Canterbury Health Ltd

Opinion – Case 99HDC07727/AM

Commissioner's Investigation

Matters Investigated

In July 1999 Canterbury Health advised the Commissioner that due to equipment failure there was a potential transmission of infection for 1331 consumers who had endoscopies during the period 29 January to 27 April 1999.

The Commissioner initiated an investigation into the events that occurred from January 1999 to July 1999 within the Gastroenterology Department at Canterbury Health Limited. In a letter dated 13 July 1999 to the Chairman of the Canterbury Health Limited Board of Directors, the Commissioner advised:

This investigation will review quality control processes within the department. It will include an inquiry into whether standards exist and are documented, whether standards have been met for machinery and personnel, whether routine infection control processes occurred, what other quality processes are in place to reduce risk and the time frames for release of information to the public following discovery of the fault. In other words, I will overview all matters of consumer rights under the Code of Rights including overall patient safety, documentation of procedures, compliance with relevant regulations and standards, communication issues and quality matters.

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Commissioner's Investigation *continued*

Information Sources

Information was obtained from:

Mr Richard Webb	Chief Executive, Canterbury Health Limited
Mr Michael Hundleby	Company Solicitor
Mr Syd Bradley	Chair, Canterbury Health Limited Board
Dr Bramwell Cook	Clinical Director, Gastroenterology Dept
Dr Bruce Chapman	Gastroenterologist
Dr Michael Burt	Gastroenterologist
Dr Murray Barclay	Gastroenterologist
Ms Jan Nicholson	Corporate Quality and Risk Manager
Ms Shona MacMillan	Quality Manager, Christchurch Hospital
Dr Mona Schousboe	Clinical Director of Infection Control
Mr Tony Kampkes	Infection Control Nurse Practitioner
Ms Jo Lester	Charge Nurse, Gastroenterology Dept
Mr Andrew Dickerson	Service Manager, Gastroenterology Dept
Ms Liz Thompson	Former Charge Nurse, Gastroenterology Dept
Ms Lynley Robertson	Policy and Procedures Co-ordinator
Ms Yvonne Williams	Quality Assurance Nurse
Ms Jan Merry-Martin	Clerical Supervisor, Gastroenterology Dept
Mr John Sharman	Business Manager, Core Laboratory & Haematology Services
Ms Lisa Brennan	Business Manager, Microbiology, Specialist Chemistry and Anatomical Pathology
Mr John Luhrs	Acting General Manager for Diagnostics and Support
Prof Philip Bagshaw	Associate Professor, Surgeon
Mr Malcolm Ward	Surgeon representative, Infection Control Team
Dr Michael Beard	Consultant and General Practitioner
Dr Steve Chambers	Infectious Diseases Physician
Mr Rob Robertson	Clinical Director, Dept of General and Vascular Surgery
Dr Jeremy Foate	Chair, Christchurch Hospitals Medical Staff Association (CHMSA), Anaesthetist
Dr Evan Begg	Deputy Chairman, CHMSA, Clinical Pharmacologist
Mr Gary Nicolls	Professor of Medicine
Dr Steve Gibbons	Transfusion Medicine Specialist, NZ Blood Service, Southern Region

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Commissioner's Investigation ***continued***

Mr John Wallis	General Manager, NZ Blood Service, Southern Region
Mr Grant Cameron	Solicitor
Dr Alistair Cowen	Australian Gastroenterologist, International expert on infection control and standards
Mr Bob Boyd	Chief Advisor, Safety and Regulation, Ministry of Health
Dr Trevor Nisbet	MedSafe, Wellington
Mr Denholm Patterson	Managing Director, Science & Technology (NZ) Limited (SciTech)
Mr David Marston	Technical Services Manager, SciTech
Ms Sally Wilkinson	Interim Chief Executive, Health Funding Authority

Infection Control Investigation Team: This team was led by Dr Mona Schousboe and assisted by Ms Jan Nicholson, who together produced the Report, *Gastroenterology Incident: Microbiology/Virology Investigations.*

Special Project Team: Ms Brennan, Dr Chapman, Dr Cook Mr Dickerson, Ms Forbes, Mr Hundleby, Ms James, Dr Jennings, Ms Lester, Mr Luhrs, Ms Nicholson, Dr Schousboe, Mr Sharman, Mr Garry Smith, Mr Webb and Mr Young.

The Commissioner viewed the Gastroenterology Department at Christchurch Hospital, the plans for the proposed department and the video about the incident.

Canterbury Health submitted approximately 200 documents for the investigation including minutes of operational and Board Meetings. The New Zealand Nurses Organisation sent signed statements from gastroenterology nurses. Twenty consumers were interviewed randomly by telephone and a further three were contacted via their solicitor. One consumer submitted a letter to the Commissioner.

The Commissioner received advice from an Ethicist. The Ministry of Health's report, *"Results of an Inquiry into Possible Contravention of Regulation 19(b) of the Hospitals Regulations 1993"* was also considered as part of the investigation.

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Outcome of Investigation

Events up to Identification of Pump Failure

The Department

The Gastroenterology Department (the Department) located within Christchurch Hospital currently performs approximately 5000 endoscopies a year. An estimated 35% of the total number of endoscopies performed each year are acute (urgent/unplanned). The remainder are elective, which means they are booked in ahead of time. There are five gastroenterologists, two gastroenterology registrars, and eight surgeons who use the facilities. Twelve nurses work in the Department with hours ranging from one to five days a week.

During the investigation some of the Department's staff commented on issues which they consider have led to less than optimal functioning of the Department. Concerns raised include the following:

- ***Physical layout and location.*** The Department is located away from the main surgical area, there is a hospital thoroughfare connecting with wards that runs through the middle of the Department and staff considered there to be insufficient space (two rooms) resulting in cramped conditions and unsuitable administrative areas.

- ***Resources.*** The Department is also cited as having an unacceptably long waiting list for endoscopies, low payments for each procedure compared to some other Hospital and Health Services and no automatic capital replacement programme for worn-out endoscopes. An increasing volume of acute endoscopies means that volumes for elective cases are not always achievable given current resourcing levels. In order to try to reduce the elective waiting list, staff have worked long hours, despite low staffing levels, resulting in high staff turnover and reduced time spent on administrative matters such as quality assurance, training and planning etc.

