

**GISBORNE HOSPITAL
1999 - 2000**

A report

by the

Health & Disability Commissioner

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Table of Contents

	Page
Executive Summary	
1. Introduction and Environment	
Introduction	
Environment	5
Nursing issues	12
Relations with Maori	16
Opinion	18
2. Quality Assurance Systems	
Introduction	20
Quality planning process	25
Perceptions of quality	26
Quality activities and related issues	27
Leadership	36
Education and training	38
Opinion	41
Recommendations	44
3. Incident Reporting and Complaints Procedure	
Introduction	46
External review	46
Scope of Incident and Complaint Management Policy	47
Practical issues related to incident reporting	49
The complaints procedure	55
Opinion	59
Recommendations	62
4. Operating Theatre Protocols, October 1999 - June 2000	
Introduction	67
Dr Lucas' employment	68
Re-use of syringes	72
Throwing syringes and bloody needles	83
Ripping or cutting patients' gowns	86
Inappropriate use of ice	89
Tilting the operating table	97

	Page
4. Operating Theatre Protocols, October 1999 - June 2000 (continued)	
Fentanyl incident	101
Methods used to induce children	107
Mixing of opiates	113
Failure to document medication	114
Unlabelled syringes	118
Waking patients early and putting conscious patients in the lithotomy position	120
Refusal to attend patient in recovery	125
Incident reporting	130
Summary Opinion	132
5. PSA Testing Procedures, April 1998 - June 2000	
Introduction	134
Prostate Specific Antigen (PSA) Testing	134
What went wrong?	139
Response of Tairawhiti Healthcare	148
Organisational, management and institutional factors	156
Problems of a small and isolated laboratory	162
Opinion	162
Recommendations	169
6. Patient Care in ICU and Surgery, April-May 2000	
Introduction	173
How and why the nurse raised concerns with NZNO	174
Review of ICU patients' files	175
Quality assurance in ICU	175
Opinion	177
Appendix	188
Glossary	193

EXECUTIVE SUMMARY

1. BACKGROUND

- 1.1 In June 2000, Gisborne Hospital became the focus of concerns about patient safety, after the New Zealand Nurses Organisation (NZNO) wrote to the Minister of Health and spoke to the media. The admitted re-use of syringes by visiting Canadian anaesthetist, Dr Brian Lucas, and the potential risk of disease transmission to patients, was widely published.
- 1.2 Alarm increased when Tairāwhiti Healthcare Ltd (THL) announced in July 2000 that an error had occurred in Prostate Specific Antigen (PSA) testing at the Gisborne Hospital laboratory. Approximately 117 patients were notified of the error and advised to consult their general practitioners about the need for re-testing.
- 1.3 Against this background, I initiated an inquiry into patient care and quality assurance systems at Gisborne Hospital, with the following terms of reference:

“As a result of allegations concerning standards of patient care and quality assurance systems at Gisborne Hospital, the Health and Disability Commissioner, Ron Paterson, is to commence an independent inquiry under section 35(2) of the Health and Disability Commissioner Act 1994.

The following matters will be investigated to determine whether any action by Tairāwhiti Healthcare Limited or any individual health care providers at Gisborne Hospital has breached patients’ rights under the Code of Health and Disability Services Consumers’ Rights:

- Operating theatre protocols and compliance with such protocols between October 1999 and June 2000
- Quality assurance systems at Gisborne Hospital including incident reporting protocols and systems
- The handling of incidents reported by staff between October 1999 and June 2000, including the issue of re-use of anaesthetic syringes
- Allegations of inadequate standards of patient care in surgical and intensive care services in April and May 2000
- PSA testing procedures from April 1998 to June 2000.”

- 1.4 During the course of my inquiry, the Minister of Health dismissed the Board of THL in July 2000 and appointed Mr Wayne Brown as the interim Chairperson. The Chief Executive, Ms Sheryl Smail, resigned in October 2000, and was replaced by Mr Jim Green in December 2000.

The investigation

- 1.5 An extensive investigation was undertaken from July through September 2000. Seventy-eight people were interviewed, including patients, staff, management, NZNO representatives, community organisation representatives, and members of the Māori community. The majority of

interviews occurred in Gisborne. Five hui were held at Gisborne, Te Karaka, Tolaga Bay, Te Puia and Ruatoria.

- 1.6 Independent expert clinical advice was obtained from nursing and medical advisors, including an anaesthetist and a chemical pathologist, in October and November 2000.
- 1.7 A provisional opinion was written in December 2000 and sent in January 2001 to persons adversely commented upon, in accordance with the requirements of the Health and Disability Commissioner Act 1994, section 67(1)(a).
- 1.8 In February 2001, the responses of persons sent a copy of the provisional opinion were received, further information was gathered and expert advice sought. The final report was submitted in March 2001.

2. SUMMARY FINDINGS

- 2.1 Patient care at Gisborne Hospital in 1999-2000 was suboptimal for some patients in the operating theatre (on whom anaesthetic syringes were re-used) and some laboratory patients (whose PSA test results were incorrect).
- 2.2 The affected patients were contacted by THL as part of a “look back” programme. This was distressing for them and their families and whanau, but thankfully no one suffered any physical harm.
- 2.3 Tairāwhiti Healthcare was an unhappy organisation in 1999-2000, marked by suspicion and distrust between management and staff. Some doctors and nurses felt powerless and thought that patient safety was at risk. Quality assurance systems – including incident reporting and complaints handling – were not up to scratch. This did have the potential to compromise patient safety.
- 2.4 The level of concern generated by NZNO’s actions and by publicity about Gisborne Hospital in mid-2000 seems disproportionate in light of the findings in my report. It is unfortunate that the incidents in theatre and intensive care could not have been resolved within the organisation. A culture of teamwork and trust needs to be developed.
- 2.5 I have made a number of specific recommendations, which have been accepted by Tairāwhiti District Health Board, to address problem areas identified by my investigation.
- 2.6 Although improvements in some areas are needed, the people of Gisborne and Tairāwhiti should be reassured about the safety of the services spotlighted in my report. There is reason to be confident about the future of Gisborne Hospital under the Tairāwhiti District Health Board. It is time for clinical staff and management to make a fresh start in the co-operative endeavour that should be at the heart of any hospital: safe and effective care for patients.

3. THE ENVIRONMENT

- 3.1 My investigation team found a traumatised community within Gisborne Hospital, and a worried community beyond. Relationships between management and clinical staff were strained. Senior doctors and nurses felt disenfranchised, unable to exercise an effective clinical voice in management decisions. Suspicion and distrust was endemic, and senior managers were targets for criticism.
- 3.2 THL instituted major changes, including restructuring of the medical and surgical wards and the nursing workforce, in 1999-2000. The key driver for the changes was the financial imperative for THL to live within its budget. Senior managers saw the necessary changes as an opportunity to improve clinical practice, but encountered opposition from a workplace culture that was resistant to change.
- 3.3 Relations between THL and the large Maori community that it serves in Gisborne and the Tairāwhiti region need significant improvement. This presents both a challenge and an opportunity for the Tairāwhiti District Health Board.

4. QUALITY ASSURANCE SYSTEMS

- 4.1 Tairāwhiti Healthcare had a plethora of quality processes in 1999-2000. But the system was largely lines on paper. The reality of poorly co-ordinated activities and insufficiently involved staff did not match the rhetoric about quality.
- 4.2 Professional leaders, who play a vital role in promoting good quality healthcare within a hospital, have been missing from Gisborne Hospital. There was no Director of Nursing from August 1999 to July 2000, and (apart from a brief interlude) there has been no Medical Director since April 1999.
- 4.3 The key quality activity in 1999-2000 was seeking accreditation after the failure to gain accreditation in a Quality Health New Zealand survey in July 1999. Paradoxically, an unrealistic push for accreditation in 2000 seems to have diverted staff from sustained and embedded quality improvement.
- 4.4 Problems with incident reporting in theatre, and lapses in quality control in the biochemistry section of the laboratory, were symptomatic of a failure to 'close the quality loop'. Staff and management contributed to this failure, which had the potential to adversely affect patient care.
- 4.5 THL's failure to provide a quality assurance system with due care and proper co-ordination amounted to a breach of Right 4(1) and Right 4(5) of the Code.

5. INCIDENT REPORTING AND COMPLAINTS PROCEDURE

- 5.1 The THL Incident Reporting and Complaints Management Policy is unsatisfactory in a number of respects. It fails to differentiate between incidents (situations where harm could have occurred) and adverse events

(situations where harm does occur, due to a health care intervention). It fails to capture “near misses” as a category of incidents.

- 5.2 The current policy has also proved problematic in practice. There are no guidelines for completion of incident reports, no mechanism to track filed reports, and inconsistency about which incidents are drawn to the attention of the Senior Management Group.
- 5.3 Where incidents were reported in the period under review, THL paid lipservice to the concept of root cause analysis, but staff personally involved in the incidents experienced criticism and blame. Incident reporters often received no feedback.
- 5.4 Quality and continuity of care for patients at Gisborne Hospital was potentially compromised by the failure to have an effective incident reporting system, and THL therefore breached Right 4(5) of the Code.
- 5.5 Complaints were also not well handled by THL. The complaints database was incomplete and the response to complainants was variable. The policy does not ensure that consumers are informed of any relevant internal and external complaint procedures, and THL therefore breached Right 10(6)(b) of the Code.

6. OPERATING THEATRE PROTOCOLS, OCTOBER 1999 –JUNE 2000

- 6.1 A raft of allegations of inappropriate conduct in operating theatre by Canadian anaesthetist, Dr Brian Lucas, was central to staff concerns at Gisborne Hospital, the NZNO decision to intervene, and my investigation.
- 6.2 I found that Dr Lucas was a skilled and competent anaesthetist, who complied with professional standards, but who got offside with nurse and anaesthetist technician colleagues. The majority of the allegations against him were unsubstantiated.
- 6.3 Dr Lucas’ admitted re-use of syringes did, however, expose patients to a tiny but avoidable risk of infection, which necessitated a “look back” programme for affected patients. No evidence of disease transmission was found. By failing to provide services in a manner that minimised harm to patients, Dr Lucas breached Right 4(4) of the Code.
- 6.4 On some occasions Dr Lucas failed to dispose of sharp instruments in theatre in an approved manner, in breach of a Gisborne Hospital protocol and therefore in breach of Right 4(2) of the Code. No actual harm to any patient resulted.
- 6.5 On two separate occasions Dr Lucas failed to comply with the legal requirements of informed consent, and breached Right 6(1)(b) and Right 7(7) of the Code respectively.

7. PSA TESTING PROCEDURES, APRIL 1998 – JUNE 2000

- 7.1 The biochemistry section of the Gisborne Hospital Laboratory has had a troubled history. Problems have included periodic lack of a resident

pathologist, staff shortages and professional isolation, and have resulted in de-registration by International Accreditation New Zealand (IANZ) in 1992, 1998 and July 2000, after the PSA problem was discovered.

- 7.2 The PSA testing errors, which affected 500 test results and 117 patients, were due to failures of quality control and human error.
- 7.3 The head of the biochemistry section of the laboratory, Mr John Rutledge, made serious errors of judgment. He failed to comply with relevant standards and breached Right 4(2) of the Code.
- 7.4 THL failed to address the systems problems that IANZ had highlighted, and bears organisational responsibility for the lapses that occurred. THL's failure to exercise due care was a breach of Right 4(1) of the Code.
- 7.5 Fortunately, none of the 117 affected patients suffered any harm apart from the distress of being notified of the error and the need for re-assessment.

8. PATIENT CARE IN ICU AND SURGERY, APRIL – MAY 2000

- 8.1 The NZNO letter to the Minister of Health called for an independent audit of standards of care in the Intensive Care Unit (ICU) and surgery in April and May 2000. The attached anonymous letter from a senior ICU nurse described five patient care situations as examples of safety concerns.
- 8.2 THL commissioned a confidential independent review of the files of 10 patients admitted to ICU in April and May 2000, which concluded that overall the standard of care was impressive.
- 8.3 Recommendations by external reviewers of ICU and the incident reporting system at Gisborne Hospital have been, or are being, implemented. This follow-up, and Tairāwhiti District Health's positive response to the recommendations in my report, reassure me that the public can have confidence in the standard of patient care in ICU and Surgery at Gisborne Hospital.
- 8.4 The five cases referred to in the anonymous letter are not dealt with in my report. They are being dealt with under the Health and Disability Commissioner's standard investigation processes and will be reported on separately. Those investigations will be confidential to the persons involved.

Chapter 1

Introduction and Environment

1. INTRODUCTION

Concerns about patient safety at Gisborne Hospital

- 1.1 On 13 June 2000 Brenda Wilson, Chief Executive of the New Zealand Nurses Organisation (NZNO), visited Gisborne Hospital and met with nursing staff. Ms Wilson also met briefly with the Chief Executive and advised in general terms that, on the basis of her discussions with nursing staff and local NZNO representatives, she had a number of serious concerns about patient safety at Gisborne Hospital. Specifics were not discussed.
- 1.2 On 14 June NZNO wrote to the Minister of Health expressing concern about standards of care at Gisborne Hospital, seeking an independent review and noting that NZNO would not have confidence in a review undertaken by the Ministry of Health. This letter attached two documents: the first, a memorandum dated 1 June 2000 from a regional NZNO representative to NZNO head office outlining a number of issues of concern in relation to Dr Lucas – including re-use of anaesthetic syringes and Gisborne Hospital's response to this issue; the second, an anonymous letter from a nurse at Gisborne Hospital which expressed concerns about “increasingly poor levels of medical, surgical and management practices and accountability”. The writer described five recent cases of alleged inadequate patient care. These documents are set out in the Appendix.
- 1.3 Tairawhiti Healthcare Ltd (THL) learnt of NZNO's complaint to the Minister of Health and its concerns about patient safety from a Radio New Zealand news story the following day, 15 June. In a discussion with NZNO representatives on 20 June, the Chief Executive requested that NZNO provide Tairawhiti Healthcare with the names of patients cited in the anonymous letter, so that it could investigate. NZNO refused to provide the names of the patients and instead responded by advising that it wanted an independent retrospective audit of ICU and surgical cases over the last three months. The reason NZNO gave THL for refusing to provide the names of the patients was that the nurse who had provided the information requested anonymity.
- 1.4 In a Radio New Zealand interview on 16 June, NZNO called for an investigation by the Health and Disability Commissioner. This call was repeated in the media over the following days. However, at no stage did NZNO approach the Commissioner and exercise the right that any person has under section 31 of the Health and Disability Commissioner Act 1994 to make a complaint to the Commissioner.
- 1.5 By a letter to NZNO dated 23 June, the Chief Executive again requested the names of the patients and stated that “it is simply not acceptable (legally or ethically) for registered health professionals to refuse to disclose to the HHS [public hospital] relevant information, while complaining to other authorities

about lapse of care in relation to specific patient It is essential that I have this information to investigate the concerns.”

- 1.6 By a letter to the Chief Executive dated 28 June, NZNO stated that it was “absolutely aware of nurses’ obligations to report adverse incidents [and] also aware of how risky this proves to be for individual nurses”, and that it held no further information, “apart from that which may identify the nurse making the complaint”. NZNO stated that “we should be ashamed that the element of fear which permeated the New Zealand Health Service under the previous administration has resulted in nurses’ inability to raise concerns with their own management”. The letter was copied by NZNO to the Minister of Health.
- 1.7 The Minister of Health and THL both signalled their intention to inquire into the quality of care at Gisborne Hospital in response to the NZNO allegations, which had been extensively covered in the media.
- 1.8 In these circumstances, as Health and Disability Commissioner I considered the allegations and the mounting public concern, and decided to commence an independent investigation into patient care and quality assurance systems at Gisborne Hospital. The first four terms of reference were announced on 30 June 2000.
- 1.9 THL then became the subject of further allegations, this time involving the Gisborne Hospital laboratory and allegations of inaccurate PSA testing (used as an indicator of prostate cancer). On 12 July 2000 the terms of reference of my investigation were extended to cover the laboratory issue.

Terms of Reference

- 1.10 On 30 June 2000 I announced the following terms of reference for an inquiry into patient care and quality assurance at Gisborne Hospital:

“THE HEALTH AND DISABILITY COMMISSIONER’S OWN INITIATIVE INQUIRY INTO PATIENT CARE AND QUALITY ASSURANCE SYSTEMS AT GISBORNE HOSPITAL

As a result of allegations concerning standards of patient care and quality assurance systems at Gisborne Hospital, the Health and Disability Commissioner, Ron Paterson, is to commence an independent inquiry under section 35(2) of the Health and Disability Commissioner Act 1994.

The following matters will be investigated to determine whether any action by Tairāwhiti Healthcare Limited or any individual health care providers at Gisborne Hospital has breached patients’ rights under the Code of Health and Disability Services Consumers’ Rights:

- Operating theatre protocols and compliance with such protocols between October 1999 and June 2000;

- Quality assurance systems at Gisborne Hospital including incident reporting protocols and systems;
- The handling of incidents reported by staff between October 1999 and June 2000, including the issue of re-use of anaesthetic syringes;
- Allegations of inadequate standards of patient care in surgical and intensive care services in April and May 2000.”

The terms of reference were extended on 12 July 2000 by the addition of the following term of reference:

- “PSA testing procedures from April 1998 to June 2000.”

- 1.11 During the course of the inquiry, the Minister of Health dismissed the Board of THL on 12 July 2000 and appointed Mr Wayne Brown as the interim Chairperson. The Chief Executive of THL, Ms Sheryl Smail, resigned at the end of October 2000, and was replaced by Mr Jim Green, formerly of Northland Health, on 4 December 2000.

The Investigation Team

- 1.12 The investigation team included two clinical advisors and a project manager:

Dr Sharon Kletchko BMSc, MD, FRCPC, Cert Neph, FRACP, FACEM
 Mrs Debbie Penlington RGON, BA (Nursing), M Ed
 Mrs Alyson Howell M Phil, BA.

Additional clinical expertise was obtained from:

Dr A N Barker BSc, MBChB, MSc, MAACB, FRCPA
 Dr Malcolm Futter BSc, MBBS, FRCA, FANZCA.

How the investigation was conducted

- 1.13 I visited Gisborne Hospital with my investigation team for the first time on 17 July 2000. Open meetings were held with staff and management to brief them on the process of the investigation. Posters were placed around the hospital to ensure that all staff knew about the process. Advertisements were placed in the local newspaper. The Health and Disability Commissioner’s 0800 number was advertised to ensure staff could make confidential contact with the investigation team. THL staff co-operated fully with the investigation team to ensure that staff knew about the investigation.
- 1.14 Some staff were approached by the investigation team and invited to take part in the interview process. Other staff came forward of their own volition. Seventy-eight people were interviewed (and six people were re-interviewed). The majority of interviews occurred in Gisborne. Five hui were held in Gisborne, Te Karaka, Tolaga Bay, Te Puia and Ruatoria. Current and former

staff and THL made extensive documentation (1142 documents) available to the investigation team.

1.15 The people and organisations interviewed included:

- Patients of Gisborne Hospital
- The relatives of former patients
- Members of the Maori community
- Current nursing staff
- Current anaesthetic technicians
- Support staff
- Current medical staff
- Former medical staff
- Current laboratory staff
- Former laboratory staff
- Management staff
- Former management staff
- Former directors of THL
- Representatives of unions
- Representatives of community organisations.

Two people were interviewed by conference call. All other interviews were conducted face-to-face.

1.16 My investigation team was not prepared for the visible distress shown by clinical staff during their interviews. The events leading up to my inquiry, and the process of coming forward to give evidence, was obviously upsetting for many interviewees.

1.17 The Health and Disability Commissioner's staff took notes of the interviews. These notes, once transcribed, were returned to the interviewees for checking and signing, and were used as the source material for the report writing process.

The report

- 1.18 This report is based primarily on information gathered between July and September 2000, and refers principally to events that took place in 1999 and 2000. The employees of Tairāwhiti Healthcare referred to are those employed as of that time, not as at the publication of this report. For example, the references to the Chief Executive relate to Ms Sheryl Smail and not to the new Chief Executive, Mr Jim Green.
- 1.19 For the most part, events in this report are described referring to the positions held by people, rather than by their names. There is a Glossary of positions, names and dates of tenure, and of abbreviations, at the end of the report.
- 1.20 The allegations made are contained in the Appendix. It is important to understand the environment out of which these allegations arose. A description of the environment at Gisborne Hospital in 1999-2000 follows.

2. ENVIRONMENT

Financial pressures

- 2.1 In 1998-99 THL faced challenges similar to most smaller New Zealand public hospitals. There was a need to rationalise physical and human resources, provide safe care in a region isolated geographically, and meet financial imperatives. THL had a budget of \$40 million and was faced with an overspend of 20% (\$8 million). There were clear signals from Wellington that THL needed to work itself out of financial difficulties, as a priority. The shareholders and the Board embarked on a process of reform to ensure that spiralling costs were halted and that it kept within budget. To this end, Business Plans and company objectives were developed and endorsed by the Board. It is difficult to over estimate the impact of the changes that ensued.
- 2.2 The Chief Executive explained:

“The organisation was in major difficulty financially, not only making a major loss but also vastly over spent against budget by 31 December 1995. Both medical and nursing staff expressed strong dissatisfaction to me with the status quo. There was no nursing position above that of charge nurse, nor medical director. While there was a high level of consensus processes among the service managers, this did not extend into the organisation and the processes used did not result in actions to achieve Business Plan commitments nor to resolve the difficulties that the organisation had.”

Major changes

- 2.3 The Ministry of Health, in its final clinical review of THL's Business Plan, in November 1998, noted the breadth of the planned changes, and referred to the following examples:

“The amalgamation of four wards into one; downsizing medical/surgical, maternity and A,T&R bed numbers; changes to the staff's employment conditions; the introduction of a number of clinical pathways; ambitious targets for reducing the average length of stay; and there will be some redundancies.”

- 2.4 The Ministry's clinical review highlighted the critical importance of gaining the support of staff for such a raft of changes:

“The HHS [public hospital] advises that there is variable support for the above changes amongst the clinical staff and in particular, the clinicians are concerned about the planned reductions in bed numbers. You will be aware from our previous clinical reviews that the Ministry is concerned that the HHSs involve staff in the development of major initiatives, such as those proposed by THL, and ensure that the initiatives are supported by staff. We consider that support from staff will be critical to the success of the initiatives, and we are concerned about the effect on staff morale when a number of operational changes are implemented in a short space of time. We note that the HHS also recognises this as a risk and has made some efforts to engage the clinical staff in the changes.”

- 2.5 In the event, staff were not supportive of the changes that occurred in 1998 and 1999. As in many organisations undergoing a major change management exercise, senior management - in particular the Chief Executive (Ms Sheryl Smail) and the Group Manager (Community and Support Services) (Mr Mike Grant) - became the focus of concerns and unhappiness about the process of change and the decisions that were implemented.

Strained relations

- 2.6 The position of Chief Executive in a New Zealand public hospital setting is demanding. There is a large, highly skilled workforce to manage along with the infrastructure associated with delivering safe and effective health care and meeting the expectations of the community. The staff and the community look to the Chief Executive for leadership.
- 2.7 Relationships between management and senior medical staff at THL were strained. The issues include clinical staff leadership, the difficulties experienced in recruiting and retaining staff, debate over the appropriateness of the current management structure, the role of Clinical Directors in the management of THL, and issues associated with some significant management decisions, for example, the reconfiguration of wards, the reduction of beds and the nursing restructuring.

- 2.8 Poor communication and consultation was cited as a reason for strained relationships between management and senior medical staff. A middle manager commented that previously Gisborne Hospital had a far better track record of consultation and staff involvement. The effect of the lack of consultation was described: “The reconfiguration of the adult medical surgical floors was never endorsed by staff, was carried out at great cost and has resulted in significant stress for staff, an inability to provide flexible services and risk to patient care.”
- 2.9 The former Chairperson of the Board gave an insight into the consultation environment at THL when she commented on the Board’s expectation that nursing staff would be consulted over the ward reconfiguration. The Chairperson stated that she “believes there was a level of consultation, but how much notice was taken of people’s comments is what begs the question”. She commented that “probably not a lot of cognisance was taken of concerns that were raised, because of the key driver to break even together with the low level of bed utilisation”.
- 2.10 The Chief Executive said that she was conscious of the need for effective communication and consultation. She gave presentations to staff on the proposed new structure, including a separate session for medical staff, at their request, and the proposal was modified in response to feedback from staff. She held monthly forums with “an open invitation to all staff ... to meet and hear directly from me the priorities the Board and management team were working on, and to discuss any issues and concerns”. The Chief Executive accepted that she was not “out and about in the organisation as frequently as I would have liked or staff would want”, but noted that “this is the experience of most if not all chief executives in the New Zealand health sector”.
- 2.11 However, the Chief Executive accepted that “with the quantum of financial savings that had to be achieved and the timeframe available, the approach I used was more top down than is ideal”. She did not accept that she was non-consultative.
- 2.12 Despite the Chief Executive’s efforts, and the presence of Clinical Directors on the Senior Management Group, senior medical staff felt increasingly disenfranchised. One senior doctor commented:
- “There is no forum for communication. Very few people want to speak out because they think the system will come down on them. Those people who want to stay are unwilling to participate in dialogue in an honest way because they feel the system will not support them.”
- 2.13 A Clinical Director stated that the management style of THL led to an adversarial relationship with medical and clinical staff and affected their behaviour over the last few years. In his view, morale had been declining progressively over eight years. He noted that the hospital was happy until the driving force was to stay within budget and save money. This change impinged on the quality of patient care and the focus and performance of clinical services. Senior medical staff reported making attempts to tell management of their concerns and said that often no action followed.

- 2.14 Senior nurses also felt disenfranchised, having no Director of Nursing to take their concerns direct to the Chief Executive. For example, some surgical nurses described feeling stymied in their efforts to be heard:

“Nurses are at a loss about whether they should take their concerns up another step because they are then told to take the matter back to their line manager. Systems seem to be in place that are designed to stop communication and other systems that do not promote it. Communication is a key issue. The nurses do not feel part of the process. Nurses are unable to approach other disciplines without going through their line manager.”

Suspicion and mistrust

- 2.15 A sense of not being supported by management led some clinical staff to develop negative perceptions of their organisation. The investigation team heard the organisation variously described as destructive to a person’s wairua, unappreciative of nursing staff, a dysfunctional family, lacking strong leadership and bureaucratic.

- 2.16 A senior doctor stated:

“The atmosphere at the hospital is one of suspicion and mistrust. Doctors and nurses do not feel supported by the system that exists Clinicians [feel] fatalistic about having an impact upon the system. There is no place to solve problems. There is no sense of ownership. To get the system to work I have come up against one barrier after another. The system was a) disorganised b) void of leadership amongst medical and management staff and c) communication is absent.”

- 2.17 Poor communication and consultation patterns were linked to the lack of trust between some senior managers and the workforce. In one doctor’s opinion this lack of trust was linked to the workforce’s unwillingness to fill out incident forms: “The problem in Gisborne is lack of trust between workforce and management Basically people did not have any faith in incident reporting and it was not due to the system – the system was robust enough.”

- 2.18 The Chief Executive responded that although she accepted “there were events which did not generate an incident form and should have”, she did not believe that staff at THL in general had this approach to incident forms.

- 2.19 Concerns were also expressed about the use of discipline at THL. It is inevitable that large organisations have a certain amount of disciplinary activity. However, a number of interviewees suggested that THL had used the disciplinary process in situations where good management practices may have prevented the breakdown in the relationship. THL responded that disciplinary action had been used sparingly and was reserved for serious situations where all other avenues of resolution had been exhausted.

Targets for criticism

- 2.20 The changes that the Group Manager (Community and Support Services) was responsible for were extensive. Many interviewees were highly critical of the role he played, and there was a strong perception amongst many clinical and other staff that he was central to the problems that occurred in the laboratory and other areas in which he was involved.
- 2.21 The Group Manager expressed the view that he would expect others to make critical comments about him: “Clinicians will provide a negative view of me. They see me as a change agent who took out millions of dollars in order to break even over the past 12 months.” His view was that what he had taken out he put back in a different way. One clinician observed that the Group Manager was “heir to all the grievances and misfortunes which may have nothing to do with him”.
- 2.22 The Chief Executive further noted:

“While with hindsight there were ways in which this process could have been improved, particularly in terms of communication regarding the outcomes sought, I believe it was inevitably going to be a difficult process with a high likelihood that because of the impact on individuals there would be negative reactions. I want to make it clear to senior medical staff that I see it as inappropriate to attach all the negative repercussions on [the Group Manager].”

- 2.23 In his own defence, the Group Manager pointed out:

“My management of change projects has involved 300 staff out of a total of 500 employees. It is inevitable that there will be critical comments emanating from within, however, there has not been one personal grievance associated with the management of change projects.”

- 2.24 The Group Manager (Hospital) (Mr Dan Madden) also attracted some criticism for his central role in the reconfiguration project. Some nurses felt that he did not effectively represent their views while he was Director of Nursing, and that their views about reconfiguration were not heard once he assumed the Group Manager (Hospital) role.

Workplace culture

- 2.25 The problems that developed at Gisborne Hospital can only be understood against the backdrop of the culture of the organisation.
- 2.26 The Group Manager (Community and Support Services) referred to the THL workplace culture – “the way we do things around here” – as “at the heart of the organisation’s difficulties in many aspects of service delivery”. He believed it was necessary to challenge the “closed family, provincial town thinking” in order to achieve the Board’s and shareholders’ objectives. He also felt a responsibility, as a senior manager, to “insist on clinical practice that ensures that the community of Gisborne receives the highest standard of

treatment” – for example, by pushing for the introduction of credentialling of medical staff at THL, a move that met a lot of resistance.

- 2.27 Many senior managers in New Zealand public hospitals encountered similar resistance to organisational changes that impacted on clinical staff in the mid to late 1990’s. It is clear that the statutory requirement for CHEs (Crown Health Enterprises) to operate “as a successful and efficient business” (Health and Disability Services Act 1993, section 11(1)) had a lingering impact. The financial imperative continued in the 1998-2000 period, notwithstanding the change in name to HHSs (Hospital and Health Services) and the revised requirement, from 30 June 1998, to operate “in a businesslike and effective manner” and “on a not for profit basis” (Health and Disability Services Act 1993, section 11(2), as amended by the Health and Disability Services Amendment Act 1998, section 5(1)).
- 2.28 What appears to have been distinct, though probably not unique, about THL compared with other New Zealand public hospitals is that initial resistance to necessary changes hardened into outright opposition and a breakdown in effective communication and co-operation between management and clinical staff.

Clinical voice in management

- 2.29 A common theme in interviews with medical staff was that there had not been an effective clinical voice in management at THL, and there were no real avenues for exchange of ideas between clinicians and managers.
- 2.30 The Chief Executive described the 1998 management restructure as being “driven by an attempt to involve the medical workforce in management”.
- 2.31 The Senior Management Group at THL included six Clinical Directors, together with the Director of Nursing Practice and the Medical Director. The Chief Executive described the Medical Director’s role as to “provide advice to the Chief Executive and the Board”. There have been two Medical Directors. The first appointment was from April 1997 to April 1999. The second was for a few weeks only, from May 2000. Since that time THL has had no Medical Director.
- 2.32 THL explained the overall management structure as follows:
- “THL has a management structure overall which is ‘bicameral’ – for every manager there is a clinician with equal status and responsibility in the management of the particular area. There is no ‘them and us’ approach to managing the organisation. A significant number of the managers have been, or are, registered health professionals. Clinical input is obviously essential to the functioning of the organisation as a whole. There is considerable irony that the complaints about the changes which took place in 1999 arise out of a determined effort by THL to involve clinicians more in management decision making at THL.”

THL also pointed to the numerous consultative committees for both medical personnel and nursing staff.

- 2.33 The Clinical Directors were pivotal to the success of the organisational structure. Changes to the Clinical Director role were agreed after consultation. The Chief Executive noted that, in relation to the changes to the Clinical Director role: “Medical staff felt that the changes did not go far enough and they would have liked more budgetary control Non-medical staff were however very apprehensive about the degree of control in medical hands.”
- 2.34 Several Clinical Directors expressed their frustration with the role: “The role was supposed to be about partnership between management and clinicians but that was not so. The bottom line was the budget. The Clinical Director was very much the subservient partner.”
- 2.35 THL denied there was any management policy to refuse to listen to clinical issues:

“Many of the decisions made were made with the agreement of nursing or medical representatives, and even where decisions were not met with universal approval, they were made after consultation with relevant stakeholders. Overall, THL feels that the complaints which the Commissioner’s investigators have heard from clinical staff tend to derive from dissatisfaction with some outcomes, as opposed to process. In the end, decisions have to be made based on all the usual constraints. It is inevitable that not everyone will agree with the changes. However, the board, through management, has the right to determine the governance of the hospital. Obviously agreement or consensus is preferred, but it cannot always be achieved, especially in an organisation in extremely straitened financial circumstances as THL was at the time.”

- 2.36 In response to the statement that there had been a communication breakdown that impeded the flow of information to clinical staff, THL commented:

“While obviously THL must accept some responsibility for this, the responsibility is two-way. Many clinicians were involved in management decisions or discussions. The purpose of having those clinical representatives was that those people would be able to discuss proposed changes with, or otherwise serve as a conduit of information to, their respective constituencies. It may be that many of those processes did not work ideally either. Information sharing is a dual responsibility. When failures occur, responsibility must also be shared for those failures.”

3. NURSING ISSUES

Introduction

3.1 The decision by THL to redevelop the medical and surgical wards, and restructure the nursing workforce, was linked by many interviewees with the events that sparked the terms of reference for this investigation.

3.2 The following themes consistently emerged in interviews with nursing and other staff:

- the lack of professional leadership and its impact, particularly during new initiatives such as the Clinical Career Pathway development and implementation of the redesigned nursing structure
- changes to the nursing structure (particularly to key leadership positions) and the impact of these changes
- consultation processes (eg, around the redevelopment of the physical layout) and the effectiveness of these processes
- the combined effect of the restructuring, the millennium and accreditation
- the non-responsiveness to concerns raised by nursing staff (eg, to the disestablishment of the Clinical Nurse Leader role in ICU)
- the nature of the work environment.

3.3 In response THL stated that “the Commissioner could uncover similar levels of complaint at any hospital under going major reconfigurations”. THL pointed to the success of recent configurations of other services at Gisborne Hospital, in the medical unit, ambulatory services, and the A&E Department. Finally THL noted:

“No configuration will suit all user groups. It is all a question of compromise given the physical and financial constraints.”

Ward reconfiguration

3.4 THL faced declining occupancy and what it identified as inappropriately configured ward spaces. To address these challenges THL proposed a single floor inpatient unit (SFIU). There was significant opposition from clinical staff to the reconfiguration of the medical and surgical wards.

3.5 The Chief Executive stated:

“Even with an ideal process it would have been a near impossible task to get endorsement by staff to reduce beds. This reluctance to accept a

reduction in beds was understandable and understood. As a high percentage of admissions to Gisborne Hospital are acute, the hospital has a very variable occupancy in the medical and surgical wards. Average occupancy may be low in a month when staff have had to tightly manage available beds for numerous days in the month.

Further, Gisborne Hospital had previously not experienced the tight management of beds and elective admissions required every day that has been accepted practice in most other hospitals in New Zealand and overseas for many years. For these reasons the number of beds in the reconfigured medical/surgical floors is higher than the statistical analysis showed was required.”

- 3.6 After working on the SFIU concept since 1 March 1998, management modified the proposal and adopted a dual floor inpatient service in April 1999, in response to the concerns expressed by clinical staff. THL said that this was an example of management being responsive, despite strong pressure to retain the single floor concept to maximise financial savings. This change in direction required further changes to the nursing structure plans, which were well under way.

Nursing leadership

- 3.7 Up until August 1999 the Group Manager (Hospital) (Ms Rachel Haggerty) and the Director of Nursing (Mr Dan Madden) worked together on the ward and nursing restructuring projects, with input from Clinical Directors. The Group Manager (Hospital) appointed the Director of Nursing as project team chair for the Nursing Professional Structure Review.
- 3.8 When the Group Manager (Hospital) left THL in August 1999, the Director of Nursing, Mr Madden, was duly appointed to that position and became the new Group Manager (Hospital). He took up the new position immediately.
- 3.9 It took eleven months for a new Director of Nursing to be appointed in July 2000. The Clinical Nurse Educator resigned on 14 January 2000, and at the end of October 2000 that position was still unfilled (although it has since been filled). Nurses were therefore without professional leadership (other than through the Nursing Reference Group) at a critical time.

Changes to the nursing structure

- 3.10 Charge Nurse positions were replaced in a restructuring exercise in 1998 by Nurse Unit Managers and Clinical Nurse Leaders (CNLs). Clinical Nurse Leaders provided clinical co-ordination and leadership at a local (ward) level. Nurse Unit Manager positions were created to manage the surgical and the medical services. In September 1999 Clinical Nurse Leaders were to be replaced by Clinical Nurse Specialists.
- 3.11 A special project, the Surgical and Adult Medical Service Nursing Professional Structure Review, was put in place in October 1998 with the purpose:

“To develop a professional nursing structure that supports the service development initiatives being planned in a single floor unit including:

Support best practice in nursing
 Redesign nursing leadership
 Reinforce the clinical career pathway for nursing
 Facilitate the development of multi-disciplinary teams.”

The nursing professional structure redesign was scheduled to be completed by 23 December 1998.

- 3.12 The Clinical Nurse Specialist (CNS) was to perform a crucial role. The positions were planned to provide front line nursing clinical leadership, with responsibility for patient assessment, care planning and evaluation, discharge planning, patient and staff education, maintenance of clinical standards, orientation, preceptorship and development of junior staff.
- 3.13 There was debate over how many CNS positions THL should have. The former Director of Nursing reported that the project group’s preferred option was to identify staff with clinical nurse specialist abilities through the Clinical Career Pathway (CCP) process. CNSs were to be people already employed at THL who had the necessary expertise, training and qualifications. Potentially THL could have any number of CNS positions in each team.
- 3.14 The former Group Manager (Hospital) advised that the CNSs were intended to co-ordinate the nursing interventions from the nursing workstations in the reconfigured wards. It is significant to the eventual outcome of the nursing changes that no appointments to the CNS positions were made at this time, since there were no applicants. To date no CNSs have been appointed.

Clinical Career Pathway

- 3.15 An essential building block for the successful restructuring of the wards was the introduction of a nursing Clinical Career Pathway (CCP) process. A clinical career pathway would ensure that a pool of nurses with the appropriate skills would be identified and ready to deliver the type of care appropriate to the reconfigured wards.
- 3.16 As the success of the CCP process depended on identification of staff with clinical nurse specialist skills, the fact that no one came forward and there was no leader promoting the CCP process doomed it to failure.
- 3.17 THL made the following comments about the attempt to introduce a Clinical Career Pathway:

“The CCP initiatives that were attempted to be introduced at THL have been run successfully elsewhere in the country. Why did this fail in Tairāwhiti? ... A clinical career pathway is a well recognised and accepted process for developing nursing. However, in Tairāwhiti, the staff associated implementation of a CCP process with the restructuring.

CCP fell into disfavour and was avoided by nurses [even though] CCP implementation and management occurred within the consultation framework set out in the collective employment contract between THL and the NZNO.”

- 3.18 Embarking on a radical restructure of nursing structure without the foundations of a CCP framework in place meant that nurses were unable to connect the proposed changes to their own personal career development needs. Positions and responsibilities were disestablished before the replacement structure and processes were ready to be implemented. In some cases no attempt was made to reallocate responsibilities. There was no risk assessment of the project. If this had occurred it would have been evident that the CCP programme was integral to the success of the SFIU or the double floor inpatient service.

The millennium celebrations

- 3.19 Parallel with the nursing restructuring and planning for the ward reconfiguration, was the need to plan for the millennium celebrations. Predictions suggested that Gisborne would be host to a huge population influx over the New Year period. The world media were very interested in Gisborne 2000, and Tairāwhiti Healthcare realistically anticipated that an influx of tourists would result in an increased demand for service.

Nurses' concerns in 2000

- 3.20 Early in 2000, after the millennium celebrations, the full effects of the physical restructuring were apparent. Surgical and orthopaedic nurses outlined in writing their concerns about staffing levels. The nurses linked the staffing level situation to the ward reconfiguration. They argued that the revamped physical layout of the wards changed the way they could deliver nursing care, and pointed to a range of problems.

“The nursing structure basically fell apart. The physical restructure happened and with that the old clinical nurse leader positions were disestablished. These positions were disestablished before the clinical nurse specialists and unit managers were in place.”

- 3.21 Nurses at THL expressed the opinion that they were working in an environment in which they were not valued or listened to. They believed that patient care would suffer.

4. RELATIONS WITH MAORI

- 4.1 My investigation team attended a number of hui in Gisborne and the surrounding areas. It was apparent from the hui and the associated interviews that relationships between THL and Maori could be significantly improved.
- 4.2 The THL 2000-2001 Business Plan records that “the district has the highest proportion of people who identify with Maori ethnicity (45%) whilst the representation of other ethnic groups is below the national average”.
- 4.3 Tairawhiti Healthcare has a Maori Health Manager (with 27 years leadership/management experience) who is a member of the Senior Management Group and reports directly to the Chief Executive. He explained that “the function of this position is to monitor, advise and advocate on all Maori related issues at all levels within THL, and to consult with staff, management and iwi on Maori health and policy issues”. The Maori Health Manager facilitates the development of appropriate and culturally sensitive organisational and departmental policies and assists with support and advice for staff at all levels. The role involves an element of auditing, to ensure that staff – particularly new arrivals – are aware of Maori issues, and training of staff in all matters related to Maori culture and perceptions.
- 4.4 The Business Plan includes goals aimed at meeting the needs of Maori in various services. They include the intention to undertake a cultural audit of each service in the medical and surgical services, and determining what holistic and person centered strategies mean for Maori in the Public Health Unit. The Business Plan records the close working relationship with the two major Maori providers, Ngati Porou and Turanga Health.
- 4.5 The new Clinical Director of Surgery stated that it is very important for THL to have something in place for new people coming in regarding cultural awareness and the Treaty of Waitangi. “It is a Maori area and it is very important to understand the tapus about death and the Coroner and various rituals.”
- 4.6 Recently employed overseas trained doctors reiterated the comment that THL needs to ensure that newcomers are familiar with the needs of Maori in the health care setting.
- 4.7 At the hui attended by my investigation team, a range of issues pertaining to Maori health and the role of THL were raised. They included:

“Cultural issues

- The effect on Maori of there being no pathologist at Gisborne
- Issues around cultural appropriateness of treatment
- Racism

- Fear amongst consumers about complaining

Communication

- Lack of discharge planning
- Training for medical and nursing staff around communication with Maori
- Cancelling and rescheduling of surgery
- Informed consent

Laboratory /Standards of Care

- Te Puia Hospital is no longer using THL laboratory because it takes too long
- Comments on restructuring and standards of care
- Privacy
- Isolation/infection control
- Orthotics.”

4.8 The Chief Executive strongly refuted any implication that THL was culturally insensitive in its care of Maori. She pointed to the following examples of THL’s positive relationship with Maori:

- “Tairawhiti Healthcare’s public health unit received strong support from the Maori community during a recent accreditation review
- Tairawhiti Healthcare had two longstanding joint ventures with the two Runanga. Recently Tairawhiti Healthcare advocated to the HFA for Maori to provide the programmes themselves.
- Tairawhiti Healthcare enjoyed excellent participation by Maori representatives in the District Health Board planning phase and received positive feedback on the process from central government review of the plan.
- Tairawhiti Healthcare worked collaboratively with the two major Maori health providers to develop an agreed approach to any new health service contract the HFA wished to deliver in Tairawhiti.”

The Chief Executive did, however, agree that THL “similarly to all health care providers, can still improve its relationship with Maori”.

- 4.9 The New Zealand Public Health and Disability Act 2000 provides mechanisms for District Health Boards to enable Maori to contribute to decision making on, and to participate in the delivery of, health and disability services.
- 4.10 I believe that the Tairāwhiti District Health Board needs to respond to the themes as well as the specific issues raised at the hui. Accordingly, I am delivering to Tairāwhiti District Health Board a copy of the hui reports prepared by my investigation team, for the Board’s consideration.

5. OPINION

- 5.1 As stated by the Privy Council in *Roylance v General Medical Council* [1999] 3 WLR 541, 559, “the care, treatment and safety of the patient must be the principal concern of everyone engaged in the hospital service”.
- 5.2 It is notable that staff at Gisborne Hospital appeared to be diverted from being totally focused on patients. Patients were very rarely mentioned in interviews with staff. While there was an underlying theme of concern for the patients, the staff interviewed by my investigation team did not present the patients as their first concern.
- 5.3 Management and staff relations at THL contributed to an endemic atmosphere of distrust. This level of distrust got in the way of the organisation embracing change and moving forward. The result was that sensible and forward looking plans became stymied for the wrong reasons.
- 5.4 I endorse the following statement of Professor Grant Gillett:
- “Health care managers have a duty to provide the conditions in which clinical activity can flourish and provide maximal benefit to the maximum number within certain fiscal constraints.”
(Gillett, G, *Gastrogate: The ethical responsibilities of doctors and administrators. NZ Medical Journal* 2000;113:232-233)
- 5.5 Conversely, although clinicians owe their primary duty of care to their own patients, if they work within a hospital service they have a duty of loyalty to their employer. These duties should not conflict. Clinicians should be vigilant to ensure that patient care is not compromised, but they should as far as possible support the organisational endeavour to provide health services of an appropriate standard.
- 5.6 There is a need for ethical leadership both professionally and managerially within the restructured New Zealand public health and disability system (cf Bryson, J, *How should our public hospitals respond to increasing ethical challenges? NZ Medical Journal* 1999;112:47-49).

- 5.7 The new Tairāwhiti District Health Board and the new Chief Executive will need to show their commitment to providing safe and effective health services to all the people of Tairāwhiti. Tairāwhiti District Health needs to develop a culture of teamwork and trust. The co-operation of all clinical staff will be essential. This in turn will enhance staff and public confidence in Gisborne Hospital.

Chapter 2

Quality Assurance Systems

1. INTRODUCTION

Overview of quality structure

- 1.1 In 2000 the Tairawhiti Healthcare Ltd (THL) quality structure consisted of the Chief Executive, Senior Management Group, Core Quality Group, Quality and Risk Management Committee, Group Managers, Clinical Directors and three quality resource roles (Quality Co-ordinator, the Infection Control Nurse and the Occupational Health Nurse).
- 1.2 The committee structure supporting quality consisted of the Clinical Board and a range of committees. These committees included Core Quality, Quality and Risk, Clinical Records, Maternity Services, Medicines and Therapeutics, Control of Infection, Medical Appointments, Medical Credentialling, the Nursing Reference Group and the Wound Management Group.
- 1.3 Terms of reference were available for all committees except the Medical Credentialling Committee, the Wound Management Group and the Maternity Services Committee.
- 1.4 Also in place, but not presented on the quality structure diagram, is the Board of Directors' Audit Committee. This committee reported directly to the Board and at any one time consisted of a chairperson and two other Board members. The committee employed Mr Clive Gough from Gough, Brown Giffney Ltd as an external contracted auditor. On its own initiative and with assistance from management, this committee identifies the key projects to be reviewed each year. The extent of clinical input to this process was not specified.
- 1.5 THL informed me that the Board has established an audit (financial) committee and intends to establish a quality committee when additional Board members are appointed.
- 1.6 The Senior Management Group minutes of 13 April 2000 recorded discussion on an alternative draft structure diagram developed by the Human Resources Manager, the Chief Executive and the Quality Co-ordinator showing how quality related to the overall structure of THL. The Human Resources Manager was to review all committees to determine where/if they should be included in the quality structure. THL explained that "the drive came from the Board's desire to have an *accredited hospital*".

