE CHANGES AT KEMH POST INQUIRY

Lewin's (1951) theory provides a framework in which to place the findings of this study. In essence, pre inquiry at KEMH the status quo, in terms of the clinical governance processes of medical credentialing and clinician performance review, was one where there was no formal credentialing processes and either a complete absence, or if processes were present, deficient performance review processes. In terms of involvement of consumers in care, the status quo was one where there was poor communication with women and families, psychosocial concerns were poorly addressed, there were inadequate responses to poor outcomes, and a lack of involvement of women in decision-making (Douglas et al., 2001). The social field or contextual conditions contained both driving forces and restraining forces (barriers) of change. The driving forces were the presence of committed and caring clinical staff, consumer and patient expectations, public sector accountability expectations, political expectations, and advances in medical and technical research. While these forces were exerting pressure on the organisation to change, the desired changes were not happening. Thus, there must have been an increase in the restraining forces (barriers) to change. These restraining forces included the inward looking culture, lack of leadership, medically dominated culture and the public sector and political focus on efficiency and fiscal outcomes to the virtual exclusion of clinical governance outcomes.

To achieve sustainable changes in the status quo of the clinical governance systems, there needed to be an unfreezing in the pre Inquiry status. This could occur by some mechanism or process that increased the driving forces, reduced the resisting forces, or a mixture of both. To provide detail and specificity to this particular context Lewin's (1951) model must be expanded to identify the critical factors within the unfreezing process that were required to improve the clinical governance

systems at KEMH. The Inquiry was the instrument that provided the unfreezing mechanism. The critical factors, as identified previously were the TOR, which detailed the scope of the Inquiry, the inquisitorial and investigatory methodology employed by the Inquiry, and the external scrutiny that provided the exposure to, and dissemination of, the evidence, both within the organisation and also, to the public. Where changes did occur post Inquiry, in both the medical credentialing and performance review, and consumer involvement in care, the Inquiry methodology employed provided a plethora of irrefutable evidence. Thus, in terms of Lewin's (1951) model of change, data was presented and then disseminated in such a way that clearly demonstrated suboptimal performance and challenged the status quo.

This challenge led on to the second stage, that of moving. In this stage, the demonstration of suboptimal performance and the subsequent challenge to the dominant group norms and views led to a change in the group views and behaviours, and an increase in influence of those who saw the need for change, thus an increase in leadership and empowerment of staff. This was brought about by the external exposure of the evidence that meant that not only was this available to the public (with resulting political pressure) but also those within KEMH were continually confronted with the weight of the evidence that was difficult to rationalise away as inaccurate and unreasonable. Consequently the pre Inquiry restraining forces were diminished, and in such a way, that the impetus for the improvements as an effect of the decreased restraining forces, was owned by the group rather than imposed. The second influence of the Inquiry, which resulted from the media exposure, political pressure, and the consumer awareness, was the development of an external monitoring system of clinical governance changes at KEMH. This increased the driving forces for change. These increased driving forces were an imposed force for change and it is unlikely that it would have been enough to ensure changes post Inquiry without the additional forces created by diminishing the restraining forces.

The last stage of Lewin's change theory (1951) involves refreezing. That is the new state of status quo where the new group views and behaviours have become the accepted dominant culture. The new status quo at KEMH involved the development of new policies and processes, such as the medical credentialing and performance review processes, and policies and procedures for both credentialing and consumer involvement. Nevertheless, it must be noted that this new status quo of the clinical governance systems is still one where there are deficiencies in terms of those areas that were the focus of this study. Specifically improvements are still required in those areas concerned with communication with patients in difficult circumstances and involving patients in care decisions. In this instance, a large section of the report that provided the evidence, which potentially could have changed the dominant cultural group views and behaviours about the need for change, was withheld from the public. Without this knowledge, the group norms and views about patients needs in regards to psychosocial support requirements were not challenged because there was no compelling data presented to change how the group saw their own situation and that of other groups. The forces resisting the changes required to improve the areas of patient communication and involvement (training and education) therefore, were not diminished. As well, by withholding the Inquiry report chapters, there was no external exposure of this information and thus no increase in political and consumer pressure as a driving force for change. The result is that there was no sustained change in the clinical governance processes and procedures concerning the provision of training and ongoing up skilling in communication skills and processes for involving patients in care decisions.