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Outcome of Investigation *continued*

- ***Communication.*** There is a degree of conflict between specialist gastroenterologists and the surgeons who use the facilities. Surgeons consider they do not have an adequate say in running the Department despite doing a significant amount of work there. While an Endoscopy Users Group was set up to overcome these problems, this group does not meet on a regular basis.

Endoscopies

An endoscope is an instrument used to view the interior of the body. It consists of a tube with a light and an optical system or a miniature video camera which transmits an image to the examiner's eye. The endoscopic procedures performed at the Department include gastroscopy, colonoscopy and endoscopic retrograde cholangiopancreatography (ERCP).

- A **gastroscopy** is a procedure where an illuminated optical instrument is used to inspect the interior of the stomach.

- A **colonoscopy** is a procedure for examining the interior of the entire colon and rectum.

- An **ERCP** is where a catheter (a flexible tube) is passed through an endoscope into the bile duct and injected with radio-opaque medium to outline the pancreatic duct and bile ducts radiologically. This is the most complex and difficult of the three processes.

At Canterbury Health during the 98/99 financial year there were 2886 gastroscopies, 1487 colonoscopies and 253 ERCP procedures performed, giving a total of 4626 procedures.

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Outcome of Investigation *continued*

Cleaning Process

After each procedure the endoscope is cleaned and chemically disinfected. This includes two principal stages:

- The first is a manual cleaning process where the endoscopes are wiped externally, and cleaned internally with long brushes, over a period of five to seven minutes in a sink of enzyme detergent solution. This enzyme detergent solution will disrupt and kill viruses especially HIV and Hepatitis C virus.

- The second step involves the transfer of the endoscopes to an adjacent room where they are placed in the Labcaire Autoscope machine. The endoscope is connected to one of four spigots via a connecting device with a luer fitting at one end and specific fittings at the other end for each of the channels of the endoscope. The endoscope then undergoes an automatic washing/disinfecting cycle inside the machine using fresh filtered water and detergent, fresh filtered water, glutaraldehyde, a chemical disinfectant, and finally two washes with fresh water again, with air-drying of the channels between each step of the cycle. Total time in the machine is dependent upon the length of time selected for the glutaraldahyde step, but is never less than 18 minutes. The endoscopes are fully immersed in the cleaning or disinfecting solution for most of this time.

Other cleaning steps which occur include:

- At the end of the day, the endoscopes are flushed through with alcohol and hung up to dry. The alcohol dries the tubes ensuring an unsuitable environment for bacterial growth.

- At the beginning of the day endoscopes are flushed through a full cycle, with a shortened (five minutes) glutaraldehyde irrigation and immersion step.

- Any endoscopes on loan to the clinic go through a full cycle before being used.

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Outcome of Investigation *continued*

As an additional quality assurance check, routine bacteriological tests are performed on the endoscopes on a weekly basis. This procedure, called washings, consists of pouring distilled water down the endoscope tube, collecting it in another container and sending it to Microbiology to test for bacterial growth. All results are forwarded to the Department for their information and positive results are reviewed by the Infection Control Team.

Cleaning Machines and Servicing

In 1996 the Gastroenterology Department installed two new machines to assist in the cleaning of the endoscopes. These machines provided a means of automatically pumping glutaralderhyde through four endoscopes at a time. Known as Labcaire Autoscope Endoscope washers, these machines were installed by the local agents, Scientific and Technical (NZ) Limited, (SciTech). Until 1999 Christchurch Hospital's Technical Service Department undertook servicing for these machines and would usually call SciTech for anything other than simple problems. On 29 January 1999 SciTech was called in for a repair. Its report of the job states:

Self disinfectant not transferring – strip down water trolley. Remove valve and [overhaul]. *Clean tank and assemble – test – OK.*

NB Water tank should be overhauled to remove remaining crystals caused by using non approved disinfectant. (Sodium hypochlorite solution should be used – ideally in liquid form.)

On 8 March 1999 SciTech once more provided service with its report stating:

Some functions on [right-hand side] *not working. Check system – keypad suspect. Fitted temporary keypad – functional. Supplied and fitted new keypad. Tested OK.*

On 22 April 1999 a Preventative Maintenance Contract was signed with SciTech which includes a minimum of two preventative visits per year. Accordingly a SciTech technician performed a routine maintenance check on the two machines and discovered on the evening of 26 April 1999 that one of the four pumps on the machines had failed.

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Outcome of Investigation ***continued***

Events from Date of Failure until Public Notification

The Incident Report

The Department's Charge Nurse, Ms Jo Lester, was informed by the SciTech technician immediately of the pump failure and filled out an incident form on 27 April 1999 which stated:

The Lab-Caire machine that we use for cleaning of our endoscopes was undergoing a routine service under a new service Agreement with Technicians from Sci-Tech Ltd. They informed me that one of the pumps that pumps Glut and water through the scopes channels was not operating ? they do not know for how long.

Action – *have taken scope washings of all scopes and sent to micro*
– *informed Dr Cook, Clinical Director, and ICN* [Infection Control Nurse].

Ms Lester stated her first action was to undertake bacteriological testing on the endoscopes. The results of these initial washings were all negative.

The technician advised Ms Lester that nursing staff should always check the endoscope tips for water flow during the initial wash cycle to indicate the pump is working. This procedure involves interrupting the first cycle of the wash by opening the Perspex lid of the machine, which sets of an alarm to indicate the lid is open. The nurse then lifts the tip of the endoscope to check if water is flowing through the tubing. Ms Lester stated that neither she nor any of the other nurses in the Department were aware of this requirement. As a result of the technician's advice, Ms Lester promptly advised other nursing staff they must now carry out this procedure and, in addition, signs were placed by the machine to remind staff.

The Department's staff advised the Commissioner that routine bacteriological checks on the endoscopes had not been undertaken on a regular weekly basis for some months. A nurse aide who had the responsibility for this task until December 1998 ceased fulfilling this function when she went on leave.

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Outcome of Investigation *continued*

No individual was assigned to fulfil the function of taking endoscope washings, nor were there checks in place to ensure this happened. The previous Charge Nurse resigned from her position and left the Department on 26 March 1999 and the position was not filled until 19 April 1999. The Clinical Director, Dr Bramwell Cook, did not notice that the washings were not being performed regularly as only those results showing bacterial growth were drawn to his attention. As most results showed no growth, the Clinical Director did not consider it unusual that he received fewer reports than usual.