Senior Management Group (SMG)

- 1.7 The Senior Management Group was established in November 1998. It is made up of the Chief Executive, Group Managers, Hospital and Community, Clinical Directors and the Corporate Managers (Human Resources, Finance,

Director of Nursing, Maori Health and the Medical Director). The role of Medical Director is currently vacant. The SMG meets weekly.

- 1.8 The SMG's role in quality assurance activities is described in the quality structure diagram as to "define and set quality goals". The terms of reference for this Group state the role is to "oversee, via a subcommittee approach, the specific portfolios of organisational quality, risk management, health information and capital expenditure".
- 1.9 There is little evidence yet that the SMG is fulfilling this important role. It was envisaged in March 1999 that the SMG would review one quality standard (with a view to accreditation) at each weekly meeting, but that does not appear to have been done consistently. There has been general discussion of quality standards at SMG level, but the minutes of the SMG meeting of 15 June 2000 state that work on organisational standards was suspended and discussion on general progress with accreditation began. THL responded that SMG is fulfilling its quality assurance role, and that the SMG minutes do not reflect all the activity undertaken.

Core Quality Group (CQG)

- 1.10 The Core Quality Group (described by a Group Manager as a "subset" of SMG) was established in June 1998. Membership of the CQG consists of the SMG and the Quality Co-ordinator. This group meets monthly and is scheduled to spend half an hour on quality, but usually spends more time than that.
- 1.11 The quality structure diagram states that the CQG's role is to "develop, monitor, review and prioritise organisational quality plans". The terms of reference for the group state the following specific functions:
- "establish an organisation approach to quality improvement
 - identify and prioritise quality objectives for THL
 - develop an effective quality structure
 - co-ordinate and monitor quality improvement activities across THL
 - identify, prioritise and make recommendations on resource allocation issues related to the quality programme."
- 1.12 The function of the CQG is described in the terms of reference as to "facilitate the effective implementation of quality processes throughout THL to achieve the direction set out in the organisation quality plan". According to the 1998-99 Business Plan, the CQG provides oversight of quality activities including accreditation preparation, clinical audit, policy development and cultural audit. The CQG sets the overall tone and direction of the quality mission at THL.

Quality And Risk Management Committee (Q&RMC)

- 1.13 In October 1999 the Quality and Risk Management Committee was established. This group replaced the Risk Management Committee. The Q&RMC meets regularly on a monthly basis for one hour. This committee is composed of Group Co-ordinators/Team Leaders, the Maori Health Manager, the Director of Nursing, the Occupational Health and Safety Nurse, the Medical Director, the Infection Control Nurse, the Quality Co-ordinator and an Allied Health Representative.
- 1.14 The Maori Health Manager is the current chair of the Q&RMC and is the only Senior Management Group member on the committee. It is unclear in practice whether there is any regular medical representation.
- 1.15 The Q&RMC reports to the Chief Executive, as well as reporting quarterly to the Audit Committee of the Board. The link between the Q&RMC and the CQG was described as being through the SMG members that sit on both groups (which includes the chairperson of the Q&RMC). A link is provided also by the Quality Co-ordinator, who sits on both CQG and Q&RMC.
- 1.16 The THL quality structure diagram records that the Q&RMC “co-ordinates, implements and reports on progress of quality plans”. Terms of reference for the committee state that its specific functions are to:
- “1. Identify, implement and report on quality improvement initiatives at unit, services and organisational levels. This includes quality planning and monitoring the progress of quality initiatives.
 2. Facilitate integrated and innovative approaches to quality improvement and risk management.
 3. Implement a comprehensive quality and risk management programme which includes identification, evaluation and prioritisation of risks and formulation of risk management plans, including the regular monitoring and improvement of:
 - incident reporting system
 - complaints management system
 - workplace hazard management system
 - occupational health and safety
 - claims management of insurance risk issues
 - legislative compliance system
 - infection control programme

- clinical audit
 - voluntary and mandatory sector standards
 - disaster and emergency planning.
4. Make recommendations for policy development and decision-making to the Chief Executive Officer or other managers, clinical directors and THL committees where relevant and appropriate.
 5. Produce specific and ad hoc reports to the Chief Executive, as required, including a quarterly report for the information of the Audit Committee.”
- 1.17 The Q&RMC was described by the Human Resources Manager as “the operational arm of the core quality group”. The Chief Executive described it as “a cross-organisational mechanism”.

Group Managers, Clinical Directors And Quality Resources Positions

- 1.18 The quality structure diagram differentiates between Group Manager and Clinical Director roles. The Group Managers are responsible for developing service quality plans, providing resources for Clinical Quality Indicators and reporting progress against the plan, while the Clinical Directors are responsible for clinical quality monitoring and audit.
- 1.19 The quality programmes are supported by the three quality resource roles, the Quality Co-ordinator, Infection Control Nurse and Occupational Health Nurse. In addition, three positions have been established recently to further support the quality programme – a Quality Administrator, Mental Health Quality Co-ordinator and a new surgical quality position.

Clinical Board

- 1.20 Membership of the Clinical Board includes Clinical Directors, the Director of Nursing, the Medical Director, a senior Allied Health representative, the Chair of the Senior Medical Staff Association and a representative of the Nursing Reference Group. (The Quality Co-ordinator also joined the Clinical Board in October 2000.) The Clinical Board meets fortnightly. The Chief Executive stated that the Clinical Board has a quality brief and has a number of sub-committees with specific functions that impact on quality processes, for example, the Medical Appointments Committee.
- 1.21 The Clinical Board’s terms of reference state that its function is: “to provide senior clinical advice to the Chief Executive and to seek continual improvements to the quality of clinical services within THL”. Specific functions include co-ordinating various clinical quality improvements functions and developing and monitoring a range of clinical performance indicators. Clinical Board minutes from 4 October 1999 to 26 June 2000

(inclusive) contain no discussion on the development and/or monitoring of clinical performance indicators.

- 1.22 The interface between the Clinical Board and SMG, CQG and Q&RMC is not defined in the terms of reference of these groups. Clinical Board members' representation on other quality committees at THL was as follows:

SMG: Chief Executive, Director of Nursing, Clinical Directors
 Q&RMC: Medical Director, Director of Nursing
 CQG: Chief Executive, Director of Nursing, Clinical Directors, Medical Directors

Interviews with a number of senior clinical staff reflected a somewhat negative image of the Clinical Board as ineffectual, although a recent improvement was noted. Comment was also passed on the limited representation of nurses.

- 1.23 THL replied that the Clinical Board is “a very important body” and noted that it can only work if clinicians commit to making it work – ensuring that it makes good decisions that are implemented.
- 1.24 A specific function of the Clinical Board is to advise the Chief Executive on clinical issues. There does not appear to be a widespread belief that the Clinical Board does this effectively. Nor do some clinical staff see the Clinical Board as an available conduit for their views to be heard by management. However, the Chief Executive attends the meetings of the Clinical Board, and feeds back information to SMG.

Quality Co-ordinator position

- 1.25 The co-ordination of the quality activities at Gisborne Hospital is the responsibility of the Chief Executive and SMG. The Quality Co-ordinator, who was appointed on 1 April 1998 and reports to the Human Resources Manager, has responsibility for implementing agreed actions.
- 1.26 The SMG minutes of June 2000 acknowledged that the Quality Co-ordinator required more assistance. Two new quality positions have recently been introduced to support the Quality Co-ordinator position. One is a Quality Administrator, the other a Quality Facilitator. The Quality Administrator position is designed to provide creative administrative support services to the quality team, clinical departments and services. The Quality Facilitator position is to assist with quality systems and processes for clinical departments and services. As of November 2000, these positions have detailed job descriptions identifying key tasks and performance measures. After a three month appraisal review the appointments have been made permanent.
- 1.27 The key focus of both the Quality Administrator and Quality Facilitator positions is to provide support and resource to the units and departments (in response to feedback from those areas) and to assess what is available in the units, including policies and procedures.

- 1.28 A new quality person has recently been appointed for mental health services. No formal link to the Quality Co-ordinator has been identified. However, the Quality Co-ordinator indicated that they could provide support to each other.

2. QUALITY PLANNING PROCESS

- 2.1 The Quality and Risk Management Policy states that the Chief Executive is responsible for ensuring that a comprehensive and effective quality and risk management programme is developed and evaluated at least annually.
- 2.2 THL's 2000-2001 Business Plan notes that THL is wanting to shift to a culture of continuous improvement. The quality component of the THL 2000-2001 Business Plan lists strategies for the current year. These are to:
- promote and support a customer service focus
 - achieve and maintain compliance with appropriate standards
 - integrate and co-ordinate delivery of care that meets or exceeds expectations
 - achieve external accreditation.
- 2.3 Accountabilities and time frames for achieving these strategies are not stated, and there is no overview of other aspects of the quality programme – eg, the audit and clinical indicator programmes. No evidence was sighted of an annual evaluation of the quality and risk management programme. Terms of reference for committees and groups that form the quality structure do not state where accountability lies for annual evaluation. In reply, THL pointed out that the service plans and Business Plan included numerous specific quality projects and improvement targets, as well as requiring monthly progress reports to the Board.
- 2.4 Interviews indicated a lack of staff involvement in the quality planning process and a perception that it was a financially driven process, although THL stated that there are no financial obligations tied to achievements with the quality assurance programme. In an attempt to address staff's lack of participation and increase their knowledge the Quality Co-ordinator held workshops on accreditation and standards around the hospital. The first workshop looked at quality and staff were encouraged to participate in the development of their own service quality plans.
- 2.5 The Quality Co-ordinator was concerned about the lack of alignment between the THL Business Plan and individual service plans. It appears the links between individual services and management, in relation to service goals, are not well developed.
- 2.6 The Chief Executive stated that business and service plans set out individual service objectives in terms of quality, and line managers are accountable for

meeting these objectives. Each area within the organisation has been charged with meeting objectives which evolved through the accreditation process.

- 2.7 Quality Health New Zealand Accreditation surveyors previously noted the need for a comprehensive approach in July 1999. Following the unsuccessful accreditation survey in 1999, Quality Health New Zealand and THL developed a Quality Action Plan. This included proposed actions and timeframes to guide THL to meet accreditation standards. The draft document was tabled at the Core Quality Group meeting on 23 March 2000. However, limited evidence was available to the investigation team regarding the use of this document. THL noted, however, that the plan was widely circulated, and progress evaluated and reported to SMG.

3. PERCEPTIONS OF QUALITY

- 3.1 The definition of quality used at THL is incorporated in the Quality and Risk Management Policy. Quality is defined as:

“The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.”

- 3.2 This definition may be contrasted with that adopted by the Institute of Medicine, where the focus on the patient is manifest:

“The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” (Lohr, KN, (ed), *Medicare: A Strategy for Quality Assurance*. National Academy Press, Washington DC, 1990.)

- 3.3 A member of the SMG stated that this group has put in place processes to review Quality Health New Zealand standards. Managers are responsible for ensuring quality in their service. The SMG is focused on accreditation as an end in itself, rather than quality as a goal. At the corporate level there was a strong emphasis on accreditation and policies and procedures.

- 3.4 The Human Resources Manager, to whom the Quality Co-ordinator reports, stated:

“Quality is the responsibility of each manager. The manager has to match the organisation quality plan with action plans.”

“Clinical Directors are accountable for quality in medical areas. The assumption is that the Clinical Director will be accountable for disseminating information on quality standards including the revised incident report form.”

It is unclear how these expectations were transmitted to the relevant staff.

- 3.5 The contribution of the Quality Co-ordinator was consistently acknowledged in interviews but it was also said that the new systems were not working effectively yet.
- 3.6 The investigation team heard evidence of no or very limited understanding of the quality system from several staff. In light of the labyrinthine quality system described above, this is hardly surprising.

4. QUALITY ACTIVITIES AND RELATED ISSUES

- 4.1 The Human Resources Manager, who is responsible for THL's quality programme, stated that "Tairāwhiti Healthcare's Business Plan strategies are about quality of care for patients. Quality Assurance in terms of efficiency and credentialling demonstrate that people can have confidence in the services provided". It appears that in addition to accreditation, other quality activities in place at THL include Mortality and Morbidity meetings, monitoring of indicators, audit programmes, clinical audit, incident reporting and complaint management.

Accreditation

- 4.2 The key quality activity previously undertaken by THL appears to have been questing after accreditation by Quality Health New Zealand. This is also a strategy in the current Business Plan. Seeking accreditation has clearly been a driving force in improving quality activity. In early 2000, in response to staff concerns that the timetable was unrealistic, the Chief Executive informed the Board that the Senior Management Group had decided accreditation was not going to be a goal for 2000. The Chief Executive believed that "a strong commitment to quality from the staff and ownership of accreditation as a target was more important and would better sustain a quality improvement approach than achieving the shorter deadline". The Board directors made it very clear to the Chief Executive that they did not share her view, and the target stood.
- 4.3 Gisborne Hospital had previously had an accreditation survey on 13–16 July 1999. The survey report stated that there was early development of a Quality Improvement System at Gisborne Hospital and a growing knowledge and commitment to quality which included training of key staff in Clinical Quality Improvement activity. As a number of the key standards were not substantially achieved, Gisborne Hospital received nil accreditation.
- 4.4 THL said the accreditation survey was confidential to THL and Quality Health New Zealand, and requested that it not be published in this report. I have considered that request in accordance with the provisions of the Official Information Act 1982 and the likely impact of disclosure on THL and the implications for the health sector more generally. I have decided to refer to the accreditation survey and some of the recommendations for the following reasons.
- 4.5 It is well known in the health sector that THL received "nil accreditation". There is no shame in that; a number of health care providers have received that

rating. The accreditation process involves raising standards and setting high ones against which to measure current performance and to assist in the achievement of best practice. The findings of the survey are in line with those of my investigation team. It is important that independent collaboration be cited wherever possible. As a result of the events that led to my investigation, public interest in quality of care at Gisborne Hospital has been high. In this instance, in my opinion the public interest in disclosure outweighs THL's interest in the preservation of confidentiality.

- 4.6 Areas where standards did not achieve a rating of Substantial Achievement in the accreditation survey by Quality Health New Zealand included: assessment and planning of care, human resource management, safe environment, infection control, central sterilising services, ward 4 paediatrics, operating suite/day procedure service, special care units (ICU and neonatal), inpatient mental health service, nursing clinical practice, medical clinical practice and continuous quality improvement.
- 4.7 The recommendations for medical and nursing clinical practice included involvement in, and documentation of, quality activities and the monitoring of practice to ensure it meets contemporary standards.
- 4.8 Feedback from the survey team relating to quality included the following observations:
 - an absence of an overall structured approach, which is understood and consistently implemented across the organisation
 - many quality activities occurring throughout the organisation are essentially a list of activities
 - important to ensure Senior Management Group have a clear commitment to quality activities and develop a systematic programme for integrating continuous quality improvement across the organisation
 - no evidence of a systematic approach to quality improvement that ensures all services and staff have responsibility for quality activities
 - levels of staff awareness of continuous quality improvement processes variable across services
 - few services have a system to capture their quality activity at a unit level and be able to demonstrate the quality cycle of assessing, planning, evaluation and feedback of results
 - quality activities tend to be a whole range of separate items rather than a systematic, organisation-wide service-linked programme, making it difficult for managers and staff to evaluate the effectiveness of the quality system/quality plan

- few services are able to provide evidence of improvements resulting from quality assurance due to a lack of documentation and the quality loop not being closed.
- 4.9 The Group Manager (Hospital) stated that action taken since the accreditation survey included establishment of the Q&RMC, work on policy and procedures at department/unit level, and continued integration of the patient assessment/plan of care form and staff education.
- 4.10 Following the survey, each area in the organisation was charged with meeting objectives initiated by the accreditation process. The concept was that each area would meet on a regular basis to review each standard in the service and this would occur across the organisation.
- 4.11 More than a dozen groups were established to review their standards against the Quality Health New Zealand standards and these groups are responsible for putting together the documents needed to meet the quality assurance standards in each department. Concerns were expressed that the committees were falling behind in their work and about the absence of an overview of who was doing what.

Mortality and Morbidity meetings

- 4.12 Medical staff hold monthly Mortality and Morbidity meetings. The Stage One Clinical Audit in December 1998 suggested minutes be kept and recommendations from these meetings be implemented. Written guidelines were put in place for these meetings following the Commissioner's request for information about the implementation of the audit recommendations. The written guidelines state:

“The meetings take place under [Part] VI of the Medical Practitioners Act and the information is therefore protected to encourage full and frank discussion of clinical events.

Documentation is in the form of a brief written account of the anonymised cases and any learning points or particular clinical issues of note. The record is taken by the secretary to the Senior Medical Staff Association. The written record is presented the following week at the Senior Medical Staff Association Meeting where it is checked for accuracy and further discussion can take place.

Annually there will be a presentation at an M&M Meeting of all the notes taken during the year in order to check that the recommendations have been implemented and to make sure that all staff are aware of the recommendations.”

- 4.13 Views differed about the usefulness of these meetings as a learning and quality improvement exercise. THL was concerned to learn of this and expected attendees to address any such problems in order to maximise the usefulness of the meetings.

Monitoring of indicators

- 4.14 Achievement indicators are listed in the Business Plan and monitoring occurs against the 14 points listed on page 21 of the Business Plan. There is monthly reporting to the Board on the quality management role to monitor the achievement of indicators. The Human Resource Department's quality management role includes developing indicators.
- 4.15 The 14 points listed in the Business Plan are broad statements, which follow four Quality Strategies. For example:

Quality Strategy One:

- promote and support a customer service focus
- empower active participation by patients in goal setting.

Quality Strategy Two

- achieve and maintain compliance with appropriate standards
- ensure that our facility is safe for patients and staff
- control vermin ingress.

Quality Strategy Three

- integrated and co-ordinated delivery of care that meets or exceeds expectations
- [patient] involvement in assessment and planning care of meetings
- timely and accessible health care.

Quality Strategy Four

- external accreditation.

- 4.16 It was not clear to the investigation team how far the SMG or Clinical Board monitor the achievement of indicators and the development of action plans or identification of trends.

Audit programmes

- 4.17 The surgeons at Gisborne Hospital are involved in national audits. Several people raised the need for administrative support for these audit programmes. Without adequate administrative support, it is difficult, if not impossible, to complete national audits in a timely fashion. It was reported that it had been a problem to complete a recent Healthcare Otago surgical audit.

Clinical audit (medical)

- 4.18 In December 1998 an internal audit was conducted by Gough Brown Giffney Ltd to review current audit activity, report on findings and make recommendations. This included the development of a framework of 20 domains against which clinical audit could be reported, monitored and managed.
- 4.19 Between April 1997 to mid 1999, when he was in the position of Medical Director, Dr Danny Stewart stated he worked on Step One of the internal audit facilitating active utilisation of clinical and peer audit systems.
- 4.20 Gough Brown Giffney Ltd conducted Stage Two of the internal audit in August 1999. The focus was to audit progress against the responsibilities and timeframes THL had accepted as a result of Stage One of the internal audit. The Stage Two report concluded there had been significant progress in most areas covered by the initial clinical audit, noting:
- high participation in formal continuing medical education programmes together with speciality training and conferences
 - the number and breadth of activity in clinical audit projects and clinical pathway development.
- 4.21 The report noted some progress had stalled owing to the lack of a confirmed Medical Director. The report stated that the efforts of Senior Management and the Clinical Directors needed to be directed toward annual reviews of individual senior medical staff performance.

Medical Practitioners (Quality Assurance Activity: Tairawhiti Healthcare) Notice 1998

- 4.22 THL obtained approval for its quality assurance activity to take place under Part VI of the Medical Practitioners Act, by notice notified in the Gazette on 29 October 1998. The notice is in force for a period of five years after the date it is issued unless it is revoked sooner.

4.23 Activities THL sought to have covered by the notice include:

- examination of patient records
- analysis of patient data (admission, discharge, mortality, morbidity, outcomes of treatment)
- identification and analysis of good and adverse outcomes
- holding of peer review meetings
- review of patients' care/treatment decisions
- monitoring of performance of individual medical practitioners
- making of recommendations on how medical practitioners can improve performance
- facilitation and monitoring of the implementation of any such recommendations
- review of incidents.

4.24 Of these areas, monitoring of the performance of the medical staff has not yet been addressed. The Human Resources Manager stated that “the ASPIRE system has not been adopted by medical staff. There is no formal system for performance assessment of medical staff. Credentialling has not been introduced, although medical staff are motivated towards using credentialling and know the models they want to use.”

Other forums for medical staff

4.25 Other forums for medical staff in the Paediatric and Medical departments to discuss medical problems include senior medical officers' lunches, Grand Rounds and orthopaedic Grand Rounds (twice weekly). Regular monthly Paediatric/Obstetrics meetings and monthly meetings with Radiology have recently been set up and a combined Surgical meeting has now commenced.

Standard of nursing practice

4.26 Historically there had not been formal standards of nursing care, but procedures and policies had been developed. In early 1999, formal standards of nursing care were developed through the Clinical Practice Committee and Nursing Reference Group, but enforcement of these had fallen by the wayside in the absence of a Director of Nursing. The Group Manager (Hospital) (formerly the Director of Nursing) advised that there are no formal strategies in place to monitor nursing standards. There is a compliance checklist for policies. The format for the development of organisational policies requires outcome standards so it was proposed that an audit regime be developed to test

policy compliance. The Group Manager (Hospital) advised that a tool to test policy compliance began to be drafted in 1999 and it was intended that the nursing leaders would develop a nursing audit regime but this never happened. THL responded that, while monitoring may not have occurred, adherence to nursing standards did continue during this period.

- 4.27 The recently appointed Director of Nursing described the fundamentals of nursing care at Gisborne Hospital as “superb” but noted that nursing standards are not in place at Gisborne Hospital, and the monitoring of standards of nursing practice is extremely informal. There is no structure in place in theatre to audit the quality of nursing care delivered. Nursing staff and anaesthetic technicians stated seniors monitor juniors informally.

Nursing quality activities

- 4.28 With continuing staff shortages it has been difficult to get quality initiatives off the ground but some progress has been made. Initiatives underway in the surgical area include:

- an audit of care plans and feedback to staff
- quality initiatives on staff meeting agenda
- quality meetings on a Friday
- one policy a week put out to staff to draw their attention to it.

- 4.29 Other quality activities in place that relate to the quality of nursing practice are audit programmes on infection control and staff education.

- 4.30 Perceptions of what is in place vary. The Inpatient Co-ordinator has conducted an audit of nursing documentation. Her first priority is to assess the effectiveness of a tool related to assessment and planning of care. Staff will also audit each other to see how others work; in this way self-assessment will be a component of the audit programme.

- 4.31 The Quality Co-ordinator noted that some nursing documentation audits have been done recently. No formal staff satisfaction surveys are in place.

Incident reporting

- 4.32 Details of incident reporting and complaint management are set out in chapter 3.

Policies and procedures

4.33 A number of groups are involved in the development and/or approval of policies or procedures including:

- the SMG, which defines and sets quality goals
- the Q&RMC, which makes recommendations for policy development to the Chief Executive
- the Clinical Board, which reviews, formulates and recommends clinical decisions and policies to the THL Board of Directors
- the Infection Control Committee, which develops and recommends clinical policy and procedures to the Chief Executive
- the Clinical Practice Committee, which formulates, reviews and revises the policies/protocols and procedures that guide clinical nursing/midwifery practice.

4.34 The Quality Co-ordinator has developed a database policy review mechanism to indicate when policy updates are due. It is now specified in Unit Manager job descriptions and performance requirements that unit policy review is their responsibility. This occurred as a result of Quality Health New Zealand feedback.

4.35 Departmental managers are responsible for updating manuals on their wards, and there is an unwritten expectation that staff will then be updated on policy updates.

Closing the loop

4.36 A number of interviews carried out by investigators highlighted that closing the loop, or completing actions to finish or follow up issues, is not consistently being achieved at THL. For example, there was a recommendation from the Technician Training Board that anaesthetic technicians at Tairāwhiti Healthcare needed further training. One recommendation was that trainees go to a larger hospital for about two weeks to increase their confidence, share ideas with others about ways to manage issues and to see how procedures are done elsewhere. To date this has not occurred. This is not to suggest that every recommendation made by an external body must be followed, but it should be considered and, if disagreed with, reasons given.

4.37 Nurses reported that one of their concerns is lack of feedback from the process of filling in incident forms. It is not known if similar errors occur again as there are no trends to look at. They reported there was more information available two years ago. There used to be a report on incident forms sent to the wards.

- 4.38 The former Chairperson of the Board of Directors and the Human Resources Manager believed that lack of people, resources, time and training contributed to the quality issues at Tairawhiti Healthcare. The former Chairperson stated:

“Because there is a limited resource of clinical and management expertise at THL issues may get raised but not followed up as quickly as they might otherwise. There are only so many hours in the day and a limited number of people to deal with issues. There is no spare resource at THL at all.”

- 4.39 The Human Resources Manager echoed this sentiment:

“What is not provided is quality time to ensure people have the ability to close the loop. It is one thing for concerns to be raised, it is another to deal with these concerns. It is necessary to look at the competencies of people dealing with those concerns to ensure they have the ability to do so _there is a willingness but no training to support action.”

- 4.40 The lack of a clear process for initiating changes to practice emerged as an issue during interviews by the investigation team.

- 4.41 THL pointed out weaknesses in the previous system of incident reporting and noted that the following improvements have been made:

“The reporting mechanisms have now been greatly improved. The incident form has a tick box for reporters to indicate their request for feedback. The incident reporting policy states that anyone can access incident reports to find out what occurred Until the changeover of the incident reporting system to an electronic system, there was no trend reporting capability in the system. The previous reports circulated consisted of a spreadsheet that had a one-line description of the incident but no review and so on. The use of the electronic database has already led to trends being identified and acted upon. Examples include:

- staff back injuries – resulting in the improvement of the bed maintenance programmes;
- needle sticks – supported change to a different sharps disposal unit;
- patient falls – trend monitoring indicated an increase in the number of falls occurring leading to a full review. This review extended into the period prior to the database and a hand search of all incident reports was necessary as there was no other way of obtaining the information; and
- patient cancellations – led to the development of a cancellation reporting form and database to monitor cancellations.”

External review

- 4.42 In May 2000 Quality Health New Zealand (on behalf of the Health Funding Authority) completed an assessment of THL’s compliance with the draft

Health and Disability Sector Standards. It was a paper exercise, as THL had recently had an accreditation survey, so the information from the survey (ie, self-assessment and surveyor's findings) was used as the basis for the audit.

4.43 The findings identified that:

- there is no effective method of ensuring organisational co-ordination and evaluation of Clinical Quality Improvement activities
- some quality improvement activities have been undertaken, but not documented
- specific service policies and procedures that reflect contemporary practice need to be developed
- linkage of the infection control programme to the quality system needs to be established.

4.44 There was inadequate information to specify:

- whether services collect, assess and evaluate quality improvement data
- whether hazard identification and documentation had been undertaken by all service areas.

5. LEADERSHIP

Nursing

- 5.1 Nursing leadership at Tairāwhiti Healthcare is provided by the Director of Nursing, the Clinical Nurse Educator and the senior nursing position within each area. With the revised Clinical Career Pathway (CCP), that leadership was to be complemented by the Clinical Nurse Specialist position.
- 5.2 A Director of Nursing was in the post until one Friday in August 1999 when he was appointed to the Group Manager (Hospital) position, which he commenced the following Monday. The Director of Nursing position was then vacant until July 2000.
- 5.3 While Tairāwhiti Healthcare sought to recruit a Director of Nursing, limited interim arrangements were implemented to ensure nursing leadership and nursing initiatives continued until the position was filled. Aspects of the Director of Nursing role were handed over to the Clinical Nurse Educator, and the three Nursing Group Co-ordinators. This long vacancy at the top of nursing management, exacerbated by the resignation two months later of the Nurse Educator, caused anxiety and left a large gap in the professional support services available for nurses.
- 5.4 The Clinical Nurse Educator resigned in January 2000 and the position was filled in August 2000. When the CCP was reviewed the role of Clinical Nurse

Specialist was established to ensure that patients received appropriate care. This was a clinical leadership position. Currently no Clinical Nurse Specialists are in place in any areas, resulting in a lack of clinical leadership.

- 5.5 Moving through the CCP is voluntary so it is possible that no staff will choose to progress to the position of Clinical Nurse Specialist. During the introduction of the CCP, the possibility of difficulty in filling the Clinical Nurse Specialist position was not discussed. Nursing staff perceived there was no job description for Clinical Nurse Specialists and no extra money attached to the role. THL responded as follows:

“The job description for CNSs was the same as for standard registered nurses, but the performance criteria were more rigorously applied. The selection criteria for CNSs was agreed with the NZNO, as was a remuneration package. There has always been an additional salary step available for nurses achieving level 4 of the CCP and this has been available ever since implementation.”

- 5.6 The main concern of the nurses interviewed was the lack of nursing structure. There was no positive nursing structure or leadership and no professional guidance a year after the restructuring. Nurses felt they were not listened to and felt undermined. Their morale dwindled and this impacted on the quality of their care.
- 5.7 Another key leadership change was the disestablishment of the ICU Clinical Nurse Leader position in 1999, without transferring responsibilities elsewhere.
- 5.8 In an external review of Gisborne Hospital’s intensive care services commissioned by THL in June 2000, Dr Jack Havill (Clinical Director, Waikato Hospital Critical Care Unit) and Ms Hayley McConnell (Operations Manager, Waikato Hospital Critical Care Unit) noted:

“Despite the seniority and experience of the nursing team they can best be described as ‘rudderless’. Without the day to day support of one nursing leader the team covers only the day to day patient care and housekeeping duties required of them. There is a clearly identified lack of quality plans and assurance taking place. This has resulted in the poor maintenance of patient management guidelines, clinical audits, education programmes, in-service training, regular meetings, forums, research programmes and other QA activities.”

In response, THL noted that many attempts have been made to fill the nurse leader position but it is “not an easy task” to get a suitable person.

Medical

- 5.9 The Medical Director position was occupied by Dr Danny Stewart, Clinical Director (Paediatrics), from April 1997 until April 1999. There is concern that no one has occupied the position of Medical Director at the hospital since Dr Stewart resigned. One Clinical Director stated “nobody has wanted to fulfil this position (Medical Director) because it is an absolutely powerless

position”. Another Clinical Director thought credentialling would have progressed in the first three months of this year but for there being no Medical Director.

5.10 The Stage Two Clinical Audit report also noted:

“A number of action points Tairawhiti Healthcare was to have completed stalled, because of the lack of a confirmed Medical Director. This has affected agreement on a formal reporting system for major adverse clinical events and the initiation of a credentialling system. Senior management and clinical director efforts needs to be directed towards annual reviews of individual senior medical staff performance.”

5.11 Lack of a Medical Director and Director of Nursing for extended periods of time diminished the senior clinical input to the SMG, the CQG and the Clinical Board. Nevertheless, the six Clinical Directors remained on the SMG, the CQG and the Clinical Board.

6. EDUCATION AND TRAINING

Performance management: the ASPIRE system

6.1 The current performance assessment system is the ASPIRE system. The ASPIRE system is a system of performance analysis. It has been in use at THL for one year.

6.2 The system is intended to identify people’s needs and guide the staff training programme. The Human Resources Manager stated:

“ASPIRE reviews are done three months after each staff appointment and thereafter on each anniversary of the ASPIRE review. The Human Resources Department generates the requirement for a review and sends forms to the appraiser, who will be, for example the manager or the team leader. Following review, the forms are returned to the Human Resources department where results are monitored. If 20 reviews are sent out, the department ensures 20 reviews are returned. The ASPIRE system is still reasonably immature. The ASPIRE system rewards progression through scales and offers opportunities for personal development. Staff complete a self-assessment form against competencies and their manager also completes an assessment form. Staff may elect to have peer review. Staff review their goals and set new goals. There is provision for staff to make their own comments throughout the ASPIRE form. Staff can obtain a copy of the completed form if they wish. The original is kept on their file in the Human Resources Department.”

6.3 As yet there is no formal system in place for performance of medical staff. The Chief Executive stated that the Clinical Directors on the Senior Management Group made it clear that they would only support the introduction of the ASPIRE system if it did not include medical staff. Clinical

Directors are responsible for performance review of senior doctors in their service.

6.4 The ASPIRE system is different from the nurses' CCP system. Nurses have varying views on the value and applicability of the ASPIRE system. The NZNO's view is that there are "huge problems" with the ASPIRE system: principally that it is indiscriminate – "it works from the gardener on up" - and does not have a clinical focus.

6.5 THL pointed out in response:

"NZNO has never expressed any reservations about ASPIRE to the human resources department. This was never raised at the consultative committee meetings. There is, in fact, a clinical focus to ASPIRE with the ASPIRE nursing criteria being developed from the CCP job description. A lot of work was undertaken to link the CCP into ASPIRE resulting in the CCP competency being included into ASPIRE for all nursing appraisals. Once again, it needs to be pointed out that, prior to ASPIRE, many nurses did not have appraisals regularly and that the framework, while not absolutely perfect, was an improvement on what was in place previously."

Orientation

6.6 The induction programme for new staff members is co-ordinated through the Human Resources department. At least four times a year a day-long programme is held for new staff, which provides them with all the relevant information on how the organisation works. Each department has responsibility for inducting new staff to their department. The induction package includes the organisational handbook. Medical staff are involved in the induction programme but sometimes doctors do not attend as priority is given to treating patients.

6.7 The Maori Health Manager commented that he does not meet many of the itinerant doctors as there is no process in place to meet them. He pointed out the need for a cultural training process within the organisation, a comment echoed by a recently appointed locum anaesthetist from North America.

6.8 Gisborne Hospital employs a significant number of overseas trained doctors, as do many other public hospitals. A hospital is responsible for orientating new doctors, especially overseas trained doctors, to their new work environment, otherwise they will continue to work from a prior frame of reference.

Quality training

6.9 The Quality and Risk Management Policy states that the Chief Executive shall ensure there is an effective mechanism in place to ensure that staff are educated in quality and risk management principles commensurate with their position in the organisation.

6.10 Quality Strategy 2 in the Business Plan states that education and training on the use of the incident and complaints process will be completed during the 2000-2001 period. This had not been achieved at the time of the investigation, but THL has advised of its intention to do so.

6.11 The Quality Co-ordinator currently has only a half hour time slot at orientation, which is shared with others. It does little more than allow a face to be put to a name, but it is recognised that there is much material to cover and a risk of information overload.

Ongoing education: nursing

6.12 A number of nurses commented on access to ongoing education:

- “Education doesn’t happen unless you do it yourselves. There is no downtime for inservice education, there is no inservice programme in the hospital.”
- “When I went from [one clinical area to another] the transition was extremely difficult. I was buddied for one week. The process was disjointed. I am only becoming confident after a year. There wasn’t anything formal to help; I was thrown in at the deep end.”
- “There is no advanced education for nurses available locally other than by correspondence.”
- “Upskilling is haphazard and there are different habits of practice.”

6.13 THL responded as follows:

“Single verbatim comments from some nurses documented in this way present an unbalanced and one-sided picture. There could equally be comments on how generous the organisation has been in supporting nurses in ongoing education and development by providing study fees, study leave, conference registration and so on. It is not entirely the organisation’s responsibility to ensure clinical staff are up to date and adequately educated. Clinical staff have a professional responsibility to maintain skill levels as well.”

6.14 A recovery nurse is allocated one day a week to provide one-to-one intravenous therapy training for nurses throughout the hospital. However, she has been unable to provide this training because there are insufficient staff to replace her in the recovery unit. This has been a problem for over a year and she reported bringing the matter to the attention of the Group Manager (Hospital) and Theatre Manager. The result of this nurse not being available to provide training is that nurses do not get assessed on pain management, epidural, IV training or central line assessments, and certification takes twice as long.

- 6.15 THL replied that the Clinical Nurse Educator supported the IV resource nurse, and theatre staff are available for her to be released to do the training.

Ongoing education: medical

- 6.16 The Clinical Audit Stage Two concluded there is high participation in formal continuing medical education programmes together with speciality training and conferences. A consultant stated “there is good medical education money available for doctors at Gisborne hospital”.

7. OPINION

Organisational care

- 7.1 The right to receive good quality care is central to the Health and Disability Commissioner Act and the Code of Consumers’ Rights. The statutory purpose, set out in section 6 of the Health and Disability Commissioner Act 1994, is “to promote and protect the rights of health consumers” or patients. At the core of patients’ rights is the right to receive services of an appropriate standard (section 20(1)(f)). This key right is affirmed in Right 4 of the Code, entitled the ‘Right to Services of an Appropriate Standard’.
- 7.2 A quality assurance system is no more or less than the system that an organisational provider, such as a hospital, puts in place in order to meet its ethical duty and (by virtue of the common law and the Code) legal duty to provide services of an appropriate standard. Although a quality assurance system cannot guarantee that the care actually delivered to patients is appropriate, it seeks to ensure (‘assure’) that the structure, policies and procedures of the hospital will result in staff providing appropriate care for patients.
- 7.3 There is evidence of decisions being made that impacted on THL’s ability to maintain an effective quality system and ultimately on the standard of the care that is delivered. A significant example is the disestablishment of the ICU Clinical Nurse Leader position (discussed in chapter 1). There is no evidence of any monitoring of indicators to measure the impact of this decision. Further examples are the lack of analysis of the impact of the vacant Director of Nursing and Clinical Nurse Educator positions on the provision of nursing services.
- 7.4 THL had a strong emphasis on accreditation and policies or procedures, but limited emphasis on other aspects of quality, such as credentialling and monitoring quality and clinical indicators.
- 7.5 It is evident that the system that existed to ensure quality of care at Gisborne Hospital in 1999-2000 was a ‘quality assurance system’ in name only. As an organisational provider, THL did not have in place a system to ensure that the services provided at Gisborne Hospital complied with the legal standard of due care (“reasonable care and skill”) specified in Right 4(1) of the Code.

- 7.6 The fragmented quality system at Gisborne Hospital failed to ensure due care. The rhetoric of quality assurance did not match the reality in 1999-2000. In my opinion Tairawhiti Healthcare Ltd therefore breached Right 4(1) of the Code.

Organisational co-ordination

- 7.7 Right 4(5) of the Code states that “every consumer has the right to co-operation among providers to ensure quality and continuity of services”. It is clear, whatever the level of co-operation between individual staff working at Gisborne Hospital in 1999-2000, care was not well, or even adequately, co-ordinated at a systems level.
- 7.8 One specific defect in the quality activities at Gisborne Hospital was the lack of co-ordination between the various quality committees, between the Board of THL, management, and staff, and between doctors, nurses and other clinical staff at Gisborne Hospital.
- 7.9 Despite the criticism in the Quality Health New Zealand survey of 1999, there continued to be a lack of a well co-ordinated approach to quality activities across the organisation. Quality activities were conducted unevenly, service by service. There was a lack of staff education, with the potential for inconsistent or poor quality care.
- 7.10 The quality planning process did not sufficiently involve staff and ensure ownership of quality at all levels and across all services. There was limited nursing quality activities and monitoring of the standard of care actually delivered. There was a lack of documented and explicit standards that state what performance levels are expected. Quality requires teamwork across disciplines, and this was not apparent. There was a lack of systems to monitor quality, such as for monitoring indicators and incidents. There were far too many uncoordinated layers in the present committee structure.
- 7.11 It is also obvious from chapter 1 that restructuring had occurred at a rapid pace, without adequate consultation or sufficient thought about the impact on morale and the quality of care for patients. Many decisions were driven by financial imperatives without sufficient regard to the provision of a quality service by a highly motivated workforce. Many legitimate concerns raised by staff fell on deaf ears.
- 7.12 Key personnel were not in place to manage the restructuring. This meant that when change did occur, there was a lack of clinical leadership and management support to make the changes work. The end result was a climate of suspicion and distrust between management and staff.
- 7.13 The problems with incident reporting in theatre and elsewhere, and the lapses in quality control in the biochemistry section of the laboratory, were symptomatic of a widespread malaise within Gisborne Hospital. THL responded that these problems could not be laid solely at the door of management, and that NZNO and staff resisted change and were unwilling to help find solutions.

- 7.14 All of these factors led to a break-down in communication and co-operation throughout Gisborne Hospital, and a consequent failure to ensure quality of care for patients.
- 7.15 In my opinion Tairawhiti Healthcare Ltd therefore breached Right 4(5) of the Code.

The way forward

- 7.16 Tairawhiti Healthcare has embarked on a journey, the end of which must be an effective, hospital-wide, integrated and transparent quality assurance system; one that is 'owned' by all levels of staff (clinical and non-clinical). In 1999-2000 the quality system was largely lines on paper. An edifice of committees will not assure quality for patients.
- 7.17 An effective quality system is one in which there is a systematic approach to quality improvement, involving all levels of staff from all services (clinical and non-clinical). This extensive involvement is required due to the interdependent nature of clinical service provision and recognition that quality is everyone's responsibility.
- 7.18 The quality system should include:
- a) a quality vision developed with staff involvement
 - b) a quality statement/policy or philosophy
 - c) a quality structure with clearly defined accountabilities
 - d) a quality planning process involving staff and linking organisational and unit quality objectives
 - e) a quality plan (or inclusion of a quality component in the Business Plan) that presents an overview of quality activities
 - f) written standards that are both descriptive and measurable defining quality of care and communicating the organisation's expectation of care (including policies/procedures, clinical protocols and practice guidelines)
 - g) staff orientation and education that also includes a quality component
 - h) an information strategy that ensures appropriate data (financial/business and quality) is collected, analysed and produced as management information to enable staff to be fully aware of trends and progress
 - i) credentialling processes
 - j) peer reviews
 - k) risk management, infection control and OSH programmes

- l) an accident/incident and complaints policy and procedure
 - m) a communication plan to ensure every staff member is aware of the organisation's quality objectives and how they can contribute
 - n) annual quality objectives that set specific and achievable targets
 - o) the nomination of a range of indicators that will be used to assess quality and outcomes and provide a basis for recording and monitoring variance
 - p) the auditing of existing policy and procedures (clinical and non-clinical) to ensure they are being implemented effectively
 - q) a process to identify opportunities for improvement during the year (when the quality plan is already in progress) and enable project plans to be developed, implemented and monitored
 - r) monitoring of performance against standards to identify trends and ensure action plans are developed, implemented and reported on
 - s) performance standards reflecting both patient expectation and professional requirements
 - t) monitoring of patient satisfaction
 - u) annual evaluation of the effectiveness of the system.
- 7.19 Quality activities are designed to prevent poor quality occurring, detect it at the earliest opportunity and make improvements where it does occur to ensure it is not an ongoing issue (ie, services are continuously improved).
- 7.20 Organisations may also participate in external peer review processes such as accreditation. However, this should be complementary to, and not in place of, other quality activities outlined above.

8. RECOMMENDATIONS

- 8.1 The effectiveness of the Tairāwhiti District Health quality system should be evaluated and changes made immediately to ensure a systematic approach to quality improvement that ensures all services and staff have responsibility for, and are involved in, quality activities.
- 8.2 In consultation with staff the definition of quality to be used should be reviewed.
- 8.3 A robust quality planning process with involvement of staff should be established and implemented.
- 8.4 A range of quality activities that reflect the needs of internal and external customers should be undertaken.

- 8.5 Information on quality activities should be presented in a way that demonstrates the range and effectiveness of these activities.
- 8.6 Ongoing monitoring of performance against procedures, policies, protocols and standards should be undertaken.
- 8.7 Clinical case reviews by specific professional groups and multidisciplinary teams should occur.
- 8.8 Credentialling for medical staff should be established.
- 8.9 Individual quality activities should be reviewed and improvement demonstrated.
- 8.10 Tairāwhiti District Health should develop an orientation programme suitable for newcomers to the area and to New Zealand. This should include an introduction to the Code of Health and Disability Services Consumers' Rights.
- 8.11 New recruits should be supervised through their first weeks so that they have the opportunity to clarify issues and learn how to handle matters at Gisborne Hospital.
- 8.12 The quality programme should be evaluated on an annual basis.
- 8.13 Data collection, analysis and reporting processes should be reviewed ensuring staff receive feedback, eg on patient satisfaction.
- 8.14 Quality assurance activities undertaken under the Medical Practitioners Quality Assurance Activity: Tairāwhiti Notice 1998 should be reviewed to ensure that the statutory purpose of encouraging “effective quality assurance activities in relation to health services provided by medical practitioners” and “improving the practices” of medical practitioners (Medical Practitioners Act 1995, sections 66(1), 67) is fulfilled.
- 8.15 The Quality Co-ordinator and clinical staff should be involved in the evaluation of the effectiveness of the recently established Quality Facilitator and Quality Administrator positions.
- 8.16 Management and staff should identify key performance indicators for the organisation and individual services (clinical and non-clinical) and establish acceptable/non acceptable levels against which performance is measured.

Response to recommendations

8.17 Tairāwhiti District Health advised that it had either actioned or commenced action on the above recommendations.

Chapter 3

Incident Reporting and Complaints Procedure

1. INTRODUCTION

- 1.1 Tairawhiti Healthcare's intention to continuously improve aspects of incident reporting is evident from its Business Plans. Complaint management and incident reporting were identified as components in the 1999-2000 Business Plan. This was followed in the 2000-2001 Business Plan with an emphasis on the education and training of staff in the use of the incident and complaint process.
- 1.2 Up until mid 1999 the incident reporting process was a manual, paper based process, which was co-ordinated by the Occupational Health team. In February 1999 responsibility for the incident reporting system was transferred to the Quality Co-ordinator and from July 1999 information technology was used to support the incident reporting system. A dual system (manual and electronic) was maintained initially, to ensure effectiveness of the new approach. The electronic database allows for information to be extracted in the form of trend reports, rather than lists, as previously generated.
- 1.3 In March 2000 the incident reporting and complaints policy was reviewed, approved and incorporated into the corporate policy manual. Timeframes for incident management are given in the policy. Staff are required to report incidents within 24 hours of the event. Some incidents may not require individual review. These are closed at the time of logging and trend monitored and reviewed by the Quality and Risk Management Committee (Q&RMC). Incidents that require individual tracing and review are required to be forwarded within 24 hours to the appropriate staff member. All reviews are to be completed within 14 days of notification.

2. EXTERNAL REVIEW

- 2.1 On 31 August 1999 a review of the Tairawhiti Healthcare incident reporting system was completed for the Health Funding Authority (HFA). THL stated that, at that time, it was informed that the review was an information gathering exercise only, that would lead to the establishment of national best practice guidelines.
- 2.2 The main areas where Tairawhiti Healthcare was assessed as not meeting HFA requirements included:
 - Lack of a process for promptly informing senior management/Chief Executive of serious incidents
 - Consumer related issues eg, notification of the consumer, recording his or her view of the incident and advising the affected consumer of the findings of an incident investigation

- A process for identifying areas that under-report incidents
 - A process for ensuring that recommended changes or improvements are implemented
 - A process for reporting that includes commentary on trends, issues or cautions about data contained in the report.
- 2.3 It appears that progress has been made in some areas - eg, development of a flow chart and some changes to reporting - but that other significant issues raised have not been addressed in THL's revised Incident and Complaint Management Policy.