The critical factors then, in terms of unfreezing the status quo and generating improvements post Inquiry at KEMH were the:

- TOR & the inquisitorial and investigatory methodology employed by the Inquiry; and

- External exposure of this information.

In the moving stage the significant factors were:

- Changes in the dominant group views and behaviours;
- Empowerment of staff;
- Leadership developed at all levels;
- Increased power of patients;
- External monitoring; and
- Increase political and consumer pressure for improvements.

The refreezing stage involved the:

- Development of new processes, procedures and policies

These critical factors are now presented in the context of an expanded model of change based on Lewin's (1951) model.

MODEL OF CHANGE: POST INQUIRY CHANGES IN CLINICAL GOVERNANCE PROCESSES AT KEMH

The central research question for this study was: *Did the Douglas Inquiry influence changes in the clinical governance systems at KEMH in specific areas of: medical credentialing and clinician performance management, and the involvement of consumers in care.* To facilitate answering this question several specific questions were identified. To reiterate, these were:

Were there changes in the medical credentialing and clinician performance management systems post Inquiry?

Were there changes in the involvement of consumers in care post Inquiry?

If the Inquiry did influence change in the specific areas, how and why?

If the Inquiry did not influence change in the specific areas, why not?

The discussion to date has detailed the findings in relation to these questions. The following model (Figure 23 below) brings together the findings from the data analysis and the resultant discussions of the findings with reference to the literature. Based on Lewin's (1951) theoretical perspective discussed above, this expanded model answers the central research question by demonstrating that there were changes in some areas and not in others. The factors from the inquiry that influenced the changes are identified. The model provides a graphic explanation as to why these factors influenced the change process in the way they did.