On completing the incident form, Ms Lester informed Dr Cook and Service Manager, Mr Andrew Dickerson of what had occurred. Dr Cook, who has been Clinical Director for over ten years at the unit, stated:

I thought there was a problem but did not know how serious. I did not feel we could ignore it but neither did we have a plan at that point. It was not until later that we realised a large scale notification process should occur.

In a memo on 5 May 1999 to the Quality Assurance Nurse, Ms Yvonne Williamson, Ms Lester wrote:

…The technicians have placed signs on both cabinets stating – to hold camera end of endoscope out of water during pre wash phase to insure water is pumping and therefore indicating that the pumps are working. This will avoid another incident in the future.

On 5 May 1999 the results of the washings that Ms Lester had taken after the incident became available and were negative.

The Quality Assurance Nurse reviews all incident reports and decides on actions. This particular incident was unusual and thought to be serious. It was therefore referred to Ms Shona MacMillan, Quality Manager of Christchurch Hospital on 7 May 1999. Ms MacMillan appraised the situation and contacted the Department Charge Nurse by telephone on 10 May 1999. Ms MacMillan and Ms Williams contacted Mr Tony Kampkes, Infection Control Nurse Practitioner, to discuss the situation.

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Outcome of Investigation *continued*

On 11 May 1999 Ms MacMillan informed Ms Jan Nicholson, Corporate Quality and Risk Manager about the incident by e-mail:

There has been an incident in the Gastro Lab (27/4) where a fault has been found in one of the machines that cleans scopes. It is unclear how long the fault may have been present, however the department are supposed to send weekly samples to the lab checking – Tony K can only locate the last one as done in February….

On 12 May 1999 Ms Lester met with Ms MacMillan and Mr Kampkes to discuss the incident and actions to date. A meeting then took place later in the day where Ms MacMillan advised Ms Nicholson and Mr Michael Hundleby, the Company Solicitor. Mr Richard Webb, Chief Executive Officer was then informed.

On 13 May 1999 Ms Nicholson, Ms Lester, Mr Dickerson, Dr Mona Schousboe and Mr Hundleby met. Dr Cook was invited to this meeting but was unable to attend. A meeting was arranged later with Dr Cook as a result.

Ms Lester stated, "*The meeting was legally privileged and confidential. It was not to be discussed with anyone."* Canterbury Health's policy on serious incidents is for the matter to be discussed with senior staff and the Corporate Solicitor to promptly determine the level of associated risk. Legal privilege allows information shared between a client and solicitor to be treated in confidence and is a means of allowing the organisation to manage potential risk.

On 14 May 1999 Ms Lester met with the Policy and Procedures Co-ordinator to draft a new Procedures Manual that would incorporate all the necessary instructions to staff, including the need to lift the tip of the endoscope during the automatic wash cycle and protocols to ensure routine bacteriological testing was continuous. The existing manual was incomplete and out of date.

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Outcome of Investigation *continued*

Canterbury Health's policy on incident reporting which was current in April 1999 when the incident occurred was documented in *Canterbury Health Policy and Procedure Manual* (D2 1-6, Vol 6 Nursing). The policy has since been updated into *Canterbury Health Nursing Policies and Procedures Manual* (28 June 1999, Pages 17 to 24).

Microbiology and Virology Testing

Microbiology and virology testing refers to the science of testing for bacteria and viruses respectively. Dr Schousboe, Clinical Director of Infection Control, led the investigation into the incident which is outlined in the report, *Gastroenterology Incident Microbiology/Virology Investigations*, co-written by herself and Ms Nicholson, and completed on 16 July 1999.

Earlier that month, Dr Schousboe, who constantly monitors infections around the hospital, had discussed the incident with Mr Kampkes in the context of routine investigations into the previous month's blood culture results. Her formal involvement with the incident did not commence until 13 May 1999.

Initially the investigation identified all patients who had a gastroscopy, colonoscopy or ERCP between October 1998 and 27 April 1999. This involved a review of approximately 3000 records. Firstly, all blood culture results on those who had received an endoscopy were reviewed. A blood culture is where a blood sample is tested for possible bacterial growth in the blood system. Dr Schousboe was looking for any "*detectable increase in the number and frequency of positive blood cultures*" during this period.

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Outcome of Investigation *continued*

On 13 May 1999 it was decided to investigate whether there was a possibility of viral transmission in spite of manual cleaning processes, by testing the endoscopes after being used by a patient who was positive for cytomegalovirus (CMV) or Hepatitis C. However there was no patient in this category scheduled to have an endoscopy in the next two weeks. On 17 May 1999 Ms Lester and Ms Nicholson discussed the possibility of getting a patient with hepatitis to the Unit to test the endoscope. Ms Nicholson wrote in a memorandum:

Identified possible Hep C patient: Contact made with GP pt April 98 – Hepatic Cellular Damage. No reference in notes to HepC. Will need to wait to speak with Bruce Chapman when he returns from leave 24th May. He sees to HepC patients.

On 18 May 1999 Ms MacMillan e-mailed Mr Kampkes with the following note:

Can you please get in touch with Jo Lester and arrange with her the new Quality Assurance checks that we wanted in relation to the scope washings. This was where washings are taken that relate to both a scope and to a pump. You said that you would also get the results sent to you, we need a documented process as to who is responsible – and one that works if Jo and you are on leave. Dr Cook should also have a role to play in this eg signing of results. We want the new weekly system to start as soon as possible. Can you advise me if there are any problems with starting this straight away.

On 20 May 1999 SciTech were able to confirm the dates from which they could guarantee the functioning of the pumps in the Labcaire machines. SciTech stated:

…Both [the SciTech service manager] *… and I can confirm that both irrigation pumps were working on the date of this service – ie 29 January 1999.*

This was confirmed in a standard test / check which we routinely do, as well as in discussions with [the former charge nurse] *on the systems operation. We hope these details help. I will also put some medisafe literature on cleaning systems in the mail for you tonight.*

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Outcome of Investigation ***continued***

This meant the review period could be narrowed from 29 January 1999 until 27 April 1999. Accordingly the number of procedures under review were reduced from 3000 to approximately 1400.

By 27 May 1999 the blood culture results were available which showed that 32 consumers had blood cultures taken within seven weeks of endoscopy and of these, 5 consumers showed bacterial growth within 7 weeks of the procedure.

Initial Viral Infection Tests

The Infection Control Investigation Team also began a virology review, by looking up on the laboratory database those who had Hepatitis B, Hepatitis C, CMV or HIV positive tests performed. The results showed four patients had positive serology results for Hepatitis B antigen or Hepatitis C antibodies. No HIV patients were identified. However it was discovered at a later time that two HIV positive people had endoscopies during this period but were not able to be identified immediately because their names were coded.