3. SCOPE OF INCIDENT AND COMPLAINT MANAGEMENT POLICY

- 3.1 The purpose of the current policy is stated to be “to guide the management of incident and patient complaints throughout Tairāwhiti Healthcare”. The corporate policy on incident reporting notes that “Tairāwhiti Healthcare uses one form for all incidents/accidents or near miss incidents”. This appears not to be the case. Tairāwhiti Healthcare's Mental Health Service currently uses a different incident form than other areas, and the laboratory has set up its own incident reporting system because staff in the laboratory felt that the hospital incident forms were for more serious incidents.
- 3.2 The lack of incident reporting by medical staff was identified as an issue by management, and work was commenced by the previous Medical Director to create a separate medical incident reporting system. It is not clear how the creation of a separate medical incident form could address the many possible reasons for under-reporting of incidents by medical staff.
- 3.3 The Tairāwhiti Healthcare incident reporting policy notes that “there is no limit to the uses of incident reports”.
- 3.4 The term “incident” is defined in the policy as an “internally reported event” that:
- “Results in serious harm as defined by the Health and Safety in Employment Act 1992.
- Has resulted in or potentially may have resulted in harm to patient, staff or visitors, or loss or damage to property or the environment.
- Results in loss to systems or process.
- Contravenes THL policy, protocol or procedure.
- Is inconsistent with generally acceptable service/standards of care.”
- 3.5 Incidents and adverse events are not differentiated and the policy does not explicitly mention adverse events. These terms are often used

interchangeably, but adverse events are more correctly identified as a subset of incidents, where actual harm has resulted. An “adverse event” is:

“Any unintended event or circumstance caused by healthcare management rather than a disease process, which leads to hospitalisation, prolonged hospital stay, morbidity at discharge, or death.” (Brennan, TA, et al, Incidence of adverse events and negligence in hospitalized patients. *N Eng J Med.* 1991;324:370-84)

An “incident” is:

“Any event or circumstance which could have or did harm anyone or that could lead to a complaint. It may or may not have been preventable and may or may not have involved an error on the part of the health care team.” (Australian Patient Safety Foundation, 2000)

- 3.6 The definition in Tairawhiti Healthcare’s incident reporting policy refers to internally reported events that may potentially have resulted in harm, loss or damage, ie, a “near miss”. However, no reference is made to a “near miss” in the text of the policy, and the incident report form does not include “near miss” as a category.
- 3.7 The text of the Incident and Complaint Management Policy combines statements on incidents and complaints, and is difficult to follow.
- 3.8 The incident review form asks for incidents to be categorised as 1, 2, or 3. These categories are not defined or explained on the review form or in the policy statement. The policy gives no guidance on the type or severity of incident to be reported. Less serious incidents reported ranged from the loss of a TV aerial to refusal to pay for a meal allowance.
- 3.9 The Incident and Complaint Management Policy states that some incidents may not require review (statement 7). No formal definition or criteria are given to guide the Quality Co-ordinator on which incidents are to be managed by that office as opposed to requiring review external to the Quality Co-ordinator’s office. This lack of detail also makes it difficult for staff to know which incidents they can anticipate may require such review. A transparent process has the potential to reduce staff members’ fear of the system.
- 3.10 The policy requires incidents that need tracing and review to be sent to the appropriate staff member (statement 8). However, no indication is given as to what level of staff may be delegated responsibility for reviewing incidents, so it is difficult to target education effectively.
- 3.11 Guidelines are given in the policy on the action to be taken if complaints are not resolved within the 14 day time period (statement 10). The Q&RMC is delegated responsibility for monitoring the implementation of recommendations made as a result of incident investigation (statement 11). The investigation team found no evidence of this occurring.

- 3.12 The policy states that the outcomes of incident reviews are not reported back to the reporter in all cases but they are available (statement 13). No detail is given of where they are available from and who can access them.
- 3.13 The incident reporting flowchart requires staff to determine whether immediate notification of the appropriate staff member/manager is required. No detail is given to assist staff to determine which incidents require immediate notification (step 3).
- 3.14 The Incident and Complaint Management Policy lists a range of monthly and quarterly reports that will be made to the Q&RMC, Core Quality Group (CQG) and the Audit Committee. The CQG (which is the most senior quality group of the organisation) is to receive a monthly summarised report of complaints but not of incidents. Incidents are reported to the Q&RMC. The policy provides no direction on the dissemination of report findings to staff.
- 3.15 Minutes of the CQG meeting of 16 August 1999 stated that there was still a need to define “incident” and to clarify what needs to be reviewed and what needs to be cumulatively reported. The revised Incident and Complaint Management Policy was approved on 6 March 2000. The last two of these requirements were not addressed in the newly approved policy and remain outstanding.

4. PRACTICAL ISSUES RELATED TO INCIDENT REPORTING

Practical matters

- 4.1 A review of the documents, and discussions with staff, highlighted a number of practical issues.
- 4.2 Categories have been introduced on the review form - for example, cultural distress and contractor complaints - with no guidance as to their meaning. In the absence of clear guidelines there may be inconsistent trend reports.
- 4.3 Incident forms are not printed with a number and, as a result, tracking can be difficult. Both copies of the incident form are easily detachable and may become separated en route to the Quality Co-ordinator’s office. The Quality Co-ordinator commented that there is currently no mechanism to track filed incident report forms and it cannot be guaranteed that they all arrive in her office. An example of this is the initial incident form (October 1999) regarding Dr Lucas’ reuse of syringes which was witnessed as being completed and handed in to the Theatre Manager. However, the report was never entered into the system and the Quality Co-ordinator had no record of having received it.
- 4.4 The length of time between the completion of an incident form and review by the reviewer was also identified as an issue in relation to the reuse of syringes. The November 1999 incident form relating to Dr Lucas took three weeks to go from the clinical area to the Quality Co-ordinator and then to the reviewer, during which time additional risk could have been prevented.

- 4.5 There seemed to be no consistency about when senior management was informed about incidents. The Chief Executive stated that “there is no formalised policy in place on what clinical events should raise a red flag with the Senior Management Group”. A senior manager stated that “there were no hard and fast rules about identifying incidents I considered critical. However, my rule of thumb was that: if there was a significant patient, legal, financial, reputational or regulatory risk then the CEO would be informed”. It is unlikely that all staff had this level of insight.

Review of individual incident reports

- 4.6 The report of an expert group on learning from adverse events in the British National Health Service entitled *An Organisation with a Memory* (Department of Health, UK, 2000) concluded that analysis of failures needs to look at root causes, not just the proximal events (p 46). Human errors cannot be sensibly considered in isolation of wider processes and systems.
- 4.7 This view is congruent with the THL Incident and Complaint Management Policy which states (point 9, p 2) that the review of complaints and incidents should include “root cause identification”. Despite the lipservice to this concept, its application in practice was not apparent in the review of incidents analysed by the investigation team.
- 4.8 This failure is illustrated by an incident report that identified that a staff nurse connected an intravenous infusion at the rate for a 12-hour infusion when it was intended to be administered over 24 hours. The staff nurse reported the incident two hours after it occurred. A senior nurse reviewed this incident. The focus of the review was on the medication error. Language used in the documentation of the review was punitive and blaming. There is no evidence in the typed incident review that the conditions in which the incident occurred were considered.
- 4.9 The reporting nurse’s account of the incident, which was recorded on the incident form and available to the incident reviewer at the time of the review, provides the following information:
- the nurse had had no meal break or drink for over seven hours immediately prior to the incident occurring
 - there was 10 minutes’ notice of the patient’s admission and the patient required ventilation
 - there were no spare beds in the area
 - an emergency arrest in the Accident and Emergency Department required attention during this time
 - there were four staff on duty in ICU and two CCU patients and four ICU patients (two of whom were ventilated).

- 4.10 Further examples of Tairāwhiti Healthcare’s failure to identify the root cause of incidents are reflected in the response to incidents relating to Dr Lucas. The focus of management actions was on proximal events and there was no tracking back to root causes. For example, there was no initiation of a multi-disciplinary forum for discussing proposed changes to practice prior to the introduction of restraints (straps), or resolution of communication difficulties between Dr Lucas and theatre staff.
- 4.11 Another issue discussed by some interviewees was the responsibility and accountability for following up incident reports. One senior clinician noted that there is a gap between the general management reporting pathway and the Clinical Director pathway when there are recommendations for action on an incident. He commented that “the gap appears when it comes to identifying who ultimately takes responsibility for those recommendations”. He observed that “there are often debates at Senior Management Group meetings over who should bear responsibility for dealing with incidents”. The Human Resources Manager illustrated the dilemma. He asked rhetorically, in relation to the alleged needle throwing incident, “who is responsible for handling the incident, the Clinical Director as a professional issue or the Group Manager as a disciplinary matter?”

Feedback to staff following incident reporting

- 4.12 The investigation team consistently received strong comment from staff that they expected, but had not received, feedback on the incident forms they submitted. The persistent lack of feedback has severely damaged the credibility of the incident reporting system in the eyes of many staff. The New Zealand Nursing Organisation stated in its submission: “NZNO members have a strong view that completing incident forms was a waste of time because feedback was rare and frequently negative Professional responsibility and an awareness of the importance of documentation led staff to continue filling in forms, rather than the belief that the situation would be addressed.”
- 4.13 One senior doctor stated that “to fill in an incident form and get no feedback is like hitting your head against a brick wall. The perception is that the incident form goes into a big dark hole so there is no point in filling them in.”
- 4.14 One of the strongest advocates that feedback should occur was Dr Lucas (see also para 4.40). His suggestion to that effect was passed on to the Senior Management Group by a Clinical Director.
- 4.15 In contrast to the staff experience of receiving no feedback, the Human Resources Manager, who oversees the system, expected “the person who completes the incident form will be spoken to. The process is that the incident form is completed, the manager investigates and provides feedback to that person.”
- 4.16 THL stated that:

“The system is only as good as the people who use it. The staff need to fill in incident reports and there is no excuse for not completing them.

Staff can ask for feedback on the incident reports and THL should not be criticised if they fail to, or elect not to, do so.”

- 4.17 It should be noted that the new incident reporting form clearly provides a space for staff to indicate they want feedback.

Incident analysis and reporting

- 4.18 The reporting and analysis of incidents is essential if the data gathered in the incident reporting process is to be used effectively as a learning tool to prevent recurrence of the risk.
- 4.19 THL’s progress towards meeting the reporting requirements outlined in the Incident and Complaint Management Policy was unclear. The requirements are monthly reports to the Q&RMC and CQG, and quarterly reports to the Audit Committee.
- 4.20 Differing views were expressed on the type of reports the Q&RMC was receiving. One member of the committee stated that the committee was receiving reports including summaries. The Quality Co-ordinator commented that the committee received graphs to identify trends but no summaries of events or incidents. The Quality Co-ordinator’s view is “that there should be a summary of incidents and a report on where to from here to follow through and ensure the incident does not happen again”. Of course, incident reporting cannot provide definitive information on trends, since it is dependent upon the comprehensiveness and accuracy of the reporting.
- 4.21 It is apparent from the interviews and reports available to the investigation team that the framework outlined in the policy is not yet in place. Monthly reports are not submitted to the Q&RMC and as at September 2000 only two quarterly reports (December 1999 and March 2000) had been produced. The format of the two quarterly reports varies and there is no breakdown of what is included in the category of patient incidents. In light of this, the Q&RMC role in monitoring and discussing incidents as outlined above would not have been achievable.
- 4.22 In addition, there is a lack of follow-up on incomplete reports. The process for this was described by the Quality Co-ordinator as “informal” and as a task to be achieved.
- 4.23 The extent to which incident trend reports presented to the Q&RMC are disseminated to staff is unclear. Copies of these quarterly reports are not distributed to individual services. The Quality Co-ordinator noted that “while there is nothing to prevent these reports being passed on to staff there is nothing currently in place requiring this to occur”. Her general feeling was that they are not passed on.
- 4.24 The Quality Co-ordinator also stated that she was unsure if the reports went to the Clinical Board, as she understood they do not currently have a role in relation to incidents.

- 4.25 THL advised that Clinical Directors receive reports through the Clinical Board and SMG, and they are required to provide feedback to staff and their services.
- 4.26 Staff recall receiving feedback previously on incident findings, for example by way of a bulletin to the wards and staff cafeteria. Staff found this feedback very valuable.
- 4.27 The Quality Co-ordinator has identified the need for staff feedback and is currently establishing a timeframe to implement monthly reports to individual services. The expectation is that once individual services receive these reports they will report back to the Quality Co-ordinator on what has been put in place as a result of information in the report.
- 4.28 The incident forms reviewed frequently lacked one or more of the following:
- date
 - hospital number
 - ward
 - patient sticker
 - time
 - incident description.

One form contained only a date, signature and the question “anaesthetic protocols required?”

- 4.29 The Quality Co-ordinator expressed concern that there is over-reporting of non-serious incidents and under-reporting of serious incidents. The effectiveness of the incident reporting system is influenced by staff knowledge of the system and their responsibilities.

Internal reviews of the incident reporting system

- 4.30 Interviewees described two major reviews of the incident reporting system. One involved a roundtable discussion including senior managers and occupational health staff on how the incident reporting system could be improved. A series of actions were identified.
- 4.31 The Human Resources Manager and the Quality Co-ordinator, in consultation with the Senior Management Group and the Q&RMC, carried out the more recent review. The apparent intention was to address gaps in the policy. There was no evidence, however, of a formal process (eg, focus groups or a survey form) for seeking feedback from a wide range of users on the effectiveness of the system.

- 4.32 The Human Resources Manager commented that he was not aware of any feedback from staff that they were unhappy with the current incident reporting policy. This lack of reported feedback may be more reflective of a lack of an appropriate forum in which to discuss these issues with the Human Resources Manager.
- 4.33 Based on their experience of using the system, staff were very forthcoming during interviews with the investigation team in identifying deficiencies and suggesting improvements to the system.

Effect of incident reporting on the culture of the organisation

- 4.34 The response individuals receive to an incident they have reported may influence whether they use the system in the future. A blaming culture promotes cover-up because of fear of retribution. If a staff member chooses not to use the incident reporting system the opportunity for the organisation to learn from an incident or “near miss” is lost.
- 4.35 The Human Resources Manager talked of incidents being valued in Tairāwhiti Healthcare and used as a mechanism for feedback. This is not reflective of the experiences of a significant number of staff. It appeared from interviews that staff felt the incident reporting process has become personalised and a criticism of individuals rather than an opportunity to increase safety and patient focus. Several staff experienced disapproval of incident reporting and spoke of a culture of fear.
- 4.36 THL stated:

“No matter how well the system is structured, some staff will always feel they have been blamed or victimised when an incident is investigated, and improvements suggested (or, alternatively, no action taken because analysis showed no need for further action). A cultural change is needed across all agencies investigating complaints or incidents before this perception will change.”

- 4.37 The Chief Executive stated:

“If staff are not happy with the way in which an incident is resolved they can take it to their Group Manager. The Group Manager and the Clinical Director both report to [the Chief Executive]. Staff who are dissatisfied with the response from their Group Manager or Clinical Director can take it up the line themselves or they can get someone to advocate on their behalf such as the Human Resources Manager or the Quality Co-ordinator or their union.”

- 4.38 It appeared to the investigation team that many non-medical staff did not feel able to follow this advice. Staff perceived a climate of fear and retribution, and experienced their immediate manager not taking action on their concerns. In the situations involving Dr Lucas, staff also felt unable to work with medical colleagues to address the issues. As one staff member explained:

“The surgeons would have witnessed much of the behaviour. None of it was addressed. There was a view that the issues were about us not liking Brian Lucas, about a personality problem between us.”

- 4.39 It was reported that a member of the medical staff had said to a nurse: “I bet they wouldn’t have made an issue if he was young and handsome.”

Dr Lucas’ comments

- 4.40 Dr Lucas was asked by the investigation team to comment on the most serious issues that Tairawhiti Healthcare needs to address, relating to theatre practice. He responded:

“There should be a timely incident reporting process. Those issues that are brought up in incident reports are worthy of discussion, so the first thing is to have a hospital-wide incident report process that produces results and resolution and completion on things during a staff member’s lifetime in a timely way. As a subset of that, could there not be a real good attempt at getting an interdisciplinary discussion or getting a forum started if it isn’t already? In the first quarter of this year after the millennium there didn’t seem to be anything.”

- 4.41 Analysis of the current policy and feedback from staff using the system indicates that further review and development of the system is essential if it is to become an effective component of THL’s quality management system.
- 4.42 In light of the issues raised regarding Dr Lucas, the Chief Executive commented that the challenge for THL “is to get the process right and ensure that staff get appropriate feedback” on incident forms submitted.

5. THE COMPLAINTS PROCEDURE

Complaints handling

- 5.1 Complaints are defined by Tairawhiti Healthcare in the Incident and Complaint Management Policy as “a formal expression of dissatisfaction or grievance”. Enquiries are defined as “an observation or remark that queries some aspect of service”. The policy does not cover staff complaints.
- 5.2 The policy notes that complaints are to be passed on to the appropriate senior manager and Clinical Director where applicable within 24 hours of logging. The policy states: “Review of complaints is the responsibility of the appropriate senior manager. All complaints are reviewed.”
- 5.3 All reviews of complaints are to be completed within 14 days, and in the event of the review being unable to be completed within that timeframe the senior manager must notify the complainant in writing of progress. The complainant must be furnished with progress reports as required by the Code of Rights (Rights 10(3) and 10(7)).

- 5.4 Tairawhiti Healthcare has an appeal process for complaints management where the complainant disputes the outcome. The investigation team requested documents relating to the appeal process for the period covered by the terms of reference. It was advised that the appeal process had not been used. The policy does not state that consumers can be referred to the Health and Disability Commissioner or a Health and Disability Services Consumer Advocate where they dispute the outcome of the THL inquiry complaints process.
- 5.5 Tairawhiti Healthcare has a separate database for tracking the management of complaints. The database was introduced late in 1999. Copies of all correspondence are forwarded to the complaints co-ordinator. There is no statement in the policy as to how long the complaint documents should be stored, or about the safety and security of their storage.
- 5.6 Complaints are grouped into eight categories:
- access to service
 - adverse outcome
 - communication
 - cultural
 - facilities
 - privacy
 - services
 - system error.
- 5.7 Complaints entered on the database are presented to the Q&RMC as percentages in the categories described. The December 1999 report to the Q&RMC noted that “Group Co-ordinators/team leaders have been invited to identify the information they wish to have reported for their services”.
- 5.8 Of 127 complaints entered on the database and provided to the investigation team, 87, or 68.5 percent had outcomes entered. Sixty-two percent of those outcomes involved a letter rather than a meeting as the main contact with the complainant. THL does not appear to have a culture of meeting complainants. It was also not possible to tell from the database information given to the investigation team which manager was responsible for the stewardship of each complaint.
- 5.9 Complaints to Tairawhiti Healthcare are handled by the Quality Co-ordinator. She advised the investigation team:

“Sometimes the Quality Co-ordinator responds to the complaint and sometimes a senior manager or other person who is dealing with the complaint responds to the complaint. Medical staff seldom respond, but sometimes write reports on complaints that involve them.”

- 5.10 Consumers have the option of taking their complaints to the hospital, the Health Consumer Trust Advocate or the Health and Disability Services Consumer Advocate. The Chair of the CQG, in his capacity as Maori Health Manager, advised the investigation team that if people discuss their concerns with him and then wish to make a complaint, he assists them with their complaint by filling out an incident form and passing it to the Quality Co-ordinator. If they are not satisfied with the outcome of the complaint he advises them to come back to him, and he will then follow up where possible. If thereafter further follow-up is required, he will assist complainants by referring the matter on to the independent Health and Disability Services Consumer Advocate.
- 5.11 People working within THL appeared to have very different impressions of how the complaints system operated depending on their place in the organisation. The former Group Manager (Hospital) (Ms Rachel Haggerty) described there being “quite structured processes around reviewing complaints, including reviewing clinical records, identifying process changes that need to be made and following up on those. They had a reasonably good level of closure with consumers. I would meet personally with the patients and their whanau. Very few people would just get a letter” However, this view was not shared by others.

Complaints review procedures

- 5.12 The 1998 Stage One Internal Clinical Audit noted in the section on complaints/systematic learning that, while there was learning from individual complaints, it was unclear whether there was “systematic learning from a regular analysis of the overall frequency and nature of the complaints”. The Group Manager (Hospital) noted in response: “there is regular analysis with review of complaint[s]. Trends are looked at but there is at present no link to QA mechanisms.”
- 5.13 The Stage Two Internal Clinical Audit conducted in August 1999 noted that a PC-based computerised database “has been operating for 2 weeks. Data will be analysed and action taken via Clinical Board and/or Executive Management.” There was no evidence of any discussion of complaints in the Clinical Board or Senior Management Group minutes provided to the Commissioner’s investigation team.
- 5.14 A monthly report on complaints is made to the CQG, with a quarterly summary to the Audit Committee. This report includes a summary of complaints reported and reviews of those complaints. There was no evidence from the CQG minutes supplied to the investigation team of any discussion on the monthly complaints report. There is no evidence that the Board of Directors receives a regular summary of the complaints being handled by Tairāwhiti Healthcare.

The consumers' views

- 5.15 At the hui attended by my investigation team, comments were made by consumers about the Tairāwhiti Healthcare complaints process. The Māori Health Manager reflected such complaints, saying that he “receives a lot of complaints from Māori about the manner in which they are treated at maternity services”.
- 5.16 A member of the Gisborne Health Committee advised that: “people will not come out and complain readily because the fear is someone will find out and they will not be treated”. She said it is a perceived fear because she has never known of any reprisals, but that fear is there, especially with Māori and Pacific Island people.
- 5.17 The Gisborne Health Committee reported that it has always been able to get appointments with the Chief Executive to discuss their concerns. The Committee has found that the senior managers do listen and minutes are taken “but the Committee is not sure if action is always taken”. The Committee sees its role as keeping community concerns on the agenda.
- 5.18 An advocate who was involved with the Cancer Society noted that “coastal patients with cancer are not referred [by Gisborne Hospital] for palliative care services from the Society. Newly diagnosed patients with cancer get missed and there are no formal referrals.”
- 5.19 Another hui attendee, who had formerly worked at Tairāwhiti Healthcare, commented:

“The complaints process is not genuine or sincere and was set up to fail.

Patients would attend meetings and then they would go nowhere. The complaint lives a short life and dies.

The manager/s responsible managed and controlled the process and would use time to wait out the process so the complaint would go away. Complainants would still have ill feeling and would not feel like the matter was resolved.

Kaumātua are often not up front, reluctant to complain or push the issue.

The process is a genuine attempt to minimise problems in the organisation so the organisation does not have a bad image and nobody in the organisation is fingered as a bad performer.”

6. OPINION

Incident reporting

- 6.1 For incident reporting to be a significant tool at THL, all levels of the organisation need to be educated about the value of incident reports within an

- effective hospital wide quality system. Starting with the Senior Management Group, there needs to be a demonstrated commitment to open discussion of incidents, identification of any trends, and development of achievable projects to address significant risks.
- 6.2 To minimise risk and maximise patient safety, staff at Gisborne Hospital need to experience the educative benefits of reporting incidents in a learning culture. They currently experience reporting incidents in a blaming culture.
 - 6.3 The incident reporting process at Gisborne Hospital has become personalised. Staff interpret the completion of an incident form as a criticism against an individual staff member rather than an opportunity to improve patient safety.
 - 6.4 Staff do not trust the current incident reporting system to address their concerns and have used other mechanisms, for example, the anonymous letter that was part of the background to this investigation.
 - 6.5 An effective incident reporting system is one that captures all incidents or unintended events, including those that have resulted in injury, adverse events, potential incidents and “near misses”.
 - 6.6 The capture of this information enables investigation of the root cause of the incident, monitoring of the extent to which it is occurring, and the taking of steps to reduce the risk of the incident recurring.
 - 6.7 Awareness of the nature, causes and incidence of failures is a vital component of prevention. Low-level incidents or “near misses” can provide a useful pointer to more serious risks and can allow lessons to be learned before a major incident occurs.
 - 6.8 There are two ways of viewing incidents or human error, the person centered approach, and the systems approach, with the former being the more commonly used. Quick judgements and the assignment of blame to individuals (which are characteristic of the person centered approach) obscure a more complex truth. Although a particular action or omission may be the immediate cause of an incident, closer analysis can reveal a series of events or departures from safe practice, each influenced by the working environment and the wider organisational context.
 - 6.9 The process of investigating in-house incidents should be able to be carried out by in-house personnel without staff feeling there is a conflict of interest. THL does not have a Medical Director and at the time of the syringe incident did not have a Director of Nursing. An effective incident reporting system relies on people in key positions with the authority and mana to carry out an internal investigation.
 - 6.10 Effective risk reduction means taking account of all the factors and changing the environment, as well as dealing with personal errors and omissions. This cannot take place in a culture where disciplinary considerations are always put first. Blame and disciplinary sanctions lead inevitably to defensive reactions, withholding of information and difficulty in ascertaining the facts.

- 6.11 Guidelines are given in THL’s Incident and Complaint Management Policy (Statement 10) on the action to be taken if complaints are not resolved within the 14-day time period. A similar guide is needed in relation to incident reports so that relevant staff are informed of progress with a review and resolution of an incident.
- 6.12 Feedback is essential if learning and/or changes in practice are to occur as a result of incidents. Feedback can take a variety of forms (for example, trend reports) and does not necessarily mean time-consuming one-to-one feedback.
- 6.13 There is an urgent need for clarification of which incidents staff can expect feedback on, education on the use of the system (to avoid trivial reporting), and clear accountabilities for follow-up. Staff receiving limited or negative feedback are unlikely to continue using the system in the medium to long term. Education will contribute to addressing the issue of over-reporting of non-serious incidents and under-reporting of serious incidents.
- 6.14 There is no written framework in place to guide what needs to be reported. The Quality Co-ordinator makes a personal judgement based on her clinical background. This is an inappropriate responsibility for one clinician and will result in inconsistency of reporting should the role at any time be undertaken by another person.
- 6.15 As the Clinical Board’s purpose is to seek continuous improvement to the quality of clinical services, its role in incident reporting requires review. Clinical leaders require feedback, eg monthly reports, to manage and further develop the service they provide to patients.
- 6.16 The incidents involving Dr Lucas provide an excellent illustration of the complex inter-related issues discussed in this review of the incident reporting system. An incident form which was witnessed as being completed and handed in was lost. The root cause of the issues were not identified nor addressed. There was a lack of clarity about what should be reported and different views of this resulted in criticism and blame. Finally, the lack of feedback to staff who were genuinely concerned about issues resulted in them utilising other avenues to have the issues recognised and addressed.
- 6.17 As a provider of health services at Gisborne Hospital, THL was a health care provider subject to the duties and providers specified in the Code of Consumers’ Rights. Under Right 4(5), every consumer is entitled to “co-operation among providers to ensure quality and continuity of services”.
- 6.18 In a hospital setting, providers include hospital staff, whether managers, doctors, nurses, technicians or support staff, who provide, or support the provision of, health services to patients. Right 4(5) requires such individual providers, working within an organisational provider, to work together co-operatively. The rationale for this legal duty is spelt out in the closing words of Right 4(5): to ensure quality and continuity of services.

- 6.19 In my opinion, patients of Gisborne Hospital could not be assured that incidents that impacted, or had the potential to impact, on their safety and the quality of their care would be reported and followed up. Where individual providers, such as nurses, filled out incident reports, THL and its managers did not “co-operate” by taking appropriate action and giving feedback to the reporter. The quality and continuity of care for patients at Gisborne Hospital was potentially compromised by the failure to have an effective incident reporting system that staff could have confidence in.
- 6.20 In my opinion, by its failure to have in place an effective incident reporting system at Gisborne Hospital, Tairawhiti Healthcare Ltd breached Right 4(5) of the Code.

Complaints procedure

- 6.21 Right 10(6)(b) of the Code requires an organisational provider to have a complaints procedure that ensures that the consumer is informed of any relevant internal and external complaints procedures.
- 6.22 In my opinion, the complaints procedure at THL did not comply with the requirements of Right 10(6)(b) of the Code. The policy does not ensure that consumers are informed of any relevant internal and external complaints procedures, including the availability of Health and Disability Services Consumer Advocates and the Health and Disability Commissioner. In this respect I find that Tairawhiti Healthcare Ltd breached Right 10(6)(b) of the Code.
- 6.23 In light of the evidence submitted by consumers to my investigation team, I am left in doubt whether Tairawhiti Healthcare Ltd also breached Right 10(3) of the Code by failing to “facilitate fair, simple, speedy and efficient resolution of complaints”. I am also sceptical about whether Tairawhiti Healthcare Ltd was complying with its duty under Right 10(8) to inform consumers “as soon as practicable” after deciding whether it accepted that a complaint was justified, of “(a) the reasons for the decision; (b) any action the provider proposed[d] to take; that and (c) any appeal procedure ...”. However, I make no specific findings in relation to these issues.

7. RECOMMENDATIONS

Continuous quality improvement

- 7.1 A cross-functional team (with clear terms of reference) should be established to evaluate and further develop the current incident reporting system, with a particular emphasis on developing a framework that guides: what to report; which incidents will be reviewed; and by whom.
- 7.2 The purpose of the Incident and Complaint Management Policy should be extended to include a statement that reflects the value of complaints and incidents as learning opportunities for the organisation and as a component of continuous improvement.
- 7.3 An internal investigation of a complaint or review of a reported incident should lead to internal disciplinary processes or mandatory training only where there is evidence of repeated poor performance that breaches professional standards of conduct or constitutes a major departure from the standard of care and skill reasonably to be expected in the circumstances.
- 7.4 Definitions of reportable incidents should be reviewed and consideration given to clearly differentiating “incidents”, “near misses” and “adverse events”.
- 7.5 The layout and content of the incident report form should be reviewed and consideration given to further information that it may be valuable to capture, such as the location where the incident occurred, the outcome, contributing factors, and whether the incident was preventable.
- 7.6 Numbers should be printed on the incident forms to enable tracking, and hard copies should be kept in the reporting department.
- 7.7 Consideration should be given to categorising incidents (eg clinical/non-clinical; major/minor; actual/potential) to enable investigation, reporting, quality improvement and monitoring to be effectively targeted.
- 7.8 The text of the Incident and Complaint Management Policy should be reviewed and requirements relating to incidents and complaints should be more clearly differentiated from each other.
- 7.9 A standardised approach to incident investigation should be adopted across Tairāwhiti District Health to enhance consistency of investigations, reduce staff anxiety and provide the basis for educating staff who have this responsibility.

Culture

- 7.10 Consideration should be given to confidential (but not anonymous) reporting of “adverse events” or “near misses” until the culture of fear changes.

- 7.11 Feedback should be sought and utilised from users of the system. Staff satisfaction with the incident reporting system should be formally monitored at designated timeframes.
- 7.12 A system-centered approach should be initiated, rather than a person-centered/blaming approach.
- 7.13 Support people should be welcome at incident review discussions.

Education

- 7.14 The education of staff on the incident reporting system (at orientation and thereafter on a regular basis) should be reviewed so that staff are clear about the philosophy behind incident reporting.
- 7.15 All staff groups should receive sufficient education to gain a clear understanding of the incident reporting system and their responsibilities within it.
- 7.16 A standardised education programme for all staff groups should be implemented as an urgent priority at Tairāwhiti District Health.

Incident review process

- 7.17 The process for incident review should be clearly defined.
- 7.18 Staff delegated incident review responsibility should receive appropriate education for the role.

Reporting and monitoring

- 7.19 Monitoring should be introduced with a focus on ensuring that serious failures are not recurring.
- 7.20 All evaluation methods listed in the Incident and Complaint Management Policy should be implemented: ie, monthly reports to the Quality and Risk Management Committee and Core Quality Group, and quarterly reports to the Audit Committee.
- 7.21 “Near misses” should be reported and analysed to identify common factors and causes.
- 7.22 Accountabilities for monitoring incident trends should be clarified and clear processes established to ensure accountability. (The Quality and Risk Management Committee is currently responsible for the regular monitoring and improvement of the incident reporting system. The Committee’s responsibility for monitoring the outcomes from the system is less clear.)
- 7.23 The Clinical Board should establish a timetable (eg, three monthly) for analysing reported incidents across Tairāwhiti District Health with a view to discerning trends.

- 7.24 The Clinical Board should be given responsibility for monitoring the implementation of action plans designed to address organisational trends identified in clinical incidents.
- 7.25 Each area should receive regular (eg, monthly) reports on incidents occurring in their area (including trends); such reports should be discussed at a staff meeting and action plans implemented as appropriate.
- 7.26 Clinical leaders and line managers should monitor repeated incidents involving the same individual.

Notification

- 7.27 A clear statement should be made to staff at all levels describing types of incident that require immediate notification to the line manager.

Follow-up

- 7.28 The recommendations in the Medical Practitioners Quality Assurance Activity: Tairawhiti Notice 1998 related to incidents should be implemented consistently.
- 7.29 The findings of the Health Funding Authority audit (31 August 1999) should be reviewed to identify any outstanding areas still to be addressed.

Complaints handling

- 7.30 Complaints offer a provider organisation the opportunity to understand the needs of the consumer and in so doing to enhance the level of service, trust and connection between the organisation and its community. This is especially true for public hospitals. Wherever possible, complaints should be resolved face-to-face, and followed up by letter.
- 7.31 The complaints system at Tairawhiti District Health will be enhanced by an effective and fully operational database.
- 7.32 There is a need to link complaints data to risk management processes and educational processes at Tairawhiti District Health.
- 7.33 If Group Managers and Service Managers are to be responsible for managing the complaints in their areas, there is also a need to train them in conflict resolution and the management of complaints.
- 7.34 As an alternative to recommendation 7.33, the Quality Co-ordinator, as the person at Tairawhiti District Health with overall responsibility for managing complaints, needs to be adequately resourced.

Response to recommendations

- 7.35 Tairawhiti District Health accepted all of these recommendations, and advised that they have been implemented or are in the process of being implemented.
- 7.35 It would appear that significant progress is being made by Tairawhiti District Health in the improvement of the incident reporting and complaints procedure.

Chapter 4

Operating Theatre Protocols October 1999 _ June 2000

1. INTRODUCTION

- 1.1 The focus of this chapter is the allegations made against Dr Brian Lucas, and staff and management responses to those allegations. This raises the issue of the applicable protocols and standards, and whether they were complied with. This chapter relates to three of the terms of reference. The key relevant term of reference concerns whether or not “operating theatre protocols and compliance with such protocols between October 1999 and June 2000” breached the Code of Health and Disability Service Consumers’ Rights. Another important term of reference deals with the handling of incident reporting (which was a problem in relation to complaints about Dr Lucas) and in that regard specific mention is made of the re-use of anaesthetic syringes (which Dr Lucas admitted doing on occasion). There is a more general term of reference on quality assurance, which includes incident reporting as well. The terms of reference overlap.
- 1.2 The allegations against Dr Lucas all arose in the theatre at Gisborne Hospital. The theatre facility is generally regarded as well equipped with modern technology and easy to work in. The layout of the theatre facilitates good anaesthetic practice.
- 1.3 Actual operation of surgical and nursing services in theatre at the relevant time appears to have been far from ideal. Almost everyone spoken to by the investigation team had a concern of one sort or another: low morale, lack of leadership, restructuring, staff losses, poor communication, inadequate ongoing training, etc. It has not been necessary here to refer in any detail to those complaints. It is, however, background to be borne in mind. The environment in theatre appears not to have been happy before Dr Lucas arrived. The schisms created by Dr Lucas’ attitude and behaviour may have been, in part, symptomatic of pre-existing suspicion and distrust; they certainly exacerbated it.
- 1.4 THL stated:

“The Commissioner would be hard-pressed to find a hospital in New Zealand where the staff do not have a [concern] of some kind about their workplace if pressed (or given the invitation and opportunity as presented in this extraordinary case). Health services have been under constant review and have been operating for years under tight financial constraints. THL was no different from any other small rural and isolated hospital in New Zealand.”

2. DR LUCAS' EMPLOYMENT

- 2.1 Dr Brian Lucas, a Canadian anaesthetist, was employed as a locum anaesthetist at THL from 27 September 1999 to 25 March 2000, following temporary registration by the Medical Council of New Zealand. He was employed by the former Group Manager (Hospital) (Ms Rachel Haggerty). Dr Lucas' references were checked by the Head of Department (Anaesthesia) (Dr James Carstens). The Head of Department commented that the references were "favourable". The references included the following statements:

"He was an Anaesthetist very well trained especially in O & G and had no complaints regarding his technical ability. He was not unduly prickly and had no problems with the staff. He was obsessional about things being done correctly in patients' interests and disliked sloppy standards."

"He was competent, very thorough, congenial, a good teacher, had done numerous locums for [the referee] and got on well with surgeons and nurses. He was slow, meticulous, careful and was slick with needles especially spinal and epidural techniques. He had good all round knowledge and [the referee] would re-employ him anytime."

Apart perhaps from the reference to Dr Lucas being obsessive about correct standards, there is nothing here to warn of the difficulties that arose at Gisborne Hospital.

- 2.2 Dr Lucas' appointment was approved on 25 June 1999 by the Medical Appointment Committee, a sub-committee of the Clinical Board.
- 2.3 During the course of Dr Lucas' employment at Gisborne Hospital there were a number of incidents involving him which were brought to the attention of the Theatre Manager (Ms Helen Stephenson), the Group Manager (Hospital) (Mr Dan Madden), the Clinical Director (Surgery) (Dr Ian Burton), the Head of Department (Anaesthesia) (Dr James Carstens), and the Quality Co-ordinator (Ms Lynsey Bartlett). Those incidents are considered in turn below.

Dr Lucas' impressions of theatre

- 2.4 Dr Lucas was not impressed with the way theatre worked at Gisborne Hospital. He believed significant changes needed to be made:

"I had a sense that I had been brought to Gisborne at a pretty high cost. When I arrived at Gisborne Hospital I saw a mess. I had a choice to either contribute to the mess or fix it up in six months. That was how long I was at Gisborne Hospital. I did not leave at the end of six months because I wasn't happy. It was because of my wife's nursing career that we decided to go to Gisborne Hospital for only six months. I tried to do as much good as I possibly could in the time available. Timeframes sometimes require me to be forceful. I only had six months at Gisborne Hospital so I couldn't wait five years for something to happen."

- 2.5 Dr Lucas was very concerned at the frequency with which theatre sessions were cancelled. He described the theatre as “horribly inefficient”.

“Often the first 8.30 patient would not be in the theatre and available for my care until 8.50. I am used to an 8.30 booking to mean that the cut is made at 8.30. Another cause for delay was that the nurses preferred to prepare their instruments in an anteroom and would not come into the theatre until the patient was asleep. Sometimes they seemed to require coaxing even at that point. They preferred to attach the brackets for the various table attachments only after the patient was asleep. They preferred to check the function of the fluoroscopy machine only after the patient was asleep and when it did not work immediately, anaesthesia was needlessly prolonged. In all of these examples the rationale of their approach was that they didn’t want the patient to be frightened; they didn’t want the patients to see the instruments. To me this seems a very condescending attitude to patients. What did the patients think they were in theatre for?”

- 2.6 Dr Lucas’ drive for efficient use of the theatre upset the routine of others; he got off-side with them. He also used techniques that were not commonly employed in Gisborne (for example, his use of ice, and the demand for clip-on straps for theatre tables), and this led to misunderstandings.

Staff perceptions

- 2.7 Staff perceptions of Dr Lucas are important to an understanding of the incidents that are alleged to have occurred in theatre and the allegations made. A range of comments were made about Dr Lucas from the very negative to the very positive. The following comment from a senior doctor may explain much about staff perceptions:

“[Dr Lucas had] difficulty in reading social cues. He would not have wanted to have hurt anyone. He was naïve, oriented to doing a good job and not attuned to social banter. He was honest to the point of being blunt.”

What to one person is bluntness is to another humiliation. This was the response of the anaesthetic technician who said she was called incompetent and useless by Dr Lucas in front of others and felt “like a piece of dirt”. Dr Lucas denied calling anyone incompetent or useless, either alone or in front of others.

- 2.8 A surgeon stated of Dr Lucas:

“He is an interesting and quite sophisticated person. Some of what he said could be perceived in a negative way especially by those who have no sense of humour, limited intelligence or perhaps a bad will. He is somewhat extraordinary but in a good way. No doubt he is a serious, intelligent, sensible, very well qualified and trained medical professional. If he demanded something he would be persistent about it.

He often insisted on getting things done and it was always for the benefit of the Operating Theatre.”

- 2.9 The technical and nursing staff’s ability to raise their concerns with Dr Lucas at the time the alleged incidents happened was influenced by their perceptions of his likely response. The investigation team was told by nurses and anaesthetic technicians: “If we challenged Brian Lucas he became aggressive and also became rude to the patients. After a while we chose not to challenge him because he would take it out on the patients as well as staff.”
- 2.10 One surgeon’s impression of Dr Lucas was that he had a personality problem and was a bit arrogant. The surgeon commented that nursing staff did not like Dr Lucas and he did not like them. He witnessed antagonism between Dr Lucas and nursing staff.
- 2.11 The Group Manager (Hospital) said of Dr Lucas:

“He was always looking for a way to smarten things up. Dr Lucas was different to what provincial staff at Gisborne were used to.”

- 2.12 It is fair to say that Dr Lucas polarised the people he worked with. His colleagues who were doctors tended to appreciate his contribution more than his nursing and anaesthetic assistant colleagues. A prevalent view among the latter group was that no action was taken against Dr Lucas because senior clinicians and managers thought it was nothing more than a personality clash. A “them-and-us” attitude, which was probably there already, intensified.

Anaesthetists

- 2.13 The Australian and New Zealand College of Anaesthetists provides the following standard for specialist anaesthetists:

“Specialist Anaesthetists recognise that:

Regular work in anaesthesia of appropriate volume and complexity is necessary to maintain clinical skills.

Participation in an ongoing programme directed at maintaining proper clinical standards of practice is required.”

[The Standards of Practice of a Specialist Anaesthetist (1994) p 16]

- 2.14 The practice at Gisborne was for each anaesthetist to develop his or her own subspeciality.

Anaesthetic technicians

- 2.15 The anaesthetic technician’s role is to assist the anaesthetist. The role was described as setting up for the procedure, assisting the anaesthetist, drawing up the drugs, occasionally putting an IV line into a patient, and checking the

anaesthetic machine. The Charge Anaesthetic Technician orders anaesthetic equipment.

2.16 There were at the relevant time six anaesthetic technicians at Gisborne Hospital. Of these, three were fully registered, and two of the others were in the process of training when Dr Lucas arrived.

2.17 Dr Lucas had not worked with anaesthetic technicians before coming to Gisborne. He did not know what their role was and who they were answerable to administratively. He thought that they came somewhere below a nurse. An anaesthetic technician stated:

“Dr Lucas said he was used to working alone. I got the feeling that he didn’t like technicians doing anything. In fact he wanted the technician out of the room.”

2.18 Dr Lucas stated:

“I queried whether they are answerable to the nurses because on occasion when I asked the chief technician for a certain item or piece of equipment, like for example, the famous straps [theatre table restraints] the chief technician said that she would have to take that [request] to the charge nurse. The theatre technician’s role job status and training status was never clearly defined to me by anyone. I got the sense that they were not as trained as nurses and that they were assigned to help the anaesthetists. I observed anaesthetic technicians did errands in theatre.”

2.19 There was some confusion about who the technicians in theatre reported to with different accounts given to the investigation team of the reporting lines. This was evidenced by the confusion amongst technicians and other theatre staff about who was responsible for the technicians’ performance appraisals. THL advised that the anaesthetic technicians report to the Theatre Manager, who is responsible for their appraisals, but during anaesthesia the technicians are responsible to the anaesthetists.

Dr Lucas’ orientation to theatre

2.20 The Human Resources Department co-ordinates the induction programme, which is now run monthly. Each department is responsible for inducting new members of staff to that department.

2.21 Dr Lucas described his orientation as follows:

“When I arrived at Gisborne Hospital I was anxious to start my job. I was concerned that it took about a week for me to be taken through the orientation process in the hospital. I thought that this process could have been completed in a day because all I needed were some lab coats, a pager, a cell phone, to have my picture taken and arrangements made for salary payments.”

- 2.22 Dr Lucas' orientation programme was co-ordinated by the Charge Anaesthetic Technician. The Charge Anaesthetic Technician described Dr Lucas' orientation to theatre as follows:

“On his first day he was shown all the equipment and what was available. Dr Lucas asked about the role of the anaesthetic technicians. It was explained to him that he would always have an assistant in every general anaesthetic case. [The Charge Anaesthetic Technician] explained that anaesthetic technicians were not the equivalent of nurse anaesthetists. Dr Lucas said that nurse anaesthetists do most of the work and have an overseer anaesthetist. Dr Lucas was happy that someone would be allocated to him, specifically for anaesthetics and not to be shared with the surgical side.”

- 2.23 The Head of Department (Anaesthesia) advised that he:

“spent a lot of hours going over pre-operative assessments, the lists, his core responsibilities and duties with Dr Lucas as part of [his] induction. I tried to make him feel at home. I spent time with him socially, inviting him to my home. Dr Lucas spent the whole day with the senior anaesthetic technician who showed him around the hospital, including ICU. His role in the department was explained to him and the complementary role of staff.”

- 2.24 Dr Lucas advised that he was not aware of any theatre protocols while he was at Gisborne Hospital and he was not invited to read any theatre protocols. Dr Lucas advised that usually protocols come in a binder that is about four inches thick and he was not sure in fairness whether he would have sat down and thumbed through the theatre protocol if it had been presented to him. THL stated that staff clearly recall that Dr Lucas was either given the orientation manual prior to his arrival or upon arrival.

- 2.25 Dr Lucas advised he was given a small Department of Anaesthesia protocol binder but this mainly consisted of history and physical requirements. He was not given the orientation manual, relating specifically to THL's processes and procedures, provided to new junior doctors at Gisborne Hospital.

- 2.26 Dr Lucas stated in his telephone interview:

“No-one from Tairāwhiti Healthcare ever discussed with me what was expected of me in the anaesthesia room. I was shown the anaesthetic equipment by the Head of Department (Anaesthesia). The machine was one I was familiar with, as were the anaesthetic agents.”

- 2.27 Dr Lucas did not receive any formal induction in terms of Maori culture and protocols. THL said the Group Manager (Hospital) referred Dr Lucas to the Maori Health Manager and also advised him to look at the Code. Dr Lucas informed me that he did know about the Maori Health Manager and sought his advice and help about Maori patients on at least two occasions. Dr Lucas said he enjoyed the enrichment of Maori culture: “I made a point of going to the

Tolaga Bay Wild Food Festival and Ngati Porou Hui for the cultural immersion and where I ate not one but two kinds of huhu grubs.”

- 2.28 The Group Manager (Hospital) advised that “given concerns regarding Dr Lucas, measures have been taken to improve the orientation given to overseas Doctors”. The Clinical Board is reviewing the orientation material provided to senior doctors.

3. RE-USE OF SYRINGES

The alleged incidents

- 3.1 Dr Lucas was alleged to have breached consumers’ rights to services of an appropriate standard by re-using “single use only” syringes periodically from October 1999 to March 2000.
- 3.2 A single-use disposable syringe is defined as a “device that is intended [by the manufacturer] to be used on one patient during a single procedure. It is not intended to be reprocessed [cleaned and disinfected/sterilised] and used on another patient” (definition from the United States Food and Drug Administration Agency, November 1999). It is generally considered that many items marked “single use” by manufacturers can be safely sterilised and that devices are marked “single use” to protect manufacturers.
- 3.3 According to the Charge Anaesthetic Technician, at the time of induction she “specifically mentioned [Gisborne Hospital’s] non re-use policy” to Dr Lucas, bringing to his attention that syringes were for single use only and indicating the words “single use only” on the packet. Dr Lucas disputed this.

Timeline

- 3.4 The Chief Executive provided the following timeline of events relating to this allegation.

27 September 1999	Dr Lucas temporary registration commenced, Class 3b, temporary locum consultant anaesthetist
30 September 1999	Employment commenced
1 October 1999	First theatre list by Dr Lucas
Approx 1-2 weeks later	Head of Department (Anaesthesia) approached Dr Lucas, advised practice unacceptable
Approx 2-4 weeks later	Group Manager (Hospital) approached Dr Lucas
26 November 1999	Incident form reported by Theatre Manager. “It has been brought to my attention that Dr L[ucas] continues to re-use syringes although [the Head of Anaesthesia] has spoken to him about this being unacceptable.”