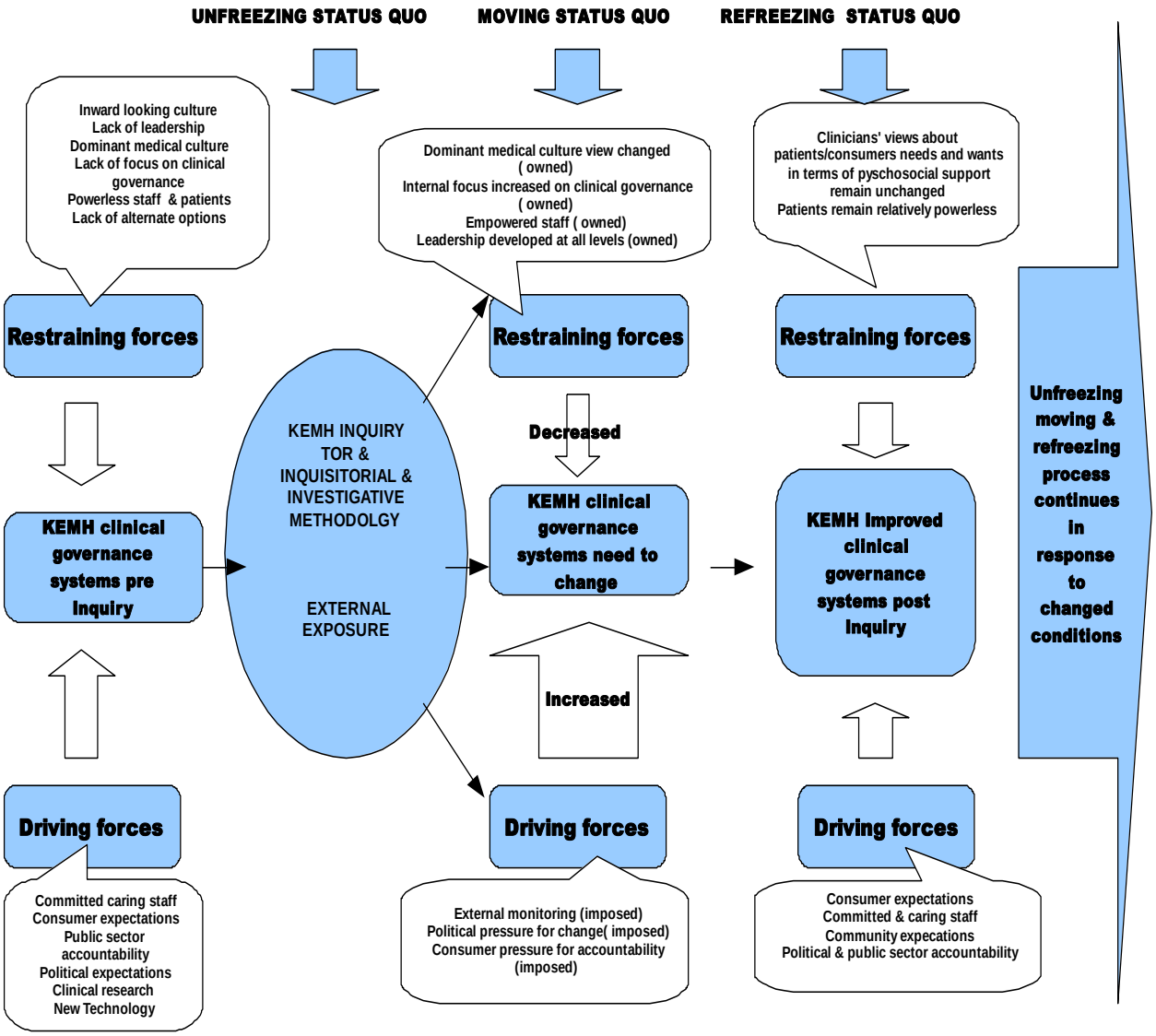


Figure 23: Model of Change applied to KEMH pre and post Inquiry (Based on Lewin's (1951) model of change)

As discussed in Chapter 2, this case study is an instrumental study in that the Inquiry into KEMH was a significant case and as such, studying the outcomes at KEMH post Inquiry may provide insight to the vexed question of how to improve clinical governance systems and prevent further healthcare failures. The significance of the findings from this case study and the possible transferability of these findings, are presented as a proposed conceptual model for change to improve clinical governance systems.

CONCEPTUAL MODEL OF CLINICAL GOVERNANCE CHANGE

In developing the research methodology, and describing the boundaries of the case of interest for this study, several aspects were identified that indicated that potentially the findings from this research may be transferable to other similar contexts. These aspects, detailed in the first two Chapters, recognised the use of a case study to provide understanding of a broader issue (Creswell, 2007; Punch, 2005; Stake, 1995; Yin, 2003). In addition, a further aspect to support the possibility of generalisability or transferability is that KEMH, as a public sector acute tertiary metropolitan hospital context, has many similarities with other public sector hospitals' contexts (Duckett, 2003; Eager, 2004; Hindle, 2003). Thus, significant findings from this research, which have been identified as those that have influenced change, may have generalisability or transferability to other similar situations.

The expanded model, which builds on Lewin's (1951) model, identified that there were significant factors that influenced the unfreezing of the pre Inquiry status quo. These were the TOR and the investigatory and inquisitorial methodology of the Inquiry, and the external exposure with resulting internal and external pressure for change. Thus, the critical factors were the capability to gather evidence disconfirming current group views and behaviours, and external scrutiny. If these factors were to be applied generally to other organisations to decrease those restraining forces acting as barriers to change then a process with the following elements would be required:

- Recognition and acknowledgement by the stewards of the system that there is a possibility that an organisation is not performing within the area of clinical governance as well as it should be;
- An external review process with the powers and capability to collect data demonstrating the gap between current and optimal performance;

- Disconfirming data is promoted in a way that that will ensure that confrontation with the facts of the data by the majority of the dominant cultural group is unavoidable. This leads to changes in group views, norms and behaviours, which induces an increase in leadership for change from within organisation and empowers individuals to drive changes;
- Disconfirming data is promoted in a way that is transparent to the public – with the resulting consumer and political pressure for change; and
- Ongoing external process to report and monitor improvements.