On 25 May 1999 testing was done on samples for viral traces of CMV and human protein. CMV was chosen as it is present in approximately 50% of the population and was therefore likely to be present in these samples. The results were available on 27 May 1999 and in all three samples there was no evidence of the presence of human DNA or CMV viral fragments. Dr Schousboe concluded that these results confirmed her working hypothesis that viral transmission was extremely unlikely and a low risk.

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Outcome of Investigation *continued*

Dr Schousboe stated she was convinced that the presence of bacteria was a possible marker for transmission of viruses. However a person with HIV, and then another with active Hepatitis B, who had both undergone endoscopies, came to her attention which made her concerned about potential viral transmission. This occurred at a clinical meeting on 28 May 1999, when an HIV positive patient was discussed who had lost a lot of blood and had been vomiting. While Dr Schousboe stated she considered that the alcohol rinse performed on the endoscopes routinely at the end of the day would take care of any possibility of HIV transmission, she asked a virologist, Dr Lance Jennings, to continue testing in her absence. She was due to go overseas on leave from 29 May until 20 June 1999.

Scientific Analysis

On 27 May 1999, following the initial blood culture review, Canterbury Health decided to investigate whether there was a relationship between an individual's endoscopy and the subsequent request for a blood culture. Dr Michael Beard, a physician and scientist, formerly a medical advisor at Canterbury Health Ltd, was contracted to undertake this investigation on 35 patients who were identified as having blood cultures taken during the review period.

Dr Beard's report, which is legally privileged and therefore could not be reviewed, was commenced on 27 May 1999 and completed on 9 June 1999. During his investigations, Dr Beard stated he had discussions with Dr Steve Chambers, Infectious Diseases Specialist and Professor Abbott, Senior Medical Officer and Dr Schousboe.

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Outcome of Investigation *continued*

Dr Beard reviewed the notes of 35 patients who had had blood cultures taken. Dr Beard noted that in general this group consisted of those who had major surgery following their endoscopies and had clinical tests for post-operative fever. None of this group had blood cultures performed solely for the reason of having an endoscopy. Dr Beard concluded there was no apparent relationship between the endoscopy procedure and the subsequent request for blood culture. He also concluded there was no evidence that bacterial transmission occurred as a result of their endoscopy. Dr Beard stated that he considered the risk of (bacterial or viral) transmission to be low and thought at first it would not be necessary to test everyone, but only those who came before or after someone with positive serology results. These consumers were classified as the "high risk" category. For example, if a consumer was known to have Hepatitis B, C or HIV, the person who had an endoscope immediately prior would be tested to determine whether this result was related in any way and then those following would be tested for possible viral transmission.

Dr Beard also undertook a second report for Canterbury Health on a deceased patient whose family was concerned about the circumstances of his death. This report was completed on 26 July 1999. This patient had a number of endoscopy investigations, and a blood transfusion after which he was discharged. Two days later he returned to hospital with a respiratory infection, developed septicaemia and died within two days. The resulting blood culture grew a type of bacteria called Pseudomonas Aeruginosa which is often associated with hospital-acquired infection. Dr Schousboe was already aware of this particular case from her routine review of blood culture results. The conclusion drawn in Dr Beard's report was that it was unlikely for this patient to have contracted the infection from the endoscope but more likely from another patient or from aspirating some gastric contents during the endoscopic procedure. The Commissioner was advised this is not uncommon during a gastroscopy.

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Outcome of Investigation *continued*

On-going Viral Testing

In late May, to eliminate the possibility of viral infection, "live viral testing" began which involved performing a washing after an endoscopy procedure with a known positive serum sample. This technique consisted of flushing serum containing Hepatitis B and C through a gastroscope on 9 June 1999 and a colonoscope on 11 June 1999. Washings were obtained from two stages of the cleaning process: after the manual wash and after the machine disinfection. The samples were then sent for virology testing by an advanced technique called PCR (polymerase chain reaction). Hepatitis B testing was done at the Institute of Environmental Science and Research (ESR) in Porirua as facilities were not available in Christchurch.

The first results of these tests were not available until 28 June 1999, with the Hepatitis B result available on 2 July 1999. Samples from the gastroscope site showed the presence of Hepatitis B and C viral fragments, while samples taken from the colonoscope showed only the presence of Hepatitis B viral fragments. Both results were found in washings taken at the end of the manual wash. After the glutaraldehyde wash, there was no evidence of viral fragments in the samples taken. The *Microbiology/Virology Investigations* report further states that the presence of viral fragments does not mean that virus particles capable of causing infection are present.

Clinical Case Mix Review

As well as reviewing laboratory records, an additional review was undertaken on 16 June 1999 by the Clinical Case-mix Team (Canterbury Health Analysts), led by Mr Keith Young, Corporate Reporting Manager. The purpose of this review was to identify additional patients who were positive for Hepatitis B, C or HIV who might not have been picked up from laboratory records. All patients' records in the review period were checked for these viral conditions based on ICD9 codes. The ICD9 codes used were broad, which meant that when a match occurred the person's case notes had to be reviewed to confirm the diagnosis. In addition the case notes of all outpatients, approximately 900, were reviewed by a nurse to check for references which may indicate hepatic exposure.

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This review revealed seven consumers, including one without a positive diagnosis but who was "high risk", as possible positive for Hepatitis B, C or HIV. These results were combined with the laboratory data base review to give a total of nine patients with positive serology in the group under review. An additional five were thought to be positive but were reviewed by Dr Beard and found not to be.

On 18 June 1999, at Dr Bruce Chapman's suggestion to conduct tests on "real" patients, two suitable patients were scheduled for endoscopies: one had Hepatitis C and the other HIV. Samples were collected following the manual washing procedure but before the glutaraldehyde pump-cycle and sent to the laboratory for testing for Hepatitis C and HIV respectively. The Hepatitis C result was available on 28 June 1999 and showed that viral fragments were detected. The HIV result on 10 July 1999 was negative.

On about 27 June 1999, Dr Schousboe advised that the review of laboratory records relating to possible increases in the number and frequency of positive blood cultures revealed no observable increase. However the investigation continued and in her absence Dr Schousboe contracted two people to undertake a study on a control group. Using the records of those who had a gastroscopy or a colonoscopy between October 1998 and 29 January 1999, they looked for evidence of bacterial infection and positive serology. The results, available on 5 July 1999, showed the control group had slightly more blood cultures done than the group under review. Dr Schousboe stated the study did not show anything that was surprising or that would indicate cause for alarm.