7 December 1999	Incident report reviewed by Clinical Director (Surgery)
16 March 2000	Northland issue reported on TVOne news
17 March 2000	Northland issue reported in NZ Herald
17 March 2000	E-mail from Northland CEO re “anaesthetic issue” (this alluded to previous media story): “We have a problem with one of our anaesthetists. My initial enquiries have disclosed some interesting facts which I am told are common practices in this country. No-one counter checks Although many things are counted and recounted in theatre, syringes are not.”
	CEO e-mail query to Theatre Manager, Clinical Director (Surgery) and Hospital Manager re “What is our practice? Do we have a similar risk?”
	Clinical Director (Surgery) e-mail to CEO “We have recently had a minor problem with a locum anaesthetist but it was very rapidly dealt with and so I don’t think we have anything to be concerned about.”
26 March 2000	Dr Lucas’ employment ceased
1 May 2000	Northland patient notification date
9 May 2000	CEO advised that Dr Lucas had re-used syringes
9 May 2000	File note, Chapman Tripp contacted
17 May 2000	Audit Committee briefed
23 May 2000	Legal advice provided by e-mail
23 May 2000	Board of Directors briefed at meeting.

Dr Lucas’ explanation

3.5 Dr Lucas described his practice as follows:

“My practice was to refill the rather expensive propofol and rocuronium syringes and re-use them. The injection site I would use was either of the two on the administration IV set. The type of intravenous cannula that is used at Gisborne has an injection site integral to the cannula but I preferred not to use that one, its being too close to the patient. Within a week (perhaps two) of starting, Dr Carstens approached me and told me that the practice was considered substandard at Gisborne. I subsequently stopped the practice with only very rare subsequent lapses as I changed my habit after 26 years of practice in Canada.”

3.6 Dr Bruce Duncan, as acting Medical Director and then Clinical Director (Public Health), who investigated Dr Lucas’ practice of re-use in May 2000 for THL, summarised a telephone call with Dr Lucas. The following is an excerpt from an agreed summary of that telephone conversation:

“In our interviews with anaesthetic technicians they confirmed that you had a particular preference for intravenous fluids and that the usual practice was to give IV fluids during the anaesthetic. There was general agreement that, if an IV line was in place, you would have used the injection port on the line to administer any agent.

The technicians commented that there would have been a small number of cases where there would not have been an IV line. MUA was one category. In that situation you would have given agents through the cannula.

In your reply you indicated that the number of cases where an IV line was not in place would have been very small. You accepted, however, that there were some. You commented that the type of case where it might happen were very unlikely to have been part of a routine list. For such cases your practice would have been not to re-use syringes from such cases. This was because the syringes were used in such proximity to the patient and would have presented a risk to subsequent patients and in those cases [you] would discard the syringes after use.”

Explanations of re-use

- 3.7 Dr Lucas described his re-use of syringes as a habit of over 20 years. It was suspected by anaesthetic technicians and theatre nurses that subsequently Dr Lucas re-used syringes intentionally, in order to save money for the hospital. The Head of Department (Anaesthesia) gave as an explanation that “Dr Lucas came from Canada. In Canada they do not have a set written standard not to re-use a syringe.”

Staff observations of re-use

- 3.8 Dr Lucas admitted to the occasional lapse in re-using syringes after being told it was not acceptable practice at THL. A few staff (one nurse and two technicians) saw him re-use on isolated occasions, but it was suspected he re-used more frequently than that. Apparently, in order to pre-empt this, technicians began to throw out syringes between patients, but Dr Lucas was not happy about that and told at least one technician not to do so.
- 3.9 Two of the surgeons interviewed by the investigation team reported that they did not see Dr Lucas re-use syringes. A locum surgeon reported never seeing Dr Lucas re-use syringes and not being aware of any conflicts about the re-use of syringes until he read about it in the newspaper. He asked other surgeons and some of the anaesthetists whether they had seen Dr Lucas re-using syringes. “They only heard, but never actually saw it for themselves.” Two anaesthetic technicians never saw Dr Lucas re-use or refill syringes.
- 3.10 The Head of Department (Anaesthesia) stated that only two of the six anaesthetic technicians saw Dr Lucas re-use syringes. He confirmed that given “anaesthetic technicians are there all the time, they would have seen it had Dr Lucas been constantly re-using syringes”. A surgeon reported a doubt that anyone witnessed Dr Lucas re-using syringes.

Reporting of staff concerns and initial management action

- 3.11 In the first week of Dr Lucas' employment a dental list went over time. Dr Lucas thought the fault lay with an anaesthetic technician because she had been throwing out his used syringes. The anaesthetic technician mentioned the incident to the Charge Anaesthetic Technician and reported filling out an incident form about the re-use of syringes. A witness saw the technician fill out an incident form and hand it in, but the form was apparently lost. Some senior clinicians and managers questioned whether the incident form was handed in.
- 3.12 The Charge Anaesthetic Technician informed the Theatre Manager in October 1999 on the Manager's return from leave that Dr Lucas was re-using "single use" syringes. The Theatre Manager, who was on leave, when Dr Lucas started work, informed the Group Manager (Hospital) about the re-use of syringes issue in writing. She also reported speaking to the Quality Co-ordinator about her concerns.
- 3.13 Within the first few weeks of Dr Lucas' employment the Head of Department (Anaesthesia) was told by the Theatre Manager that Dr Lucas was re-using syringes. The Head of Department took Dr Lucas aside and told him "it was an absolute no-no". He also spoke to the Group Manager (Hospital) about the re-use incident and told him that he had spoken to Dr Lucas.
- 3.14 It appears the Head of Department (Anaesthesia) acted in response to the incident in October, despite the fact that the incident form was lost. The Head of Department believed that Dr Lucas had ceased his practice of re-using syringes. He was very upset when he discovered that Dr Lucas later disobeyed his specific instructions.
- 3.15 A further incident form relating to the re-use of syringes was completed by the Theatre Manager in November. This form is undated but was registered in the incident reporting system on 26 November 1999.
- 3.16 The Quality Co-ordinator received this report and sent it within 24 hours to the Group Manager (Hospital) and the Clinical Director (Surgery). She was not aware that there had been an earlier report in October about this issue, because that report was mislaid and so never reached her office. After the incident was brought to their attention, the Group Manager (Hospital) and the Clinical Director (Surgery) discussed the matter.
- 3.17 The Clinical Director (Surgery) delegated the matter to the Head of Department (Anaesthesia) because he was concerned that Dr Lucas was close to leaving due to the criticisms levelled at him and thought that his involvement might precipitate a resignation. He was concerned at the possibility of losing Dr Lucas with the approaching millennium. In his view "the issue of re-use of syringes was about anaesthetic technique". Dr Lucas responded that he did not consider resigning and gave no indication that he would do so.

- 3.18 Before the millennium celebrations there was a desire on the part of several management and clinical staff not to take action that might precipitate Dr Lucas' resignation. After those celebrations, at a meeting in February, staff were advised to "hang on" as Dr Lucas' contract had only a few weeks to run.
- 3.19 The Charge Anaesthetic Technician reported becoming desperate when nothing appeared to be happening despite the incident reports and meetings with management. She wrote out a list of concerns and showed the list to an anaesthetist to get his opinion in early February 2000. The Charge Anaesthetic Technician wanted to know whether it was right to raise these concerns. She reported being reprimanded about this action "because she had taken her concerns to the wrong person in the chain of command". She thought the criticism related to a matter of professional ethics. The Charge Anaesthetic Technician was advised that it was not right to report concerns about one anaesthetist to another anaesthetist. Anaesthetic technicians and nursing staff were not clear on who could help them with their concerns. None of the anaesthetic technicians or theatre or recovery nurses the investigation team interviewed had any confidence in the quality assurance and incident reporting systems.
- 3.20 For the anaesthetic technicians and the nursing staff the situation was complicated by Dr Lucas' part in other incidents. Anaesthetic technicians and nursing staff found it increasingly difficult to work with Dr Lucas.

Whangarei Hospital incident

- 3.21 After Dr Lucas left Gisborne Hospital there was an incident at Whangarei Hospital involving an anaesthetist re-using syringes. THL received an e-mail from Northland Health about this. The Clinical Director (Surgery) originally advised the Chief Executive that the re-use of syringes was not an issue at THL, and that the matter at Gisborne Hospital had been dealt with.
- 3.22 There is disputed evidence as to when the Chief Executive became aware of syringe re-use at Gisborne Hospital. The Chief Executive says she did not know until 9 May 2000, but the Quality Co-ordinator was certain she told the Chief Executive months earlier. Be that as it may, after the media attention on syringe re-use at Whangarei, in June 2000 the Chief Executive instituted an internal inquiry into syringe re-use at Gisborne. Reports were written by the Group Manager (Hospital), the Clinical Director (Surgery) and the acting Medical Director. The acting Medical Director first contacted Dr Lucas on 24 May 2000.
- 3.23 The acting Medical Director and the Group Manager (Hospital) consulted with theatre staff, other clinical staff, the Ministry of Health, a specialist physician from another centre and Dr Lucas. Staff were so stressed by the syringe incidents that they requested counselling. Counselling was supplied on 5 July 2000, by an external counsellor. The key issues that emerged were: lack of management attention to incident reporting and follow-up, relationship difficulties with the Theatre Manager, staff morale and professional safety issues.

- 3.24 It transpired that technical and nursing staff felt that there was a conflict of interest in THL's own investigation into the re-use of syringe incidents being carried out by the acting Medical Director and the Group Manager (Hospital).
- 3.25 As a result of the THL June 2000 inquiry, and advice received by THL, a "look back" programme was put in place. Patients considered at risk were contacted and advised to see their general practitioners.
- 3.26 The draft report from the acting Medical Director (I was not provided with a final report) stated:

"There is no debate that syringes were re-used in the first two to three weeks of Dr L's locum. No written information allows a more precise estimate of the critical time period. While trying not to re-use in the period thereafter, Dr L acknowledges that a 20+ year habit does not go overnight, and that he cannot exclude a further use thereafter."

- 3.27 The report contained a section on the Relevant Infectious Diseases:

"The key infectious diseases to consider are hepatitis B and C and HIV (human immuno-deficiency virus, the causative agent of AIDS – acquired immuno-deficiency syndrome).

The three are all transmitted through blood products and other body fluids. Hepatitis B is the most easily transmitted of the three diseases. Viral load in an infectious person is high, and the infective dose (in terms of amount of body fluid) is very small. While the other two are infectious, their degree of infectivity from small inoculations of blood is far less. The transmission of hepatitis B through needle-stick injury is well recognised: indeed, it is an occupational hazard for health workers. While there is evidence of spread of HIV through needle stick, the risks are of an order of magnitude less.

The prevalence of hepatitis B is higher in Tairāwhiti in general, in particular Māori and Asian populations. While HIV is prevalent in New Zealand, Tairāwhiti is a low prevalence (though not zero) area. The prevalence of hepatitis C is thought to be low.

Hepatitis B is, therefore, by far the most infectious of the diseases under consideration. The local prevalence increases one aspect of the risk of syringe re-use. To become infected there has to be the following chain. Firstly, a preceding patient has to be infectious for the disease concerned. Secondly, there has to be transfer of sufficient viral particles for infection, thirdly, the host patient has to be receptive, that is, non-immune.

Patients were possibly exposed to an infection risk through the transfer of virus particles from one patient's blood or serum to another's through the re-use of a contaminated syringe.

The risk of contamination of the syringe through the process described by the anaesthetist and staff is estimated to be ‘very low’. The risks from the Northland experience were thought to be very low. It is relevant to note that the proximity to the patient’s vasculature in the Northland case was closer than in Gisborne.

In discussion with outside experts, the risk of infection is considered to be extremely low, ‘inestimably low’ was one comment. However, while the risk would seem to be virtually zero, it cannot be claimed to be zero.

One factor that may become important later is the ability (or lack of) to link an identified infection with a potential exposure. For example, for most hepatitis B infections, a definite source cannot be identified. This will be an issue if re-use is a potential source.

While the assessment of risk of transmission suggests a low risk to patients, the risk cannot be stated to be zero. While the risk is thought to be extremely low, actual quantification of risk is not a precise science, instead more of an art, indeed, a numerical assessment of risk is impossible and probably meaningless. The actual risk will vary according to a number of factors. Firstly, is the assessment of risk based on actual occurrence, rather than on recall, influenced by unfolding events? The impact of this on actual risk is impossible to quantify.

The likelihood of re-use was much higher in the first two to three weeks, but as the practice cannot be categorically excluded in the rest of the six month period, it has to be assumed that it could have happened at any point during that time.

The prevalence of hepatitis B is probably around 3%, in infectious form. This measure is one point on a range of estimates. Infectivity itself will vary, according to stage of infection. Some carriers will have low infectivity, others high, depending on ‘e’ antigen status. The prevalence of Hep C and HIV is thought to be low, though no precise estimates are available. However, if the blood or serum from one highly infectious patient, early on a theatre list, were to contaminate a syringe, this could potentially infect the subsequent list of patients.

The challenge will be to communicate the risk in such a way as to be meaningful to people, including the impact of the community perception of risk, where the actual hazard is modified by the public ‘outrage’ at the event happening at all.”

3.28 A second inquiry was instituted by the Board of THL. The former Chairperson of the Board stated:

“About 3 weeks before the HDC Inquiry, I asked for a review of all circumstances. My frustration is that if this had been made known within the organisation possibly people would have stopped writing letters to the Minister. I do not believe management gave this feedback to staff to

assure them management had heard and was taking their complaints seriously.”

- 3.29 The second inquiry was an internal audit conducted by Dr Peter Gow (Chairman of the Clinical Board, South Auckland Health) and Mary Gordon (Director of Nursing Practice, South Auckland Health). The Gow/Gordon audit report, dated 22 September 2000, recommended:

“A more formal procedure to acknowledge receipt of incident forms to the quality co-ordinator needs to be in place. A copy of the incident form needs to be kept in the service area from which the report has come. This would then allow an audit by the service of the action which results from the reporting of incidents. The incident reporting system needs to be accompanied by an educational process, which could be enhanced by details of the protocols for reporting being attached to the incident form booklet.”

Appropriate standards

- 3.30 Following problems in both Melbourne and Whangarei of syringe re-use by an anaesthetist, the Council of the Australian and New Zealand College of Anaesthetists agreed upon a clarification and expansion of the College’s “Policy on Infection Control P28” (1995). This recommendation was issued in May 2000 (after Dr Lucas’ departure from Gisborne).

- 3.31 The text of this recommendation is:

“Recommendation of Re-use of ‘Single Use’ Equipment for Invasive Procedures – May 2000

The labelling of products as ‘single use’ is an indication by the manufacturer that the product is either unable to be re-sterilised or its safe function may be compromised by the re-sterilisation process.

As sterilisation is required for the apparatus that will be used for any invasive procedure (eg intravenous access, regional anaesthesia and invasive monitoring), such apparatus labelled ‘single-use’ must not be reused. This includes all apparatus that is in continuity with the vascular system.”

- 3.32 As Dr Alan McKenzie, Deputy Chairman of the New Zealand National Committee of the Australian and New Zealand College of Anaesthetists, made clear to Dr Peter Schaap of Gisborne Hospital in a letter dated 13 June 2000, this recommendation “makes perfectly clear that re-use of ‘single-use’ devices for invasive procedures or accessing the vascular system of patients is not an acceptable practice”. The recommendation was sent to the Chief Executives of all surgical hospitals and to all doctors identifying anaesthesia as an area of practice in information supplied to the Medical Council of New Zealand.

- 3.33 Before this recommendation was issued the position of the College on the re-use of “single use” equipment for invasive procedures had not been explicit

and there was no agreed international standard on the re-use of syringes. A review of North American literature indicates that a sizeable body of anaesthetists have re-used syringes and that there is no absolute ban on re-use in terms of national standards. This also reflects the New Zealand practice until the recent policy change in May 2000.

- 3.34 The College Policy before May 2000 relating to the minimisation of infection risk to patients stated:

“3. MINIMISATION OF INFECTION RISK TO PATIENTS

Measures to protect patients against acquiring infections through anaesthesia procedures need to address (i) risks related to invasive procedures; (ii) risks or potential risks related to airway management. In both situations appropriate levels of sterility, disinfection and decontamination are to be applied to all equipment used.

Frequent handwashing by the anaesthetist and the anaesthetic assistant is a most important infection control measure. Hands should be washed before handling a new patient or equipment to be used on a new patient, after leaving a patient, whenever they become contaminated and before any invasive procedure. For the anaesthetist’s protection protective gloves are to be worn whenever the hands may contact blood, saliva or any other body fluid and are to be removed after such a procedure to minimize contamination of the workplace.

3.2.1 Disposable Items

Items of airway equipment to be placed in direct contact with the respiratory tract such as endotracheal tubes and airways labelled by the manufacturer as disposable or for single use only should not be re-used.

3.3 Presentation of Drugs for Injection

Because of the potential for cross infection, the use of the contents of multiple dose vials and ampoules for more than one patient is not recommended except in a dispensing situation where different doses are drawn up before the administration of the first dose to a patient. Likewise it is recommended that the contents of a single dose ampoule are to be used for one patient only.”

- 3.35 An independent anaesthetist provided the following advice on syringe re-use:

“Although there may appear to have been too slow an evolution of standards specifically forbidding re-use, in fact there has been ongoing debate concerning risk versus benefit. Re-use of syringes poses a risk to patients; reduction of anaesthesia costs should, theoretically, result in benefits by increasing the number of treatments or access to other treatment modalities. It has to be remembered that many of those engaged in this debate have a very good understanding of the mechanisms of cross infection and that the ‘slow’ change of practice has

not been a result of ignorance or cavalier pursuit of cost containment. As much in response to changed attitudes as to a careful analysis of risk it is now considered unacceptable to re-use syringes except, possibly, under circumstances where there have been precautions taken to eliminate any conceivable risk.

As your investigators' research has shown, Dr Lucas came from a culture that within the last ten years had accepted syringe re-use. It was certainly accepted in New Zealand until a few years ago. It has to be considered that the way the syringe is used will contribute enormously to the risk that re-use poses. The two extremes are the re-use of a syringe which has been in continuity with a system containing blood and re-use when the syringe has been attached at a site remote from the patient, as part of a system which contains valves to prevent backflow.

...

In reviewing Dr Lucas' use of syringes it has to be admitted that it did not conform to current standard practice and that when told that his practice was unacceptable he may not have consistently modified it. Whether this latter failure was intentional or a result of thoughtless habit is not clear."

Opinion

- 3.36 At the core of this issue of re-use of syringes is the fact that though the risk of transmission may be very small, no one can guarantee that it is non-existent. In this situation there are two principles to be kept in mind. The first principle is the prudent avoidance principle, which says that wherever possible risks should be minimised, when it does not cost too much to do so. In the case of re-use of syringes, there is very little convincing evidence offered that the cost of new syringes was a major factor in the practice. It would therefore be in keeping with this principle not to re-use. The second principle is the precautionary one, which provides that when an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. Again, according to this principle, there is no defence for re-using syringes. (Editorial. Caution with the precautionary principle. *Lancet*, 2000;356 (9226):265)
- 3.37 In my opinion, although Dr Lucas' re-use of syringes did not conform with standard anaesthetic practice current in New Zealand from October 1999 to March 2000, it appears that technically he did not breach professional standards. The Australian and New Zealand College of Anaesthetists introduced more stringent standards in May 2000. However, Dr Lucas complied with anaesthetic standards in New Zealand at the relevant time, for re-use of syringes, and therefore did not breach Right 4(2) of the Code.
- 3.38 Right 4(4) of the Code states that "every consumer has the right to have services provided in a manner that minimises the potential harm to ... that consumer".

- 3.39 Re-use of anaesthetic syringes is not a practice that “minimises potential harm” to patients on whom a syringe is re-used. As noted by my anaesthetic advisor, re-use of syringes “poses a risk to patients”. Although the risk of infection may be minimal, it is nonetheless real, as was acknowledged by Tairawhiti Healthcare’s appropriate decision, in June 2000, to implement a “look back” programme and contact 134 Gisborne Hospital patients on whom Dr Lucas may have re-used syringes.
- 3.40 It is no answer to a claim that patient safety is compromised by the re-use of single-use medical devices to say that the minimal risk to the individual patients is outweighed by the overall benefit to patients (more of whom may be treated if scarce health resources are “stretched” by re-use). I do not accept that the patient safety standard of “minimal potential harm”, affirmed in Right 4(4) as an individual right, should be watered down. In my opinion, even if a utilitarian approach is adopted, there is likely to be an overall dis-benefit to patients if clinicians compromise safety for individual patients in the hope of maximising benefit for the community of patients.
- 3.41 I endorse the following helpful statement from the Medical Practitioners Disciplinary Tribunal in *Re White* (Decision No. 69/98/36C, 30 April 1999):

“The prevention of infection and cross infection is fundamental to basic medical practice. Patients have a right to be confident, during examinations and other medical and surgical procedures, that they are not unnecessarily exposed to the risk of infection. For any medical person trained in sterile techniques and aware of the problems of transmission of infection to deliberately disregard this training and information, is, in our view, simply repugnant. Regard must be had for a patient’s safety and well-being. This is fundamental to the contract between a patient and a doctor. That relationship must be based on the patient’s expectation that the doctor will try to do his or her best for the patient under all circumstances.”

- 3.42 In my opinion, by his admitted re-use of anaesthetic syringes, Dr Lucas failed to provide services in a manner that minimised potential harm to his patients and thereby breached Right 4(4) of the Code.

4. THROWING SYRINGES AND BLOODY NEEDLES

The alleged incidents

- 4.1 Dr Lucas was alleged to have breached consumers’ rights to services of an appropriate standard by throwing syringes and bloody needles in theatre, rather than attempting to place them in the receptacle provided.
- 4.2 The NZNO memorandum dated 14 June 2000, which was sent to the Minister of Health and contributed to my decision to inquire into events at Gisborne Hospital, noted that:

“Nurses from other areas (notably ICU) report to me that the anaesthetist [Dr Lucas] was in the habit of throwing sharps – ie, syringes and bloody

needles – at random when events did not go smoothly. I have not yet ascertained whether he aimed at people or just tossed at random. This behaviour was also reported by anaesthetic technicians in theatre and confirmed in conversation today by nursing staff.”

- 4.3 There appear to be no incident reports specifically relating to the throwing of sharps. Incident summaries, not written on the official THL incident form, record the circumstances at the time of the syringe throwing incident but do not specifically mention syringe throwing. There is no evidence to indicate whether or not these summaries were given to management.
- 4.4 Four anaesthetic technicians described their experiences in relation to this allegation. The first stated that Dr Lucas did not “misbehave such as by throwing things in theatre”. The second technician reported seeing Dr Lucas throw an IV cannula across the room on more than one occasion. Other people were present when Dr Lucas threw the cannula but the second technician could not remember who they were. “I was the only one in the room when he threw a 22 gauge needle from one corner of the room to the other. It was a bloody needle. On another occasion he threw a 20 gauge needle onto the floor because he couldn’t get it in the vein.” This technician described Dr Lucas’ behaviour as a temper tantrum. “He would pick up a tray and throw it on the floor if he did not like its position.” According to this technician, Dr Lucas acted like this from the beginning of his time at Tairawhiti Healthcare.
- 4.5 The third anaesthetic technician saw Dr Lucas throw cannulas. The technician observed that:
- “Dr Lucas would get agitated if things didn’t go right. If he could not insert a cannula on the first attempt the cannula would go flying. I observed this on one occasion. Dr Lucas was trying to insert a cannula and couldn’t the first time. The patient was still awake and Dr Lucas pulled the cannula out. There was a sharps bucket in theatre and Dr Lucas threw the cannula towards the sharps bucket but it ended up on the floor. Dr Lucas walked over to the trolley to get another cannula. I cleaned up the mess on the floor. I heard that Dr Lucas did not like objects on top of the anaesthetic machine and would throw them off. While I did not observe this, a colleague did.”
- 4.6 The fourth technician did not see Dr Lucas throw sharps. He saw him toss a sharp half a metre on to an anaesthetic tray, “but it was tossing not throwing”. The technician would not expect other anaesthetists to toss sharps and he has not seen other anaesthetists do so at Gisborne Hospital, but he commented that “people get stressed and do not always behave by the rule book”.
- 4.7 A nurse reported that she saw Dr Lucas throwing sharps in theatre. She reported that Dr Lucas became very frustrated when treating a badly hurt child. He could not get a line into the child’s arm. “He threw a sharp across the room. I didn’t think his action was justified. He threw the sharp away to the corner of the room and not into the sharp receptacle which was situated behind him.”

- 4.8 In a group interview with anaesthetic technicians and theatre nurses it was reported that: “Once he flung a lead apron across the room in orthopaedic theatre, after speaking to an anaesthetic technician. He would go bright red in anger. Who knows the reason. It was irrational behaviour.”
- 4.9 A surgeon described having seen Dr Lucas get angry once. At that time he saw Dr Lucas throw a plastic syringe into a container from a distance of about two metres. He said Dr Lucas did not endanger anyone by throwing the syringe.

Dr Lucas’ explanation

- 4.10 Dr Lucas denied ever throwing a tray at any time, under any circumstance. Dr Lucas also denied ever throwing things off the anaesthetic machine. He said the top of the machine is an important work surface. At Gisborne this surface was “cluttered” and he remembered that “at least once a blue plastic tray was accidentally pushed on the floor”. The tray “contained things that would have been more efficiently stored in the top drawer of the machine as [occurred] in every other hospital I have worked in”.
- 4.11 Dr Lucas provided the following explanation about the alleged incidents:

“The account of this as I read it in the newspaper, seemed to conjure up the image of sharp blood contaminated needles arching across the theatre near personnel. That did not occur. It was frequently my technique to kneel on the floor in order to insert the IV cannula into a vein while the patient’s arm remained hanging down by the side of the table. Occasionally when I was not successful this first time I would make a second attempt and while still kneeling push the needle used in the first attempt out of harm’s way along the floor towards my anaesthetic cart which sat by the wall some five feet away. This happened about three or four times while I was in Gisborne. When I did this I invariably did so after looking to see that no personnel were near by. When the IV had been started I would pick up the needle and put it in the ‘sharps’ container. The first I heard of this being viewed as a concern was in the newspaper.”

Management response

- 4.12 The Group Manager (Hospital) commented to the investigation team that the issue of sharps throwing was raised after Dr Lucas had left THL. A couple of anaesthetic technicians mentioned to an anaesthetist, who left Gisborne before Dr Lucas left, that Dr Lucas was throwing dirty needles around the place because he was upset. That anaesthetist reported to the investigation team that the anaesthetic technicians felt physically endangered. The anaesthetist reported orally passing this information on to the Group Manager (Hospital) before he left Gisborne. The discussion was “off the record”. The anaesthetist commented that he had mentioned the matter to the Group Manager (Hospital) because he felt that the Manager might do something about it.

- 4.13 The Chief Executive told the investigation team that she first heard about the needle throwing incident on Radio New Zealand ‘Morning Report’. A meeting was planned to discuss issues and concerns about Dr Lucas with NZNO and theatre staff. She could not understand why there was no incident form about the needle throwing, and thought the incident was seen by staff in terms of Dr Lucas “throwing a paddy rather than safety”.
- 4.14 The Group Manager (Hospital) told the investigation team that the allegation seemed to him to relate to the dislike of Dr Lucas by one theatre nurse and one anaesthetic technician, and the negative attitude towards Dr Lucas. The Group Manager (Hospital) found out about the sharps in relation to an orthopaedic case:

“[A surgeon] was on duty with Dr Lucas and there was a ‘run in’ in theatre. This was when Dr Lucas was alleged by technicians to have thrown sharps in theatre. [The Group Manager (Hospital)] was asked by [the Theatre Manager] to come down to theatre to talk to staff as they were upset. Technicians and nursing staff considered Dr Lucas had been unreasonable and there was an antagonistic relationship between all the parties. A child had been anaesthetised and [a nurse and a technician] were concerned about how Dr Lucas had treated the child and the mother. Both sides were ‘prickly with each other’. Dr Lucas had run away from the theatre and had had words with ... the orthopaedic surgeon. In the [Group Manager (Hospital’s)] opinion the matter was farcical, and in Dr Lucas’s view [the nurse and the technician] were unco-operative.”

Appropriate standards

4.15 THL's policy on sharps disposal includes the statement:

- “3. Whenever sharps are used, approved sharps containers will be available for disposal.
4. The original sharps user is to dispose of it at its point of use in an approved sharps container.”

The policy on the treatment of used items at THL is: “When handling used items universal precautions shall be followed at all stages of handling to prevent exposure to blood and body substances.” Under universal precautions it is recommended that all health care workers take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices. The policy states: “All single use items should be discarded appropriately after use according to local regulations”.

Opinion

- 4.16 Although the allegation was sensationalised and some of the people involved did not like Dr Lucas, there is evidence that Dr Lucas did not follow THL's policy on sharps disposal. Specifically, he failed to dispose of sharps in an approved sharps container or temporarily place them in a suitable alternative receptacle.
- 4.17 In my opinion, by failing to comply with a “relevant standard” Dr Lucas breached Right 4(2) of the Code.

5. RIPPING OR CUTTING PATIENTS' GOWNS

The alleged incidents

- 5.1 Dr Lucas was alleged to have failed to treat consumers with respect and provide services in a manner that respected the dignity of individuals, by ripping or cutting off patients' gowns and objecting, between anaesthetic procedures, to nurses or technicians covering women's breasts after their gowns had been removed.
- 5.2 In the letter to the Minister, NZNO noted that Dr Lucas “had a practice of ripping or cutting gowns off patients, invariably [those of] women”.
- 5.3 The Head of Department (Anaesthesia) advised the investigation team that maternity patients came to theatre with gowns wrapped round them, not operating gowns with the usual split up the back. The gowns needed to be pulled up to gain access to insert the epidural and to tape tubing on patients' backs. Dr Lucas wanted patients to wear the standard operating gowns to prevent all the tugging and pulling of the wrap-around gowns. “It was difficult to turn patients on the narrow bed, and it is far better to have a clearer view when inserting an epidural. It is better for the patient.” It was the way Dr Lucas did this that was said to create conflict and a tense atmosphere.

- 5.4 The technicians, nurses and midwives objected to Dr Lucas departing from the practice of lifting the theatre gowns. Cutting the gown was perceived as unnecessary and revealed more of the patient's body than was thought necessary. Respect for dignity appears to have been the reason why pre-slit operating gowns were not used at Gisborne Hospital. The midwives were opposed to their use.
- 5.5 An incident form dated 23 December 1999, referring to the general practice of cutting gowns, records an incident where a maternity patient had her gown cut by Dr Lucas. There is no recorded outcome for the incident form dated 23 December 1999 and no official "reply" or evidence of an investigation was received by the Manager of Maternity Services.
- 5.6 No complaints about the cutting of gowns were ever received from patients.
- 5.7 Concerns were raised with the Group Manager (Hospital), and he met with maternity staff, and later with Dr Lucas. THL stated that following these meetings the issue was resolved.

Dr Lucas' explanation

- 5.8 Dr Lucas stated: "This whole issue [cutting and ripping of gowns] had been the subject of an incident report and had been discussed with Mr Madden, long before I returned to Canada."
- 5.9 Dr Lucas noted that patients needing Caesarean sections wore long mid-calf length gowns that did not open at the back:
- "These gowns interfered with theatre preparations of the patient including placement of ECG electrodes, and administration and subsequent testing of regional anaesthesia. Trying to move these full length gowns out of the way was at best uncomfortable for the patient and at worst not safe as the theatre tables are quite narrow. Furthermore, struggling with gowns was an inefficient and unnecessary consumption of theatre time. All other patients arrive in theatre in the standard theatre gown which is specially designed for safety and efficiency with opening back and arms."
- 5.10 Dr Lucas preferred the traditional back-opening gowns. He considered these were less disruptive to the patients as they provided better spinal access. Dr Lucas advised that "theatre gowns in theatre are such a basic given".
- 5.11 Dr Lucas asked the midwives to send patients to the theatre with the usual theatre gowns that all other patients have worn for decades. He also went to the obstetric ward and expressed his preference to the Charge Midwife.
- 5.12 When Dr Lucas' request to the midwives did not work he simply cut the gown at the back "rather than jostling and bustling the pregnant ladies who really resent moving when they are in late pregnancy – the less moving the better".

5.13 He told the patients what he was going to do:

“I simply cut [the gowns] up the back to revert their function to a theatre gown. I informed the midwives that would be my practice as long as they sent long theatre unfriendly gowns. I told the patient what I was going to do. I did not rip, tear, avulse nor ravage the gowns off!! I simply cut them up the back to convert their function to a theatre gown. The gown so cut was not removed from the patient’s shoulders but could be pushed up to expose the patient’s abdomen and chest as necessary for the operation. I reject totally that the cutting of the gown was done in a disrespectful way to the patients. It was done for their comfort and safety and was explained to them.”

Management response

5.14 The Group Manager (Hospital) felt that the issue relating to the cutting of gowns was sensationalised in the media. He felt there was a witch hunt against Dr Lucas with regard to the issue of the gowns. He reported having spoken to Dr Lucas about the incident.

5.15 Dr Lucas advised that Mr Madden asked him not to cut gowns again. Dr Lucas does not know whether the nurses ever knew that he was asked not to cut gowns again. Dr Lucas further advised that there was no hard copy proof that the nurses were requested to send the patients with theatre friendly gowns. In his opinion, “the whole thing just went off in an inconclusive fog”.

Audit report

5.16 The Gow/Gordon audit report recommended:

“Although it is acceptable to suggest changes in procedure, it is critical that these be discussed formally by a multi-disciplinary group of those affected by the changes, preferably also including the patient or client, in a co-operative environment of consensus decision making. If agreement cannot be reached consideration could be given to using a senior multi-disciplinary clinical group leader, such as the clinical board, to facilitate the process.”

Appropriate standards

5.17 My expert medical advisor stated that the ability to access a patient’s lower back for spinal anaesthesia is essential for good clinical anaesthetic practice. The patient needs to be in the lateral position with her or his shoulders curled in and their knees bent upwards towards the chin. Exposure of the lower back area is essential to determine the landmarks required for insertion of spinal anaesthesia. It is important that this area be kept as sterile as possible throughout the procedure. This requires that any clothing, drapery or other items be away from the insertion site of the needle.

5.18 My expert anaesthetist advised: “Patients coming to theatre should have a gown which will permit arms to easily be withdrawn from sleeves and be

opened to allow application of ECG electrodes or administration of spinal or epidural anaesthesia.”

- 5.19 THL has no documented policy on the use of gowns.

Opinion

- 5.20 I accept the advice of my expert clinical advisors that access to a patient’s lower back for spinal anaesthesia is essential for good practice. Although, to a lay person, the notion that the anaesthetist might cut or rip open the back of a theatre gown is surprising, I accept that Dr Lucas’ decision to cut gowns open, and his manner of doing so, was consistent with professional standards. I note in passing that no patient who ever experienced Dr Lucas cutting the back of her gown in theatre made a complaint. Whatever the disquiet of some of Dr Lucas’ colleagues, who were concerned about patient dignity, the patients themselves do not appear to have voiced any concerns.
- 5.21 Accordingly, in my opinion Dr Lucas did not breach Right 4(2) of the Code in relation to this matter.

6. INAPPROPRIATE USE OF ICE

The alleged incidents

- 6.1 The manner in which Dr Lucas used ice to check the level of anaesthetic block was alleged to have been inappropriate. In particular, it was alleged that ice cubes were rubbed over women’s nipples until the cubes melted and until after the patients had confirmed they had no feeling above the relevant area.
- 6.2 The investigation team gathered first-hand evidence of Dr Lucas’ use of ice from two nurses, four anaesthetic technicians, a surgeon and a patient. Apart from one nurse, those who recorded incidents in writing relating to Dr Lucas’ use of ice had not personally seen him using ice, but were recording concerns they had heard from witnesses.
- 6.3 An anaesthetic technician reported to the investigation team what she had seen in relation to a patient who was having an epidural steroid:

“The patient was on her back, and had already been given the epidural steroid. The patient had a gown on and Dr Lucas started rubbing ice down the patient’s side to the groin area and he did it over and over. [The anaesthetic technician] went and got another technician, to see what the other technician thought of it, because [she] had never seen ice used in this way before. The other technician had seen ice used before, but not to that extent. The epidural steroid patient had had back and leg pain and she had received an injection of corticoid steroid. Dr Lucas explained that he was checking how far the epidural block had gone up. [The technician] was concerned about the length of time that it took Dr Lucas to test the epidural block with the ice because the patient was getting cold and Dr Lucas only did one side with the ice. Dr Lucas went down the left side of the patient, down the side of the nipple, down to the

hip and then he pulled the gown up and rubbed ice down the side of the patient's groin. Dr Lucas used three to four normal sized ice blocks to test the epidural block. By the time Dr Lucas had finished, the patient was pretty wet. The patient was in the room for about three quarters of an hour."

6.4 Another anaesthetic technician reported:

"Dr Lucas would talk to the patient and explain what he was doing. He would draw the ice up over the breast nipple and pat up there repeatedly. He would do this well after the patient had said she could not feel it. I had an unimpeded view from where I was standing of the patient's breasts."

6.5 The Charge Anaesthetic Technician saw Dr Lucas use ice once when she assisted him to put in an epidural. She felt uncomfortable about the way in which he used ice. In her view he went too far up the woman's body, although he was not rubbing the ice all over the woman's breast.

6.6 Two nurses reported notifying management in writing about the inappropriateness of Dr Lucas' use of ice. However, the Group Manager (Hospital) was not aware of any formal written notification (either an incident report or hand-written note) being received.

6.7 A nurse stated to the investigation team that Dr Lucas used the ice up and over the breasts and over the nipple:

"The ice definitely connected with the nipple. He exposed the patient's breasts which is not my idea of what is appropriate – you should maintain the patient's dignity. Between testing we would surreptitiously attempt to cover up the patient and Brian Lucas would uncover the patient. He got annoyed that we had covered the patient. He was aggressive."

This nurse reported filing an incident report with a page of notes stapled to the official incident report about the earlier ice incident, which she did not witness, but which she heard an anaesthetic technician describe.

6.8 A handwritten note was completed on 10 February 2000 by another theatre nurse, documenting her concerns at Dr Lucas' use of ice to check the extent of the anaesthetic block. This handwritten note does not appear to have been registered as a formal incident. The nurse was concerned about the patient's dignity. She attempted to maintain the patient's dignity by covering the patient's breasts. Dr Lucas instructed her not to do this again. She stated:

"As the anaesthetic was beginning to work Brian Lucas rubbed ice around her breast. The ice did not go over her nipple, but over both sides of her breast. I tried to cover her up between applications of ice and each time he would uncover her again. When everyone in theatre was ready Brian Lucas said to her 'Legs up'. He spoke rudely to her. I could see she was upset and felt uncomfortable."

- 6.9 One anaesthetic technician had seen ice used before. The anaesthetic technician commented that for those anaesthetic technicians who had not seen ice used before, it became a “big issue”. The anaesthetic technician compared Dr Lucas’ use of ice with other anaesthetists the technician had worked with:

“Dr Lucas however went for maximum exposure of the patient and very aggressive touching. Staff tried to cover the patient once he had tested an area. Dr Lucas would start at the thigh and work right up to the shoulders. The ice went over the breast but I could not tell if it was rubbed over the nipple but I do not think so. I did not see it. It was the way in which Dr Lucas used the ice which was different from how I had seen it used elsewhere. He used a large amount of ice and rapid movements. He had an aggressive manner. If the patient gave the wrong answer he would rub the ice again and again until the patient got confused and could not say whether the sensation was cold because if you rub ice long enough on skin, the skin starts to feel numb anyway. Patients looked confused.”

- 6.10 A surgeon reported never witnessing any inappropriate use of ice. His view was that Dr Lucas’ use of ice was not suggestive or disgusting, and the ice was not used in a sensual way.
- 6.11 A patient who was to have a vaginal hysterectomy recalls Dr Lucas applying the ice to her thighs. She wanted a general anaesthetic but Dr Lucas preferred to administer a spinal. The issue of whether to have a spinal or a general was debated in the theatre and the patient became upset. A spinal was initially administered but Dr Lucas gave a general when he realised that the patient wanted a general. While Dr Lucas was administering the spinal, ice was used to measure the extent of the block. The patient found it difficult to describe the sensation. Because she was “dilly dallying” with her answers to Dr Lucas “he got short with me” and said “listen to the question, I’ll rephrase it”. The patient remembers this as brusque. The patient reported that she “felt like a little school girl”.
- 6.12 This patient wrote to me expressing her concerns about the ice and her right to choose the anaesthetic method that was used:

“On February 10th 2000, I had a vaginal hysterectomy and pelvic floor repair at Gisborne Hospital, performed by [a surgeon]. My anaesthetist was Mr Brian Lucas, and I was not happy with the way I was treated by him, at the time leading up to the operation. I had decided long before, and stated to several different people, including I think, ... the House Surgeon, that I definitely did not want to be awake during surgery, yet Mr Lucas continued, while I was on the table preparing to be anaesthetised, to try to persuade me to have only a spinal anaesthetic. To illustrate his point he began pushing me on my hip area for what seemed unnecessarily long, saying that this is how it would feel while the operation was in progress. At one point he became annoyed when I did not answer the question correctly, and spoke to me like one would a small school child.

He tried to persuade me not to have a ‘general’ for so long that I became tearful. The ice treatment I had never struck before and found it difficult to tell where the numbness stopped, and I also did not think it necessary to keep testing with the ice right on up to and including my bosom area.

All in all, I was upset by the whole proceedings with Mr Lucas.

I did not like his manner, and feel it should be reported.”

Reports to management

- 6.13 There are varying accounts of how concerns about Dr Lucas’ use of ice was brought to the Theatre Manager’s attention. A technician who had observed Dr Lucas using ice thought one of her colleagues had advised the Theatre Manager. According to the Theatre Manager this ice incident occurred on the same day that she completed the incident form about Dr Lucas’ re-use of syringes, which was in November 1999. The Theatre Manager’s undated handwritten document, written after her return from leave on 11 October 1999, referred to an anaesthetic technician reporting an ice incident. The Theatre Manager has not been able to find this incident form.
- 6.14 The Charge Anaesthetic Technician was absent from the theatre when the ice incident occurred on about Wednesday 10 November 1999. She was told about it on her return. She was not sure what to do about her staff’s concerns (two anaesthetic staff and several nurses were present at the meeting), so she took the evening to think about it. When she got to work the next day she happened to hear Dr Lucas ask for the name and phone number of the “ice incident” patient. She was very concerned about this.
- 6.15 Dr Lucas responded to this as follows:

“Reading [para 6.14 of the Report] has given me new insight into a situation that I had reported to Mr Madden and have reported to your [investigation team]. It had to do with a patient who had been admitted solely for an epidural steroid injection for chronic back pain, which I did. When injecting the steroid, it is standard practice to verify the position of the needle by injecting some local anaesthetic with it and demonstrating an area of anaesthesia on the skin, in my case using ice. I wanted to make a follow-up telephone call to the patient to ask about possible side effects of the procedure and its effect on her pain. The theatre nurses who would not use their access to the computer to obtain the telephone number thwarted me in my efforts. I had no idea that the ice-use dynamic was going on subversively in the background. Having consultants contact their patients post operatively is seen by many as an exemplary level of practice. I took this issue to Mr Madden but he was unwilling or unable to persuade the nurses to give me a telephone number.”

- 6.16 The Quality Co-ordinator informed the investigation team that she had never received an incident form on any ice incident. A theatre nurse who had

completed a formal incident form commented: “I don’t know where the report is. We didn’t get any feedback on the incident report. To my knowledge there were no other channels available. I thought incident reporting was the proper channel.”

- 6.17 The Group Manager (Hospital) commented in his interview on the lack of reporting of the allegations regarding “unconscious women having ice rubbed on their breasts. None of these matters were formally documented or reported.”
- 6.18 The Chief Executive reported learning of staff concerns about Dr Lucas’ use of ice through either the Clinical Director (Surgery) or the Group Manager (Hospital). The Chief Executive was advised that she needed to know about the allegations of inappropriate use of ice. “The concern was that there may be inappropriate behaviour with sexual implications.” The Chief Executive then received feedback that Dr Lucas was using ice but was using it appropriately.

Dr Lucas’ explanation

- 6.19 Dr Lucas responded as follows:

“This procedure was carried out in standard fashion for proper medical reasons. The skin level of anaesthesia necessary for a comfortable intra-abdominal procedure, regardless of its location, is the fourth thoracic dermatome. The skin landmarks for this level are the nipples (on male and female). The state of the art method of testing the level of anaesthesia is with an ice cube. It provides a uniform stimulus unlike a needle and unlike a needle, does not injure. The testing for the level of block is done immediately, rapidly and repeatedly once the spinal medicine is administered, as head up or head down positioning of the patient can influence the level of the block, if done quickly. The whole procedure is a trifle frenetic and the level is established in less than ten minutes. The procedure is done with some sensitivity to modesty and the gown is left across the chest and is pulled up no more than is necessary for the testing. If, during that process, a nurse or a technician continually pulls the gown down to obscure where I am testing, they will be criticised for getting in my way. I think it is important to ask how my anaesthetics for Caesarean sections compared in terms of quality, speed and safety, with those of the other anaesthetists. I can say that more than one of the local anaesthetists had asked me about the details of my technique of doing a spinal.

I might add that between the years of 1982 and 1997 I worked in Vancouver’s tertiary obstetrical hospital and treated countless Canadians just the same as I did the women of Gisborne.”

Management response

- 6.20 The Theatre Manager reported to the Group Manager (Hospital) what she had been told about Dr Lucas’ use of ice. The incident was treated as serious in

that one of the anaesthetic technicians who had witnessed Dr Lucas' use of ice was called to a meeting with the Group Manager (Hospital), the Head of Department (Anaesthesia) and the Clinical Director (Surgery). Questions were asked about Dr Lucas' use of ice and whether Dr Lucas had used the ice in a "normal way" or whether it was done in a "sexual way". The technician replied that it was not used in a sexual way.

6.21 The anaesthetic technician was clear that there was no sexual connotation to Dr Lucas' actions. However, the message that the Group Manager (Hospital) had received was that there was a sexual connotation. It appears that others may have interpreted the earlier incident and other unreported ice incidents as having a sexual connotation. The Group Manager (Hospital) thought that the ice incident had been sensationalised.

6.22 The Chief Executive reported:

"It was only when I found out about the re-use of syringes issue [May 2000] that she also found out that theatre staff had not resolved their concerns about the sexual propriety of Brian Lucas' use of ice. In my discussions with the Clinical Director (Surgery) I asked him why he was so confident there was no sexual impropriety. The Clinical Director (Surgery) reported that he had discussed the incident with the person reporting it and specifically asked the question as to whether they thought the incident involved sexual impropriety and the person had said no."

Ice was not commonly used at THL though some technical and nursing staff in theatre realised it was an acceptable practice. NZNO reported that when the issue was raised with Dr Lucas, and other anaesthetists, NZNO members were told they were out of date.

6.23 There was no protocol on the use of ice or other methods of determining the level of anaesthesia.

Appropriate standards

6.24 It is clear that the use of ice to test the level of anaesthetic block is an acceptable and appropriate practice. My expert anaesthetist described it as "completely normal". The issue for anaesthetic technicians and theatre nurses was not whether ice could be used, but whether the way it was used was appropriate. The Head of Department (Anaesthesia) advised the investigation team that: "ice is used as a standard practice to determine the level of anaesthesia. The alternatives are pins or pinching You are allowed to use ice to determine the level."