This proposed model of change for clinical governance system and process improvement is presented below in Figure 24. This model incorporates the elements identified above and ensures that the forces for change have a strong element of being owned by the group rather than predominantly imposed on the group. Without these factors, challenging the dominant cultural paradigms that sustain group views and behaviours would make it difficult to achieve improvements in clinical governance systems and processes.

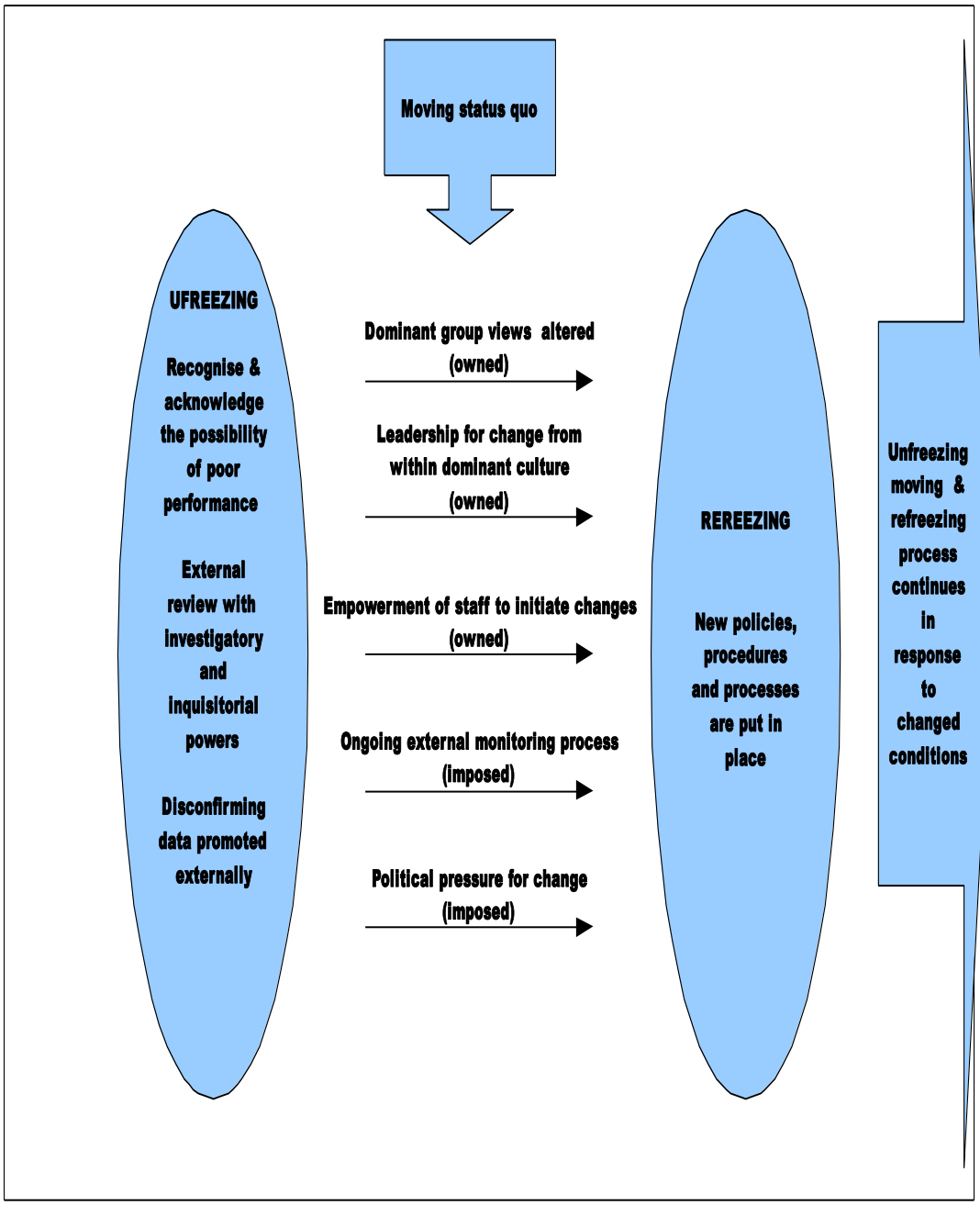


Figure 24: Conceptual model of change for clinical governance system and process improvement

CHAPTER SUMMARY

The focus of this chapter was a discussion of the findings of this case study with reference to other research studies reported in the literature. Lewin's (1951) theory as applied to change processes was presented to answer the research question: Did the Douglas Inquiry influence changes in clinical governance at KEMH? The findings of this study were

considered in relation to the possibility that they could be generalised to other similar healthcare organisations. Within this discussion, a conceptual model for improving clinical governance was presented. The final chapter will identify the limitations of this research and discuss some implications for the future.

CHAPTER SIX

LIMITATIONS, RECOMMENDATIONS, IMPLICATIONS FOR FUTURE RESEARCH, AND CONCLUDING THOUGHTS

There is no law of nature that says that energy and working hard must produce a forward or beneficial effect. Energy will only produce an effect when it is coordinated towards action"(De Bono, 1991:2)

INTRODUCTION

The final chapter in this report presents a brief overview of the research study. This is followed by a discussion of the limitations of this study. Recommendations arising from the study are noted and some suggestions are made in regards to further research. The report concludes with some final reflections in regards to clinical governance change.

RESEARCH OVERVIEW

The purpose of this study was twofold. Firstly, to ascertain if inquiries into healthcare failures lead to changes in the clinical governance systems and secondly, to identify factors within the Inquiry that may have influenced changes either in a positive or negative way. The review of the current literature in the early stages of this report clearly identified that there are significant issues with patient safety in hospitals. This is evidenced by a lack of improvement in the adverse events rate and the series of high