On 5 July 1999 further testing was undertaken with Hepatitis B, C and HIV samples flushed through a gastroscope and a colonoscope at various stages of the washing procedure. The hepatitis results were available on 9 July 1999 and the HIV result on 10 July 1999. All results showed no Hepatitis C, B or HIV viral fragments were detected.

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Outcome of Investigation *continued*

Rationale for the Number of Tests

The Infection Control Investigation Team went to such lengths in conducting tests to determine subsequent actions and responsibilities, so that if someone returned in the future to ask questions about the incident Canterbury Health could clearly show what determined its decisions at that time.

Dr Schousboe said when the pump failure was identified on 27 April, it was too late to give patients the opportunity of having prophylactic medication for any possible viral infection. The HIV prophylaxis would need to be given within four hours of exposure, Hepatitis B within 3 to 4 days and for Hepatitis C there is no known prophylaxis.

Minutes of Gastroenterologists' Meeting of 1 June 1999

On 1 June 1999 the Department's medical and senior nursing staff met at a routine monthly business meeting. According to the minutes, those present included Doctors B Cook, M Burt, M Barclay, B Chapman, C Stedman, G Nind, B Dobbs, Charge Nurse Ms Jo Lester and clerical supervisor, Ms Jan Merry-Martin.

The minutes record under Scope Disinfection:

- *Testing ceased in December 1998*
- *The pump 4 failure (approx 30/1/99 – 27/4/99) may have been a problem, we may have to recall up to 1,400 patients. Jo has organised for a cleaning at 1pm tomorrow. There appears to have been no bacterial infection. Jo has nurses checking manually to ensure pump is working and signing off on this.*
- *Audit of disinfection – Jan Nicholson and Jo are working on this.*

Recorded next to this in hand-writing is a note which states, "*Phoned Jo 14/6. Next meeting Tuesday 15/6. Information re Scope disinfection will be removed. Will read scope disinfection was discussed.*"

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Accordingly, at the next meeting of gastroenterology staff held on 15 June 1999 the minutes of the last meeting were re-distributed and under Scope Disinfection read, *"A discussion was had about the disinfection of instruments."*

The minutes of the 15 June 1999 meeting record that minutes of the previous meetings were accepted. Under Scope Disinfection the minutes stated:

- *A long discussion was had re the follow through on this.*
- *Jo is setting up protocols for everyone to follow.*

Present at this meeting were Doctors Burt, Chapman, Cook, Nind, Stedman, Ms Lester, and Ms Merry-Martin.

Elapsed Times for Virology Test Results

The test results for viral infection were relatively slow for the first batch begun on 9 June 1999 compared with times for the results on the third testing carried out on 5 July 1999.

The first testing for viruses began on 9 and 11 June 1999 using washings from samples containing the live virus. The results of these tests showed viral fragments were present. It took 17 days for Hepatitis C tests to be completed and 21 days for Hepatitis B. (Hepatitis C results were completed on 28 June 1999 and the Hepatitis B results on 2 July 1999).

Meanwhile, on 18 June 1999, washings using actual patients with positive serology were collected and testing was completed in 10 days for Hepatitis and 22 days for HIV. Confirmation tests were carried out on 5 July 1999. On this occasion, for Hepatitis B and C the tests took four days to complete and the HIV tests took five days.

Actions after testing showed viral fragments

On Monday 5 July 1999 the Infection Control Investigations Team communicated the test results indicating the presence of live viral fragments to Ms Nicholson and Mr Hundleby, who notified Mr Webb, Chief Executive Officer.

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Outcome of Investigation ***continued***

On Tuesday 6 July 1999 Mr Webb called a meeting with Infection Control, Infectious Diseases and Gastroenterology experts, Medical Advisors, management and senior nursing staff. Present at this meeting were Doctors Burt, Cook, Chapman, Jennings, Schousboe, Abbott, Beard, Ward, Ms Lester, Ms Nicholson, Mr Hundleby, Ms James, Ms Forbes, Mr Webb, Mr Smith and Ms Skiba.

Mr Webb informed the Commissioner that he called the meeting to decide what the clinical response should be in relation to a screening programme. Mr Hundleby advised the Commissioner that the thinking at this stage was to first inform those in the "high-risk" category identified by the investigations team and then, once those immediately prior and after this group had been tested, to then notify the remaining people in the group. At this meeting Dr Jennings and Dr Schousboe emphasised that the DNA fragments found following the live viral testing may not be viable but there was no certainty. They also noted that as the material was fed down the tube, it may mean it was more infectious than under usual circumstances.

At the end of this meeting it was agreed that a smaller group would continue to meet to discuss the issues further. Included in this smaller group were Dr Chambers, Dr Jennings, Dr Schousboe, Dr Chapman, Dr Beard, Mr Hundleby, Ms Lester and Ms Nicholson.

Planning and Implementation of Public Advice

On Wednesday 7 July 1999 a Board Meeting was held where Mr Webb advised members of the testing programme's results, in particular the implications of the 2 July 1999 results. Dr Cook and Dr Chapman attended this part of the meeting to brief Board members. Mr Webb explained that results of testing showed fragments of Hepatitis B and C were present after the manual cleaning process but were thought not to be infectious by the investigation team. However, Mr Webb told the Board he had been advised by clinicians on 6 July 1999 that widespread testing of patients was the only way to be sure and eliminate all risks. The strategy of first informing and testing those in the "high-risk" categories continued at this stage.

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Outcome of Investigation *continued*

There was discussion of this new information from 2 July and the Board agreed that all those who received an endoscopy between 29 January and 26 April would be notified as soon as possible in a sensitive way minimising unnecessary harm.

The minutes of this 7 July meeting state that Mr Webb gave the following answer to the question of why it took so long to decide to notify consumers:

The issue in overseas literature is that there is only one instance identified in the world where Hepatitis B had been transmitted by scopes of the millions carried out though the world. There were no cases of HIV and the evidence was less well quantified in relation to Hepatitis C as there was a French study which indicated that risk is possible but this study was from years ago and involved poor cleaning. With all the data gathered together there is a growing confidence that the risk is lower than originally assessed. The reason for the delay was all early tests were absolutely clear. Viral infection was considered by the clinicians so unlikely that the bacterial issues were done and run to ground first. Bacterial testing is a marker for viral testing. The DNA human residual and CMV viral testing were also clear, so we went to the next stage which was trying to infect the scopes and then testing other infected patients. It was only when the final results came in on 2 July 1999 indicating fragments of virus, which are unlikely to be viable, that it was felt that we should take the approach of a mass screening to eliminate all risk. It was only then that we had any evidence that would support it.