6.25 An anaesthetist who worked at Gisborne Hospital in the early part of Dr Lucas' employment stated:

"I sometimes use ice with epidurals to measure the level of loss or change of feeling. Certainly the use of ice is an appropriate technique. It is usual to stay in the midline – away from women's breasts. The

women are awake and their partners are often there. It is not usually necessary to go laterally – you go in the midline either side of the sternum, to know if your block is even. It is necessary to know that either side of the midline the levels of the epidural are roughly equal. Sometimes the levels can be ineffective on one side and that is not satisfactory. But there is no need to go as wide as the breasts unless the block appears ‘patchy’ or uneven. A patchy block implies one or two nerve roots may have been missed. There may be a band which is unaffected by the epidural. It may be necessary to ascertain where the band is. The band could probably be ascertained from the midline without the need to go laterally. Using ice over the nipples would rarely be justifiable.”

6.26 The following advice was provided by my expert anaesthetist:

“It is never necessary to touch the nipple during the course of testing although it might conceivably be done accidentally. I would disagree about the use of midline testing ... since this technique may not reliably detect a discrepancy in block height on the two sides in my practice testing would involve placement of the ice in the mid-axillary line allowing most of the breast to remain covered. The upper level of testing may go as high as the axillae and inner surface of the arms. The nipple line is certainly not too high if the planned surgery is Caesarean section.”

6.27 Dr Lucas responded as follows:

“The level of block necessary to be sure of comfort during an intra-abdominal procedure is the 4th thoracic dermatome to assure blocking of the T5-10 splanchnic sympathetics. T4 is not only too high, it is likely the minimum level to be reliably assured of comfort. That is at the level of the nipples in the midline, not in the mid_axillary line. Other useful cutaneous landmarks are the symphysis pubis at T12, the umbilicus at T10, and the xiphisternum at T7, all measured in the midline. I am uncertain if anyone knows the cutaneous landmarks for the T4 dermatome if measured in the mid axillary line; I don’t; it is not described [in] any textbook that I am aware [of]. I would disagree with my colleague [quoted in para 6.26].

Having said that, the skin at the midline of the abdomen receives enervation from both sides and so testing there may lead to ambiguous results in the event of an asymmetric block. I therefore disagree with my colleague [quoted in para 6.25]. One is always trying to rule out a patchy block. Stay away from the midline I would advise.

Thus, I choose the mid-clavicular line, in sight of the midline but well away from the midline. Testing is done first on one side and then on the other. Necessarily, one moves the ice on to the breast but as the nipple is approached the ice is moved medially to avoid it. I did not run the ice over the nipple.

I think it would be fair if you acknowledged the fact that more than one anaesthetist asked me how I did my spinals implying that my technique was worth emulating on the basis of its results. Why had they not chosen to emulate the anaesthetist that you quote in [para 6.25]?”

Opinion

- 6.28 The use of ice by Dr Lucas was described as “aggressive” and by himself as “a trifle frenetic”, but there appears to be no evidence that it was clinically inappropriate. I accept my expert advice that Dr Lucas did not breach professional anaesthetic standards in his use of ice. Nor do I find any evidence that Dr Lucas breached ethical standards by using ice in an improper manner. Accordingly, in my opinion, Dr Lucas did not breach Right 4(2) of the Code by his use of ice.
- 6.29 Right 6(1) of the Code states that “every consumer has the right to all information that a reasonable consumer, in that consumer’s circumstances, would expect to receive”.
- 6.30 Dr Lucas noted that from 1982 to 1997 he treated countless Canadians in the same way as he did the women of Gisborne. In my opinion female patients in New Zealand, on whom ice is to be rubbed for anaesthetic purposes prior to a surgical procedure, would expect a reasonably full explanation of how and why the ice is to be applied. Any surgical patient is likely to be apprehensive about surgery and may be ill at ease in the unfamiliar surroundings of an operating theatre. A procedure which involves intimate parts of the body may cause additional stress and embarrassment.
- 6.31 One patient wrote to me that she did not “think it necessary to keep testing with the ice right on up to and including [her] bosom area”. This patient was entitled to an explanation of how and why Dr Lucas proposed to apply the ice. Had such an explanation been given, her concerns could have been alleviated, or another method of testing the level of an anaesthetic block could have been offered to her.
- 6.32 I note that, although a number of Dr Lucas’ nurse and anaesthetic technician colleagues expressed concern about his use of ice, only one of the many female patients on whom he used the technique complained about it, notwithstanding the widespread publicity in Gisborne about the allegations and the availability of my investigation team for interviews.
- 6.33 In these circumstances, I find that Dr Lucas failed to give one patient the information that a reasonable patient in her circumstances would have expected to receive, and therefore breached Right 6(1) of the Code.

7. TILTING THE OPERATING TABLE

The alleged incidents

- 7.1 It was alleged that Dr Lucas failed to treat patients with respect and failed to provide services in a manner that respected the dignity of individuals by tilting

the operating table on a number of occasions so that patients had to cling tightly to the table to stop sliding off.

7.2 NZNO stated in the letter to the Minister of Health:

“The anaesthetist [Dr Lucas] claimed thick leather straps were essential to secure patients to the operating table. The Theatre Manager refused to order these items and the anaesthetist responded by tipping the table so women, especially Caesarean section women having epidurals, had to cling tightly to the table to stop sliding off. All the surgeons approached the Theatre Manager individually to urge the purchase of straps until the anaesthetist departed. Since then there have been no requests for straps.”

7.3 Dr Lucas denied tilting the table to obtain straps. He says he tilted the table “either because a 15 degree table tilt is standard of obstetrical care for Caesarean section or because table tilt was a necessity for laproscopic cholecystectomies”.

7.4 The theatre had canvas straps available. According to nurses and anaesthetic technicians, Dr Lucas disliked these straps and wanted new ones that would click on the side of the table. Dr Lucas said the available straps seemed difficult to use, were not reliably available in every theatre and because they did not attach to the edge of the table potentially would allow a leg to fall off the table. An anaesthetic technician described the existing straps as adequate and had suggested to Dr Lucas that boards be made to support the patients’ legs, but Dr Lucas wanted straps. The same technician described Dr Lucas tipping the table “to the extreme”. The technician commented that Dr Lucas did not have to tip the table to such a degree that the patient is “hanging on for dear life” but that a tilt was necessary for Caesarean section patients pre-delivery. Dr Lucas said that the necessary tilt for Caesarean is 15 degrees and that “may be seen as ‘extreme’ for the under-informed”.

7.5 The Charge Anaesthetic Technician discussed the restraints issue with Dr Lucas. She suggested that alternative leg supports be used instead of the theatre purchasing new straps. Dr Lucas was happy with this for a while but then returned to wanting straps.

7.6 The Theatre Manager claimed that only one doctor was in support of Dr Lucas’ request for straps, but the investigation team found that there was wide support for the use of straps. The Theatre Manager stated: “Staff are not used to strapping patients to flat tables. Mr Burton was the only doctor supportive of the idea. Since Dr Lucas left, no-one except Mr Burton has ever asked for table straps.”

7.7 A Gisborne Hospital surgeon reported that straps are used practically everywhere else except for Gisborne Hospital. He stated that they are important where the position of the patient is changed. In the surgeon’s opinion, Dr Lucas kept asking for the safety belts because he was serious about patient care. Dr Lucas went to Orthotics to show them how to make the belt. The surgeon stated that Dr Lucas “cared about the hospital where he was

only a locum doctor for six months. He was an asset to Gisborne Hospital and I am sorry that this was not always sufficiently appreciated.”

- 7.8 Straps were discussed at a theatre management committee meeting. Mr Burton said he was happy to have the straps, as were the other surgeons, especially for obese patients when tilting for certain surgery. The minutes record:

“[The Theatre Manager] said the nursing staff were researching policies on restraining patients. The straps are to go ahead at minimal cost made by orthotics. [The Group Manager (Hospital)] is happy to write a patient restraint policy for theatre.” (Minutes dated 22 March 2000. This policy was not produced for the investigation team.)

Dr Lucas’ explanation

- 7.9 Dr Lucas responded as follows:

“It is common practice to use uterine displacement in a supine woman being positioned for Caesarean section. This position minimises aorta-caval compression and consequent foetal compromise. The displacement can be achieved by placing a pad under the hip to produce the requisite 15 degrees of lateral pelvic tilt and a corresponding torsion of the torso which, I believe, contributes to post operative backache. A superior method in my opinion, is to tilt the whole table 15 degrees. This causes the mother (both New Zealand and Canadian) to feel like they are going to fall off the table but they are less frightened if they are pre warned that the table is going to tilt. Feedback I received from Mr Madden suggested that I was conspicuous compared to my colleagues, in the length to which I explained things to my patients, obstetrical and otherwise. I also tried, against nursing resistance, without much success, to institute the routine of placing a pillow behind the knees of supine parturients, also as a method of reducing post operative backache. A second group of patients, who are tilted even more than in obstetrics, are the people having laparoscopic cholecystectomies.

In both these groups of patients, or for that matter, in everyone who is anaesthetised or has anaesthetised legs, it has been my observation that a wide safety strap is placed across the legs at mid thigh level. This does not happen at Gisborne.”

- 7.10 When Dr Lucas asked for the straps at Gisborne he was told by a nurse that they were against the hospital policy regarding abusive and excessive patient restraint. Dr Lucas took this issue to the Group Manager (Hospital) who assured him it was not against policy.

Management response

- 7.11 In the opinion of the Group Manager (Hospital):

“Patient straps was another red herring. The Theatre Manager came to me regarding Dr Lucas’ concern about obese patients’ legs and arms falling off the operating table when the patients were being anaesthetised. In my view there was nothing in this. What got reported in the media was blown out of all proportion.”

- 7.12 The Clinical Director (Surgery) explained why in his view straps were necessary:

“With the large size of patients that are operated on at Gisborne Hospital there can be a risk of patients sliding off the table, particularly with gall bladder operations where it is necessary to elevate the head of the table/rotate the table. Dr Lucas suggested the use of straps to minimise the risk of patients sliding on the table. The straps were suggested to secure patients to the table and Ian Burton and others agreed it was a very good idea. Straps were discussed at a theatre management group meeting and Ian Burton understood that [the Theatre Manager] was to arrange for straps to be made in the Orthotics department. The reason no more requests for straps have been made has nothing to do with Dr Lucas’ departure. Ian Burton thought that a request had already been made for the straps and that theatre would be getting the straps. Once the request had been made it was not necessary to have to ask again.”

- 7.13 The Head of Department (Anaesthesia) noted that the use of restraints was totally appropriate and justified:

“I totally supported his request. Patients often come to theatre who are overweight. When the table is tilted, their legs and arms can drop off over the side. It is a safety measure to use straps and a good one.”

- 7.14 Management never responded to staff concerns about Dr Lucas’ request for straps. The Chief Executive reported knowing nothing about the staff concerns about the use of straps until she received the NZNO internal memorandum dated 1 June 2000.

Appropriate standards

7.15 The following advice was provided by my expert anaesthetist:

“A significant number of ‘injuries’ are said to be sustained by the inadvertent ‘falling off’ the operating table of the limbs of unconscious patients. In some centres the application of well padded straps to anaesthetised subjects is quite common. The use of lateral tilt (usually to the left) during Caesarean section is well nigh mandatory. The normal degree of tilting is 15 degrees which normally causes patients to feel they are going to roll off the table unless assurances are given that they are secure. Either the table is tilted to the left and a support placed along their left side which, when they come to rest against it, is often more reassuring than the alternative of a wedge under the right buttock. Legs which are insensible and flaccid as a result of epidural/spinal anaesthesia often need strapping onto the table. Once again Gisborne appears not to have been familiar with this not-so-recent trend in practice.”

7.16 I was also advised by an expert medical advisor that the newest operating tables are being developed to provide maximum flexibility. Optimal patient positioning is of the utmost importance to facilitate the best surgical outcome. Equipment provided to improve patient safety includes flexible arm constraints and pelvic and thigh straps or belts. Instructions for many of the operating tables specify that patients over 135 kilograms are difficult to accommodate safely and require significant additional safety constraints. Failure to constrain patients during anaesthesia may create a potentially unsafe environment for the patient with the increased possibility of developing nerve and local blood vessel damage, skin damage, injury to bones, poor cardiovascular return and, in some cases, increased risk of myocardial and cerebral infarction.

7.17 The THL physical restraint policy is largely focused on behavioural situations. It does not appear relevant to the theatre environment.

7.18 It appears from anaesthetists interviewed that restraints are universally used and are standard procedure. One stated: “The use of straps is common. I would use straps if I was worried about a patient, particularly bigger people, rolling.”

Opinion

7.19 Dr Lucas chose to tilt the operating table when positioning women for Caesarean sections. He attempted, without success, to obtain adjustable straps to restrain patients during the tilting procedure. I accept that Dr Lucas’ use of the tilting procedure, even without straps, was appropriate to facilitate optimal surgical outcomes.

7.20 In my opinion, Dr Lucas exercised reasonable care and skill in providing anaesthesia services to women undergoing Caesarean sections, and did not breach Right 4(1) of the Code.

8. FENTANYL INCIDENT

The alleged incident

- 8.1 It was alleged that Dr Lucas failed to treat patients with respect and failed to provide services in a manner that respected the dignity of individuals, by giving the drug fentanyl to a patient who claimed she was allergic to this drug.
- 8.2 The patient was a nurse who worked on the medical ward at the hospital at the time of this incident. In 1981 her dentist extracted her teeth and administered fentanyl. The patient experienced anaphylactic shock and was admitted to hospital. She was advised to wear a medic alert bracelet advising of her allergy to fentanyl.
- 8.3 The patient's medical record documented her previous allergy to fentanyl. The patient said that she specifically requested that she not be administered fentanyl. It was noted on the anaesthesia form that the patient had been given fentanyl as part of the anaesthesia.
- 8.4 The operation took place on 22 December 1999. She was first on the surgery list for that day. A consent form for treatment (surgery) and anaesthesia was signed by the patient on the day of the operation in the presence of a house surgeon. There is no note on the consent form about the patient's fentanyl allergy. There is an unsigned pre-admission examination form dated 22 December 1999 which contains the house surgeon's writing. There is a separate anaesthesia consent form also signed by the house surgeon. It appears that there was no pre-anaesthetic clinic for this patient.
- 8.5 There is also an undated and unsigned pre-anaesthetic record which records the patient's allergy to fentanyl. The handwriting on this form matches that of Dr Lucas. A reasonable inference can, therefore, be drawn that Dr Lucas filled in this form. The form, under the heading "OTHER", states: "Description of allergy that of simple overdose in patient without IV fluids." Under the heading "PLAN", the form states: "Give fentanyl under controlled conditions to rule out allergy or idiosyncrasy and allow woman to have [fentanyl]."
- 8.6 The patient said in her original letter to NZNO: "I arrived in theatre to be met by a rude and arrogant anaesthetist who informed me he was going to anaesthetise me with IV fentanyl."
- 8.7 The patient felt that her rights as a patient were violated because Dr Lucas ignored her request not to be anaesthetised with fentanyl. The patient stated:

"He just arrived at induction and said that he was going to anaesthetise me with IV fentanyl. Dr Lucas knew about me and my allergy to fentanyl because he had my case notes. Nevertheless, Dr Lucas spoke to me as though I was not even there, as though I was 'nothing, just a woman, just a Maori'. Dr Lucas put his face in my face and intimidated me."

- 8.8 The patient reported being very frightened when she went under the anaesthetic. She worried about her two small children and that she might not be there for them at Christmas.
- 8.9 Theatre staff told Dr Lucas that the patient was allergic to fentanyl but he ignored them. The patient thought that because her surgeon, Dr Burton, was there she would be safe.
- 8.10 After the operation Dr Lucas told the patient that she was not allergic to fentanyl, and that her dentist had overdosed her in 1981. The patient accepts that she was overdosed because 100mg of fentanyl IV is probably an overdose. However, at the time of the operation she said she “begged [Dr Lucas] not to give me fentanyl as I was allergic to it”.

Staff observations

- 8.11 An incident form was completed:

“Patient brought to theatre with documentation stating allergy to fentanyl with previous adverse affects from this drug. Noted on this anaesthetic form that patient had been given this drug as part of anaesthesia once patient had arrived in recovery. Discussed with anaesthetist rationale for giving fentanyl. Patient monitored closely during recovery phase. Nil adverse effects noted.” (Incident report no. 416, dated 22 December 1999.)

- 8.12 The incident form was completed by a nurse who said Dr Lucas filled up the syringe and told the patient it was pethidine. To the recovery nurse he said, “see, she was given fentanyl and nothing happened”. Dr Lucas said that he “told no one that I had given [the patient] fentanyl until the end of the case. Then, I told the recovery room staff and the patient.” Dr Lucas denies that he told the patient that he was going to give her pethidine.
- 8.13 The investigation team asked the nurse to confirm that Dr Lucas had said he was giving the patient pethidine, but in fact he gave the patient fentanyl. The nurse replied “yes, on the nursing sheet it was recorded that she had a fentanyl allergy. It was not recorded on Dr Lucas’ purple sheet.”
- 8.14 The nurse was asked by the investigation team about the comment on the incident review form that there was careful discussion with the patient prior to surgery. The nurse recalled that “there was a discussion of two to three minutes” and said “I don’t believe there was a careful discussion”.

Dr Lucas' explanation

8.15 Dr Lucas remembered quite a lot about the fentanyl incident:

“I did not inform the patient that I was going to give her fentanyl. She arrived in the theatre being described by the nurses and technicians as being terrified before I had said a word to her.”

8.16 Dr Lucas took a careful history of the events of the patient's last anaesthetic, and concluded that whatever misadventure caused the crisis it was not a drug allergy. Dr Lucas advised me:

“When I met her on the morning of surgery ... I took a careful history of the events of that anaesthetic, as would be expected of a consultant anaesthetist, and concluded that whatever misadventure had caused the crisis, it was not a drug allergy.”

8.17 Dr Lucas felt that the patient had been mislabelled or misdiagnosed. Dr Lucas stated that while there are other narcotic alternatives to fentanyl, it is an excellent, widely used narcotic and he believed that it was not in the patient's best interests to spend the rest of her life not having fentanyl available to her. Dr Lucas had discussed the issue with the patient prior to the procedure. During the anaesthetic and thus in a very controlled clinical environment, with her airway intubated and ventilated, and with all the resuscitative drugs for anaphylaxis close at hand, Dr Lucas first administered a tiny test dose of fentanyl. When the patient's condition remained absolutely stable, Dr Lucas continued to use fentanyl as the intra-operative narcotic. The patient was alert when Dr Lucas took her to the recovery room. When Dr Lucas reported the events to the recovery room nurse she seemed appalled. When Dr Lucas explained to the patient what he had done, it was his impression that she thanked him very sincerely.

8.18 When asked specifically whether the patient gave her consent for him to test and trial fentanyl on her when she was asleep, Dr Lucas responded that no, the patient did not give her consent, but she did not forbid him to use fentanyl. The patient was terrified of the prospect of fentanyl anaesthesia because of what had previously happened to her. Dr Lucas did not think it was true to say that the whole debate about fentanyl terrified her. Dr Lucas believes that he did not push the issue about asking her for permission to use fentanyl. In his response to my provisional opinion Dr Lucas summed up his position as follows:

“I did not give an anaesthetic without consent. I had the patient's consent to give an anaesthetic and from my discussions with her I believed that she did not forbid me to give her fentanyl.”

8.19 Dr Lucas advised that he thought it was relevant that the patient was a nurse. He felt betrayed by her because he thought she had thanked him.

8.20 Dr Lucas' view before the operation was that the patient was not allergic to fentanyl. She did not give a history in any way consistent with anaphylactic

shock. He considered that she had had a reaction. He believed that he would help her if he could prove to her that she was not allergic to fentanyl. He said he was motivated by the prospect of restoring to this patient “the availability of a very useful narcotic and at the same time dispelling a delusion about allergy that was terrifying her”.

The surgeon’s view

- 8.21 The patient’s surgeon, Dr Ian Burton, thought that it had been explained to the patient outside the theatre that fentanyl would be used. “She may have been so frightened that she would suffer a significant reaction that it was difficult to determine whether consent was informed.” Dr Burton stated that if he had honestly thought that the patient would suffer an anaphylactic reaction, then he would have cautioned Dr Lucas against using fentanyl. Dr Lucas said he does not know how Dr Burton could have known he was going to use fentanyl. He had discussed it with the patient, and no one else, until afterwards.
- 8.22 The surgeon said that he admired Dr Lucas for taking such a courageous step and testing the patient’s response to the drug. The surgeon carefully reviewed the notes and listened to the anaesthetist. He was satisfied that Dr Lucas was not taking an unnecessary risk.
- 8.23 The surgeon described being almost able to “feel the antagonism of the nursing staff present at the operation”.

The records and pre-anaesthetic checks

- 8.24 The undated pre-anaesthetic record for this patient is described in para 8.5. It recorded the fentanyl allergy and adds under the heading “Other” “description of allergy that of simple overdose in patient without IV fluids”, and notes under the “Plan” “Give fentanyl under controlled conditions to R/O [rule out] allergy ...”. The handwriting on this form appears to be that of Dr Lucas.
- 8.25 While at THL, Dr Lucas stated that he did “quite a bit of the pre-anaesthetic clinic work”. He continued:

“Consent was not an issue at the pre-anaesthetic clinic because I was assessing people and checking out their health pre-anaesthetic. I was not determining or doing informed consent at a pre-anaesthetic clinic. I pointed out to patients at pre-anaesthetic clinic that I would not necessarily be the one who was going to give them their anaesthetic before their surgery.”

- 8.26 A colleague made the following observations about the pre-anaesthetic clinic Dr Lucas worked in every Monday:

“He dealt with the difficult and complex cases and gave a detailed excellent report on each patient and was extremely helpful. I am sorry that this is not continued anymore For every consultation done by Dr Lucas there was usually at least one page of history, examination and

recommendations. It is kept in the Outpatients Department They were excellent and mostly appreciated by all of us.”

- 8.27 The same colleague also commented on Dr Lucas’ technical skills in relation to interviewing and examining patients in the induction room before the operation:

“I am also often there to see my patient before they go to sleep. I found Dr Lucas very careful, precise and professional. He talked to the patients and explained what was going to happen in great detail. He spent quite a lot of time with patients and made them feel secure.”

Management response

- 8.28 The Clinical Director (Surgery) reviewed the incident form. He was also the surgeon in the operation. He was irritated that a nurse new to theatre had completed an incident form on this matter. He wrote on his investigation report: “This is a totally unnecessary incident form. The staff who filled it in should be disciplined and informed of when incident form completion is appropriate.”
- 8.29 The Clinical Director (Surgery), in his written note to the investigation team, explained that he thought it was “quite inappropriate for an inexperienced nurse new to theatre to question a very experienced anaesthetist’s decision regarding the administration of a particular drug”. However, the nurse’s concern centered on the use of fentanyl without consent, not the usefulness of fentanyl itself.

Audit report

- 8.30 The Gow/Gordon audit report commented:

“The comment about disciplining staff who fill out incident forms is unacceptable, both in general terms and particularly with respect to this incident. The Australian Council of Healthcare Standards’ Clinical Indicator relating to drug allergy states that this is a sentinel event. In this instance there is no documentation in the notes relating to this discussion with the patient.

In addition, the giving of an anaesthetic without obtaining informed consent, particularly at a time of vulnerability for the patient, is also unacceptable practice.”

Appropriate standards

8.31 The THL Informed Consent policy notes:

“3. No health care procedure should be undertaken without the patient providing informed consent, except under specific circumstances outlined below [which were not applicable]

11. For surgical or medical procedures which also require an anaesthetic in operating theatres, separate consent should be given for both the procedure and any general or regional anaesthetic required.”

8.32 The Australian and New Zealand College of Anaesthetists (ANZCA) has adopted the following standard:

“1. Patients have the right to: ...

2.3 be informed, with a clear and understandable explanation, of proposed peri-anaesthesia care and procedures including their alternatives and known side effects and risks. Risk should be explained in terms of matters which would be significant to a ‘reasonable’ person in a similar situation.

2.4 refuse the proposed treatment without prejudice to alternative anaesthesia management strategies provided that the implications of the changes are understood by all involved”

Opinion

8.33 The right to refuse consent to a medical procedure is a fundamental recognition of patient autonomy, and is well established in ethics, the common law, and New Zealand statute law. Section 11 of the New Zealand Bill of Rights Act 1990 states that “everyone has the right to refuse to undergo any medical treatment”. Right 7(7) of the Code confirms that “every consumer has the right to refuse services and to withdraw consent to services.”

8.34 It is no answer for Dr Lucas to say that he was motivated by his patient’s long-term safety – in the event of further anaesthetic procedures – in seeking to discover if she was truly allergic to fentanyl. Informed consent is at the heart of patients’ rights, and includes the right to withdraw consent for a health care procedure.

8.35 In my opinion, by proceeding to administer fentanyl to a patient at Gisborne Hospital, in the face of her specific refusal to consent to such administration, Dr Lucas breached Right 7(7) of the Code.

9. METHODS USED TO INDUCE CHILDREN

The alleged incidents

- 9.1 Two nurses completed an incident form (no. 379, dated 21 December 1999), which described the process Dr Lucas had used of inserting a hypodermic needle into a child with no topical anaesthetic:

“5 year old patient for general anaesthetic to excise tongue lesion. IV cannula [subsequently changed to hypodermic needle by unnamed person] inserted whilst child still awake, with no topical anaesthetic, which resulted in child screaming for 5-10 minutes and parent visibly distressed. Child was then physically restrained. Anaesthetist has been previously advised that gaseous induction is the accepted practice for paediatric patients in this hospital. Anaesthetic given by Dr Brian Lucas.”

“Dr Lucas gave IV pentothal via a hypodermic needle into this child’s hand. No IV cannula was inserted. The anaesthetic tech was required to hold the patient’s hand still during this procedure. The child was very upset and struggling and the suxemethonium went extravascularly therefore putting not only the anaesthetic tech at risk but also the patient.”

- 9.2 This incident form was reviewed by the Group Manager (Hospital) on 24 February 2000. He recommended “Anaesthetic protocols required”.
- 9.3 On 29 January 2000 two incident reports were completed on plain paper (and apparently not put on the data-base by the Quality Co-ordinator) relating to the rapid sequence induction of two children. The first stated:

“Rapid sequence induction [with] Mother present. Support nurse with mother [was] able to screen mother from anaesthetic process. Dr Lucas debated with the anaesthetic technician the amount of air in the ET tube cuff. Dr Lucas removed the syringe from the technician and forced another 10 mls of air into a 6.5 ET tube. While Dr Lucas was speaking to [the technician] and debating the issue [amount of air in the tube] Dr Lucas surreptitiously removed the extra air. His tone was condescending to [the anaesthetic technician]. The nurses and the surgeon were uncomfortable with the level of communication but they did not intervene as they believed they could exacerbate the situation. During this case Dr Lucas indicated that [the next case] would be another rapid sequence induction.”

- 9.4 The other incident form stated:

“Patient calm/happy on arrival – prepared well for OT.

Dr Lucas arrived whilst the patient was still in the airlock, he placed his head beside the child’s head on pillow, spoke into child’s ear. Child became inconsolably distressed. 1920 hrs child subdued enough to enter

OT. Child calm when entering OT 3, mum and [technician] speaking with child. Dr Lucas entered OT 3 and approached child in the same way as in airlock. Child became distressed again.

Dr Lucas approached [the anaesthetic technician], and asked to speak with her in the anaesthetic room. [The anaesthetic technician] returned to the operating theatre. Dr Lucas did not.

Dr Lucas had discussed anaesthetic process with the [technician] and sequence of events for this anaesthetic.

1950 hrs [Dr Lucas] still not present. I then spoke with the [surgeon] in OT3 set up room with regard to the situation. [The surgeon] found Dr Lucas and discussed matters.

Dr Lucas indicated that [the technician] wouldn't assist him with his proposed method of anaesthetic induction. Dr Lucas requested the opportunity to instruct [the technician] and then he would proceed. The surgeon, the nurse and the technician spoke and agreed that [the technician] would be instructed and that I would accompany [the technician] whilst taking instruction. We believed that by [doing so] the patient's best interests would be accommodated.

We duly proceeded with above – unfortunately we could not locate Dr Lucas in the OT. Having searched the department we returned to the reception area – Brian was then present. We proceeded as above. Dr Lucas instructed [the technician]. His instruction was not pertaining to anaesthetic techniques but how she should position her body whilst restraining the patient and acting as a tourniquet.

I offered the assistance of the two RNs present – this offer was refused. We proceeded to OT3 and began the anaesthetic.

2010 hrs. Dr Lucas used a syringe and needle to administer the IV drugs. No IV line was used. Therefore there was no IV access during the procedure.

[The technician] was unable to pre-oxygenate the patient as was occupied restraining patient. [The technician] was unable to assist with intubation as above.

When Dr Lucas was absent from OT he had phoned [the Charge Anaesthetic Technician] and two other technicians requesting assistance as he believed [the technician] was refusing him assistance.”

9.5 The Theatre Manager described these two rapid sequence inductions as follows:

“One weekend, there were two children in a row who had limbs to be manipulated. A nurse asked Dr Lucas if he would gas induce the children. This request made Dr Lucas quite irate. He would take out his annoyance on patients, by being rough and aggressive. Dr Lucas left a child on the table in the operating theatre (the mother was present in theatre) and disappeared for about 45 minutes. Dr Lucas apparently did not want to work with [the technician] in theatre. He was trying to find another technician to come to theatre and work with him.”

Dr Lucas’ explanation

9.6 Dr Lucas advised me:

“Several months before this event my doing intravenous inductions in children had become an issue and had not yet been resolved. I can remember receiving a memo in which [the Group Manager (Hospital)] asked the Department of Anaesthesia to develop some guidelines about intravenous induction of anaesthesia in children but to my knowledge nothing was done. In this case, while I was in the theatre getting ready before the patient arrived [the] Nurse entered and started her preparations. That I intended to do an intravenous induction came up in the conversation and she said something to the effect, ‘I wouldn’t let you give an anaesthetic to my child’. This made me feel quite unsupported by the nursing staff. I wanted to have the induction to go smoothly and so, before we got started, I asked the technician to come out into the quiet and privacy of the pre-anaesthetic room where I could go over the steps necessary for helping me. I thought asking her to come out there would save her face if that was an issue. Her response was to get quite angry and exclaim something to the effect of ‘Oh Brian, just get on with it’ implying that I was being insufferable. She stormed back into the theatre leaving me alone. Under these circumstances, I was not prepared to anaesthetise the child. I went to the theatre office and first called [the Head of the Department of Anaesthesia] for advice. He advised that I call [the] chief anaesthetic technician who said she herself could not come in. I explained to [the surgeon] what my problem was and he seemed understanding. Finally, the nurse and technician arrived in the office, I told them that the prerequisite for my doing the case with that technician was that she listen to the way I wanted it done. She listened and we did the case. I did not tell anyone that she refused to do the case with me; I told them that I was afraid to start the case with her because I did not trust her to help me in the manner that I wished.

I might add that this was the technician who seemed always to want to help me in the way she had learned to help some other anaesthetist. For example I can’t remember a single time that she inflated the cuff of an endotracheal tube in the way that I had, repeatedly, requested. She seemed more concerned than most nurses I have met about the

possibility of blood contamination in general. Sometimes this concern seemed to affect her overall performance. This has some bearing on intravenous inductions because I note that one incident report listed danger to the assistant as being a criticism of intravenous inductions in children. I have never heard of that being a consideration either before or after being in Gisborne. Again, it is my opinion that, if it is hospital policy for the nurses and technicians to critique the choice of procedures done by senior medical staff, then that was not at all well brought [out] in my orientation. I do not do intravenous inductions in children because I believe they are as good as or as safe as inhalation inductions; I do them because I believe they are superior to and safer than inhalational inductions. This is not a criticism of anaesthetists who do inhalational inductions; it is the prerogative of each consultant to choose what is safest in his or her own hands. I don't believe the Nurses or the Administration grasps the subtlety of this point."

Staff comments on Dr Lucas' method of child induction

- 9.7 A surgeon commented that although Dr Lucas was said to be insensitive and uncaring in the way he induced children, the locum who replaced Dr Lucas induced children the same way, yet was not subject to complaints about his methods of induction.
- 9.8 The acting Medical Director noted that in the interviews he conducted with staff about the syringe incident one staff member was concerned at the way a child was put under anaesthetic by Dr Lucas. Another senior anaesthetic technician thought he was "great" at working with child patients.
- 9.9 One anaesthetic technician considered the intubations in the rapid sequence discussed above involved a safety issue, but at the end of the day Dr Lucas "carries the can", so he can do procedures the way he wants. He did not talk to Dr Lucas about his concerns in relation to this incident because of the need to get the procedure done. After this incident the anaesthetic technician tried to avoid working with Dr Lucas whenever he could. This did not need explaining as everybody else was doing the same thing by trying to avoid Dr Lucas' list. "Those who came to work earliest in the morning could choose the list they did."

Management response

- 9.10 The Group Manager (Hospital) stated that the practice at Gisborne Hospital for anaesthetising children is gas induction. The matter was discussed at a theatre management committee meeting. The Group Manager (Hospital) wrote to the anaesthetists collectively and he copied this correspondence to the Theatre Manager.

9.11 His letter stated:

“There have been a few incidents lately regarding the induction of anaesthesia on young children. In the interest of safety and harmony, these issues need resolution. I request that the Anaesthetic Department review the available medical evidence and determine the best practice related to childhood anaesthesia. Further I would appreciate the development of written protocols to outline the appropriate techniques/agents to be used within Gisborne Hospital. As the next Theatre Management Committee is scheduled for March, perhaps the committee could review this material at that time.”

9.12 Comments made by the Head of the Department (Anaesthesia) to the investigation team suggest that he was not consulted by the Group Manager (Hospital) about the need to develop protocols. When asked whether Mr Madden talked with him about the need for protocols he replied: “No. There isn’t a set standard in existence. I told Dan Madden there were practice variations about whether to put the IV first or induce with gas. Both are totally in line.”

9.13 The minutes of the Theatre Management Committee meeting held on 22 March 2000 do not disclose any discussion of best practice related to childhood anaesthesia or protocols on the subject. THL confirmed, however, that the matter was discussed at that meeting but the discussion was not recorded in the minutes. Dr Lucas said there was no established practice at Gisborne as far as he was aware. He said he asked for a protocol to be established but the issue was not resolved before he left.

Audit report

9.14 The Gow/Gordon audit report recommended:

“Practice guidelines/protocols should be developed after review of the literature and discussed with all parties in a multi-disciplinary forum prior to endorsement and implementation.

There needs to be consideration given to leadership development, including time for training and for clinical resources to be supplied in order to free up clinical leaders to both undertake this development and to apply it in practice. Staff will also require dedicated time in order to discuss the particular guidelines in a dedicated forum. This may well require additional resources from purchasing authorities.”

Appropriate standards

9.15 My expert anaesthetist advised that the induction of anaesthesia in children is different from that in adults. The emotional aspects of entering the operating room and the associated actions leading to induction can be quite frightening for paediatric patients and their families. Paediatric anaesthetists have the responsibility of quickly gaining the confidence of parents and children.

- 9.16 The choice of the most appropriate anaesthetic approach will be influenced by the history of the child and family and the results of examination. There is no “one way” to induce anaesthesia in children.
- 9.17 A common paediatric induction method is the “mask” induction. During this type of induction, a mask is gently applied to the child’s face and increasing concentrations of an inhalation agent (usually halothane, or more recently sevoflurane) are added to oxygen with or without nitrous oxide. The advantage of mask induction is that it can be relatively rapidly instituted and does not require insertion of intravenous (IV) catheters in awake patients. IVs can easily be inserted after children are anaesthetised. However, some patients need their airways to be very rapidly safeguarded against the risk of vomited or regurgitated stomach contents and mask induction may not be appropriate.
- 9.18 Such patients, along with others with specific medical conditions, or those who present to the operating room with an IV in place, are induced with IV agents. These agents include thiopentone, propofol, ketamine, etomidate, and occasionally high dose narcotics or benzodiazepines. Even when an IV is not inserted before induction, it usually is once the patient is anaesthetised in order to provide a route to give any medicines that might be required for the continuance of anaesthesia or other purposes.
- 9.19 Whether an IV line is used to give an anaesthetised child intravenous fluids depends on a number of circumstances, eg, how long the patient has been fasting and how long it is before the patient is expected to be able to take fluids.
- 9.20 My expert anaesthetist also advised that “comments from Gisborne suggest that there was a lack of familiarity with the nuances of paediatric anaesthesia”, and that Dr Lucas failed to communicate his plans and their rationale to staff. Dr Lucas responded that it was “not for want of trying”, and that he had been trying to teach that particular technician about such matters for months.

Opinion

- 9.21 In my opinion, none of Dr Lucas’ acts or omissions in administering anaesthesia to child patients amounted to a failure to exercise reasonable care and skill. Nor is there any evidence that Dr Lucas failed to communicate effectively with child patients and their parents or guardians, whatever may have been his failings to communicate to colleagues. Accordingly, Dr Lucas did not breach Right 4(1) or Right 5(1) of the Code.

10. MIXING OF OPIATES

The alleged incidents

10.1 A recovery nurse advised my investigation team:

“I was concerned about Dr Lucas’ use of opiates in theatre. He would mix opiates inappropriately. For example, 5 mg of morphine, 50 mcg of fentanyl. He would mix these opiates throughout the operation and give no total at the end. I raised my concerns with Dr Lucas and the anaesthetic technicians who told me that sometimes their count was a bit out. Dr Lucas never gave any explanation but I know there is no need to give opiates like that. Dr Lucas gave no medical reason, just liked to do it that way. He was an aggressive man. He would snap.

He would also use an opiate to treat an overdose of an opiate, for example physostigmine to reverse hypnovel – this is no use whatsoever. Dr Lucas had an epidural order chart that was his, but he wouldn’t write drugs on it. He would not chart drugs.”

10.2 No other interviewees commented on the above allegation. However, several did comment on the standard of record keeping, as discussed below.

Appropriate standards

10.3 An expert anaesthetic advisor provided the following advice:

“Morphine can be mixed (ie, given concurrently or alternatively) with fentanyl and in many instances is; neither physostigmine nor ‘Hypnovel’ (midazolam) is a narcotic; physostigmine has been used for reverse post operative sedation but is not specific for benzodiazepines (eg midazolam) and is of little benefit in midazolam induced sedation”.

10.4 Dr Lucas strongly disagreed with this view:

“Physostigmine is a non-specific centrally acting cholinesterase inhibitor and will reverse the sedation caused by a wide variety of drugs including the benzodiazepines. Thus I would strongly disagree with your expert about it being of little benefit in midazolam induced sedation.”

Opinion

10.5 I accept the advice of my expert anaesthetist that Dr Lucas did not mix opiates inappropriately. In my opinion, there is no evidence that Dr Lucas failed to exercise reasonable care and skill in his use of anaesthesia. Accordingly, Dr Lucas did not breach Right 4(1) in relation to this matter.

11. FAILURE TO DOCUMENT MEDICATION

The alleged incidents

11.1 The NZNO letter to the Minister of Health included the following statement:

“The same nurse (as in the post partum haemorrhage incident) described the anaesthetist’s consistent refusal to document and chart medication. His practice was to write medication instructions on the anaesthetic sheet and presume this would be actioned in the ward (this didn’t happen). She testified that he became aggressive and threatening when challenged.”

11.2 An incident form pertaining to the medical record was completed by an obstetrician on 3 February 2000. “No pregnancy test in chart at time of surgery. There is no consistent place for writing pregnancy results in chart. Theatre is quite often delayed while HCG results are checked.”

11.3 Dr Lucas completed two incident forms relating to record keeping:

Incident no. 513: “No IV fluid sheet in records of patient transferred to theatre. This is frequently missed.”

Incident no. 471: “No weight recorded on day case nursing record.”

Dr Lucas’ explanation

11.4 Dr Lucas advised me:

“I found the chart at Gisborne very user unfriendly and non intuitive. Doctors’ orders were put on three separate sheets; one for medications, one for fluids; other orders were not even put on an order sheet but were scattered throughout the operative note on the progress note sheet. Mr Burton and I were frustrated that the operative reports and anaesthetic charts were not segregated into one section of the chart. Dr van der Mark shared my frustration with the multiple order sheets. I put my post operative medication orders on the anaesthetic sheet because that is what I thought I had been told to do. I never refused to write orders although I sometimes needed a reminder. I have done many locums, often in places for far shorter times than in Gisborne and I have never found a chart or a system more confusing. While in Gisborne, I contacted one of my colleagues in Canada, had him mail a whole chart package and gave it to Dr van der Mark who had expressed a wish to have the charting system redesigned.”

Concern about the standard of record keeping at Gisborne Hospital

11.5 NZNO stated that it is not usual practice in New Zealand for anaesthetists to document medications to be given post surgery on the anaesthetic sheet. They are normally recorded on the medications chart. The nursing staff were

concerned that patients may be denied post-operative analgesia medication because of a failure to comply with protocols.

- 11.6 The Clinical Director (Surgery) had been concerned about the organisation of the notes for a considerable period of time. He insisted that a specific section of the notes be kept for the anaesthetic and operation records:

“To illustrate this, and it also illustrates Brian Lucas’ care, one theatre list of mine was stopped for 45 minutes while Brian took this long to find a specific piece of information in an anaesthetic record of a patient with several volumes of notes. It was only after finishing as CD [Clinical Director] that I completed this seemingly simple project.”

- 11.7 My expert advisor stated:

“Contrary to what NZNO may have implied, it is usual practice for immediate post operative medicines (ie for use in the recovery room) to be charted on the reverse of the anaesthetic sheet. Analgesic and anti emetic medicines for ward use usually go on a separate chart and would normally be prescribed by the anaesthetist.

As inferred by ANZCA’s policy (4.3) there is an acceptance that management for the first 24 hrs post operatively might be noted on the anaesthetic record. (Although it would be unusual in New Zealand to plan beyond the recovery room stay to be rostered here.)”

Management response

- 11.8 The Group Manager (Hospital) considered that the allegation is “an exaggeration of a finite number of incidents”. He challenged the implication that Dr Lucas always prescribed incorrectly and was unsure about Dr Lucas writing on anaesthetic sheets. He was unsure if there had been any instruction about the conveying of information to doctors regarding the writing of medication instructions given the differences between New Zealand and American practice.

- 11.9 The Quality Health New Zealand Accreditation Report of July 1999 included the following comments on the keeping of clinical records:

- “a) The clinical records at Gisborne Hospital had improved greatly over the previous 12 months.
- b) An active Clinical Records Committee has totally revised the content and format of the forms.
- c) the standard of documentation is generally good.
- d) With the exception of nursing there is currently no policy outlining individual responsibility for the completion of medical records.

There are examples where staff do not date entries or include their designation.”

Appropriate standards

- 11.10 The Australian and New Zealand College of Anaesthesia (ANZCA) sets out minimum requirements for the anaesthesia record (Review P6 (1996)):

“The anaesthesia record is an essential part of the patient’s medical record. The record should chart all aspects of the anaesthesia management, including the pre and post-operative management of relevance to the anaesthetist. The record should follow a logical sequence. It must include prompts to show essential information regarding the anaesthetic technique and drugs used, sufficient space to allow the anaesthetist to make more detailed comments when necessary, and a chart for graphically recording data and attaching appropriate automated records if available.

The anaesthesia record provides information which may be helpful to all staff involved in the care of the patient and is of great use to subsequent anaesthetists (both specialist and trainee). It may also be of medico-legal importance and can be used for quality assurance and research purposes. The record must be signed by the anaesthetist.”

- 11.11 The requirements set out the information that should normally form part of the anaesthesia record.

“1. Basic Information

1.1 The name of the patient, hospital, record number, age, gender and weight.

1.2 The dates of the pre-operative consultation and the anaesthesia.

1.3 The name(s) of the anaesthetist(s).

1.4 In the case of trainees, the name of the supervisor and the level of supervision.

1.5 The name of the surgeon or other proceduralist.

1.6 The procedure(s) planned to be performed and actually performed.

2. Information Prior To Anaesthesia

2.1 Documentation of pre-anaesthesia assessment of the patient, including the category of patient as defined for example by the American Society of Anaesthesiologists.

2.2 Summary of general medical status by relevant systems and diseases.

2.3 Concurrent therapy and any known drug or other sensitivities.

- 2.4 The history of previous anaesthesia and relevant surgery.
- 2.5 Assessment of the airway, dental condition and risk of gastric reflux.
- 2.6 Results of relevant laboratory data and other investigations.
- 2.7 The pre-medicant drugs, time given, route of administration and a description of any unusual response (if not recorded elsewhere).
- 2.8 Documentation of discussion with the patient or guardian on the anaesthesia plan, possible therapies and possible outcomes (if not recorded elsewhere).
3. Anaesthesia Information
 - 3.1 Medication: The details of administration of all drugs including any used by the surgeon, and a description of any unusual response.
 - 3.2 Technique: The full details of the anaesthetic technique used, whether general, regional or sedation with monitored anaesthesia care, and a description of any problems encountered.
 - 3.3 Time: The time of significant anaesthetic and operative events, observations and interventions including administration of drugs.
 - 3.4 Airway: The size and type of any artificial airway used, a description of any airway problems encountered and the method of their solution.
 - 3.5 Fluid Therapy and Vascular Access:
 - 3.5.1 Intravenous infusion: Details of intravenous solutions including the site, type of cannula and the nature and volume of fluids infused.
 - 3.5.2 Details of central venous and arterial access.
 - 3.6 Blood loss: An estimate of blood and fluid loss.
 - 3.7 Position: The position of the patient during the procedure.
 - 3.8 Monitoring: The monitoring methods used and regular documentation of relevant information obtained. Information provided as a monitor print-out must have correct patient identification.
 - 3.9 Other Interventions.

4. Post-Anaesthesia Information (if not recorded elsewhere)
 - 4.1 Respiratory, cardio-vascular and neurological status and any other relevant information.
 - 4.2 Incidents arising during this period and their management.
 - 4.3 Plan for pain management, fluid therapy and oxygen therapy for first 24 hours, especially for guidance of Recovery Room Staff.
 - 4.4 Space for documenting/recording outcome data, including Clinical Indicators, audit and quality assurance information.
 - 4.5 Space for documenting the post-anaesthesia visit.”

Opinion

- 11.12 There is no evidence that Dr Lucas failed to comply with professional standards in relation to his documentation and charting of medication. In my opinion, the allegations made about Dr Lucas’ anaesthetic records were unfounded. Accordingly, Dr Lucas did not breach Right 4(2) of the Code in relation to this matter.

12. UNLABELLED SYRINGES

The alleged incidents

- 12.1 The NZNO letter to the Minister stated:

“Recovery nurses gave evidence that the anaesthetist would come to recovery with unlabelled filled syringes in his pocket and instruct them to administer the medication. They refused.”

- 12.2 NZNO submitted that nurses working in recovery reported:

“[Dr Lucas coming to the recovery room] with filled, unlabelled syringes in his pocket and instructing them to administer the contents to patients. As the nurses did not know what the contents were they refused. This was reported to the internal hospital investigation of re-use of syringes. At least three recovery room nurses told the [internal] inquiry that this was Dr Lucas’ established and usual practice.”

- 12.3 The investigation team received only one piece of direct evidence of unlabelled syringes being used by Dr Lucas. A nurse said in her interview with Dr Bruce Duncan that Dr Lucas “would bring syringes from operating room which were unlabelled “and that she would discard them”.
- 12.4 Another nurse stated: “Only on one occasion did I see Brian Lucas re-use a syringe, and it was the time he produced the syringe from his sleeve. In that case I think he injected it into a luer, as it was early on in a case.”

- 12.5 A nurse stated: “One of the girls was quite upset when she saw him with syringes in his pocket.”