profile health system failures in the last few years (IOM, 2000). A case study strategy was chosen as the framework for the study. This strategy was chosen as it provides a framework to investigate and understand a contemporary phenomenon bounded by space and time. The conclusions from the data analyses identified that there were critical factors within the Inquiry, and the Inquiry processes, which influenced

improvements in the clinical governance systems examined. These factors were the TOR and the investigative and inquisitorial processes employed by the Inquiry. These critical factors led to alteration of the dominant group views and behaviours within KEMH and an increase in political and community pressure for improvements in, and accountability for, clinical governance change. Absence of one of these critical factors resulted in the Inquiry reinforcing the existing barriers and thus, in those areas there was no change. A proposed model of change was presented, based on Lewin's (1951) model of change, but enhanced to incorporate the significant findings of this research.

This chapter will conclude with a discussion about the limitations and strengths of the research, recommendations for the future, implications for further research and some concluding thoughts about clinical governance change.

LIMITATIONS

In this study, there are three foremost limitations. The first relates to the choice of interview participants as those who were external to the organisation. Justification for using this sample was discussed in detail. Nonetheless, the external participants perceptions are only one viewpoint and it would certainly be valuable to gain the perceptions from others stakeholders' standpoints.

As this study focused on two areas of the clinical governance systems at KEMH post Inquiry there are other clinical governance areas that have not been assessed to ascertain if there have or have not been improvements post Inquiry. Justification for choosing the particular areas studied for this research is discussed extensively elsewhere in this report. Nevertheless, there were other clinical governance issues that were the subject of a considerable number of recommendations in the Inquiry report. Considerable resources, which were beyond the scope of this study, would be required to subject these additional areas to case study

examination. Findings from such a study however, could potentially strengthen the argument for those critical factors identified in this study to become agents of change in the future.