On 7 July 1999 at 3.30pm a further meeting was held with the Special Project Team, a group whose purpose was to plan and implement the advice to consumers, all relevant providers and the public as well as plan for the mass testing of those consumers.

At this meeting the question was raised about obtaining an ethicist's opinion on the matter, but this was not followed up.

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Outcome of Investigation ***continued***

On Thursday 8 July 1999 a teleconference was held with two Ministry of Health officials, Dr Colin Feek, Chief Medical Advisor and Mr Peter Hughes, Deputy Director-General, Performance Management. Canterbury Health staff present at this meeting included Mr Webb, Mr Hundleby and Doctors Cook, Schousboe and Beard.

At this meeting it was agreed that Dr Alistair Cowen, an internationally recognised expert on disinfection techniques for gastroenterological procedures, should be enlisted to advise on the matter. The Ministry of Health funded Dr Cowen's visit from Brisbane, Australia, in order to obtain an independent report. Dr Feek and Mr Hughes were informed there were two protocol failures in the unit; one was the elevation of the endoscope tip to check the water flow and the other was in routine bacteriological testing of the endoscopes which had ceased in December 1998. There was discussion on the best means of notifying people and the necessary steps that would need to be undertaken to facilitate the smooth-running of this process.

On Friday 9 July 1999 Mr Webb held a teleconference with the Board of Canterbury Health Limited. By this time the Special Project Team's strategic thinking had changed in favour of informing all 1331 consumers at the same time. There were two reasons for this change in strategy. One reason was that if the situation became public, the wider group would experience anxiety without appropriate information while waiting for the first group to be tested. The second reason was that in any population an estimated 0.3% have Hepatitis C and a similar number have Hepatitis B without knowing it. This meant the high-risk group (that is, those immediately before and following someone with positive serology) could not ever be fully known. The high-risk group was therefore potentially larger than first thought.

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Opinion – Case 99HDC07727/AM, continued

Outcome of Investigation *continued*

Advice to Consumers

A complex and detailed planning and implementation process commenced on 7 July 1999 to ensure a smooth, well-executed approach in informing consumers and to ensure the testing process of those consumers was handled in an efficient and logistical manner.

It was decided consumers would be notified by courier on Monday 12 July 1999. A press conference would be held at 2.00pm with media coverage embargoed until 6.00pm. The reason for the embargo was to ensure all consumers were informed before finding out through the media. At the meeting on 9 July Mr Webb stated that all IPAs (Independent Practitioner Associations) were to be sent material over the weekend which would include the scientific basis for the decision to notify consumers, the risk, how testing would be undertaken and the advice that consumers would be informed in writing.

In addition a further information pack would be sent to all General Practitioners in the Canterbury region and the Chatham Islands. This pack would contain more details on the way testing was to be done, with attachments for patients and some scientific literature. The Board was alerted to some logistical problems such as trying to locate patients who were overseas or in jail.

On Saturday 10 July 1999 the Special Project Team met for further planning. Issues discussed included planning for large-scale blood sample collection on Monday 12 July 1999 and organising the mailing list. It was agreed to customise letters for different groups, for example for those aged under sixteen, for teenagers between the ages of 16 and 18, for those overseas, for those without a General Practitioner, etc. Later that day some Canterbury Health staff underwent media training.

On Sunday 11 July 1999 a further meeting took place. Dr Schousboe had devised an identification code for consumers affected so that their blood results were not available on the usual laboratory database to ensure their confidentiality.

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Outcome of Investigation ***continued***

Information packs were prepared for delivery to all consumers on Monday 12 July 1999. An information video was made on Sunday 11 July 1999 with a copy posted to General Practitioners and made available to any of the public who requested it. It was also available for viewing at the blood collection centre. The video explained how the endoscopes are cleaned and the failure of the pump and protocol which led to the current concerns. Dr Cowen also appeared on the video and concluded with the comment that someone is more at risk of dying from a road accident than contracting a virus in this way. Dr Cowen, who arrived in Christchurch at 12.30am Monday 12 July 1999, was filmed in Brisbane on Saturday 10 July 1999 and brought the taped interview with him for inclusion on the video, which was finalised later on Monday morning.

Mr John Sharman, Business Manager of Core Laboratory and Haematology and Ms Lisa Brennan, Business Manager of Microbiology and Anatomical Pathology both described their role in having input into the letters that were sent out to the consumers and in setting up an area in the physiotherapy department for the purposes of specimen collection. They had to anticipate that possibly all 1331 consumers would arrive for their blood collection at the hospital. Ms Brennan stated that in total only a small percentage chose to come to the hospital with most going to private laboratories or their General Practitioners to have blood taken.

At 8.30am on 12 July 1999 Mr Webb met with gastroenterology staff to explain the situation, including the screening process, and to inform staff that EAP (employee assistance programmes) were available if required. Staff were informed that the Department's Charge Nurse had been instructed by senior management to keep the matter confidential and so minimise possible leaks to the public which could cause unnecessary anxiety to patients.

On 12 July 1999 the information packages were sent by courier to all 1331 consumers and General Practitioners.

Canterbury Health state that during the initial notification period (that is, during the week of 12 to 16 July 1999), the Department cancelled 68 endoscopy procedures and 20 outpatient appointments. The last cancellation for this reason took place on 21 July 1999.

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Outcome of Investigation ***continued***

A media conference was held at 2.00pm with all material embargoed until 8.00pm. Canterbury Health had originally planned an embargo of 6.00pm but altered this on the advice of the Ministry of Health. General Practitioners were invited to attend a briefing that evening on the matter.

On Monday 12 July 1999, from 12 noon onwards, the blood collection facility was functioning. This area included a place to watch the video. Tea, coffee and biscuits were available as well as counsellors for people wanting additional support.

In planning this facility, care was taken to find ways of preserving patients' privacy and to make access to the unit as convenient as possible. Hospital security was on the alert for potential media intrusions. The 0800 line was activated with staff available to take calls from the public. These facilities continued to operate over the next two weeks. Staff involved described working long hours without days off during this period.