Dr Lucas’ explanation

- 12.6 Dr Lucas described two scenarios where he might ask a nurse to administer an unlabelled syringe:

- “(1) Where for the sake of speed and patient safety a nurse would give an IV injection in the presence of an anaesthetist who is already doing something for the patient, eg maintaining an airway. In that case I would ask the nurse while I watched to pick up the 5ml syringe off my cart and give 1 ml of its contents into that injection site. The responsibility remained with me. I would ask the nurse to be my second set of hands. I did not believe that it was necessary for the nurse to know what was in the syringe, but would tell them if they asked. A printed label on the syringe may not be apparent to a nurse, but I am by no means the only anaesthetist who implicitly labels my syringes by a combination of syringe size and needle colour.
- (2) Where I had drawn up a drug just before moving from theatre to recovery. I would put the syringe in my shirt pocket. If after arrival in the recovery room, the patient needed some or all of the drug, and it happened that I was standing on the side of the patient opposite the IV line I would give the syringe to a nurse standing on the IV side and instruct them what volume to give. Again, in that circumstance, I would not be asking the nurse to take even a tiny amount of responsibility for the injection. If there was drug left in the syringe I may tell the nurse what it is and leave orders for its use. At that point it would become a matter of trust between the nurse and me. If the nurse does not trust me to tell the truth about what is in the syringe, they are well within their rights to reject the syringe and draw up fresh drug. However, if they didn’t trust me why would a label matter; I could have mislabelled it.”

Management response

- 12.7 The Group Manager (Hospital) stated he was unaware of the unlabelled filled syringes until Dr Lucas left THL and believes these were unreported incidents.

Appropriate standards

- 12.8 There is no protocol for use of unlabelled filled syringes.

12.9 My expert anaesthetist stated:

“There seems to be no suggestion that Dr Lucas asked nurses to administer drugs from unlabelled syringes except in his presence on occasions when it was physically easier for them to do so. This is not uncommon practice in the operating theatre and also occurs in the recovery room. Whilst it might be conceded that in ideal circumstances the nurse would wish to have seen the ampoule opened, read its label and witnessed the contents being drawn up, this is rarely the case. Simply having a syringe with a label on it would not provide the nurse with any assurance as to the contents of the syringe. Syringe size and other identifying features is used by some to indicate what type of medicine is in a syringe.”

Opinion

12.10 I accept the advice of my expert anaesthetist that Dr Lucas did not act inappropriately in asking nurses to administer drugs from unlabelled syringes in his presence. In my opinion, Dr Lucas exercised reasonable care and skill in his instructions to nurse colleagues about the administration of drugs. Accordingly, Dr Lucas did not breach Right 4(1) in relation to this matter.

13. WAKING PATIENTS EARLY AND PUTTING CONSCIOUS PATIENTS IN THE LITHOTOMY POSITION

The alleged incidents

13.1 It is alleged that on more than one occasion Dr Lucas woke patients early, while they were still being sewn up and/or were still in the lithotomy position.

13.2 Several anaesthetic technicians and theatre nurses recalled that sometimes Dr Lucas' patients would wake early.

13.3 An anaesthetic technician described a situation where a patient was allowed to wake early:

“If [Dr Lucas] was angry he would go red in the face and yell. Then everything was wrong. Everybody paid the price. He would go on and on about how he was not happy with the hospital or the staff. Nothing was as good as where he came from. He did this right from the start. We changed so many things for him. He would take it out on the patients too. For example a man started coughing while he was being sewn up at the end of his operation. Dr Lucas refused to put him back to sleep.”

The named surgeon in this incident advised the investigation team that “Dr Lucas never allowed any of my patients to wake up prior to the completion of suturing”.

- 13.4 A nurse reported seeing Dr Lucas wake patients before their operations were finished. She remembered the case of a patient with a hernia who woke before the operation was finished and coughed. The nurse commented that “you could almost hear the stitches going”.
- 13.5 One anaesthetic technician saw Dr Lucas’ patients coming out of anaesthetic early but not regularly. The technician commented that waking patients is not an exact science:

“A couple of times, when Dr Lucas had been riled by the nurses in theatre, patients had woken early but it was hard to say whether the two were connected (ie, Dr Lucas being riled and the patients waking early). It was not for me to comment on this aspect of anaesthetic practice. Dr Lucas knew patients were waking up.”

Dr Lucas described any suggestion that he woke patients up early in response to being angry with nurses as “hideous”. He stated that “my measure of excellence is to have the patient respond to (not be conscious of) the last skin stitch”.

- 13.6 A member of the nursing staff noted that in one instance Dr Lucas asked for a patient to be put into the lithotomy position (legs up in stirrups) before the patient was under anaesthetic. Dr Lucas said of that situation, “when they got to the stage in the procedure where the patient’s legs could be put in the lithotomy position, [the patient] said I’d like to go to sleep”. This incident was the subject of an incident report described below (see paras 13.7 – 13.9). In addition, the patient wrote to me about her treatment (see para 6.12).

Incident report

- 13.7 The Theatre Manager described an incident involving a patient who requested a general anaesthetic but was told by Dr Lucas that she was to have a spinal. “The patient cried. The patient’s legs were in the lithotomy [position] When the surgery started the patient could feel the procedure. Dr Lucas then had to administer a general anaesthetic and he was very rough and jerked her head back. [The nurse] was very upset so she went to Dan Madden and insisted he come down.”
- 13.8 The nurse recorded in a handwritten incident report that was never registered by THL that Dr Lucas instructed two nurses to position the patient (who preferred a general to an epidural) into the lithotomy position while she was still awake. The nurse “spoke to Dr Lucas and stated that the patient did not want to be awake when the operation was being done or when her legs were in lithotomy and he then proceeded to forcefully administer the general anaesthetic”.
- 13.9 An anaesthetic technician recalled that Dr Lucas woke this same patient while she was still in the lithotomy position. The patient had specifically requested to be asleep during her operation. Dr Lucas told her she was to have a spinal. After considerable debate Dr Lucas gave her a general. “As a result Dr Lucas was obnoxious toward everyone, but more so to the patient.”

The technician mentioned this behaviour to the Charge Anaesthetic Technician and filled out an incident report, which “has gone missing”.

- 13.10 The nurse called a meeting with the Theatre Manager to discuss her concerns. These concerns related to the lithotomy position, the choice of anaesthesia and the use of ice. A further meeting was arranged with the Group Manager (Hospital). At that meeting the Group Manager (Hospital) asked the nurse what she wanted and she told him that she “wanted Brian Lucas to go”. The Group Manager (Hospital) “told me to hang in there another six weeks and he’ll be gone I was so angry and upset.”

Dr Lucas’ explanation

- 13.11 Dr Lucas described by letter to the Commissioner how he approached the end of surgery:

“Towards the end of surgery the anaesthetic is gradually lightened so that the end of the anaesthesia coincides very closely with the end of the surgery. There are stages of this emergence at which the patient will respond to a painful stimulus by moving and yet not be conscious. The stimulus likewise will not cause dangerous changes in the patient’s vital signs. It is an often stated cliché in anaesthesia that the ideal timing of emergence is for the patient to begin to respond to the last one or two stitches. That is what I strive for! I didn’t always achieve this level of perfection but when I did there were scrub nurses who would stop their work and expect me to deepen the anaesthetic. Under those conditions I would ask them not to worry about the patient or me but to carry on and finish the case if they still had satisfactory operating conditions to put in the last skin stitches. The comfort and safety of the patient is my responsibility. Rapid emergence minimises anaesthetic exposure and fosters efficient theatre turnover between cases.

Rapid emergence minimises anaesthetic exposure to the patient, minimises the cost of the anaesthetic, allows for rapid and efficient patient turnover in the theatre, and therefore ultimately, more patients done and fewer patients cancelled for want of time. Frankly I saw their concern over a quickly emerging patient as just another one of several examples of how their sense of propriety often got in the way of patient safety or theatre efficiency.”

- 13.12 In the same letter Dr Lucas noted:

“In this [theatre] setting it seemed inefficient to have the nurses prepare their sterile tables in an adjoining room and refuse to come into theatre or even to attach brackets for the lithotomy attachments until after the patient was asleep. I believe that they wanted to protect the patient from the upset of being aware of the instruments etc. I always felt that this was a condescending attitude towards the patients and didn’t give patients the credit for knowing and accepting the reality of why they were in the theatre. Sometimes the instruments or fluoroscopy equipment which was checked only after the patient was asleep would be

found to be deficient and thus the patient would receive the extra cost and morbidity of a needlessly long anaesthetic.”

Management response

13.13 The Group Manager (Hospital) spoke to the Theatre Manager about the fact that staff had said they could not work with Dr Lucas. According to the Theatre Manager, the Group Manager (Hospital) said that staff could not withdraw their labour. “Dan Madden told staff to carry on because there were only three weeks to go and Gisborne Hospital could not do without Dr Lucas.”

13.14 The statements in paras 13.10 and 13.13 were put to the Group Manager (Hospital) for comment. The following statement was provided:

“The theatre manager telephoned the Group Manager and asked him to come to the operating theatre to discuss with staff some issues that they had with Dr Lucas. He went immediately to the operating theatre. The meeting was an informal one and a range of topics were discussed. No formal record of the meeting was kept. The meeting involved one or two of the anaesthetic technicians, at least the theatre nurse mentioned below, possibly one more, and the theatre manager.

The primary issue discussed at this meeting was the choice of anaesthetic for a gynaecological patient who was being operated on at that very time.

The theatre nurse quoted in [para 13.10] was a friend and neighbour of that patient. The nurse was not allocated to the gynaecology theatre that session. The patient had allegedly expected to have a general anaesthetic. However, in Dr Lucas’ clinical opinion a spinal anaesthetic was warranted. The nurse had ‘advocated for the patient’, in effect arguing with Dr Lucas about the type of anaesthesia which should be administered (as far as I am aware, this is the same patient event described in [para 6.11]).

When the Group Manager attended the theatre suite to meet with staff, this patient was in having her operation. The argument between the nurse and Dr Lucas had just occurred. While the meeting was underway, the nurse received a message that stated Dr Lucas did not want her to go into the theatre where her friend/neighbour was being operated on. Later, I learned that Dr Lucas’ rationale for this position was that he believed her actions and interest in this case to be inappropriate, given her personal relationship with the patient. I agreed with this assessment.

The Group Manager does not recall whether the positioning of this same into the lithotomy position was also discussed at this time, though it may have been. Dr Lucas was known to prefer the positioning of all his patients while they were still awake. Some staff had taken exception to

this. The Group Manager had previously discussed this with Dr Lucas who had logical reasons for preferring this.

The Group Manager does not recall whether the application of ice on this same patient was also discussed at this time, though it may have been. Dr Lucas was known to use ice on patients and this had been investigated at this stage.

After discussing the gynaecology patient above, the staff informed the Group Manager about the occasion on the preceding weekend involving the induction of anaesthesia on the child, referred to in [paras 9.5 and 9.6]. Considerable time was spent discussing this.

The matter raised in [para 13.13], also occurred at this same meeting. Two of the anaesthetic staff and the theatre nurse involved above stated that they did not want to work with Dr Lucas any more. While the Group Manager cannot recall his exact choice of words – or those of the staff – it was noted by those present that there were only a matter of weeks left before Dr Lucas was to leave. It was also noted that staff could not refuse to provide a service simply because they disliked another staff member. However, it was agreed to examine the theatre roster to see if it might be arranged for those staff who did not want to work with Dr Lucas might be able to be accommodated in this for the remaining period. The theatre manager agreed to arrange this, if possible. This occurred for the nurse, but when this arrangement was subsequently offered to the anaesthetic technician who worked with him mostly, she declined the offer and agreed to continue working with him.”

Appropriate standards

- 13.15 I am advised that there are no directly relevant standards. The depth of anaesthesia is difficult to define “because anaesthetists have approached the issue in terms of the drugs available to them rather than the patient’s needs during surgery. The loss of consciousness is considered a threshold or all-or-none (quantal) phenomenon. By this definition, there can be no degrees of anaesthesia or any variable depth of anaesthesia. The definitions of anaesthesia depth have evolved with the drugs used in clinical practice. The use of potent inhaled anaesthetics, opioids, and intravenous anaesthetics in modern clinical practice has precluded simple unifying definitions” (Miller, RD, *Miller’s Textbook of Anaesthesia*. Churchill Livingstone, 5th ed, NY, 2000)

Opinion

- 13.16 My expert anaesthetic advisor noted that there is a difference between: (1) “wakening” and other signs of lighter anaesthesia, such as coughing, and (2) “wakefulness” in the context of general anaesthesia and when associated with regional anaesthesia. The advisor did note that “Dr Lucas seems to have a slightly extreme view of when to lighten anaesthesia based on a preoccupation with efficiency”.

- 13.17 Although I am left with the impression that Dr Lucas' views, and practice, in relation to depth of anaesthesia were a little unusual, it has not been established that the safety or comfort of any of his patients at Gisborne Hospital was compromised in any way. In all the circumstances, it appears that Dr Lucas exercised reasonable care and skill in the depth of anaesthesia he employed. Accordingly, in my opinion Dr Lucas did not breach Right 4(1) in relation to this matter.

14. REFUSAL TO ATTEND PATIENT IN RECOVERY

The alleged incident

- 14.1 The NZNO letter to the Minister described an incident where a patient was haemorrhaging post-partum in recovery:

“The anaesthetist refused to come and see the patient or to give written orders for medication. The nurse refused to administer medication and called a surgeon from a ward. When the surgeon arrived the anaesthetist accused the nurse of not giving the necessary medications.”

The letter noted that an “incident form was completed and actioned promptly”.

- 14.2 The investigation team was given a copy of a handwritten note describing the incident. The note was not on the official incident form. This note does not appear to have been registered as an incident form as it was not in the database information supplied by THL.

- 14.3 The recovery nurse recorded in her note:

“At approximately 10.20 I approached Dr B. Lucas about the condition of [a patient]. Her BP was 115/70 and pulse 150 (approx) and she had just passed a large no of clots PV (post Caesarean section done at 7.30 am anaesthetist was Dr Lucas). At this point Dr Lucas was in theatre anaesthetising another patient.

I explained the patient's condition to Dr Lucas and he requested ergometrin IM to be given. I had not brought the drug chart with me and explained that I would have to fetch the chart as I am not allowed to give unprescribed drugs.

Dr Lucas replied ‘don't bother then, inform the surgeon’. [The surgeon] was duly informed and attended the patient. Dr Lucas gave no other help or advice.”

- 14.4 At interview this nurse expanded on her note. The patient was a 24-year-old woman who had had a Caesarean section. She was in pain and after an initial 15 minutes of stability in recovery she had a post-partum haemorrhage and passed clots “the size of footballs”. When she came to recovery her blood pressure was very low. The nurse knew she would need fluids, bloods and haemacel.

- 14.5 Initially she tried to contact the surgeon. While waiting for him to get in touch she went to Dr Lucas and said the patient would need fluids.

“Dr Lucas said that the patient needed to see the surgeon. I asked Dr Lucas to write up Ergometrin. He refused. Half an hour later the surgeon came in. In my presence Brian Lucas twice told the surgeon that I had refused to do anything. I had been to see Dr Lucas twice. I just wanted some support.

From the time I first asked Dr Lucas for fluids to the time the surgeon arrived was a delay of about 30 minutes. I think the woman had had a spinal. She had well over 20mg of morphine because she was in pain and passing football sized clots.

Brian Lucas was in theatre with another patient but it is normal practice for the anaesthetist to move between theatre and recovery with the technician staying with the patient in theatre. I don't know what else I could have done in addition to completing the incident form. I didn't expect to hear anything or receive any feedback because there had been other incidents and this was not the worst one and we hadn't received any feedback on those incidents. At that stage we were documenting everything. This was the worst incident report that I was involved with.”

The nurse considered that the incidents around Dr Lucas brought out animosity between doctors and nurses. She commented that there should be more direct communication between doctors and nurses.

Dr Lucas' explanation

- 14.6 By letter Dr Lucas noted that he was surprised that it took so long to summon a member of the obstetric staff as they have house surgeon cover, unlike the anaesthetists. “The assessment of the uterus and its evacuation is an obstetrical matter.”
- 14.7 He commented that it is the responsibility of the anaesthetist to stay with the patient he is currently anaesthetising:

“It is the anaesthetist's absolute prerogative to decide whether he or she will leave a patient during the conduct of an anaesthetic. If it was hospital policy for an anaesthetist to leave his or her present case to attend another on the judgement of the nurses and anaesthetic technicians that was not made clear to me in my orientation. I am very puzzled now, and would likely have been very frustrated then that the nurse came to the theatre to ask for help but was not equipped with the necessary chart to take an order, nor was she willing to take a verbal order when I asked for ergometrin to be given.”

Additional comments from the nurse

- 14.8 By letter the nurse added that there were several reasons why she would not accept a verbal order:

“Dr Lucas could not/would not give me a dose. I was not familiar with ergometrin as it was not routinely used and I wished to check it before administering it. I had no witness to the order as was THL policy. It was said in a very off-hand aggressive manner and I had very little trust/faith that Dr Lucas would follow up the order with a written prescription as per THL policy.”

In response to the suggestion that Dr Lucas was too busy to attend, the nurse stated:

“Dr Lucas may have been too busy to attend the patient at that time. The case he was anaesthetising was a long case and he made no attempt to visit the patient at any time during her stay in recovery. Nor did he visit her when the case (No 2) was completed. [The patient] was still in recovery at this time.”

- 14.9 The nurse was asked to respond to the Group Manager (Hospital)’s explanation that the surgeon was present in theatre. She noted: “The case was over some time before I bleeped, the surgeon therefore would have left theatre. When [the surgeon] did attend he was not in theatre attire and came into recovery from the outside door.”

- 14.10 The nurse was asked about discrepancies between the incident report and the evidence she gave at the interview. She commented that the letter accompanying the incident report was only a short note and it was not intended to be an in depth look at this incident. At the interview she had been able to include more detail. In her subsequent letter she stated:

“I am unsure why I did not record that I asked Dr Lucas for fluids but this incident was written on the day when I was angry at his lack of support and therefore this may have been missed.”

Management response

- 14.11 The Group Manager (Hospital) said that he was aware of this incident:

“In the medication administration policy it states that, if there is a medical emergency, verbal medication orders may be given and followed. I understand that a nurse chose not to administer the medication. I understand that the anaesthetist was busy at the time with another patient when the recovery nurse sought the anaesthetist. The anaesthetist gave her a verbal instruction to administer the medication which the nurse refused to observe. I do not believe that a surgeon had to come across from a ward as stated, but believe that the surgeon was in theatre at the time.”

NZNO submission

14.12 NZNO submitted that:

“A nurse is able to give analgesia from a verbal order, and had she received such an order from Dr Lucas she would have acted upon it. Dr Lucas claims he gave a verbal order to the nurse but as he refused to either go to recovery or leave the operating theatre it is difficult to see how he did that.”

Appropriate standards

14.13 The Australian and New Zealand College of Anaesthetists’ policy is set out in Review PS10 (1999):

“The Handover of Responsibility During an Anaesthetic

1. Introduction

During an anaesthetic, the major responsibility of the anaesthetist is to provide care for the patient. This requires the continuous presence of an anaesthetist. In certain circumstances, it is necessary for the anaesthetist to hand over that responsibility to a colleague. Such handovers will not compromise patient safety provided that appropriate procedures are followed. In prolonged anaesthetics, handover may be advantageous to the patient by preventing undue fatigue of the anaesthetist.

2. Protocol for transfer of responsibility

The following matters must be considered by both the primary and the relieving anaesthetists:

- 2.1 The primary anaesthetist must be satisfied as to the competence of the relieving anaesthetist to assume management of the case.
- 2.2 The relieving anaesthetist must be willing to accept responsibility for the case.
- 2.3 Review of the patient’s health status having regard to past history and the present condition.
- 2.4 A description of the anaesthetic including drugs, intravascular lines, airway security, fluid management, untoward events and any foreseeable problems.
- 2.5 Observations of the patient according to College Policy Document.
- 2.6 A check to ensure correct functioning of the anaesthetic machine, monitoring devices in use and any other equipment which is interfaced with the patient.

2.7 Notification of the handover to the consultant anaesthetist (in the case of a trainee) and to the operating surgeon.

3. Temporary relief of the anaesthetists

This is necessary when the primary anaesthetist must leave the patient but will return to resume management of the patient.

3.1 The primary anaesthetist will only leave while the patient is in a stable state and no potential adverse events are likely to occur.

3.2 The relieving anaesthetist must have had all facts relevant to safe management adequately explained.

3.3 The relieving anaesthetist should not substantially change the anaesthetic management without conferring with the primary anaesthetist except in an emergency.

3.4 The primary anaesthetist must be available to return at short notice.”

14.14 The applicable standards in relation to the “Responsibilities of the Anaesthetist in the Post-Operative Period” are set out in Review P20 (1996):

1. The anaesthetist has major responsibility for the management of the patient recovering from anaesthesia. During this time, responsibility is shared with the surgeon or other consultant for consultative advice with respect to:

monitoring (including clinical observations),

pain relief,

fluid therapy, and

1.4 respiratory therapy.

2. The anaesthetist has responsibility for ensuring that the patient recovers safely from anaesthesia in an area appropriately equipped and staffed for that purpose.

This responsibility includes:

A formal handover of responsibility to recovery area staff with appropriate briefing as to management protocols. Such a handover of care should only occur when the anaesthetist considers that the patient is safe to leave, particularly with regard to cardio-respiratory stability.

Availability to deal with any unexpected problems or ensuring that another nominated anaesthetist or other consultant is available and has necessary information about the patient.

Ensuring that the patient remains in the recovery facility until safe for discharge to a ward. Where transfer to an intensive care unit or high dependency unit is necessary, responsibility for care remains with the anaesthetist until this transfer is complete.

2.4 Ensuring that there will be adequate post-operative care of the patient after discharge from the recovery area.”

14.15 I received the following advice from my expert anaesthetist:

“Except in case of emergency, as when a cardiac arrest has occurred, the anaesthetist should never leave an anaesthetised patient in theatre in the care of anyone other than another anaesthetist and then only after a handover. In such circumstances it would be more usual for the second anaesthetist to attend the emergency.

The cause of post partum haemorrhage is usually managed by surgical staff although if they were not contactable the anaesthetist would be expected to advise on management. Until such time as ‘definitive’ treatment of the cause was possible the anaesthetist would be expected to ensure cardiovascular stability. In the scenario described either the medicines chart would need to be taken to the theatre for the anaesthetist to prescribe treatment, or a verbal order would have to be accepted by the recovery nurse.

The description of ‘football’ sized clots is questionable.

Once again the case illustrates the antipathy that appears to have existed between Dr Lucas and nursing staff.”

Opinion

14.16 I am satisfied, on the basis of the expert anaesthetic advice that I have received, that Dr Lucas did not inappropriately refuse to attend a patient in recovery following a Caesarean section. In my opinion Dr Lucas complied with professional standards and did not breach Right 4(2) of the Code.

15. INCIDENT REPORTING

15.1 For general comments on incident reporting, and the handling of incidents not relating to Dr Lucas, see chapter 3.

15.2 Theatre incident reports were channelled through the Theatre Manager using the hospital’s standard incident form. There was no designated place in the Theatre Manager’s office to place a completed form. A number of forms were lost. Witnesses saw incident forms completed and handed in but the Theatre Manager, Group Manager (Hospital) and Quality Co-ordinator subsequently had no record of receiving these forms. Other incident forms were received but were ignored or remained unresolved.

- 15.3 One of the terms of reference refers to the handling of incident reporting by staff between October 1999 and June 2000. Many of the incidents considered in this chapter reveal serious lapses in THL's system of incident reporting.
- 15.4 The approaching millennium was given as a reason for not dealing with the concerns regarding Dr Lucas. Once the millennium was over, the impending departure of Dr Lucas was used as a further reason for not dealing with the issues. Issues were unresolved and discontent festered. (Dr Lucas asked for it to be noted that the Group Manager (Hospital) specifically requested him to stay for two weeks longer by forgoing his terminal two-week vacation and working instead, and that this was long after the millennial anxiety.)
- 15.5 The incident reporting process became personalised. There was a focus on staff relations, rather than quality improvement. (This point is taken up in the 'Quality Assurance' chapter.) Undoubtedly Dr Lucas' manner of handling conflict made it difficult to raise issues with him in a professional way. In his defence, Dr Lucas said:
- “I think my method of handling conflict was more transparent and forthright than the methods used by many at Gisborne Hospital. I don't think it was my manner that prevented issues from being presented to me in a professional way. I think that there was a culture of non-professionalism and subversion already well established at Gisborne Hospital before I arrived.”
- 15.6 Ultimately the failure of the incident reporting system led people to voice their concerns elsewhere. In this case the staff went to NZNO, which took its concerns to the Minister of Health and the media.
- 15.7 The importance of incidents at times grew out of all proportion, because they were not addressed in a timely and proper way, with prompt feedback to the staff. The syringe re-use issue is a good example of this. It turns out that syringe re-use was not a breach of any relevant standard at the time, but staff were so upset that they sought, and eventually were given, counselling to deal with this issue.

16. SUMMARY OPINION

Co-operation with colleagues

- 16.1 Dr Lucas found himself on the receiving end of a significant number of allegations, principally from nurses and technician colleagues, about his practices and demeanour in theatre.
- 16.2 It appears that Dr Lucas is an experienced and competent anaesthetist. However, I have formed a clear impression that Dr Lucas was a difficult colleague who did not suffer less skilled or experienced health professionals gladly. Although he brought valuable knowledge and expertise to the operating theatre at Gisborne Hospital, he lacked tact and diplomacy in his dealings with nurses and anaesthetic technicians.
- 16.3 It must, however, be recognised that there was fault on both sides. Some of Dr Lucas' nurse and technician colleagues seem to have resented his efficiency and resisted the unfamiliar anaesthetic techniques that he brought to theatre. Dr Lucas did not dispute that the nurses and technicians disliked him but was "hard pressed to know when or where I was not co-operative".
- 16.4 THL responded to this chapter in the following terms:
- "Communication is a key theme throughout the chapter. THL does not deny that Dr Lucas ruffled a few feathers. However, he was clearly a very capable anaesthetist. He upset the apple cart by attempting to improve practices while he was there, and also by using accepted techniques which were not familiar to other theatre staff. His personal style should not be criticised and cited as a reason for any problems there may have been in theatre. Strong personalities create polarised views. There is no evidence to suggest that his personality had any effect on patient care. The impression given by the complaints (most of which were not upheld) is that some theatre staff targeted Dr Lucas and waged a campaign against him."
- 16.5 Health professionals in a theatre environment do not practise in isolation. Teamwork is an essential element of a safe theatre. In order to ensure patient safety, and quality and continuity of care, health care providers are required to co-operate. This ethical and legal duty finds expression in Right 4(5) of the Code. Good communication facilitates effective co-operation.
- 16.6 In my opinion, Dr Lucas did not exhibit the communication and teamwork skills to operate effectively in theatre, and fell short of his duty to co-operate with his colleagues. However, co-operation is a mutual obligation. All health care providers owe this duty to co-operate. To hold Dr Lucas in breach of the duty to co-operate affirmed in Right 4(5) of the Code, I would in fairness have had to investigate fully the actions of some of his colleagues. As the circle of my investigation did not go as wide as all those persons, it would be unfair to damn them unheard or to single out Dr Lucas' uncooperativeness as a breach of the Code. In the circumstances I do not hold that Dr Lucas breached Right 4(5) of the Code.

Compliance with theatre protocols

- 16.7 Despite the raft of allegations, I have found that Dr Lucas failed to comply with theatre protocols, and breached Right 4(2) of the Code, only in relation to his failure to dispose of sharps in an approved manner. There is no evidence that any patient suffered harm as a consequence.

Compliance with professional standards

- 16.8 I have found no evidence that Dr Lucas failed to exercise reasonable care and skill, or to comply with the professional standards expected of an anaesthetist, during his time at Gisborne Hospital.

Minimisation of harm to patients

- 16.9 By his admitted re-use of syringes, Dr Lucas failed to provide services in a manner that minimised potential harm to his patients, and thereby breached Right 4(4) of the Code. There is no evidence of disease transmission to any patient as a result of the re-use of a syringe.

Information disclosure and consent

- 16.10 Dr Lucas failed to give one female patient the information that a reasonable patient in her circumstances would have expected to receive about the use of ice for anaesthetic purposes prior to a surgical procedure, and therefore he breached Right 6(1) of the Code.
- 16.11 Dr Lucas disregarded one patient's specific refusal of consent to the administration of fentanyl, and therefore he breached Right 7(7) of the Code.
- 16.12 Informed consent is at the heart of patients' rights. Although there is no evidence that Dr Lucas caused physical harm to his patients, he nonetheless infringed their autonomy, and failed to respect their right to bodily integrity by his actions on two separate occasions.

Chapter 5

PSA Testing Procedures

April 1998 _ June 2000

1. INTRODUCTION

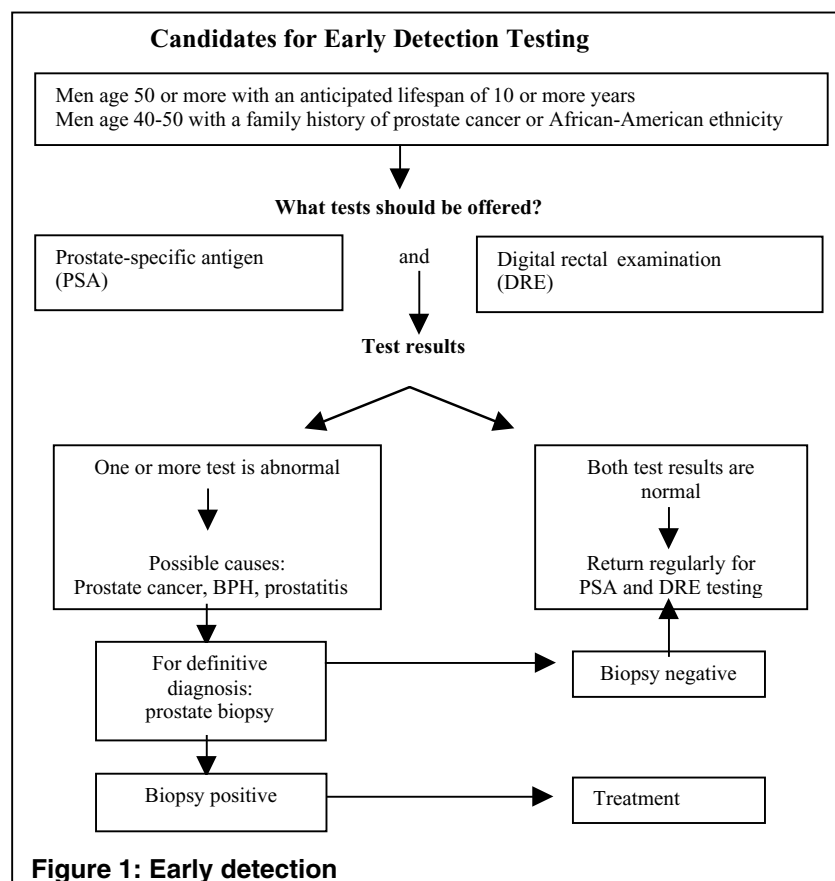
- 1.1 The biochemistry section of the laboratory at Gisborne Hospital has a history of problems relating to quality of its work spanning eight years. Following its initial registration in 1990, International Accreditation New Zealand (IANZ) has de-registered that section of the laboratory on three occasions (1992, 1998, 2000). Subsequent re-registration occurred in 1994 and 1999, when IANZ was assured that appropriate corrective actions had been taken. It is clear from subsequent events and investigations by IANZ, and from my investigation, that many of the concerns raised by previous assessments had not been adequately addressed. There are major issues of staff resourcing, equipment and materials management, and overall management of the laboratory to be addressed, and satisfactorily resolved, in order to protect the rights of health consumers and to regain and retain accreditation.
- 1.2 The problem that sparked this inquiry involved Prostate Specific Antigen (PSA) Testing. Investigation of PSA testing procedures is the major term of reference considered in this chapter. The term of reference required PSA testing from April 1998 to June 2000 to be investigated to determine whether any action by Tairāwhiti Healthcare Ltd (THL) or any individual health care provider breached the Code of Health and Disability Services Consumers' Rights.
- 1.3 This chapter explains in the following section what PSA testing is and how it operates. This is somewhat technical but provides a necessary foundation for what follows. The third section of this chapter explains what went wrong and identifies some of the underlying issues gleaned from discussions with key laboratory personnel. Section four outlines what measures were taken to deal with the errors once discovered. The fifth section considers the problems that occurred with PSA testing in a broader context and over a longer span of time. The sixth section looks at particular problems facing the maintenance of a competent laboratory in Gisborne. Finally, my opinion is set out and recommendations are made to aid the process of rebuilding the confidence of the public, and the hospital community, in the performance of the biochemistry section of the laboratory at Gisborne Hospital.

2. PROSTATE SPECIFIC ANTIGEN (PSA) TESTING

- 2.1 PSA testing is used to assess a number of prostatic conditions. Cancer of the prostate gland can cause a rise in the PSA blood test, as may benign conditions such as benign prostatic hypertrophy (BPH) and inflammation of the prostate (prostatitis).
- 2.2 Values in the 4-10 ng/ml range are considered borderline high, and may be evaluated with special types of PSA tests. Patients with values of > 10 ng/ml

or with an abnormal digital rectal examination (DRE) should have a referral to a specialist urologist for consideration of a biopsy of the prostate to rule out the presence of prostate cancer. It must be remembered that there is great variability in the presentation of prostate cancer and these values are not absolute.

- 2.3 There are a number of specialised PSA tests, which may be used to help differentiate between elevated PSA due to benign conditions and those elevations due to prostate cancer. The first is Total PSA, which then used two ancillary methodologies to improve the accuracy of the test for diagnosis of malignancy for at-risk patients; PSA velocity, which is measuring the rate of increase of PSA over a period of time, and PSA density, which is the ratio of PSA to the size of the prostate gland. The next modification introduced the PSA test. The PSA test evaluates the ratio between the PSA that is free in the blood, and the PSA that is bound to proteins in the blood. The PSA test is requested when the Total PSA test is between 4-10 ng/ml. When the PSA is low (ie, < 15%), there is a higher risk that the patient has prostate cancer. The PSA test must be evaluated in conjunction with the patient's history, physical examination (ie, DRE), and radiological studies (eg, ultrasounds). PSA is one tool in the screening of prostate cancer. The figure below outlines the general approach used clinically.



(Diagram from Abrahamsson, PA, Molecular forms of serum prostate-specific antigen. The clinical value of percent free prostate-specific antigen. *Urol Clin North Am.* 1997;24:353-65)

Purpose of quality control

- 2.4 Quality control is used to check that all aspects of the analytical processes being used by a laboratory are functioning properly. The overall purpose is to ensure that the patient's test results are as reliable as practically possible.
- 2.5 There are many aspects to quality control. These include routine maintenance and calibration of the instruments, checking and recording batch numbers of reagents, controls and calibration material, as well as using internal and external quality control samples to check the accuracy and precision (reliability) of the method being used to test patient specimens.
- 2.6 The problems with the PSA measurements at Gisborne Hospital relate predominantly to a failure to check that the correct calibrators were being used, the incorrect interpretation and response to unexpected internal and external quality control results that detected this error, and the lack of an external control programme as a final check on test reliability.

Control samples

- 2.7 Internal and external quality control programmes involve the measurement of analytes in control samples. These control samples are available commercially, in liquid, frozen or lyophilised form, and are packaged in small bottles for daily usage. When reconstituted, they resemble the patient samples as closely as possible, except that they contain known concentrations of the analytes being measured. For example, the PSA concentration in patients is measured in a sample of their serum (blood with the red cells removed). The control material used will resemble serum, but will have been spiked to provide a known concentration of PSA. This concentration will be noted on the control bottle label or on the leaflet inserted into the package containing the bottle of control material.
- 2.8 It is common practice to use at least two internal control samples containing different concentrations of the analyte being measured. This checks the validity of results across the range of concentrations one is likely to measure in patient specimens.

Internal quality control samples

- 2.9 Internal quality control samples are measured in parallel with the patient specimens, with the concentration measured in the control samples being expected to fall within pre-defined limits, close to the known and stated values. These limits allow for acceptable variation in the precision of the measuring system, but are always much less than the degree of variation that could be clinically significant in the accompanying patient specimens.
- 2.10 If, for example, the value obtained for the PSA internal control samples did not fall within the acceptable limits, then the accompanying patient test results should be discarded. There are a range of procedures that the technologist

- should then carry out to determine and rectify the cause of the out of control measuring system, before attempting to repeat the tests.
- 2.11 Internal quality control samples are often provided by the manufacturer of the instrument and/or reagents being used, although suitable control samples are also often available from an alternative manufacturer. There may be advantages in using an alternative source for control samples, as an independent check on the instrument or reagent manufacturer's system. Alternative material is also sometimes cheaper, more stable, or may contain other analytes which can be used to check other tests carried out in the laboratory. The use of an alternative source for internal control samples, as used for PSA at Gisborne Hospital, is an acceptable practice.
 - 2.12 The error made at Gisborne Hospital was that the stated values for PSA for the internal control samples were changed to fit the results obtained when the wrong calibrator was used. The wrong internal control result should have alerted them to an analytical system error and led to a series of procedures that would eventually have located the cause of the abnormal control results.
 - 2.13 Internal control samples are analysed frequently to ensure that the analytical process is under control at all times. Because the internal control values were altered at Gisborne Hospital, the error introduced into patient specimen results, as a result of incorrect calibrators being used, remained undetected until a locum technologist recognised the error.
 - 2.14 There is reference later in this chapter to the use of rules for determining whether the values obtained on internal quality control samples indicate that the patient results should be accepted or rejected. There are a number of statistical techniques, of varying complexity, for doing this. The Westgard rules and Levey-Jennings plots used at Gisborne Hospital are commonly used. These techniques were applied by entering the internal quality control sample results into a software programme (QC Reporter 2.0).
 - 2.15 The reason that rules are used to decide on rejection or acceptance of results, rather than immediate rejection if one of the control results is not exactly right, is that there is an unavoidable variation in the precision of all steps employed as part of the testing process. This in turn produces an unavoidable variation in the final control results. The rules are used to decide when this variation is excessive and clinically unacceptable, and thus alerts the technologist to problems with the instrument or method.
 - 2.16 It is essential that the internal quality control results are checked before the patient results are reported, as an unacceptable performance should cause those results to be discarded. Although the rules for acceptance or rejection of results used at Gisborne Hospital were applied correctly, the internal control results were not entered into the QC Reporter 2.0 programme until after the patient results had been reported, and thus failed to fulfil their primary purpose.

External quality assurance programmes

- 2.17 External quality assurance refers to programmes provided by an independent external source, such as the Australasian Quality Assurance Programme (AQAP) provided by the Royal College of Pathologists of Australasia. AQAP is used by the majority of laboratories in New Zealand as their external QA programme.
- 2.18 The programme organisers send out samples at regular intervals (monthly for PSA) to a large number of subscribing laboratories. The samples have target values for many different analytes, but these target values are unknown to the testing laboratory. After analysing the external control sample, the laboratory submits their results to the organisers. A report is then returned to the laboratory, which compares their submitted results with those submitted from all other laboratories, and they are also compared with the target values.
- 2.19 The external quality assurance programme thus acts as a final safety net for all other quality control procedures. If a result does not compare closely with the results obtained by the majority of other laboratories using the same instrument and same reagents, then it is clear that there is a quality problem. The presentation of data in the external quality control programme reports illustrate the type of problem a laboratory may be having.

Calibrators

- 2.20 A calibrator is a sample containing an accurately measured and known amount of a particular analyte. When an instrument is calibrated, at least two calibrators are measured, one with a low value and one with a high value. The instrument uses the readings it gets from these calibrators to draw a line (or curve if more than two calibrators), and this curve is then used to relate the read-out of the instrument to a concentration of the analyte. In effect, instrument readings on subsequent patient and internal control specimens are compared with the calibration curve to calculate the concentration of the analyte.
- 2.21 If the wrong calibrators are used, as they were at Gisborne Hospital for PSA, the calibration curve is incorrect and the concentrations of PSA calculated in internal control and patient specimens are also incorrect. The error with the internal control results was recognised, but by altering the control values, the problem was dealt with inappropriately - in effect, ignored - and the errors continued with patient specimens.
- 2.22 Because many factors are involved in maintaining quality, a system of records and documentation is needed for periodic review and evaluation by the laboratory, but also by agencies such as IANZ. These quality control records must be maintained for a period of time (often a minimum of two years) to document that testing has occurred. These records should include:
- Routine maintenance
 - Reagent lot numbers in use and expiration dates

- Calibration records that include calibrator lot numbers and expiration dates
 - Control results
 - Summary statistics
 - Quality control problems and corrective actions taken
 - Trouble-shooting reports.
- 2.23 Quality control planning should be the responsibility of laboratory management, usually the director, the manager or quality specialist. The Laboratory Medical Director, generally a pathologist who has specialised in “chemical” pathology, has a critical role in defining the quality requirements for the laboratory. The actual quality control planning function may be delegated to a manager or quality specialist but is overseen by the Medical Director. Implementation of the quality control procedure is usually delegated to supervisors and technologists who are in charge of managing specified analytical systems (eg, the AxSYM) and testing processes. Routine quality control operation is delegated to everyone who performs a laboratory test. In small laboratories, the most senior technologist may inherit the responsibilities for quality.

3. WHAT WENT WRONG?

- 3.1 Problems first came to light in the biochemistry section of the laboratory at Gisborne Hospital in June 2000, when a locum registered laboratory technologist (Ms Beverley Peterson) reported a problem with quality control procedures. This matter had been raised with the Laboratory Manager (Mr Brian Morris) upon his return from holiday on 19 June 2000, and he hired the locum technologist to assess the quality control systems in the biochemistry laboratory. This assessment raised several issues: inaccuracies in “internal quality control” procedures; trends in tests demonstrating significant deviation from the mean (bias) for a range of analytes; adequacy of response to external quality control reports; accuracy of the IRMA blood gas analyser; and reporting of results on patients prior to receiving information on “control” status. These are examined below.

Bias

- 3.2 The locum’s review of the external quality control results on cardiac enzymes indicated trends showing significant bias that had not been addressed for some time. Quite a few enzyme tests in the general biochemistry laboratory were running at or around two standard deviations (2s) rather than across the middle of the graph - that is, around the zero position where ideally the majority of tests should cluster. On checking, a significant number of analytes consistently showed the same trend, either high or low. Inquiry by the locum of fellow laboratory technologists revealed that no external quality controls

had been run for some time. According to the technologists, reliance for the accuracy of the tests had been placed totally on internal quality controls.

- 3.3 The locum confirmed that internal quality control was run each day with each batch of tests being performed by the biochemistry laboratory. The methods employed involved three controls - high, low and normal - being run to establish sensitivity and specificity levels for each analyte at all three levels. The laboratory technologist running the test then plotted these results. The locum noted that the plotting of the internal quality control results (using a Levey-Jennings Graph) was mostly done after test results were forwarded to the wards and doctors. Mr John Rutledge, head of the biochemistry section of the laboratory from mid-1998 until early March 2000, stated categorically that the checking and verification of the internal quality control checks was always carried out before the results were released to the wards and doctors, during this time at the section.

External quality controls

- 3.4 New Zealand laboratories take part in one of two sorts of external quality control programmes:
- a) Murex, a UK based world-wide programme;
 - b) The Royal College of Pathologists of Australasia AQAP programme.
- 3.5 Gisborne Hospital takes part in the AQAP programme. There are several modules:
- a) general serum chemistry;
 - b) urine chemistry;
 - c) blood gas;
 - d) bilirubin;
 - e) lipids.
- 3.6 The locum noted that the requirement for IANZ registration is that each analyte, at each laboratory, is covered by an external quality control programme. The process for external quality control requires the biochemistry laboratory, on receiving the overview reports from the external quality control agent, to review them and consider any obvious trends. This allows the laboratory to recognise any problems or local bias. It is the responsibility of the laboratory to review these reports and note the issues for internal consideration; there is no responsibility pertaining to the agent who performs the external quality controls. The external control reports are supplied primarily through the Royal College of Pathologists of Australasia.
- 3.7 The external quality control summary report lists each analyte reviewed and the results. There are two types of internal laboratory review proposed in the

summary reports. The first is that there should be a general review of results that statistically sit within the bands for all laboratories operating a particular system (eg, AxSYM) and using particular reagents. The second is a “you must review this” report. The locum noted that these recommendations are very clearly highlighted and cannot be missed. These recommendations, which went back months and in some circumstances years, did not appear to be followed up in the biochemistry section of the laboratory.

Blood Gas Analyser

- 3.8 The locum identified major problems with the IRMA blood gas analyser. The IRMA blood gas analyser gave rise to concern both before and after its purchase. There was concern expressed by many Gisborne clinical and laboratory staff (including Mr Rutledge) over the degree of consultation prior to purchase, and subsequently about where the analyser should reside in the evenings, and as to its accuracy.
- 3.9 The analyser was about 18 months old and the second one of the same type of analyser owned by the biochemistry section of the laboratory. The manufacturer had replaced the first analyser because of problems with the PO₂ results. The locum found no adequate aqueous quality control material in the laboratory to perform the tests required for internal quality control on the blood gas analyser. Apparently the material being used had been bought for the previous blood gas analyser, at considerable expense. It was used because it was still in the store, and in date. But this material was not appropriate for the current analyser.
- 3.10 Furthermore, the locum discovered that the technique being employed in the laboratory for sampling controls was inappropriate. The IRMA analyser manufacturer’s manual is very specific about the sampling techniques to be used for the analyser. The locum noted that the manual states that a needle of 18 gauge to 20 gauge should be used with the analyser. In fact, the manufacturer had modified the needle requirement down to as low as a 15 gauge (large bore). Evidently, the biochemistry section of the laboratory had, for convenience, been using a tuberculin syringe with a very small bore needle of 26 gauge for sampling the controls for the IRMA. The manufacturer’s instructions summarised for bench use by the technologists did not state the size of the needle bore required for the analyser. Mr Rutledge has pointed out that only 18 gauge needles were used during his time at the biochemistry section.

PSA tests – AxSYM analyser

- 3.11 The PSA problem was discovered on the third day of the quality audit (28 June 2000) performed by the locum. On preparing to run a batch of tests on the AxSYM, the locum did the normal internal quality control process using the three levels of quality controls – high, medium and low. The controls used were together in a box provided by the manufacturer. On the top of the box were the target ranges for each level. The bench manual, used by the technologists running the tests, had a list of analytes for the AxSYM analyser showing the target levels and the acceptable deviation ranges.
- 3.12 The locum ran the three levels of controls and then, as per protocol, checked the results against the bench manual’s list of “acceptable ranges”. On doing so, the locum noted that the low and medium controls were on the low side according to the bench manual’s list. The locum then repeated the control run with the same results. Confused as to what the problem might be, the locum checked the top of the box that contained the three controls. It was at this point that the locum noted that the bench manual’s control ranges were different from the manufacturer’s. Further, the locum noted that the target range recorded as per the AxSYM quality control manual differed significantly from the manufacturer’s stated range. The locum also noted that there were significant problems with the bench manual used by the technologists running the tests. The locum stated: “The [bench] manual for the AxSYM does not mention many of the analytes the laboratory tested for. The manual told you how to do calibrations, how to run controls, but did not give the normal ranges for the PSA or sensitivities of the test or instructions not to report PSAs as zero, because the result is not zero.”
- 3.13 The locum then repeated the calibration for the AxSYM and re-ran the controls once more. The problem was still evident. At this point, the locum decided to contact the manufacturer who advised that the most likely cause for the problem was the use of the wrong calibrator or the wrong control.
- 3.14 The locum then checked both calibrators and controls and found that:
- “The calibrators were for PSA and the controls for Total PSA. PSA and Total PSA are two different assays. The difference between Total PSA and PSA is that not only do the assays have different sensitivities and specificities and the calibrators, the actual calibrators themselves have totally different numeric values. The calibrators are also standardised differently.”
- The locum noted that the front page of the manufacturer’s PSA kit insert gives a warning in bold print that reads “WARNING: The AxSYM Total PSA (list 3c19) and AxSYM PSA (list 7a49) assays are different and cannot be used interchangeably”.
- 3.15 Investigation by the locum revealed that from April 1998 the biochemistry section of the laboratory appeared to have been using Total PSA controls with PSA calibrators. The investigation was made more difficult by the poor filing of the control reports and, in some cases, missing control files.