As discussed above, there are differing views about the question of whether findings from a case study are generalisable or transferable to other contexts. There is, though, some agreement that given an in-depth description and well-defined boundaries, a representative case would give insight to other similar contexts. The limitations of this case study's generalisability or transferability are the contexts to which it could be applied. The main features that could be applied to another setting are that the context would be a large, tertiary, metropolitan hospital, where barriers preventing clinical governance improvement are present. The literature reviewed for this study clearly identifies that the difficulties in achieving sustained improvement in clinical governance is not restricted to large, tertiary, metropolitan hospitals. Knowledge and understanding of clinical governance improvement challenges therefore, would be improved significantly if the other contexts were also studied.

The articulation of these limitations has implications for further research imperatives. These and other recommendations will be discussed in the following section.

RECOMMENDATIONS

There are two prime recommendations arising from this study. Firstly, the Inquiry and the Inquiry processes were the identified mechanism for unfreezing the status quo at KEMH. Inquiries are however, resource, time, and professionally and personally intensive. There is an urgent need to identify if inquiries are the only mechanism to unfreeze the status quo or if there are other less harsh ways to gather meaningful objective data that will challenge the dominant group culture views and behaviours. This mechanism would need to be one that demonstrates to clinicians convincingly that there is a gap between the current and the desired state.

There may be opportunities to harness the current hospital accreditation processes such as ACHS reviews, or the current public sector performance reporting mechanism. These processes however, currently lack two important factors that this case study identified as key aspects to clinical governance change. The first is the, investigative and inquisitorial processes, since the current processes rely on organisational self-generated data that may or may not be thoroughly and deeply investigated and probed. Without this feature, there is no surety that the data portrays the full picture of the status. The second important factor is that clinical governance performance data generated currently is not publicised, disseminated widely, or in most cases, even available or accessible to the public. The challenge would be in adapting the current review and monitoring processes to meet these needs.

The second recommendation centres on the need for the education and training of clinicians. This case study identified that there are still improvements required concerning communication with, and involvement of, patients in their care. Education and upskilling communication programs should be developed, implemented and deemed compulsory for all clinicians at KEMH. Based on this case study the need to challenge group views and behaviours will need to be incorporated into the educational style chosen to deliver these programs. An experiential, or behavioural framework, which incorporates patients and consumers, may provide the understanding and comprehension required to breakdown the current views and behaviours. Further to this, these types of programs should be available and encouraged for all clinicians currently working in healthcare. As well, teaching programs should be developed and incorporated into undergraduate programs and at a postgraduate level. These types of programs should also form part of health management courses.

IMPLICATIONS FOR FUTURE RESEARCH

The importance and influence of the dominant medical culture as a powerful influence on the views and behaviours of other clinician groups was identified in the literature reviewed for this case study. At KEMH, the expression of this influence on the culture was identified at the Inquiry, and by participants, as a barrier to change. Further research is required to explore this influence, especially in relation to how this affects non-medical clinicians' behaviours. In seeking deeper understanding and awareness of this, ways to harness and reframe this influence as a positive force for change should be the goal of the research undertaken.

As identified in the overview of the research limitations presented above, this study focused on a very specific area of the clinical governance processes at KEMH post Inquiry. There would be considerable merit in undertaking a further case study to examine the other areas of clinical governance at KEMH that were the focus of recommendations of the Inquiry report. The purpose would be to identify if there have been changes in these areas and to identify if the influence of the Inquiry on these changes was the same as those identified in this study.

Also identified in the limitations was that the participants for this case study, were external stakeholders. Thus, an important area for further research is to seek other viewpoints. This could include those staff working within the organisation and also patients and consumers. These groups' point of view would provide an added dimension to understanding how and why improvements do, or do not, take place in clinical governance processes after an Inquiry.