Information Sent to Consumers

All 1331 consumers were sent an individualised letter in which the situation was explained and an offer was made to participate in a screening programme to be certain no infection transmission had occurred. The letter emphasised the low risk considering only one of the four pumps had failed, other stages of the cleaning process were carried out according to usual standards and the percentage chance of contracting a virus through an endoscope under those circumstances was slight.

Canterbury Health apologised for the pump failure in this letter and offered further information through an 0800 number. Details on how to obtain a blood test through the consumer's General Practitioner were given, along with assurances the results would be available in three to five days. With regard to the times required for testing, it was explained that for Hepatitis B, Hepatitis C and HIV, tests gave 95% certainty three months following potential exposure and certainty after six months following potential exposure. This was the reason for having the second and final test six months from the time of the endoscopy.

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Outcome of Investigation *continued*

In addition, a fact sheet was supplied explaining in more detail what the problem was, the risks, why there had been a delay in notifying consumers, Canterbury Health's feelings on the matter including an apology, the screening process, the cleaning of endoscopes, the availability of a video and the expected role of the consumer's General Practitioner in providing additional support. Their General Practitioners were given the same information.

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Outcome of Investigation ***continued***

Other Matters

Consumers' Reaction to Advice

A random sample of twenty consumers was undertaken by the Commissioner with the following results.

Fifteen out of twenty people were pleased with how they were notified. A further three were satisfied but thought notification could have been improved by their being informed earlier, by the process not being so rushed, by having the opportunity on the day of notification to discuss the matter with gastroenterology staff and by being kept informed of the outcome of the incident.

Two consumers were dissatisfied with the notification process and commented that they should have known earlier and that other specialists should have been informed.

Consumers were asked whether they would prefer not to be informed at all given the low risk. Sixteen out of 20 said they would rather know. One consumer who was aged over 75 years said she would prefer not to be informed. Of the remaining three, one respondent had terminal cancer and considered the issue was irrelevant; the further two did not care either way.

All respondents in the survey were New Zealand European. Two were aged under 16 with a parent answering on the child's behalf and five were over the age of 75.

An additional three consumers were contacted via their solicitor, Mr Grant Cameron, who is considering taking a class action on the matter. Mr Cameron stated in a letter to the Commissioner that he had interest from about 49 people affected and, of these, he considered "*only 5 or 6 probably have the basis of a genuine nervous shock claim*."

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Outcome of Investigation *continued*

Of the three consumers contacted, one did not wish to discuss the matter further. Another spoke of her feelings of shock when first notified and then distress when after some delays she was informed that her result, while likely to be negative, needed further testing to be sure. The delays were due to the sample requiring testing in Palmerston North. Her General Practitioner then contacted her to say the results were negative. The consumer is now waiting to take her second and final test in late September 1999.

The third consumer believes they contracted HIV from the endoscope. However, this consumer had other life-style risk factors for possibly contracting the disease. Dr Steve Chambers, Infectious Diseases Physician stated:

We think it extraordinarily unlikely that [the consumer] *has acquired* [HIV] *from the endoscopy. The incubation period for HIV is normally regarded as three to twelve weeks and* [the consumer's] *test came back positive ten days after endoscopy. This makes it unlikely in its own right. Adding weight to this is that all three bands on the Western blot came up positive. Usually these come up in a sequence with some often being delayed.*

Secondly we have looked back at people who had the same endoscope as [the consumer], *prior to* [the consumer] *and, of these, we have two patients who are negative. We looked at patients who had the same endoscope after and found the patient immediately after was HIV negative. Of the further twelve patients following* [the consumer] *we have information on nine, all of whom are both HIV negative and Hepatitis C negative. I think it is extremely unlikely that* [the consumer] *had acquired HIV from endoscopy or transmitted either HIV of Hepatitis C to another patient.*

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Outcome of Investigation *continued*

Dr Steve Chambers quotes from *Principles and Practices of Infectious Diseases*, (ed Mandell, Douglas & Bennett) where, on page 1220, it states that the seroconversion time for HIV, from exposure to development of antibodies, is one to three months. In addition the New Zealand Blood Bank currently regards the period of infectivity prior to seroconversion (the time taken for an infection to be confirmed by testing) as 22 days and the Communicable Diseases Centre in Atlanta, USA, states the minimal period is fourteen days. Dr Chambers stresses that *"these are minimum times for seroconversion and that most take longer than that, more like six weeks."*

Results of Screening

Out of a possible 1331 consumers, 1278 (96%) came forward for screening. Of the 53 who did not take the tests, some were too ill, some had died, some were overseas and some chose not to. Follow up letters were sent by Canterbury Health to all those who did not take the test on 12 August 1999 to invite them once more to participate in the screening programme.

Canterbury Health summarised the Endoscopy Screening Results on 4 August 1999:

There is no evidence of cross infection from any of the infectious patients to other patients. Likewise there is no evidence of patients with "previously unknown" infections having acquired their infection from other patients who had endoscopies. That is, the results of all patients prior to and following infectious patients are clear.

- Hepatitis B. There are 68 people who have immunity to Hepatitis B but are not infectious. Eight were infectious for Hepatitis B with six of these previously known about. None of the positive results show any serological evidence of recent Hepatitis B infection.

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Outcome of Investigation ***continued***

- Hepatitis C. There are twelve who are infectious for Hepatitis C with ten of these previously known about. There were ten false positive results.

- HIV. There are two who tested positive for HIV and of these two, both were known about previously.

Canterbury Health also report that no complaints were registered by any of the 1331 patients or their families. The family of a man who died in April soon after his endoscopy made enquiries and were responded to in the second report by Dr Michael Beard. In total there were 919 calls to the 0800 line, with 401 calls received on 13 July 1999.

Canterbury Health reported that the total amount of spending on the notification exercise was $129,000. This includes costs of laboratory testing, mail and courier charges, some staff overtime, video production (about 500 copies) and other miscellaneous costs.

The Commissioner received no written complaints about the matter. One consumer wrote a letter to the Commissioner praising Canterbury Health's management of the situation.

Nursing staff's responsibilities in checking for possible pump failure

The Department's Charge Nurse stated she was formerly a staff nurse for the unit before being appointed to the senior position. Prior to her appointment, she had left the unit for about eight months and returned to take up the position on 19 April 1999. The Charge Nurse was present when the Labcaire machines were first installed in 1996 and was among six nurses who received training on how to use the machines. These six nurses all signed a form to say they received the training from SciTech.