- 3.16 Graphs from April 1998 showed that “new control ranges” (ie, ranges not specified by the manufacturer) were being used on the AxSYM. The new control ranges had become “embedded in the system” and were the ranges used up until the discovery of the PSA test inaccuracy. The locum was unable to discover who changed the control ranges, or why the control ranges had been changed.

Other analytes tested with the AxSYM

- 3.17 The locum subsequently checked all of the control ranges and discovered that the control range had been changed for several analytes. It appeared that each month the quality control targets were being changed to fit the previous month’s results. This was across the board in biochemistry, not just results from the AxSYM. A consultant was of the opinion that two analytes - high-density lipids and cholesterol - would have the most clinical significance. Each one had a bias to each side of the zero range; one was high and one was low.

Quality control systems used by Mr Rutledge

- 3.18 Mr John Rutledge had been appointed as a charge technologist at Gisborne Hospital in 1992 and was put in charge of the biochemistry section of the laboratory from mid-1998 until early March 2000, when he resigned. Mr Rutledge’s role was to oversee the running of the biochemistry section (dealing with reports, phone calls and supervision of staff), to make sure standards were maintained and to keep an eye on laboratory technologist training. He was full time, and his staff were one half time registered technologist and two laboratory technicians who performed the testing. Mr Rutledge pointed out that the two laboratory technicians were not available for his section all the time. In his response to my provisional opinion Mr Rutledge disputed that he was ever formally head of the biochemistry section as a contract was never finalised, but he acted as head and was treated as such by Tairawhiti Healthcare and he is so treated here.
- 3.19 Mr Rutledge explained that he and the laboratory technicians used the control results as an indication of accuracy to allow reports to be sent out to medical staff. However, to ensure that this interpretation was correct, he would enter the report data into his software programme, QC Reporter 2.0. This check on the system and process was done retrospectively, that is after patients’ results were sent out. Mr Rutledge used the Westgard Multirule test system. These rules require that the laboratory should run controls to make sure the results remain within the variance range for the test. The control, when run, should be within the specified (on the package) standard deviation. The “clustering” of results should be around the mean and, if the pattern is outside the mean, this is interpreted as a warning that the full system should be reviewed (ie, types of calibrators, controls, machine function, personnel performance, reporting and any other issue that might impact on the accuracy of the testing procedures).

- 3.20 Mr Rutledge used three quality control “systems” to assist him in determining the accuracy of the laboratory testing:
- a) An internal system;
 - b) An external system;
 - c) The QC Reporter 2.0 software programme.

Internal system

- 3.21 Mr Rutledge said the “internal quality” system was used daily. Mr Rutledge described the process as follows:

“The internal quality control system was maintained by each analyser having a printout of the mean and the maximum standard deviation allowed. When the control values for a particular test were printed off the operator would check the control results against the mean and standard deviation. If the control values were within the standard deviation, the result would be released.

If the control values were outside the standard deviation then the result was embargoed until the matter had been properly investigated and any problems corrected. The analyser would automatically post the result to a holding file on the hospital computer. That file was not accessible by the clinicians. It was only after QC validation that the results would be posted to patient records on the hospital computer and then be accessible by the clinicians.”

- 3.22 A record was kept for each analyte per month using a spreadsheet for each of the three levels of control (low, medium and high), noting the analyte, the standard deviation from the mean, the CV% (Control Value %), and any comments. Mr Rutledge noted that this took a significant amount of time.
- 3.23 Mr Rutledge indicated that if a constant deviation in the quality control was present, the programme allowed for the standard deviation line to be reset.
- 3.24 Mr Rutledge endeavoured to ensure that laboratory staff kept a log of the date and lot number of the reagents and calibrators, and whether the machine had been calibrated with new reagents and the time period between when the recalibrators and reagents were used. He needed the log for his interpretation of the quality control data and the manufacturer required the specific information on lot numbers and recalibration time periods if there were problems. In Mr Rutledge’s opinion, although this took time, it was vital. He said he was unable to achieve his objectives because the laboratory was short-staffed and the attitude of the staff was that “some of the data was being produced for no obvious benefit”.
- 3.25 The Laboratory Manager during the period under review was Mr Brian Morris. He resigned from THL on 13 October 2000. The Laboratory Manager who was a microbiologist, held the view that there was no obvious

benefit in producing the data. Mr Rutledge noted that the process for quality control in microbiology is different from that required in biochemistry. THL also thought that the transfer of data into the QC Reporter programme was of no benefit.

- 3.26 THL denied that the biochemistry section was short staffed over this period, contrary to what Mr Rutledge said. THL said:

“Currently [the section is] being run with the same staffing as was employed immediately prior to John Rutledge’s departure and all quality controls are in place and functioning with excellent results.”

- 3.27 Commenting on this section in the provisional opinion, THL said:

“The AXSYM and Beckman analysers do have on board quality control data management systems. We believe that all hospital laboratories use the ‘on board’ systems. This is less labour intensive and more accurate through eliminating transposition errors. The AXSYM analyser did not have the quality control options set up and therefore could not reject erroneous results. This is a parameter that should be set by the operator [Gisborne Hospital Laboratory] was the only laboratory we are aware of that failed to set up the analyser to review patient results. The associated printer was found to be disconnected and configured inappropriately for use on the analyser. Subsequent quality control results pinpoint exactly when there was a problem. Everything was not within limits.”

External system

- 3.28 The external AQAP programme was run by the Royal College of Pathologists of Australasia for general chemistry using the Beckman analyser. On the AxSYM, the programme was run for therapeutic drugs – phenytoin and digoxin - as well as for Human Chorionic Gonadotropin (pregnancy test or HCG). No AQAP external control samples were run by THL on PSA test results because THL allegedly considered this part of the external control programme to be too expensive.

- 3.29 THL denied this was the case. It stated: “PSA testing was part of the send away testing programme, and samples were forwarded to Canterbury Health and Medlab South for analysis until John Rutledge on his own behalf recommended the testing in house.”

QC Reporter 2.0 software programme

- 3.30 Mr Rutledge noted that to keep up with current standards of care he had introduced to the laboratory a software programme - QC Reporter 2.0 - to manage the data obtained from using controls. It was a quality control system independent of the ‘on board’ analyser QC programmes, and was used for statistical purposes and to pick up trends or variations over a longer term than that produced each day by the ‘on board’ analysers.

- 3.31 QC Reporter 2.0 was a software package created by Westgard Inc applying mathematical/statistical rules for quality control. This Westgard Rules programme was used to determine if the quality control rules were able to detect clinically significant errors, which had been introduced into the system. This programme required data to be entered before it could produce a CV% standard deviation graphically represented, so that it could be detected if results were going “out of control” (outside the tolerable limits of standard deviation).
- 3.32 The AxSYM and Beckman analysers had ‘on board’ quality control data management systems. However, according to Mr Rutledge, these quality control systems were not “easily managed in terms of data manipulation or data summary” and were more “labour intensive”. According to THL these ‘on board’ quality control systems were not in use at the time.
- 3.33 Mr Rutledge explained that it was his practice every month, using the QC Reporter 2.0 programme, to print out the quality control graphs (Levey-Jennings plots) for that month, as well as a weekly summary for the last 12 months. He could then see if over one week the results had shifted. If anything had happened he could make entries in the comments column of his spreadsheet to give an explanation for the observed variance.
- 3.34 The QC Reporter 2.0 programme required staff (usually Mr Rutledge) to take the quality control printouts off the analysers, and to sit down in the chemistry office and type in the data. The software would then assess the data against the Multirule tests and the programme would graphically represent the results as being within or outside the allowable range for that test. The programme produced a Levey-Jennings graph for each analyte. It showed what had happened over the month or weekly over a six-month period, averaging out results. Mr Rutledge thought this was superior to the analysis provided by the “on board” quality control data management systems.
- 3.35 Mr Rutledge believed “that the QC Reporter 2.0 programme allowed for easier calculations and produced good graph results to assist in analysis of the data”. He observed that “the QC Reporter programme was used over a number of years and [was] never commented on adversely in any of the IANZ reports, nor were any CARs [Corrective Action Requests] raised with regard to it”.

PSA testing

- 3.36 Mr Rutledge stressed that he had not been asked for his perspective by THL during its investigation into the cause of the problem. He has attempted to determine a cause from media reports. Without access to the relevant data he was only able to surmise and speculate on what was found by the THL internal investigation. Nor was he able to say what may have happened since he left the laboratory in early March 2000. The PSA testing error was discovered in June 2000.
- 3.37 Mr Rutledge said that he followed the manufacturer’s standard operating procedures in running biochemistry tests. He noted, “the fact is that we were not informed by Abbott Diagnostics that the [Total PSA] calibrators would

- successfully calibrate the PSA [reagents] and that the results would be lower [than they should be]. If we had not followed manufacturer[’s] instructions no calibration curve would have been produced hence ... patient samples could not be analysed.” However, the manufacturer’s package inserts warned against the incompatibility of Total PSA and PSA assays.
- 3.38 Mr Rutledge advised that Abbott Diagnostics had not been able to explain to him why the combination of these two agents did not result in a rejection of the quality control process by the machine. As far as Mr Rutledge can surmise, the AxSYM accepted the calibration data from the Total PSA calibrators using the PSA controls and indicated that “everything was within limits. It produced a valid calibration curve which means the machine is ready to accept patient samples” for analysis.
- 3.39 Mr Rutledge recalled noticing that the control results were “say, 50% lower than expected” on the Levey-Jennings plots. He believed at that point he “would have thought that something was not quite right” and run the calibrators again. The machine accepted the process and gave a valid calibration curve. Mr Rutledge acknowledged that he “relied on the machine to inform him as to whether the calibration had failed and therefore to not use it”. He thought that at the time he would have “considered that the decrease in the control value was attributable to the laboratory using a third party control and new PSA – as opposed to old [Total] PSA reagents”.
- 3.40 Mr Rutledge assumed what would have happened is that whoever was running the test would have told him that the controls were out. He would have asked if the calibrators were “okay” and if he had been told they were new calibrators he would have advised the technician to run the calibrators again. When “that was done they would have said the controls were still out. Then I would have said as the calibration has been accepted [by the machine], it must be the controls causing these problems. The controls are third party controls [made by a manufacturer other than the manufacturer of the machine being used] – therefore I would have accepted those results.” Nobody drew to his attention that the calibrators, though PSA, did not match the PSA reagent-type. He did not discover it himself.
- 3.41 Abbott Diagnostics supplied the calibrators for the PSA testing and the reagents, Mr Rutledge said the controls were supplied by a third party manufacturer. Mr Rutledge therefore concluded that he would have attributed the controls being due to the use of the third party controls and a change in the test reagent (ie, from Total PSA to PSA). Mr Rutledge recalls that he did not go back to the manufacturer of the third party controls to query the “lower than expected” results “because he had rationalised the result”. He therefore did not feel he had to go back to the manufacturers. Mr Rutledge would have concluded that the results were lower based on the difference in the test itself, not due to the process used or the substances used in the biochemistry section of the laboratory.
- 3.42 As is clear from paras 3.38 to 3.40, Mr Rutledge assumed the laboratory was using third party controls, obtained from a source other than Abbott Diagnostics. THL advised that third party controls were not used. Apparently

invoices from Abbott Diagnostics confirm that Total PSA controls were supplied and presumably were used.

- 3.43 Mr Rutledge noted that in the past, the manufacturer, Abbott Diagnostics, would have questioned an order for PSA reagents and for Total PSA calibrators, and asked if the order was what the laboratory wanted. In other words, the manufacturer would have picked up the error. Mr Rutledge surmised that this no longer occurs. THL said there is nothing to support this assertion and that Abbott Diagnostics have indicated that they have no systems that allow for that sort of checking.
- 3.44 The laboratory did not inform the clinicians as to the lower than expected results because of the change to a new PSA kit. Part of the reason for this related to the lack of ready access to a pathologist who could interpret and relay the message to clinicians.
- 3.45 Mr Rutledge also indicated that it is likely that he would have “mentioned the difference he was observing with the new PSA controls if he had been able to talk to someone at a biochemistry special interest group meeting”. He was not given the opportunity to attend these meetings. The situation did not cause him to make further inquiries because he had rationalised the results to himself. THL point out that Mr Rutledge had access to the internet, which he used extensively, and that all he needed to do was read the manufacturer’s instructions on the packet.

4. RESPONSE OF TAIRAWHITI HEALTHCARE

- 4.1 Once THL was aware of a problem with the PSA testing, prompt action was taken. The action focused on two fronts: to determine how best to respond to the affected patients, and to deal with the quality issues raised by the discovery of the problem.
- 4.2 THL did not know the full nature of the problem until Friday 7 July 2000 when it received the correlation from Canterbury Health that revealed 500 tests were involved. On Sunday 9 July it was decided to alert the Minister of Health the next day. In fact, the Minister was alerted on Tuesday, 11 July 2000.
- 4.3 A multi-disciplinary team was put together to manage the PSA incident. It comprised Ms Lynsey Bartlett (Quality Co-ordinator), Dr Bruce Duncan (Clinical Director (Public Health)), Mr Brian Cowper (Project Manager), Mrs Pat Seymour (the Chairperson of the Board), Ms Sheryl Smail (the CEO) and Mr Mike Grant (Group Manager (Community and Support Services)). The following timetable sets out the steps that were taken by THL to manage the PSA incident, from 26 June 2000 to 17 July 2000.

Incident Process

26/06/2000	Ms Beverley Peterson, BSc, BA, ANZIMLS employed as a locum technologist specifically to review QC procedures in biochemistry.
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- 28/06/2000 Ms Peterson identifies all internal control documentation relating to PSA and dating back to March 1999 to be erroneous. Identified that records suggest that tests have been conducted using Total PSA controls, Total PSA reagent but have included PSA calibrators, which are incompatible. Immediate action taken:
All PSA tests at Tairawhiti Healthcare are postponed and referred to Canterbury Health Ltd (CHL);
Advice requested from Chris Florkowski, CHL;
Dr Peter George, CHL contacted;
Abbotts Diagnostics contacted to establish effects.
- 03/07/2000 Search for QC records relating to PSA testing revealed that large quantities of information, including the QC work conducted by Mr Neil Langford, was missing.
- 05/07/2000 Confirmed by Abbott Diagnostics that test was erroneous and that they were not prepared to suggest interpretation of results.
- 06/07/2000 Advice from Dr Peter George to make correlation between tests conducted at CHL and Tairawhiti Healthcare. Arranged for 75 tests to be couriered to Tairawhiti Healthcare after being tested at CHL.
- 07/7/2000 CHL serum tested by Tairawhiti Healthcare and results returned to CHL and correlated by graph.
Results reviewed by Dr Peter George;
Correlation established;
Dr Duncan advised and conversed with Dr George;
Clinical risks appraised by Dr Duncan and Dr George;
Risk assessed as Tairawhiti Healthcare results between > 2 and < 25 ;
At risk tests established to have been conducted between specific dates.

- 08/07/2000 The following steps followed from events of 7/7/2000:
Further consultation with Dr Duncan and Dr George;
Factor analysis of correlation;
Risk group extended to include patients who were being monitored for PSA levels;
Patient laboratory test history obtained;
Patient records obtained;
Office set up (Rosey Burns) to accommodate patient records for correlation of laboratory reports and review by clinicians;
Identification of patients at dual risk of PSA testing and the anaesthetist syringe issue;
Draft letters to patients, clinicians, GPs, chairperson, Ministry of Health (MOH) and media.
- 09/07/2000 The following steps resulted from the events of 8/7/2000:
Correlation of laboratory reports and patient records;
Lists of patients, GPs, clinicians;
Notification of Clinical Director (Surgery), Dr Kyngdon;
Notification of on-call surgeon Dr Juskiewicz;
Logistics-support for patients, staff members and communications;
Review of patient records with a view to reconciling information.
- 10/07/2000 The following matters have been addressed following events of 9/7/2000:
Mr Kyngdon contacted in relation to appraisal of clinical records;
Barry Edwards, CHL contacted in relation to initiating technical review as soon as possible-appropriate technologist identified and awaiting arrangements to be confirmed 11/7/2000;
Confirmation with Barry Edwards in relation to the attendance of Dr Peter George from CHL on Wednesday, 12/7/2000, extending his visit to include the evening of 12/7/2000. Confirmation due 11/7/2000;
Review of laboratory records which have identified tests which have been subsequently conducted by CHL or Medlab South;
Meeting with laboratory staff to inform them of the current position, empathising with the knowledge that some of their friends and relatives may be affected by the current situation. Emphasis on the patient as the first priority and the need to be discreet in their knowledge. Staff advised not to be drawn into answering questions from external communications and to refer any persons with questions relative to this incident to Mr Cowper or Mr Grant;
Dr Kyngdon commenced review of patient records and

communicated with Dr Peter George;
 Dr Kyngdon advocated the attendance of a urologist and Dr Peter George as a review team. Dr Kyngdon to arrange for Wednesday if possible;
 Database information extracted for preparation of letters to GPs & patients.

11/07/2000 Confirmation of attendance of urologist Mr Pat Barry, and Dr Peter George;
 Pathologist on Wednesday 12/7/2000;
 Review of clinical records arranged with Dr Kyngdon for Wednesday 12/7/2000;
 Briefing papers prepared for MOH and Minister;
 Media releases prepared;
 Letters to patients prepared;
 Letters to GPs prepared;
 Reconciliation of lists and data reviewed;
 Confirmation of availability of appropriate technologist from CHL for review.

12/07/2000 Attendance of urologist and pathologist as identified on 11/7/00. The following actions result from a review that included Dr Kyngdon, of the information and clinical records of patients identified by the relevant data. The following matters were resolved by the clinicians:
 Strategy: The patients were divided into those that were considered to need individual review and those that did not, on the basis that clinically critical decisions are made at PSA levels <0.1, 2.5 to 6.5, and 25. These correspond to levels that are important for assessing 'cure' following radical treatment, determining the need for further investigations (TRUS or biopsy) and as an indicator of metastatic disease. Comparison of results obtained by the Gisborne assay (AxSYM) and at Christchurch (1Mx) were used to predict the PSA levels that correspond to decision points in this range.
 Patients can be classified into three groups:

1. Those with values that are unequivocally normal (or abnormal) by both methods.
2. Those who should be reviewed individually by a urologist, after repeat PSA testing. This review should aim to identify patients who:
 - Do not need further follow-up (co-existing problems, no evidence of disease or under adequate surveillance (eg by GPs);
 - Require further assessment to exclude cancer of the prostate;
 - Require further investigation or treatment of known cancer of the prostate.
3. Those that should be reviewed from the available

clinical notes:

- Age > 75 years with cancer of the prostate (may have coexisting problems or require on-going surveillance)
- If no diagnosis of prostatic disease requires GP review of medical fitness and follow-up if appropriate.

Recommendations:

1. The following patients should be offered re-testing and individual review by a urologist:
 - Patients with a “PSA” of >2 and <25 (N=111);
 - Younger patients (age <52 years) with “PSA” > 1.4 and < 2 (N=5);
 - Patients with an established diagnosis of prostatic cancer and “PSA” done in Gisborne (number is unknown, but this group will overlap with other groups). Particular attention should be paid to patients with “PSA” < 1.0;
 - Patients with a “PSA” <0.1(N=15). Patients a : “PSA” of <0.1 and NOT known to have prostate cancer;
2. Follow-up of patients over the age of 75 years should be based on clinical review of case notes and GP assessment.
3. Local GPs need a list of “affected” patients and the actual dates of the relevant periods.

Unresolved Issues

1. Need to confirm the results of re-testing the discordant samples;
2. Need to review performance on other assays performed in Gisborne;
3. Need to consider liaison with other laboratories e.g. Hamilton;
4. Need to consider statements by the representatives of the relevant Royal College(s).

13/07/2000

The following matters followed from 12/7/2000:
 Confirmation of IANZ review commencing 17 July 2000;
 Confirmation of internal review by CHL Technologist commencing 18/7/2000;
 Meeting organised by Dr Kyngdon for 18/7/2000 at 1930 hrs with GPs;
 Clinics arranged to commence from week beginning 7 August 2000;
 Establishment of 0800 number.

- 14/07/2000 The following matters followed from 13/07/2000:
 Concerns raised with Mr Max Robertson, IANZ in relation to apparent commercial conflict of interest with an Assessor from Health Waikato. Asked to supply list of other Laboratories who have been involved in commercial process and likely to have conflict of interest;
 Confirmation by Mr Max Robertson that unable to provide replacement for Assessor from Health Waikato;
 Database extraction of information relative to patients not affected in strategy described above in preparation of letter distribution;
 Weekend strategy to compile data of persons not affected by tests although they have had tests performed.
- 17/07/2000 The following matters follow from 14/07/2000:
 Letters to persons not at immediate risk distributed as required;
 Visiting Urologist Dr Gowland scheduled to meet managers and laboratory staff 18/4/2000 to review methodology used to identify at risk patients;
 IANZ review commenced.

The Accreditation

- 4.4 On 10 July 2000 IANZ was informed by the Laboratory Manager that a significant problem had been identified with testing for PSA. A special assessment was arranged for 17-18 July, and took place on those days. The focus of that assessment was on the performance of Clinical Biochemistry with special emphasis on PSA testing. On the basis of that assessment visit IANZ suspended accreditation of the biochemistry section of the Laboratory effective from 19 July 2000. The IANZ special assessment team's "Laboratory Accreditation Programme Assessment Report" recommended corrective action on a number of fronts. It was noted that some of these matters were similar to the issues that had resulted in earlier suspension of accreditation of clinical biochemistry, and which had not been adequately addressed.
- 4.5 The IANZ Assessment Report "Corrective Action Request" (CAR No. 1) noted:

"The laboratory had a documented history over several years of staffing difficulties and insufficient expertise, with concerns raised about performance in various aspects of testing.

These shortcomings culminated in the temporary suspension of Clinical Biochemistry from December 1998 until April 1999 because of inadequate and inappropriate internal and external quality control activity, and the continued suspension of cytology, histology and

mortuary, in the absence of a cytotechnologist and anatomical pathologist.

The technician in charge of the Clinical Biochemistry left the laboratory in March 2000.

The laboratory manager had attempted to address some of the issues in relation to staffing with limited success.

[Hospital] management had proposed and explored alternative structures, associations, alliances, tendering of services and management contracts. The preferred option was still under consideration, and as such, outstanding issues have not been addressed. [At the time of writing this report the laboratory is still managed by Tairawhiti Healthcare.]

The laboratory and [Hospital] management need to identify and comprehensively address all matters of concern in relation to management and operation of testing services, including those corrective action issues identified in this report.

The primary issues raised in this report relate to performance with internal and external quality control activity. There was no evidence that biased and out-of-limit values in either internal or external quality control activities were recognised, or that corrective action was taken.

These matters are similar to the issues that resulted in the previous suspension of Clinical Biochemistry [in 1998].

The large bias in some analytes may affect clinical interpretation.

The assessment team informed the laboratory that it had made a recommendation to the Chief Executive Officer of International Accreditation New Zealand that the accreditation of Clinical Biochemistry should be suspended. Following a review on Wednesday 19 July 2000, the suspension of Clinical Biochemistry will be confirmed.

The laboratory will need to confirm that at least all identified items and areas of concern have been satisfactorily addressed before reinstatement may be considered. International Accreditation New Zealand in conjunction with an assessment team, will need to complete a follow-up assessment to confirm implementation of effective corrective action measures.”

The nine other corrective action requests focused on management of laboratory staff, training of laboratory staff, laboratory quality control procedures, procurement of consumables, review of new work, corrective action procedures, control of non-conforming work, technical records, quality records, equipment, test methods and procedures, and internal audits.

The Project Plan “Quality 2000”

- 4.6 Once the extent of the problem was known, and the IANZ report was completed, THL established a special project team to address the quality issues. The aim of Project Plan “Quality 2000” is to provide best practice laboratory service in accordance with the Code of Laboratory Management Practice and to meet IANZ Accreditation requirements. The project team consists of Mr Brian Cowper (project manager), Mr John Sharman (consultant biochemist), Ms Beverley Peterson (locum technologist), and Dr Peter George (chemical pathologist, Canterbury Health Limited).
- 4.7 The project team reports to the Group Manager (Community and Support Services), and provides weekly reports to IANZ, the Health Funding Authority, and the CEO of Tairāwhiti Healthcare. Mr Cowper is working with a laboratory staff recruitment agency to hire staff for THL. Mr Sharman has written procedures about the assessment of new equipment and new methods. Ms Peterson is developing a decision tree for quality control.
- 4.8 The THL project team found that there had clearly been a mistake caused by an individual staff member’s practice. During the time that the incorrect practice was in place the laboratory had been reviewed by IANZ/TELARC three times and had a Quality Health New Zealand review. There had also been visiting pathologists. No one had picked up the mistake.

Gowland report

- 4.9 The Ministry of Health commissioned a report by Dr Stuart Gowland, a Christchurch urologist, hereafter referred to as the Gowland report. The terms of reference of this report concentrated on the adequacy of the efforts by THL to identify the men affected by the PSA testing error, the methodology for assessing the relative risks of the men affected and the methods of re-testing and re-evaluation. This report, entitled “Expert Review to Report on Tairāwhiti Health Ltd Processes in Addressing the Error in Prostate Specific Antigen Testing”, was submitted in October 2000.
- 4.10 The Gowland report found:
- “Once the extent of the [PSA testing] problem had become apparent, THL management also acted promptly and professionally and it appears at risk patients have been surveyed with diligence. Communications with patients’ GPs and the wider community were undertaken professionally.”
- 4.11 It appears that of the 500 patients affected by the incorrect testing, approximately 117 were assessed as needing to be re-assessed for prostatic disease. They were advised to consult their general practitioners, and THL offered them follow-up care in an outpatient clinic in the week of 7 August 2000.
- 4.12 Fortunately, although notification of the PSA testing error would have been distressing to those affected, no patient appears to have otherwise been adversely affected. As noted by the lay consumer representative appointed to

work with Dr Gowland, Mr Ted Wesley, an executive member of the Prostate Awareness and Support Society:

“As a lay person I was pleased with the professional attitude and the trouble being taken to track down and organise clinic visits for ‘at risk’ men following errors in PSA reporting by the laboratory at Gisborne Hospital. I am satisfied that everything possible is being done in the follow-up of these men. It is pleasing that of the men seen so far, no patient has been placed at further risk or clinically disadvantaged due to mistake in the PSA results. This, in no small part, reflects the rigorous follow-up and ongoing care they have received over the years despite the errors in the PSA tests.”

- 4.13 Dr Gowland began the summary of this report by commenting that “the THL laboratory appears to have been a disaster waiting to happen”. This is not just a retrospective view, made with the benefit of hindsight. Much the same language was used, and assessment made, by the Clinical Director (Surgery) in a letter to the Group Manager (Community & Support Services) dated 28 September 1999. The Clinical Director (Surgery) complained of the regularity with which “fundamental” mistakes were occurring in the laboratory and insisted that they required correction urgently. “These [mistakes] simply should not happen and need addressing with the utmost urgency before the disaster that is waiting to happen does happen.” The Clinical Director was not referring to mistakes in PSA testing, of course, but his assessment that the biochemistry section of the laboratory was a disaster waiting to happen was shared by others at the time, and confirmed by the events in 2000.

5. ORGANISATIONAL, MANAGEMENT AND INSTITUTIONAL FACTORS

- 5.1 As will be clear already, the problem with PSA testing must be understood in context. Several organisational, management and institutional factors clearly contributed to the environment in which the mistakes occurred.

Lack of resident pathologist

- 5.2 Over the last ten years THL has had eight pathologists. There has been difficulty in attracting and then providing sufficient work, and work of a sufficiently varied and interesting nature, to keep an active pathologist fully occupied. The last resident pathologist resigned in late 1999 and, despite conscientious efforts, THL has been unable to appoint a successor.
- 5.3 Throughout all the changes of the last few years THL has been determined to maintain an on-site pathologist, particularly in light of the needs of Maori. THL’s proposal to contract laboratory services to an alternative on-site provider (discussed later in this chapter) had at its core the requirement for an on-site pathologist. At a hui attended by my investigation team, staff were told of a perceived lack of cultural sensitivity by THL due to the lack of a residential pathologist at Gisborne. Since there was no pathologist at Gisborne, bodies were “stockpiled” before transportation to Tauranga for

autopsies. This has also been of concern to the local Coroner. THL commented:

“Transportation [to Tauranga for autopsies] is contracted to a local funeral service and is, as far as THL is aware, conducted expeditiously. There have been no incidents ‘of stockpiling’ before transportation as far as THL is aware.”

Restructuring

- 5.4 Up until 1996 there were two laboratories in Gisborne. Gisborne Hospital did all the hospital work, and there was one private laboratory owned by Dr Michael Bottrill. Dr Bottrill’s laboratory did all the private hospital and general practitioner work. Gisborne Hospital had the opportunity to purchase the private laboratory in 1995. Due to delay the hospital missed the opportunity to buy the laboratory, which was bought by Medlab.
- 5.5 In March 1996, after the opportunity to purchase the private laboratory had been lost, the hospital laboratory went into competition for work with the private laboratory. Initially the hospital laboratory was successful in this venture and secured 50% of all the general practitioner work from the private laboratory. The hospital laboratory was accredited and was able to offer access to computer systems that facilitated the processing of GP requests. The private laboratory was not accredited at that time.
- 5.6 In early 1998, precipitated by a report by a management consultant in November 1997, THL initiated a proposal to restructure the laboratory. Suffice to say this led to a good deal of unhappiness, stress and staffing changes. It was at this time that Mr Rutledge was appointed head of the Biochemistry section. Key staff were lost to Medlab Gisborne and as a consequence the GP clinics withdrew from their contractual arrangements with the THL laboratory. As a result of the loss of the GP contracts the workload in the laboratory dropped significantly.
- 5.7 The Senior Medical Association was concerned about the laboratory restructuring and expressed concern to senior management.

Staff numbers before and after the 1998 restructuring

- 5.8 There were differing views on the number of staff employed before the restructuring. A technician and union delegate said there were 25. Information supplied to the investigation team by THL shows 19.35 full-time equivalent (FTE) positions in place at June 1998. An undated organisation chart circulated to staff at the time of the 1998 proposals for change shows 20.8 FTEs. (Another position is shown on the chart but it does not have an allocation of time recorded.) A briefing paper on the options for the laboratory, written by the Group Manager (Community and Support Services), Mr Mike Grant, for the Chief Executive in May 1999 records that in March 1998 there were 22 FTEs. The Group Manager (Community and Support Services) noted that the “call back cost and overtime cost was largely divided between six employees of the laboratory. The burden of on-call and the small pool

- involved meant that most senior staff were often not available during the day.” Mr Grant wrote that the “combined on-call and call back cost was close to \$150,000” per annum.
- 5.9 THL advised the investigation team that the staff count in July 2000 was 15.6 FTEs and in December 2000 17.6 FTEs. Since November 2000 two qualified and two unqualified staff have resigned. The 17.6 staff members include four laboratory assistants who have been employed “in an effort to overcome staff shortages”. THL is currently talking to a number of qualified prospective employees.
- 5.10 A locum technician explained how staffing levels impact on the on-call roster. Because the laboratory had insufficient staff to operate adequately 24 hours a day, staff had to be on-call on a regular basis. Contractual arrangements govern the length of breaks between callbacks, and it is common for someone to be absent as the direct result of a series of calls during the night. The cost of call-outs for the period 1/2/2000 to 31/7/2000 totalled \$54,316. This equates to \$108,632 per annum.
- 5.11 Mr John Sharman (consultant biochemist, and presently acting Laboratory Manager) wrote a special report on staffing (31 July 2000). His comments on biochemistry staffing were:
- “The section head position is vacant and needs to be filled as a matter of urgency. It is imperative that the person appointed be scrutinised carefully to ensure that the required skills are present and that competence to do the job can be established.”
- 5.12 The nominal level of biochemistry staff assisting the section head was 2.5 FTEs. This is made up of two technologists in 1.5 FTE positions and a laboratory assistant occupying a 1 FTE position but seconded for half of his time to microbiology for training and to cover a staffing shortfall there. The section needs sufficient staff to carry out the routine work while releasing the section head to carry out essential background tasks. These tasks include: implementation and maintenance of quality control processes, staff training and education, review and maintenance of manuals, and cover for leave.
- 5.13 The 1998 IANZ Accreditation Report commented that there were insufficient staff. This situation went unremedied.

Accreditation history

- 5.14 As a result of an IANZ routine assessment, in late 1998, the biochemistry section accreditation was suspended in November 1998. The Laboratory Manager advised the investigation team that the accreditation was lost for the following reasons: there were no records of when quality controls were made on the analysers; samples were being sent out of the Laboratory before they were ready; and work was going out on uncontrolled samples/specimens. The report stated that the decision to suspend registration did not reflect on the personal abilities of individual staff working in Clinical Biochemistry.

- 5.15 Corrective action was requested in several areas. THL was asked to: appoint a quality manager and deputy for the laboratory; reinstate regular staff meetings; supply job descriptions for staff in key positions in all departments; address the availability of records to all staff; identify staff training needs; and develop an on-going staff training programme. It should be noted in relation to the recommendation that a quality manager be appointed, and that in the IANZ Accreditation Report in July 2000 THL was criticised for appointing a person without the appropriate technical expertise required for the position.

In addition, the following items were identified as not complying to the *New Zealand Code of Laboratory Management Practice: 1993* and the department's own documentation:

- daily quality control was being performed but not reviewed before patient results were released
- no documented review of AQAP survey
- most AQAP forms are submitted late
- no documented corrective action and follow-up for all out of limit quality control results
- no maintenance records existed for the Array analyser
- the Blood Gas analyser had no service logs for the previous eighteen months
- the analyses for Transferrin and the calculated results for Iron binding capacity from the Transferrin showed extremely poor control
- some quality control analyses eg, Uric Acid, Cholesterol, Triglyceride, and ALP were in need of attention as the results showed significant deviation from the overall mean
- no documentation since 1996 for the maintenance of the water meter that supplied the analysers
- no quality control back-up staff when the head of department was absent
- the internal quality controls for the blood gas analyser were out of control, but it was thought a recent lot change might account for those results
- lot number information sheets changeover was unable to be verified

- scant documentation for the quality control system and review of the department's internal and external quality control was non-existent.
- 5.16 THL took the suspension of Biochemistry in late 1998 seriously and took the following steps:
- employed a consultant technologist to set up a new system for quality assurance and management of the laboratory;
 - prepared an action plan which was approved by IANZ, with reporting criteria;
 - employed a Laboratory Manager, who was an IANZ accredited assessor, to manage the process; and
 - appointed a quality assurance officer with the aid of the IANZ assessor.
- 5.17 IANZ was satisfied with the remedial steps and reaccredited the biochemistry section of the laboratory. However, it is clear from both the IANZ special assessment on 17-18 July 2000 and from this investigation that many of the deficiencies identified by IANZ in December 1998 had not been adequately corrected by March 2000.
- 5.18 THL pointed out in their response to the provisional opinion that “senior management relied on the level of surveillance by IANZ, and the skills of the laboratory manager to ensure that laboratory services met quality standards”.
- 5.19 How was it, then, that IANZ lifted the suspension of registration? IANZ provides a general, overall assessment of the procedures being used within a laboratory. It does not attempt to provide a detailed audit of all of the procedures. IANZ see its function as carrying out an assessment of a laboratory that is assumed to have quality systems in place, sufficient to meet all of the standards laid down by IANZ for accreditation. In the process of carrying out the assessment, the assessors may detect practices that fall short of these standards, and these will then be raised as Corrective Action Requests (CAR). It is a very rare event for a CAR to be serious enough to result in de-registration.
- 5.20 It is a requirement of the Code of Laboratory Management Practice that internal audits be carried out by each laboratory at least once every 12 months, by a suitably qualified technologist from another section of the laboratory or another laboratory. The IANZ Assessment Report of July 2000 found this requirement had not been complied with.

The proposal to contract out

- 5.21 The THL Board received a proposal to contract out laboratory services at its meeting in May 1999. The former Chairperson commented that this was the third strategy the Board had been asked to endorse, following earlier strategies of purchase of the private laboratory and competing for community referred

work reconfigured internal operations. The directors gave approval for management to progress negotiations with a preferred tenderer. Negotiations continued until May 2000 when the preferred tenderer withdrew. The proposal to contract out laboratory services lapsed.

Loss of laboratory business

- 5.22 Te Puia Hospital formerly belonged to THL but was returned to the ownership and administration of Ngati Porou Hauora (NPH). In October 2000 NPH dropped the laboratory services provided by THL for an independent outside laboratory because THL's laboratory was taking too long to return specimens. In some instances the Tairāwhiti Healthcare laboratory was taking up to six weeks to return specimens, and in the NPH's view that was unsatisfactory.

Staff training

- 5.23 Despite the fact that the 1998 IANZ report recommended more resources be made available there was no training plan for laboratory staff instituted. Staff therefore had to ask for training opportunities and these were frequently declined. Staff perceived that they do not receive enough training.

Management and communication

- 5.24 Relationships between management and staff in the biochemistry section of the laboratory at Gisborne Hospital had been under pressure at least since the restructuring of 1998. The effect of the restructuring was described in the 1998 IANZ Accreditation Report.

“These issues [restructuring, appointment of new manager, redundancies, replacement of pathologist] have had an impact on staff morale, throughput of samples, quality control aspects and general maintenance of the quality management system.

The staff have been working under somewhat difficult circumstances and it was felt by the technical experts that given the above mentioned problems, the laboratory has been hard pushed to cope with the resources currently provided. All departments are somewhat short staffed and this is reflected in the failure to address items such as are documented in the corrective action requests.”

- 5.25 The way in which the restructuring was proposed and implemented caused a breakdown in trust between staff and management. The key reason for the restructuring given by the then Group Manager (Hospital) (Mr Mike Grant) was to address the problem of all the on-call work being shared by a group of six staff. Mr Sharman's report on staffing dated 31 July 2000 states that the on-call work is now shared by seven staff and the cost is not significantly different to that before restructuring. The restructuring did, however, result in staff losses and the consequent loss of GP contracts.

6. PROBLEMS OF A SMALL AND ISOLATED LABORATORY

- 6.1 Both the geographical isolation and relatively small size of the Gisborne Hospital laboratory has made it challenging to develop and maintain good standards of practice in the biochemistry section of the laboratory.
- 6.2 Staff at Gisborne Hospital were professionally isolated from face-to-face and regular communication with their colleagues. Therefore most problems tended to be dealt with internally rather than after seeking advice from peers. Although Canterbury Health acts as a parent laboratory, and provides considerable support, it is inevitably limited by distance and the frequency with which inter-laboratory staff visits can be made. Canterbury Health provides a testing service for more complex or non-routine tests, but cannot advise on problems arising from day-to-day procedures carried out at Gisborne Hospital, unless that advice is specifically requested.
- 6.3 THL advised that currently:

“Staff at Gisborne Hospital Laboratory are constantly in contact with Canterbury Health Laboratories. A regime of visiting pathologists has been established on a monthly basis, and is incorporated into staff training and ‘development’.”

7. OPINION

Overview

- 7.1 Since 1998 the THL laboratory has been focused on survival rather than the development of a quality service. The Board of THL noted that it had been asked to approve three different strategies in relation to the biochemistry section of the laboratory within a relatively short period of time. Quality has taken second place to structure. Staff have had very limited educational opportunities and there has been a lack of positive leadership and focus from management. Quality initiatives have developed in isolation and there has been limited feedback on quality systems. The PSA problem arose out of a troubled and tense work environment where staff focus was centered on whether they would be employed and how to protect themselves, rather than on delivering a quality service. All of the ingredients for significant risk had been created.
- 7.2 It is a blessing that no patient appears to have been adversely affected by the PSA testing errors. It cannot excuse, of course, the systemic and professional errors that occurred and potentially put patients at risk and certainly caused them distress. Such errors cannot be permitted to re-occur.
- 7.3 THL approached the PSA problem and the resultant loss of accreditation in an expeditious and professional manner. The problem was openly acknowledged and a plan was immediately put in place to correct the problem and to identify and safeguard the interests of all “at risk” patients. Staff have been involved in addressing the problems. Long-standing employment contract difficulties are being resolved as part of the remedial process.

- 7.4 The good work of Ms Beverley Petersen in discovering the error should be acknowledged, as should the impressive achievements of the Quality 2000 Project team led by Mr Brian Cowper. THL has been fortunate in securing the services of Mr John Sharman, who has put his considerable experience at its disposal.

The way forward

- 7.5 The primary aim of any laboratory service is to provide a timely and reliable diagnostic service for the ultimate benefit of the patients. With this common aim, it should be possible for the whole team to communicate so as to produce a cost-efficient and reliable service. A measure of goodwill and trust is essential if the problems, which have dogged this laboratory for a number of years, are to be resolved.
- 7.6 For some time to come, there will be a considerable focus of attention on the biochemistry section of the laboratory at Gisborne Hospital by the community, the clinical staff, the Board, IANZ, and the media. It is in the best interests of all concerned that the laboratory provides a consistently reliable service from now on. If it fails again, then it is likely that the reputation of all members of senior management, laboratory management and the technologist team will suffer equally.
- 7.7 It is vital that the risk of recurrent problems is minimised, but this will take a concerted and continuing effort from all staff involved in managing and providing the laboratory service. As stated in the Gowland report:

“There is no fundamental reason why the laboratory cannot become top class, but attitudes will need to be proactive for positive advances, not simply reactive, especially to financial pressures.”

- 7.8 The laboratory needs a vision and values statement that has quality and teamwork at its core. All staff need to be involved in creating this statement. All staff need to be involved in training on how to achieve and maintain a quality service. A few key performance quality indicators need to be set and staff need to be able to see results of their team performance against the indicators on a regular and timely basis. Staff need to take part in a trusted performance review process. An equal emphasis needs to be given to performance review and performance planning. All staff need a skills development plan that reflects the quality goals of the laboratory.
- 7.9 Tairawhiti District Health stated that its management team is committed to achieving sustained excellence in laboratory management practice. Tairawhiti District Health noted:

“There has been a clear improvement in staff morale and work practices throughout the laboratory. New staff in particular have a willingness to be more flexible and are keen to learn new skills. The skill and integrity of laboratory management and the technologists determine the reliability of the diagnostic testing service for the benefit of patients.”

- 7.10 There is reason for optimism that the biochemistry section has put its troubled past behind it and is moving forward. Implementation of the recommendations in paras 8.1 – 8.16 will go a long way to ensuring that the community can have confidence in the quality of biochemistry services at Gisborne Hospital.

Staff requirements

- 7.11 It is not possible to provide a quality service from a small laboratory with the same cost-efficiency that can be achieved by larger units. The most expensive resource is staff, but unfortunately both the number of staff and the level of training and expertise required to provide a reliable service is not directly related to the smaller workload they may be expected to handle. This is why past and present staff members saw the necessity of gaining private work to ensure viability and maintenance of expertise in the laboratory.
- 7.12 It can be difficult to attract or retain experienced and well-trained staff in a laboratory where opportunities for promotion and professional development are limited. Long-term resolution of the situation will require an active commitment to building a focused and competent team.
- 7.13 The primary requirement of any hospital medical laboratory is to have sufficient, well-qualified and experienced staff to provide a 24 hour/7 day service to the hospital. When there is a large pool of staff, as found in a moderate or large laboratory, there is less difficulty in matching the staff numbers to the peaks and troughs of the workflow. As the size of the laboratory decreases, a limit is reached of the minimum number of staff required to fill the roster to provide a 7 day service, with this limit becoming independent of the workload being handled.
- 7.14 This in itself leads to unavoidable “inefficient” employment of staff at certain times of the day, when the workload is low. The temptation for management is to reduce the cost of staff to an absolute minimum, to keep the staff “efficiently” busy, even if this means that at times the staff are working under considerable stress to cope with peak workloads.
- 7.15 Under-staffing, either in terms of numbers or seniority, almost inevitably leads to a gradual reduction in the quality and reliability of the service the laboratory can provide. The need to “get the results out” means that quality factors in their widest sense (quality control, training, continuing education) have a lower priority and are usually the first activities to be reduced. The risk of system failure is thus increased.
- 7.16 A small laboratory working in geographical isolation has the same need as any other laboratory for an adequate number of well-qualified and experienced staff, with sufficient time to perform routine work with minimal stress, as well as time to undertake relevant continuing education, updating of practical skills, and continual reviews of analytical methods and quality issues.
- 7.17 It appears that the biochemistry section of the laboratory had been working under increasing staff restraints for some time. Some of this may have been

due to recruitment difficulties, but some part would appear to have arisen from cost-saving measures. THL advised that a new senior biochemist has been appointed.

Management and communication

- 7.19 Communication and attitude problems have affected the performance of both managers and technologists. The impact that their dysfunctional relationship had on the clinical laboratory service should not be underestimated, and must be resolved if the community is to have confidence in the ability of this laboratory to maintain a quality service. There appeared to be a lack of mutual respect and trust, which is hardly surprising in light of the history of this laboratory service. There are, however, pleasing signs of recent improvement in atmosphere and attitude.
- 7.20 Laboratory staff need to be informed about the financial constraints and management goals, so that they are not surprised by proposals being made by management which may alter the staff structure or provision of the laboratory service. Equally, management needs to appreciate the essential requirements for a laboratory to produce reliable results, and the impact that their decisions may have on the quality of the service.
- 7.21 Managers appear to have underestimated the motivation and adaptability of technical staff, who will usually accept changes planned by managers if they feel that their own previous experience and judgement has genuinely been taken into account. THL said that in the restructuring process it followed the “management of change” process set out in the collective agreement contract and provided opportunities for staff and the union to participate in the restructuring. THL acknowledged, however, that “the process followed did not address all concerns or provide enough feedback to staff”.

Quality control

- 7.22 To meet expected standards of patient care, the reliability of any diagnostic test result must be of an equivalent standard wherever it is performed, even if the relative cost of providing this result is much higher in a smaller laboratory. The cost of laboratory diagnostic tests is relatively minor compared with the total cost of the patient’s treatment, and certainly less than the consequential cost of providing an incorrect result.
- 7.23 Internal quality control (QC) is designed to provide immediate feedback on the reliability of the test results, before they are sent out as the patient’s laboratory report.
- 7.24 Although a sophisticated internal quality control procedure was in place, the delays introduced by the need to re-enter data into the QC Reporter 2.0 programme meant that feedback was not immediate. Results were sent out before the internal QC had been checked and signed off. As noted earlier, Mr Rutledge denied that data was sent out to clinicians before the internal QC results had been checked. He said “the subsequent entry of data into the QC Reporter program[me] did not invalidate the internal QC programme.”

- 7.25 In addition, there is evidence that internal QC data was either changed to make it fit the expected values, and/or that there was an inadequate response to the information being shown by the internal QC programme. Mr Rutledge denied altering any data to fit expected values.
- 7.26 External quality assurance is a means of retrospectively comparing performance against that of other laboratories. It is the final check that the data being produced is valid. Failure to submit PSA results to an external QC programme meant that the final safety net was missing and the problem was not detected. Even if the cost of submitting results to the programme was considered an issue, failure to participate when a programme was available breached IANZ registration requirements.
- 7.27 It is essential that all of the staff fully understand the purpose of the QC programme, the implications of tests appearing to be out of control, and what they should do to rectify the problem. With such a small pool of staff, all of whom are expected to perform all test procedures, they all need to be included in regular section meetings to review test performance so that they know what actions are being taken to rectify any quality problems.