A central tenet that underpinned the research results presented in this study is the dissonance between the perceptions of the clinicians and those of patients/ consumers as to what patients want in terms of

communication and involvement in their therapeutic interactions from clinicians. The evidence presented at the Inquiry, and the recommendations that arose from the Inquiry demonstrated clearly the differing viewpoints. Improvement in this area requires research in several areas. Firstly, to articulate precisely the differences in perceptions of the two groups as to the requirements for quality communication interactions. Secondly, to describe specifically the behaviours required from clinicians and patients/ consumers to make improvements in this area. Finally, further research is required to identify the optimal process to align patient and consumer expectations in regards to therapeutic interactions with clinicians.

This study has paved the way for further research to investigate the outcomes of other inquiries into health care failures. The Inquiry into KEMH has not been an isolated occurrence. There were several inquiries into healthcare failures in other hospitals prior to the KEMH Inquiry, and many since. It is important to investigate whether the results of this study are similar to other healthcare inquiries and hospitals that have been the focus of an inquiry. Although considerable time and resources would be required, the benefits of a case study utilising a multiple case design would potentially be more compelling in terms of validating the critical factors required if inquiries (or other such data gathering processes) can be a mechanism of change.

FINAL REFLECTIONS

The purpose of this study was twofold. Firstly, to ascertain if inquiries into healthcare failures led to changes in the clinical governance systems and secondly, to identify factors within the Inquiry that may have influenced changes either in a positive or negative way. A comprehensive portrayal of the case of interest identified as the Inquiry, the Inquiry processes and KEMH, recognised key elements of the Inquiry processes and methodology as pivotal in terms of influence on change at KEMH post Inquiry. The elements included the importance of the TOR and the

investigatory and inquisitorial techniques employed. The review of the pre Inquiry context at KEMH identified the barriers to change that were acting as restraining forces preventing improvements to the clinical governance processes This research demonstrated that the Inquiry influenced positively and negatively some of the barriers preventing improvements in the clinical governance systems pre Inquiry at KEMH. In doing so, some barriers were reduced and others not. However, there were still some other barriers to change that were not influenced at all by the Inquiry. These were a lack of continuity of leadership and the public sector and political focus on fiscal and efficiency outcomes. Since the Inquiry, there have been several changes of executive leadership at KEMH, several organisational restructures, and the focus on indicators of financial and human and material resource management has not decreased. The reality is that any organisational context is not static and this study provides an understanding of only one aspect of change. These changes must be viewed as part of a continuum of organisational life rather than as discrete and separate happenings. Improvements in clinical governance are still required because the external environment in which all KEMH operates is not static, and some deficiencies identified at the Inquiry have not all been remedied. The influence of the Inquiry as a mechanism for change however, may have reached its limit and thus other mechanisms will need to be identified.

This case study has made a significant contribution to understanding factors that facilitate the change process that leads to the improvement in clinical governance processes. An effective clinical governance system that provides a framework to ensure care delivery is of the highest standard, and achieves optimum outcomes for patients and families, remains a necessary and laudable goal. To realise this goal further research and commitment from all those involved in care delivery is vital.

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APPENDICES

Appendix 1: Research protocol audit tool

Appendix 2: Original list of documents requested from KEMH using FOI legislation.

Appendix 3: List of possible source organisations for Interview participants

Appendix 4: Example of email invitation to participate in the study

Appendix 5: Copy of information letter provided to participants

Appendix 6: Sample of FOI applications and responses

Appendix 7: Interview Guide

Appendix 8: Example of field note post interview

Appendix 9: Example of Journal Memo

Appendix 10: Consent form to participate in study

Appendix 11: Copy of Ethics Approval Letters

Appendix 12: List of Senior Executives at KEMH 1990-2000

Appendix 13: Summary of Child and Glover review

Appendix 14: Inquiry Terms of reference

Appendix 15: Example AMA statements commenting on Inquiry

Appendix 16: List of documents used to source evidence by the Inquiry during their investigations

Appendix 17: Full list of Inquiry recommendations concerning medical credentialing and clinician performance review

Appendix 18: Full list of Inquiry recommendations concerning consumer involvement

Appendix 19: List of source documents used to identify changes in consumer involvement post Inquiry

Appendix 20: Full response to second FOI request to KEMH re information about training workshops