Mr John Rutledge

- 7.28 Mr Rutledge made a series of errors of judgement when faced with control samples for PSA that produced unexpected results. Internal quality control data alerted him to the problem, but he did not understand the significance of the data and so his response was not correct. He should have sought further advice from the reagent/calibrator suppliers and colleagues in other laboratories performing the same test procedure if the reasons for the abnormal data were not clear to him.
- 7.29 Altering QC data to fit previous results is not acceptable and makes the internal QC process pointless.
- 7.30 The rest of the technical staff, including the Quality Manager appointed after the 1998 suspension of accreditation, were also inadequately trained to understand the significance of this data. In their defence, Mr Rutledge had a special interest in his PC-based QC programme (QC Reporter 2.0), and so they probably assumed that he knew what he was doing and that there was no cause for concern. Mr Rutledge's managers knew he was using the PC-based QC system. He presented a paper about his system at a laboratory technology conference.
- 7.31 Mr Rutledge had instituted a PC-based internal quality assurance system that he believed was more user-friendly than that available on the analysers, although not all of his staff agreed with this view. Unfortunately, delays in transcribing results meant that the information it provided was not immediately available, and so it had limited practical use. On a modern automated analyser, it is the minimum normal practice to run control samples at the beginning of each day, and whenever a new batch of reagents is placed on the analyser. It would have been better to have used the analyser-based QC

- programmes, which accept data directly from the analyser without the need for transcription. This would have alerted the operator immediately if tests had been out of control.
- 7.32 No external quality assurance programme was instituted for PSA testing. Such a programme would have acted as a final safety net and shown THL's results to be erroneous when compared with peers performing the same test using the same reagents and the same type of instrument. As noted earlier at paras 3.27 – 3.29, there is a difference of view as to whether THL denied access to external quality control of PSA test results on financial grounds or whether Mr Rutledge did this off his own bat. I cannot resolve this issue. If the former is correct, I would simply say that saving costs by not using quality control programmes is never the right decision. If the latter view is correct, surely management should have been aware of the situation.
- 7.33 It is accepted that Mr Rutledge was doing his best to cope in an unsatisfactory working environment. He was working in isolation from other senior colleagues and with managers who appeared somewhat unsympathetic to the problems faced by the biochemistry section of the laboratory. At the time the PSA testing problem occurred Mr Rutledge was not receiving training, was denied the opportunity to attend user group meetings, was under stress from disciplinary action, allegedly had insufficient staff to enable him to do his job properly, and was undoubtedly working in a tense environment.
- 7.34 In the light of the context within which the errors took place and especially the history of the biochemistry section over the last eight years it may seem invidious to apportion individual, rather than systemic, blame. However, some individual failings transcended generic systems failure.
- 7.35 Taking full account of the difficult working environment Mr Rutledge found himself in, and his efforts to ensure effective quality control of the PSA test results provided in the biochemistry laboratory, it is clear that he made serious errors of judgement and failed to comply with relevant standards. Accordingly, in my opinion Mr Rutledge breached Right 4(2) of the Code.

Organisational responsibility

- 7.36 Management appears to have been less than sympathetic to the problems faced by the biochemistry section of the laboratory over recent years. The air of uncertainty, unexpected announcement of plans for the service with little explanation given, and a general disregard or non-recognition of the experience and concerns being expressed by technical staff have all contributed to a difficult and tense environment, which increased the likelihood that the system would fail.
- 7.37 Staff concerns at workload, expressed prior to and at the time of the PSA discovery, were directly related to their concerns about potential risk to patients. A colleague in Mr Rutledge's department had commented to him several times, in response to the fact that he was unable to review all the work done by biochemistry laboratory staff: "We're flying by the seat of our pants. It [is] only a matter of time before we have a major."

- 7.38 THL responded that senior management had relied on management within the laboratory. THL also pointed out a range of staffing issues, including the number of part time staff who demonstrated a reluctance to increase hours or assist in times of peak workload. THL continued:

“Everyone must take responsibility for delivering quality services. We believe that the problems with the laboratory are not all associated with management, leadership and a lack of vision. These matters relate also to the openness, conflict resolution, clinical practice and the behaviour of staff of all professions. The decisions and behaviour of nurses, both junior and senior medical staff, contribute to and impact on patient services.”

- 7.39 It is abundantly clear that the troubles at the biochemistry section of the laboratory at Gisborne Hospital existed well before the period covered by this term of reference, and that they continued to dog the section until mid-2000. The biochemistry section was, as several people observed, a disaster waiting to happen.
- 7.40 Given the record of the biochemistry section of the laboratory in the independent assessments made by IANZ, it is hard to understand why no concerted effort was made to investigate why this core diagnostic service failed to meet minimum standards on two previous occasions, to such a serious degree that it was de-registered a third time. A failure of this degree clearly warranted special attention from senior management, and significant changes or additional resources to support the technical staff and enable them to rectify the problems permanently. THL does not appear to have adopted a long-term risk management approach to the identified quality issues in the biochemistry section of the laboratory.
- 7.41 THL must accept some responsibility for the situation that developed in the biochemistry section of the laboratory at Gisborne Hospital, and for the evident failure to respond adequately to the specific problems identified in the assessment by IANZ in 1998, that led to de-registration.
- 7.42 In my opinion, THL did not ensure that consumers received clinical biochemistry services of an appropriate standard from the Gisborne Hospital laboratory. Biochemistry services were not provided with reasonable care and skill and, as a direct consequence, in June 2000 many consumers who had undergone PSA tests faced the stress and uncertainty of re-testing and review.
- 7.43 These failings by Tairawhiti Healthcare Ltd amounted to a breach of Right 4(1) of the Code.

IANZ

- 7.44 Given its limited regulatory role, it is not possible for IANZ assessors to carry out a full audit of every method, instrument, and quality system that should be in place in the time they spend on site. IANZ can sample only a number of facets, and relies to a large extent on laboratory staff to bring potential

problem areas to their attention. As the majority of laboratories are keen to attain high levels of quality performance, they are willing to raise concerns with the assessors, who will often suggest ways of addressing those concerns. Conversely, if a laboratory does not want the assessors to find out about a particular problem, then it may be a matter of chance whether it is detected during the relatively brief visit. Indeed, even if PSA had been listed as a test at the 1998 assessment, the problem may still have been missed as only a sample of all tests can be checked in detail.

- 7.45 IANZ does not have access to enough suitably experienced technologists and pathologists to act as external assessors to perform a full audit of all medical laboratories in New Zealand. It is difficult to find enough volunteers to perform general assessments. The external assessors are not paid for their service, on the understanding that most laboratories will take their turn in providing staff for assessing other laboratories if requested to do so. The cost of assessments is thus minimised, so that all laboratories can afford to undergo this peer review process.

8. RECOMMENDATIONS

Staff resources

- 8.1 There should be sufficient staff numbers within the section not only to handle the daily workload, but also to allow sufficient time to enable staff to undergo continuing practical training sessions, attend regular section meetings, attend user group meetings to discuss quality issues, keep method documentation and quality manuals up to date, and carry out any other activities to assure the quality of the service being provided by the biochemistry section of the laboratory. Quality is not an “add on”, to be attended to when time permits. True quality is integral to a safe and effective service for consumers.
- 8.2 Responsibility for the technical aspects of these tasks should not be delegated to administrative staff.
- 8.3 The minimum staff level should be increased to ensure that there is sufficient expertise available at all times to maintain the new quality systems and standards (which are being put in place by Mr Sharman and Ms Peterson) on a continuing basis.
- 8.4 It is clear that the biochemistry section of the laboratory requires the continuing service of at least one senior technologist with skills and experience similar to the locum, Ms Peterson. The employment of only one such person leaves the laboratory in a potentially fragile position, should that person go on leave, or resign. Ideally, there should be two senior technologists appointed to this section.

Professional development

- 8.5 Technical staff must be given the opportunity to meet with colleagues from other centres and undertake continuing education and practical training on a regular basis. This includes attendance at instrument user group meetings,

regional quality assurance group meetings, and other educational activities relevant to the work carried out in the Gisborne Hospital Laboratory.

- 8.6 In addition, visits by technologists to the Canterbury Health Laboratory, or any other large laboratory, should be arranged. These may be for relatively short periods but should be regular, and should focus on practical training on instrument usage, method techniques, and quality control. This should encourage a low threshold for making personal contact for advice on any new problems that arise in the biochemistry section of the laboratory at Gisborne Hospital in the future, thus reducing professional isolation. There needs to be a defined role for a senior colleague from a larger laboratory to provide professional supervision, and assistance in planning.

Pathologist

- 8.7 A general pathologist with appropriate training in all disciplines of pathology should be appointed to oversee the laboratory. Special arrangements will need to be made to ensure that this pathologist has ample opportunity to meet with colleagues and undertake continuing education and updating to ensure that she or he is not practising in isolation. This is in addition to having an agreed line of communication with peers (possibly Canterbury Health in the first instance, given the valuable links forged already) so that referral of data for a second opinion is not inhibited.
- 8.8 If it is not possible to appoint a suitable pathologist, then the frequency of visits from other pathologists needs to be such that they feel comfortable about taking responsibility for the work being performed at Gisborne Hospital laboratory. Infrequent visits and availability at the end of a telephone is not sufficient to ensure that the quality of the service is maintained at all times.

Quality control

- 8.9 All tests performed must be subject to timely internal quality control and, where an external QC programme is available, external quality assurance programmes regardless of the cost involved in subscribing to that programme. If the cost of the external QC programme is a problem, the test should be undertaken elsewhere.
- 8.10 Regular, formal meetings should take place to review the results of quality control programmes, so that all staff are familiar with the procedures, expected performance, and any problems that have been detected by these programmes. With a small number of staff expected to perform all tests, it is essential that they all understand what the data means, and how they should respond to it, and that they are all aware of any quality control issues.
- 8.11 It is clear that accreditation by IANZ is no guarantee that all is well in the registered laboratory. Even the sanction of de-registration, thrice exercised in the case of the biochemistry section of the laboratory at Gisborne Hospital, did not have the desired effect of improving competency and quality. There would appear to be a strong case for greater funding of accreditation agencies

to allow more in-depth review of laboratory standards, and a closer monitoring of claimed improvements by the provider in the quest for re-registration.

Communication

- 8.12 Communication between all levels of management and technical staff must be improved. This is perhaps the key recommendation to ensure that the biochemistry section of the laboratory provides a reliable service on an ongoing basis. Problems will recur if there is a continuation of the dysfunctional relationship evident in the past.

Reagent / Calibrator / Control Supplies

- 8.13 Reagent suppliers (not just Abbott Industries) should put checking systems in place that ensure that calibrators being sent to a laboratory match the type of reagent kitset normally supplied to that laboratory. Questions should be asked if it is not obvious from the order form why the laboratory is deviating from its normal ordering pattern.
- 8.14 The laboratory also needs to put a checking system in place so that all reagents, calibrators and controls are confirmed and signed off by a senior technologist as being the correct items before they are made available for use in the laboratory.

Response to recommendations

- 8.15 Tairawhiti District Health has accepted all the above recommendations and has either already implemented them or is in the process of doing so. The exception is recommendation 8.13 as Tairawhiti District Health believes it is “an impractical requirement for a reagent supplier and that systems should be in place in laboratories that would make such a procedure unnecessary”.

IANZ

- 8.16 THL viewed IANZ as the “primary watchdog for community safety” through its accreditation and assessment processes. I believe this view would be shared by other public hospitals and by many in the health sector, including government agencies. It has become clear in the course of my investigation that, in light of IANZ’s limited statutory role, this confidence may be misplaced. I recommend that the Minister of Health review the current regulatory framework (including the Testing Laboratory Registration Act 1972) in order to ensure that consumers are adequately protected.

Chapter 6

Patient Care in ICU and Surgery

April _ May 2000

1. INTRODUCTION

1.1 The New Zealand Nurses Organisation's (NZNO) letter of 14 June 2000 (set out in the Appendix) to the Minister of Health raised three areas of concern at Gisborne Hospital. The concerns related to the alleged re-use of syringes, the Hospital's method of dealing with incident reports, and standards of care for ICU and surgical cases in April and May 2000. The circumstances in which NZNO wrote to the Minister are set out in chapter 1.

1.2 Attached to the letter from NZNO was a copy of an anonymous letter written by a senior ICU nurse at Gisborne Hospital. The letter is set out in the Appendix. The letter expressed concerns about "increasingly consistent poor levels of medical, surgical, and management practices and accountability". The writer went on to say:

"My motives are to help improve these services.

I think a documentation audit of the previous 6-8 weeks of our acute services management will raise your concerns.

I'm scared, stressed and can no longer believe these people can lead us to do any better, only worse.

I've discussed this with [a NZNO representative] and she's advised me to let you know too.

Here are some of the recent situations."

The writer then described five patient care situations.

1.3 This chapter examines how the letter came to be sent to NZNO and in due course brought to my attention. The matters raised in the letter, and the method by which they were raised, link to issues dealt with in other chapters of this report, for example, the failure of aspects of quality assurance systems and the effect of restructuring and inadequate consultation and communication on patient care. The specific cases referred to in the anonymous letter are not dealt with in this report. They are being dealt with under the Health and Disability Commissioner's standard investigation process and will be reported on separately. Those investigations will be confidential to the persons involved.

2. HOW AND WHY THE NURSE RAISED CONCERNS WITH NZNO

- 2.1 The Chief Executive stated that she first knew of the specific allegations in the anonymous letter relating to intensive care and surgery from the media. However, it was reported to the investigation team that efforts had been made already by ICU staff to talk through their concerns with the Group Manager (Hospital), the Chief Executive and the Board. ICU staff felt they had no effective internal channel of communication open to them.
- 2.2 The nurse who wrote the letter said it was sent to NZNO because there was nowhere else to go. There was no ICU Charge Nurse, no Director of Nursing, and no Clinical Nurse Leader to turn to.
- 2.3 The letter was written to NZNO “to ask for help because we could not do it ourselves. At the time ... it felt like ICU was in a bog ... Everyone felt tired and not able to give of themselves. The level of practice was not good.”
- 2.4 The Chief Executive noted:
- “I believe it was entirely appropriate for the ICU nurse to look to the NZNO, which purports to be a professional as well as an industrial organisation, to support [the nurse] to come forward ... It is generally with respect to the sensitivities of clinical colleagues, rather than management, that staff experience some difficulty coming forward with quality of patient care concerns.”
- 2.5 NZNO submitted that the writer was not the only nurse in ICU to have concerns. NZNO stated:
- “They told us they feared expressing these views ... they believed the inevitable outcome would be disciplinary action taken against them. Even when assured by the union that there was no possibility of such an outcome, and given support to make their concerns known, they would not come forward. The level of fear operating among nursing staff within THL is high.”
- 2.6 THL said that a meeting to discuss ICU staff concerns was held with ICU staff and the Group Manager (Hospital) on 9 June 2000. “The outcome of the meeting was that the Group Manager (Hospital) was to respond to the issues raised in the meeting. Before he had an opportunity to do so, NZNO wrote to the Minister of Health on 14 June 2000.” THL also noted that the anonymous nurse did not fill out incident reports in relation to the matters in the letter.
- 2.7 According to NZNO, the nurse who wrote the anonymous letter was afraid of how THL would deal with the concerns raised. The letter was headed “To who it may concern” and was signed by the nurse. According to NZNO, the nurse was promised that in return for a signed letter NZNO would guarantee anonymity.
- 2.8 The Chief Executive advised that she did not accept NZNO’s statement that the writer of the anonymous letter was too scared to raise the issues with THL.

She said that at around this time the same nurse was advocating on behalf of two other nurses on an allowances issue and telephoned her at home after hours when dissatisfied with a Group Manager's response.

- 2.9 It was not until the week beginning 21 September 2000 that the investigation team was finally given the name of the writer of the anonymous letter. The efforts of THL to obtain the names of the patients referred to in the letter, so that it could investigate the allegations, and NZNO's refusal to provide this information, are set out in chapter 1.

3. REVIEW OF ICU PATIENTS' FILES

- 3.1 THL advised that in response to the anonymous letter, faced with NZNO's refusal to provide the names of the patients referred to, it commissioned an external review by Dr Jack Havill (Clinical Director, Waikato Hospital Critical Care Unit) and Ms Denise Cranston (Operations Manager, Clinical Services, Waikato Hospital) of the files of ten patients admitted to ICU during April and May 2000 (hereafter referred to as the Havill/Cranston review). THL was certain that most, if not all, of the cases reviewed externally were those cited in the anonymous letter.
- 3.2 The Havill/Cranston review was undertaken under the protection of Part VI of the Medical Practitioners Act 1995 and accordingly is confidential. THL advised that the reviewers concluded that overall the standard of care of the ten patients reviewed was impressive.

4. QUALITY ASSURANCE IN ICU

- 4.1 At the time the letter was written there was no designated ICU nursing leader (the Clinical Nurse Leader position having been disestablished in late 1999), no Director of Nursing, no regular quality assurance activities, a heavy reliance on one overworked clinician, difficulties in recruiting suitably qualified ICU nursing staff, friction involving ICU nurses, and a strong belief amongst ICU nurses that they were unsupported by management.
- 4.2 The writer of the letter advised the investigation team that there were no quality assurance systems in place in ICU. There was no formal opportunity for nurses and the medical team to review and discuss cases, and to take part in ongoing quality assurance activities. Forums such as the Clinical Board or the Quality and Risk Management Committee were felt to be inaccessible. The perception of nurses was that they were not encouraged to participate.
- 4.3 The doctor in charge of ICU, Dr Peter Manson, said that the situation "has created a loss of leadership among nursing staff and a deterioration of standards in ICU – not standards of patient care but standards related to educational activities, attendance at meetings and a willingness to do extra duties".
- 4.4 As noted in chapter 1, there were significant changes to the nursing structure at THL in 1999-2000. These changes manifested in ICU by a reduction in staff numbers and the disestablishment of the Clinical Nurse Leader position. ICU

staff felt that they had not been adequately consulted about the changes and that this was a key factor in the nurse's decision to communicate concerns about patient care through NZNO. Nurses felt a lack of connection with the senior managers of the organisation and felt that they were not being listened to. ICU appears to have operated, and to have been allowed to operate, as an island amid a sea of change.

4.5 THL has recently addressed the nursing leadership issue in ICU by appointing the new Director of Nursing, Carol Ford, as a nurse consultant to ICU as an interim measure pending the successful recruitment of a nurse leader to the area.

4.6 In an external review of Gisborne Hospital's intensive care services commissioned by THL in June 2000, Dr Jack Havill (Clinical Director, Waikato Hospital Critical Care Unit) and Ms Hayley McConnell (Operations Manager, Waikato Hospital Critical Care Unit) noted:

“The ICU/HDU policy and procedure manuals are in dire need of review. The policies appear out of date and overly amended There is clearly an identified lack of quality plans and assurance taking place. This has resulted in the poor maintenance of patient management guidelines, clinical audits, education programmes, inservice training, regular meeting forums, research programmes and other staff QA activities” (hereafter referred to as the Havill/McConnell review).

4.7 Quality Health New Zealand's July 1999 review recommended that:

“7.1 Staff work to current documented policies and procedures that guide the activities of the unit and reflect contemporary professional knowledge and principles of intensive and coronary care.”

4.8 THL advised that in the early part of 2000 staff were released from clinical duties by the Inpatient Co-ordinator, to give them time to attend to updating policies and procedures as part of the action plan following the Quality Health New Zealand Survey of July 1999.

4.9 The Havill/McConnell review of ICU made the following recommendations:

1. appointment of a clinical nurse leader for ICU
2. development of a roster for medical cover of ICU
3. establishment of a system for medical phone support from other ICUs
4. appointment of a Clinical Director for ICU
5. formalisation of medical oversight of ICU by a “big brother unit”
6. review of nurse staffing levels in ICU to cope with peak workloads

7. unification of management with clinical staff to give a clearly stated strategy of support for an on site intensive care unit.

4.10 The new Chief Executive, Mr Jim Green, advised that:

“Following the report of Associate Professor Jack Havill and Hayley McConnell, known as the Gisborne Hospital Quality Review of Ward 7 [ICU] which was received in August 2000, THL began a process of implementing the recommendations of the report. There were seven recommendations and by [mid-February 2001] all of the recommendations had been instituted except the final review of staffing levels, which was commenced in February 2001.

In September 2000 Peter Gow and Mary Gordon carried out a report on the Incident Reporting System at Gisborne Hospital. The final report was received in October 2000 and with the reaffirmation of the role of the Clinical Board it was decided that the Board should review and put in place a programme to implement the recommendations of this report. The Clinical Board completed and approved an action plan by December 2000. The Clinical Board now has a reporting mechanism each month from the plan with specific members responsible for reporting back to the Board on the implementation process.

Coupled with this is the wider Surgical and ICU Quality Improvement Actions Report. While this report contains actions that are the same as the Havill & McConnell report and the Gow & Gordon reports, there are also a series of actions instituted by the organisation. These are part of the ongoing quality improvement programme that has always been in place but which has been boosted over the more recent period as part of re-affirming the organisation’s focus on quality of service provision. TDH is committed to continuing this focus into the future both by the completion of the external review recommendations but also through a robust quality improvement programme centered on patients’ needs.”

4.11 The new Chief Executive provided a table of Quality Improvement Projects in intensive care and surgical services and commented:

“There has been consistent progress to improve the quality of services provided by the Intensive Care Unit and Surgical Services.”

4.12 I have reviewed the table of Quality Improvement Projects and am impressed by the range of activities being undertaken by Tairāwhiti District Health to improve the quality of patient care in ICU and Surgery at Gisborne Hospital.

5. OPINION

5.1 The anonymous letter (described in para 1.2 above) was written by an experienced ICU nurse concerned about patient safety. In a well functioning organisation I would expect a nurse concerned about patient safety to be able to approach his or her immediate leader or someone in a position of responsibility within the organisation, and to have the concerns dealt with in an appropriate manner. I do not expect that management will always agree

- with the concerns of clinical staff. I do expect that all clinical staff who raise serious matters involving patient safety will receive a fair hearing and a timely response.
- 5.2 THL submitted that “a clear message should be sent that the best results could be achieved expeditiously if proper channels are pursued. The effect of the approach taken by NZNO has been a long investigation and the creation of some animosity between employees and Tairāwhiti Healthcare, not the immediate changes to the system they desired.”
- 5.3 All District Health Boards are now required by the Protected Disclosures Act 2000, which came into force on 1 January 2001, to establish and publish to staff effective internal procedures for receiving and dealing with disclosures about serious wrongdoing. The Act establishes appropriate channels through which disclosure about serious wrongdoing must be made.
- 5.4 The purpose of the Protected Disclosures Act 2000 is to “promote the public interest –
- a) by facilitating the disclosure and investigation of matters of serious wrongdoing in or by an organisation; and
 - b) by protecting employees who, in accordance with this Act, make disclosures of information about serious wrongdoing in or by an organisation.”
- 5.5 To gain the protections set out in the Act, an employee is required to disclose information in the manner provided by the internal procedures which all public sector organisations (including public hospitals) are required to establish to receive and deal with information about serious wrongdoing. The focus of the Act is on making disclosure to nominated people in the organisation so that the organisation can investigate the allegations. However, in certain defined circumstances an employee can make disclosure to an appropriate external authority, including the Health and Disability Commissioner.
- 5.6 THL provided a copy of its draft policy on disclosure of serious wrongdoing developed in accordance with the requirements of the Protected Disclosures Act 2000 and advised that it is due to be finalised shortly.
- 5.7 The Protected Disclosures Act should provide reassurance to employees that they will be protected and receive a fair hearing and timely response if they make disclosures of information about serious wrongdoing in or by their organisation, provided they follow the correct procedures.

- 5.8 I have been provided with information indicating that Tairāwhiti District Health has commenced a number of positive initiatives to address the concerns identified by the anonymous nurse, and the issues identified in the external reviews it has commissioned.
- 5.9 Implementation of these initiatives, and Tairāwhiti District Health's positive response to the recommendations made in this report, reassure me that the public can have confidence in the standard of patient care in ICU and Surgery at Gisborne Hospital.

RECOMMENDATIONS

Quality Assurance Systems at Gisborne Hospital

1. The effectiveness of the Tairāwhiti District Health quality system should be evaluated and changes made immediately to ensure a systematic approach to quality improvement that ensures all services and staff have responsibility for, and are involved in, quality activities.
2. In consultation with staff the definition of quality to be used should be reviewed.
3. A robust quality planning process with involvement of staff should be established and implemented.
4. A range of quality activities that reflect the needs of internal and external customers should be undertaken.
5. Information on quality activities should be presented in a way that demonstrates the range and effectiveness of these activities.
6. Ongoing monitoring of performance against procedures, policies, protocols and standards should be undertaken.
7. Clinical case reviews by specific professional groups and multidisciplinary teams should occur.
8. Credentialling for medical staff should be established.
9. Individual quality activities should be reviewed and improvement demonstrated.
10. Tairāwhiti District Health should develop an orientation programme suitable for newcomers to the area and to New Zealand. This should include an introduction to the Code of Health and Disability Services Consumers' Rights.
11. New recruits should be supervised through their first weeks so that they have the opportunity to clarify issues and learn how to handle matters at Gisborne Hospital.
12. The quality programme should be evaluated on an annual basis.
13. Data collection, analysis and reporting processes should be reviewed ensuring staff receive feedback eg on patient satisfaction.
14. Quality assurance activities undertaken under the Medical Practitioners Quality Assurance Activity: Tairāwhiti Notice 1998 should be reviewed to ensure that the statutory purpose of encouraging "effective quality assurance activities in relation to health services provided by medical practitioners" and "improving the practices" of medical practitioners (Medical Practitioners Act 1995, sections 66(1), 67) is fulfilled.

15. The Quality Co-ordinator and clinical staff should be involved in the evaluation of the effectiveness of the recently established Quality Facilitator and Quality Administrator positions.
16. Management and staff should identify key performance indicators for the organisation and individual services (clinical and non-clinical) and establish acceptable/non acceptable levels against which performance is measured.

Incident reporting and complaints procedure

1. A cross-functional team (with clear terms of reference) should be established to evaluate and further develop the current incident reporting system, with a particular emphasis on developing a framework that guides: what to report; which incidents will be reviewed; and by whom.
2. The purpose of the Incident and Complaint Management Policy should be extended to include a statement that reflects the value of complaints/incidents as learning opportunities for the organisation and as a component of continuous improvement.
3. An internal investigation of a complaint or review of a reported incident should lead to internal disciplinary processes or mandatory training only where there is evidence of repeated poor performance that breaches professional standards of conduct or constitutes a major departure from the standard of care and skill reasonably to be expected in the circumstances.
4. Definitions of reportable incidents should be reviewed and consideration given to clearly differentiating “incidents”, “near misses” and “adverse events”.
5. The layout and content of the incident report form should be reviewed and consideration given to further information that it may be valuable to capture, such as the location where the incident occurred, the outcome, contributing factors, and whether the incident was preventable.
6. Numbers should be printed on the incident forms to enable tracking, and hard copies should be kept in the reporting department.
7. Consideration should be given to categorising incidents (eg clinical/non-clinical; major/minor; actual/potential) to enable investigation, reporting, quality improvement and monitoring to be effectively targeted.
8. The text of the Incident and Complaint Management Policy should be reviewed and requirements relating to incidents and complaints should be more clearly differentiated from each other.
9. A standardised approach to incident investigation should be adopted across Tairāwhiti District Health to enhance consistency of investigations, reduce staff anxiety and provide the basis for educating staff who have this responsibility.

10. Consideration should be given to confidential (but not anonymous) reporting of “adverse events” or “near misses” until the culture of fear changes.
11. Feedback should be sought and utilised from users of the system. Staff satisfaction with the incident reporting system should be formally monitored at designated timeframes.
12. A system-centred approach should be initiated, rather than a person-centred/blaming approach.
13. Support people should be welcome at incident review discussions.
14. The education of staff on the incident reporting system (at orientation and thereafter on a regular basis) should be reviewed so that staff are clear about the philosophy behind incident reporting.
15. All staff groups should receive sufficient education to gain a clear understanding of the incident reporting system and their responsibilities within it.
16. A standardised education programme for all staff groups should be implemented as an urgent priority at Tairāwhiti District Health.
17. The process for incident review should be clearly defined.
18. Staff delegated incident review responsibility should receive appropriate education for the role.
19. Monitoring should be introduced with a focus on ensuring that serious failures are not recurring.
20. All evaluation methods listed in the Incident and Complaint Management Policy should be implemented: ie, monthly reports to the Quality and Risk Management Committee and Core Quality Group, and quarterly reports to the Audit Committee.
21. “Near misses” should be reported and analysed to identify common factors and causes.
22. Accountabilities for monitoring incident trends should be clarified and clear processes established to ensure accountability. (The Quality and Risk Management Committee is currently responsible for the regular monitoring and improvement of the incident reporting system. The Committee’s responsibility for monitoring the outcomes from the system is less clear.)
23. The Clinical Board should establish a timetable (eg, three monthly) for analysing reported incidents across Tairāwhiti District Health with a view to discerning trends.
24. The Clinical Board should be given responsibility for monitoring the implementation of action plans designed to address organisational trends identified in clinical incidents.

25. Each area should receive regular (eg, monthly) reports on incidents occurring in their area (including trends); such reports should be discussed at a staff meeting and action plans implemented as appropriate.
26. Clinical leaders/line managers should monitor repeated incidents involving the same individual.
27. A clear statement should be made to staff at all levels describing types of incident that require immediate notification to the line manager.
28. The recommendations in the Medical Practitioners Quality Assurance Activity: Tairawhiti Notice 1998 related to incidents should be implemented consistently.
29. The findings of the Health Funding Authority audit (31 August 1999) should be reviewed to identify any outstanding areas still to be addressed.
30. Complaints offer a provider organisation the opportunity to understand the needs of the consumer and in so doing to enhance the level of service, trust and connection between the organisation and its community. This is especially true for public hospitals. Wherever possible, complaints should be resolved face-to-face, and followed up by letter.
31. The complaints system at Tairawhiti District Health will be enhanced by an effective and fully operational database.
32. There is a need to link complaints data to risk management processes and educational processes at Tairawhiti District Health.
33. If Group Managers and service managers are to be responsible for managing the complaints in their areas, there is also a need to train them in conflict resolution and the management of complaints.
34. As an alternative to recommendation 33, the Quality Co-ordinator, as the person at Tairawhiti District Health with overall responsibility for managing complaints, needs to be adequately resourced.

PSA Testing Procedures

1. There should be sufficient staff numbers within the section not only to handle the daily workload, but also to allow sufficient time to enable staff to undergo continuing practical training sessions, attend regular section meetings, attend user group meetings to discuss quality issues, keep method documentation and quality manuals up to date, and carry out any other activities to assure the quality of the service being provided by the biochemistry section of the laboratory. Quality is not an “add on”, to be attended to when time permits. True quality is integral to a safe and effective service for consumers.
2. Responsibility for the technical aspects of these tasks should not be delegated to administrative staff.

3. The minimum staff level should be increased to ensure that there is sufficient expertise available at all times to maintain the new quality systems and standards (which are being put in place by Mr Sharman and Ms Peterson) on a continuing basis.
4. It is clear that the biochemistry section of the laboratory requires the continuing service of at least one senior technologist with skills and experience similar to the locum, Ms Peterson. The employment of only one such person leaves the laboratory in a potentially fragile position, should that person go on leave, or resign. Ideally, there should be two senior technologists appointed to this section.
5. Technical staff must be given the opportunity to meet with colleagues from other centres and undertake continuing education and practical training on a regular basis. This includes attendance at instrument user group meetings, regional quality assurance group meetings, and other educational activities relevant to the work carried out in the Gisborne Hospital Laboratory.
6. In addition, visits by technologists to Canterbury Health Laboratory, or any other large laboratory, should be arranged. These may be for relatively short periods but should be regular, and should focus on practical training on instrument usage, method techniques, and quality control. This should encourage a low threshold for making personal contact for advice on any new problems that arise in the biochemistry section of the laboratory at Gisborne Hospital in the future, thus reducing professional isolation. There needs to be a defined role for a senior colleague from a larger laboratory to provide professional supervision, and assistance in planning.
7. A general pathologist with appropriate training in all disciplines of pathology should be appointed to oversee the laboratory. Special arrangements will need to be made to ensure that this pathologist has ample opportunity to meet with colleagues and undertake continuing education and updating to ensure that she or he is not practising in isolation. This is in addition to having an agreed line of communication with peers (possibly Canterbury Health in the first instance, given the valuable links forged already) so that referral of data for a second opinion is not inhibited.
8. If it is not possible to appoint a suitable pathologist, then the frequency of visits from other pathologists needs to be such that they feel comfortable about taking responsibility for the work being performed at Gisborne Hospital laboratory. Infrequent visits and availability at the end of a telephone is not sufficient to ensure that the quality of the service is maintained at all times.
9. All tests performed must be subject to timely internal quality control and, where an external QC programme is available, external quality assurance programmes regardless of the cost involved in subscribing to that programme. If the cost of the external QC programme is a problem, the test should be undertaken elsewhere.
10. Regular, formal meetings should take place to review the results of quality control programmes, so that all staff are familiar with the procedures, expected

performance, and any problems that have been detected by these programmes. With a small number of staff expected to perform all tests, it is essential that they all understand what the data means, and how they should respond to it, and that they are all aware of any quality control issues.

11. It is clear that accreditation by IANZ is no guarantee that all is well in the registered laboratory. Even the sanction of de-registration, thrice exercised in the case of the biochemistry section of the laboratory at Gisborne Hospital, did not have the desired effect of improving competency and quality. There would appear to be a strong case for greater funding of accreditation agencies to allow more in-depth review of laboratory standards, and a closer monitoring of claimed improvements by the provider in the quest for re-registration.
12. Communication between all levels of management and technical staff must be improved. This is perhaps the key recommendation to ensure that the biochemistry section of the laboratory provides a reliable service on an ongoing basis. Problems will recur if there is a continuation of the dysfunctional relationship evident in the past.
13. Reagent suppliers (not just Abbott Industries) should put checking systems in place that ensure that calibrators being sent to a laboratory match the type of reagent kitset normally supplied to that laboratory. Questions should be asked if it is not obvious from the order form why the laboratory is deviating from its normal ordering pattern.
14. The laboratory also needs to put a checking system in place so that all reagents, calibrators and controls are confirmed and signed off by a senior technologist as being the correct items before they are made available for use in the laboratory.

APPENDIX

NZNO LETTER TO MINISTER OF HEALTH 14 JUNE 2000

In a letter dated 14 June 2000 to the Minister of Health, the Chief Executive Officer of the New Zealand Nurses Organisation (NZNO), Ms Brenda Wilson, stated:

“Yesterday I visited Gisborne Hospital along with NZNO Nurse Advisor, Margaret Cain. We spent the day talking with members and also met with the CEO, Sheryl Smail.

Our Organisation is under considerable pressure from its members to publicly speak out on several issues concerning the standard of services provided at Gisborne.

There are three things that have to happen urgently -

1. An independent retrospective chart audit of ICU and surgical cases for the past three months.
2. NZNO seeks a full copy of the hospital report on the recent re-use of syringes. We need to clarify that syringes were re-used other than for adding medication to I.V. lines they were also used to add medication to leurs. There is a concern from members that this issue has been played down.
3. The hospital management needs to provide documentation on how it will deal with incident reports to ensure that –
 - (a) There is feedback to all involved
 - (b) That there is documentation of actions taken, follow up, etc.

NZNO will have staff in Gisborne next week – we are mindful of the further loss of confidence in our public health system if the issues raised by staff become public in an unmanaged way.

You will appreciate Minister that our Organisation would in no way support a cover up – but we believe a full independent review as requested would alleviate concerns.

I recall over our concerns relating to Christchurch Hospital that twice Ministry of Health medical and nursing advisors visited that establishment and said our issues were unfounded – it was not until the very public and lengthy review by the Health and Disability Commissioner that we were vindicated. We would not have confidence in a review undertaken by the Ministry.

I enclose, in confidence, a report taken from members. These members are too frightened to speak out – we have not come far since the Cartwright enquiry!!”

The letter was signed by Ms Brenda Wilson.

NZNO INTERNAL MEMORANDUM
1 JUNE 2000

In an internal NZNO memorandum dated 1 June 2000 to Ms Brenda Wilson, Chief Executive Officer, and Mr James Ritchie, NZNO Area Manager (Northern), Ms Gwenda Brodie, NZNO regional representative, stated:

“Further to our telephone discussions today and previously.

Facts that have emerged in respect of this matter are as follows:

1. The anaesthetist in question (Dr Brian Lucas of Canada) has admitted re-using syringes.
2. Two staff at least witnessed directly the practice on separate occasions. Both staff (1 anaesthetic tech, 1 Staff Nurse – NZNO delegate Jo Garrett) completed incident forms and drew the matter to the attention of the anaesthetist, the head anaesthetic technician and the Theatre Manager.
3. The Theatre Manager (NZNO member Helen Stephenson) completed incident forms also and reported the matter immediately to the General Manager Hospital Group (Dan Madden). She also spoke to the anaesthetist and used a packaged syringe to draw his attention to the words ‘for single use only’ on the packaging. The HAT [Head Anaesthetic Technician] reported the matter to the Head of Anaesthetics (Dr James Carstens).
4. The first incident report was forwarded in October 1999. It seems this incident form has been lost.
5. The Theatre Manager completed a second incident form early in November 1999 referring to the first form and noting no action had yet been taken.
6. The Theatre Manager was told by various unspecified medical staff to stop filling out incident forms and put up with the anaesthetist because ‘we need him’. One person giving this advice was the Medical Director of the Surgical Service at the time, Dr Ian Burton.
7. Dr Burton also instructed the Theatre Manager to apologise to the anaesthetist, apparently for criticising his practice. (The Theatre Manager did not apologise.)
8. The re-use practice apparently stopped for a short time but recommenced. Nurses who gave evidence today said they had noted that if any of them challenged him/disagreed with his practices/advocated for patients the anaesthetist reacted by aggressively responding and on more than one occasion waking women patients early – while they were still being sewn up and still in lithotomy.
9. Incident forms were completed on every occasion these things happened and actioned promptly by the Theatre Manager.
10. Nurses from other areas (notably ICU) report to me that the anaesthetist was in the habit of throwing sharps – ie syringes and bloody needles – at random when events did not go smoothly. I have not yet ascertained whether he aimed at people or just tossed at random. This behaviour was also reported by anaesthetic techs in theatre and confirmed in conversation today by nursing staff.

11. The anaesthetist had a practice of ripping or cutting gowns off patients, invariably women. He also used a technique to ascertain the level of block established. This method consisted of rubbing ice cubes all over women's breasts for a considerable period of time. Nursing staff and anaesthetic techs found this practice excessive and offensive. They were told it was accepted practice.
12. The anaesthetist claimed thick leather straps were essential to secure patients to the operating table. The Theatre Manager refused to order these items and the anaesthetist responded by tipping the table so women, especially Caesarean section women having epidurals, had to cling tightly to the table to stop sliding off. All the surgeons approached the Theatre Manager individually to urge the purchase of the straps until the anaesthetist departed. Since then there have been no requests for straps.
13. Recovery nurses gave evidence that the anaesthetist would come to recovery with unlabelled, filled syringes in his pocket and instruct them to administer the medication. (They refused.)
14. One nurse described an incident where a patient was haemorrhaging post partum in recovery. The anaesthetist refused to come and see the patient or to give written orders for medication. The nurse refused to administer meds and called a surgeon from a ward. When the surgeon arrived the anaesthetist accused the nurse of not giving the necessary meds. (Incident form completed and actioned promptly.)
15. The same nurse described the anaesthetist's consistent refusal to document and chart medication. His practice was to write medication instructions on the anaesthetic sheet and presume this would be actioned in the ward (didn't happen). She testified that he became aggressive and threatening when challenged.
16. A nurse also described the anaesthetist's common practice of telling patients he would prove they were not allergic to meds they had reported reacting to. At least once a nurse who was being anaesthetised was put under crying in fear because he allowed her to believe he had given her the drug she was allergic to. Only after she was asleep did he tell theatre staff he had not given the drug.

Intentions stated today during and after the interviews with the nurses included an external review of the anaesthetic dept and possibly theatre 'down the track, medium-term'.

When pressed hard by myself and the PSA organiser, Dan Madden agreed to meet staff to discuss other issues not specifically to do with the re-use of syringes. In conversation with me between interviews he referred to this as 'closure' and I have the strong impression there is no intent to properly investigate or engender outcomes from the other matters. I have pinned him to 20 June 00 as I will be in Gisborne on leave then and can support members. (It occurs to me it would be useful if Margaret Cain could also be present if she is available.)

Both Dan Madden and Dr Bruce Duncan (Director Public Health Unit, these two did the interviews) informed me there was only the tiniest risk to patients because of the process used to administer anaesthesia. They appeared reluctant to notify patients but eventually admitted there was an intent to do so.

The process for identifying patients is still not clear and a teleconference with the HFA and the Ministry was to be held today (1 June 00) in respect to the identification

methods proposed by THL. Dan stated the anaesthetist came into contact with 800 patients during his 6 months at THL.

When pressed very hard by both union officials, they said it was intended to notify patients by couriered letter (? – to a majority Maori population) on Tuesday 6 June and alert GPs to the need to provide counselling. THL would cover this cost and the cost of any patient who decided they wanted a blood screen. Patients are to be advised to contact their GPs.

Staff will be shown the report sent to the Board as a result of this investigation. Dan Madden stated he was not willing to share the report with the unions but that he would allow us to vet areas of the report where information taken from our members appeared. The report goes to the board next week (? On Tuesday) and will be marked 'draft'.

There is no doubt they sound very plausible and knowledgeable about the issue of risk and I imagine the board and the lay people (Janet Mackey) they propose to brief will accept their verdict of minimal, tiny risk without hesitation.

Given the trauma already suffered by the community in respect to the cervical smear enquiry it would not be helpful for NZNO to publicise this situation at present. It is, however, crucial that we present a firm, confident face to the media in respect of our members and the public when the media do strike.

Nurses have greeted with delight and relief the news that Brenda is to visit on 13 June. Their preference is to speak to her in small groups and Jacqui Greening (Convenor) is organising areas, as I will be on leave. Theatre, ICU, Surgical nurses in particular have a raft of issues additional to the above to brief her about. They will welcome national information and feedback that we have direct access to the Ministry and the Minister.

I have worked very closely with the PSA organiser (Margaret Takoko) since we found out about this debacle. We have a good, productive relationship and she has provided excellent interim support for our members in my absence. I believe our combined presence has startled and unnerved management and they are definitely defensive when we have interaction. They are also unwilling to share any information with us.

I have generated a list of members in Theatre potentially needing indemnity cover and this will be completed with current addresses tomorrow. (There are 10 definite members and one needing m'ship status clarification.) There may well be more of our members – as other issues emerge – who require protection but at this point it is impossible to gauge numbers and the level of involvement."

An unsigned copy of the memorandum was attached to the NZNO letter to the Minister of Health.

THE ANONYMOUS LETTER

The anonymous letter stated:

“TO WHO IT MAY CONCERN

My concerns are based on 20 years nursing within Gisborne Hospital
.....
(area deleted to protect identity).

My concerns are what I know are increasingly consistent poor levels of medical, surgical and management practices and accountability.

My motives are to help improve these services.

I think a documentation audit of the previous 6-8 weeks of our acute services management will raise your concerns.

I'm scared, stressed and can no longer believe these people can lead us to do any better, only worse.

I've discussed this with Gwenda Brodie [NZNO regional representative] and she's advised me to let you know too.

Here's some of the recent situations.

[Five patient care situations are described.]

A couple of weeks ago, the senior doctors of the hospital met to call for a 'no confidence vote' in recent management decisions. The vote fails by two, the two being the doctors involved in the above situations.

I hope you'll help us to remake a hospital where our community can rely on good, safe and caring practice.

(Name supplied, but writer requested anonymity)”

The anonymous letter was attached to the NZNO letter to the Minister of Health.

GLOSSARY

POSITIONS, NAMES AND TENURE

Position	Appointed	Resigned	Title	First Name	Last Name
Acting Medical Director	May 1998		Dr	Bruce	Duncan
Anaesthetic Assistant	July 1992		Ms	Tracey	Alley
Anaesthetic Technician	Nov 1998		Ms	Wendy	Dewston
Anaesthetic Technician	May 1998	Oct 2000	Ms	Eileen	Pond
Anaesthetic Technician	March 1983		Ms	Jean	Scott
Anaesthetic Technician	April 1999	Oct 2000	Mr	Phil	Tuffin
Board Chairperson	July 2000		Mr	Wayne	Brown
Charge Anaesthetic Technician	Dec 1996		Ms	Christina	Robinson
Chief Executive	Jan 1995	Oct 2000	Ms	Sheryl	Smail
Clinical Director (Public Health)	Dec 2000		Dr	Bruce	Duncan
Clinical Director (Surgery)	March 2000	June 2000	Dr	Ian	Burton
Clinical Director (Surgery)	June 2000		Dr	John	Kyngdon
Consultant Biochemist	July 2000		Mr	John	Sharman
Director of Nursing	July 2000		Ms	Carol	Ford
Director of Nursing Practice	Nov 1995	Aug 1999	Mr	Dan	Madden
Former Board Chairperson	May 1983	July 2000	Mrs	Pat	Seymour
Former Group Manager (Hospital)	Sept 1998	Aug 1999	Ms	Rachel	Haggerty
Former ICU Clinical Nurse Leader	Aug 1987	Oct 1999	Ms	Patsy	Butler
Group Manager (Community & Support)	July 1999		Mr	Mike	Grant
Group Manager (Hospital)	Aug 1999		Mr	Dan	Madden
Head of Biochemistry Section, Laboratory	June 1998	Mar 2000	Mr	John	Rutledge
Head of Department (Anaesthesia)	June 1977		Dr	James	Carstens
Human Resources Manager	June 1999		Mr	Laurie	Biesiek
Inpatient Co-ordinator	Feb 1999		Ms	Carol	Shellard
Laboratory Manager	June 1998	Oct 2000	Mr	Brian	Morris
Laboratory Project Manager	April 2000		Mr	Brian	Cowper
Locum Anaesthetist	Sep 1999	Mar 2000	Dr	Brian	Lucas
Locum Laboratory Technologist	June 2000		Ms	Beverley	Peterson
Maori Health Manager	Dec 1995		Mr	Owen	Lloyd
Medical Director	April 1997	April 1999	Dr	Danny	Stewart
New Chief Executive	Dec 2000		Mr	Jim	Green
Theatre Manager	March 1998		Ms	Helen	Stephenson

GLOSSARY

ABBREVIATIONS

A&E	Accident and Emergency
A,T&R	Assessment, Treatment and Rehabilitation
AQAP	Australasian Quality Assurance Programme
BPH	Benign Prostatic Hypertrophy
CAR	Corrective Action Request
CCP	Clinical Career Pathway
CEO	Chief Executive Officer
CHE	Crown Health Enterprise
CHL	Canterbury Health Ltd
CNL	Clinical Nurse Leader
CNS	Clinical Nurse Specialist
CQG	Core Quality Group
CV%	Control Value Percentage
DRE	Digital Rectal Examination
FTE	Full Time Equivalent
GP	General Practitioner
HCG	Human Chorionic Gonadotropin
HDU	High Dependency Unit
HFA	Health Funding Authority
HHS	Hospital and Health Service
IANZ	International Accreditation New Zealand
ICU	Intensive Care Unit
IV	Intravenous
MOH	Ministry of Health
NPH	Ngati Porou Hauora
NZNO	New Zealand Nurses Organisation
OSH	Occupational Safety & Health
PSA	Prostate Specific Antigen
Q&RMC	Quality and Risk Management Committee
QA	Quality Assurance
QC	Quality Control
SFIU	Single Floor Inpatient Unit
SMG	Senior Management Group
TDH	Tairāwhiti District Health
THL	Tairāwhiti Healthcare Ltd
TRUS	Trans Rectal Ultra Sound