Four of the nurses, including the current and former Charge Nurses, have submitted signed statements to the effect that they were never given instruction to lift the tips or check the flow of fluid through the endoscopy channels. They consider that such instruction would have been noteworthy and therefore remembered. The protocol to lift the tips was therefore never incorporated into usual practice when operating the machines, nor was it incorporated into their Procedures Manual prior to the incident.

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Outcome of Investigation *continued*

Canterbury Health advised that the manual or "User Instructions" that first came with the machine did not include reference to lifting the tip. This 5 page document (Ref: L/V4615K) was viewed by the Commissioner and there was no reference to lifting of the tips. An updated manual, called "Operating and Maintenance Manual, Issue 3/95", was supplied some months later which included instruction to lift the tip. SciTech advised the Commissioner this manual is designed as a maintenance manual for technical staff. The manual contains much information that is superfluous to the needs of the nurses. The reference for lifting the tips is found in two places. First under the section 'Connection of Endoscope to Irrigation Channels', and states, *"scope should be checked to see that when fluid is being pumped through liquid is coming out of all channels – the scope can be lifted up during the first water wash"* and second, under 'Warnings' stating, *"…Lift the endoscope during the wash cycle to ensure that the channels are being irrigated."*

SciTech's Response

SciTech advised that the user instructions which Canterbury Health were supplied with initially were prompt cards, not an official manual, and these came with the earlier machine that was on trial. SciTech stated Canterbury Health was supplied with the correct manual, that is the user manual 3/95, plus two sets of updated prompt cards (Ref: L/HT4615) at the time the machine was installed in 1996 and these included the appropriate instructions. One set of the prompt cards was tied to a machine and the other set was pinned to the notice board. SciTech also re-stated it gave the appropriate training, but that it did not wish to enter into further argument with nursing staff on this matter.

SciTech intends to upgrade the Labcaire machines later in the year and this will include an alarm system to alert for low flow through the endoscopes. However, SciTech recommends the endoscopes continue to be visually checked or lifted to ensure proper functioning of the machine. SciTech also state they will provide all Labcaire users in New Zealand with an "update" package, which will include reminders on checking the scope tip flow and information on upgrade kits, prompt cards and user suggestions.

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Canterbury Health Ltd

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Outcome of Investigation *continued*

Response by Canterbury Health Clinical Staff

Canterbury Health surgeons, especially those who used the Department's facilities, were angry they were not advised earlier of the incident and involved in the investigative process. Some considered they had ethical obligations to their patients and would have wanted to inform them earlier, and that knowledge of possible viral transmission would have impacted on their clinical treatment of some patients following their endoscopy. When clinical staff at Christchurch Hospital heard about the notification, some were upset at not being consulted. Some provided written and oral submissions to the Commissioner expressing their dissatisfaction with the process.

For example, the Christchurch Hospitals Medical Staff Association (CHMSA) expressed concern that the gastroenterologists who worked in the Department were not informed about the incident until the beginning of June and then were not able to take an active role in the process of handling the problem. Furthermore, the surgeons who routinely use the endoscopes in question were not told about the incident until the week prior to the media release. Two of these surgeons were told four to seven days before the matter became public, but the remaining six surgeons were not told until Monday 12 July 1999.

CHMSA stated they understood at least some members of the Infection Control Committee were aware of the existence of published data making the testing for viral fragments an unnecessary waste of time that delayed notification to the public. They believe that if members of CHMSA or the CPPC (Clinical Policy and Planning Committee) had been consulted, further testing to confirm the presence of viral fragments may not have been necessary. The incident was formally discussed with the Chief Executive and the CPPC in detail on 29 July 1999. The CPPC was briefed earlier on 9 and 12 July 1999.

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Outcome of Investigation ***continued***

Dr Evan Begg, Deputy Chair of CHMSA, was first informed of the incident on Friday 9 July 1999 by Associate Professor Abbott and on Saturday 10 July 1999 by Dr Cook. The Chair of CHMSA, Dr Jeremy Foate was not able to be contacted initially because he was away for part of that weekend.

Dr Begg stated that Mr Webb made no contact with their organisation until 13 July 1999 when he offered to brief them. However no CHMSA member was available at that time. Mr Webb then later made a public statement on radio that he had initiated contact with CHMSA on 6 July 1999 and they had replied they saw no value in talking with him, that they would rather talk to the media. CHMSA deny saying this and state it was 13 July, not 6 July, when Mr Webb first contacted them.

Mr Webb and CHMSA disagree on the role of the CPPC. Mr Webb advised the reason the CPPC was not informed earlier was that the CPPC is not an operational committee but provides advice on policy matters. CHMSA disagree and consider the purpose of the CPPC is to advise on any clinical matters of concern.

CHMSA also queried why the Ethics Committee were not consulted on the issue of the consumers' right to be informed.

Mr Rob Robertson, Clinical Director, Department of General and Vascular Surgery wrote to Canterbury Health's General Manager on 27 July 1999 expressing the Department of General Surgery's dissatisfaction at how the issue over endoscopy equipment was handled, in particular the lack of communication or involvement of the general surgeons in any part of the process.

However, on 26 August 1999 Mr Robertson stated to the Commissioner that he recognised the situation needed to be contained so that patients could all be informed at the same time and before media involvement. Mr Robertson believed the incident had allowed grievances to be aired and that the Department would function better as a result. He was confident that surgeons who use the Christchurch Hospital's Endoscopy facilities would have a greater say in the running of the Department with the strengthening of the Endoscopy Users Group.

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Outcome of Investigation *continued*

Infection Control Department Meeting
The Infection Control Committee meeting is held on the first Monday of every month. However the June meeting was not held as Monday 7 June was a public holiday.

Changes to the Gastroenterology Department
In a memorandum to the Department on 10 August 1999, Mr Garry Smith, General Manager of Christchurch Hospital advised that one new full time staff nurse position had been approved for the Department and three temporary positions were to be made permanent. In addition, a capital request for replacement and additional endoscopes was approved.

Planning is now well underway for a new Gastroenterology Department which will be located in an area closer to surgical wards and other out-patient facilities and have four rooms instead of the current two. The Commissioner noted these plans did not incorporate any changing facilities for consumers.

New Gastroenterology Department Procedures Manual
On 7 July 1999 Mr Dickerson wrote in an e-mail that Dr Cook had "signed off" the Department's Procedures Manual which includes clear instructions to lift the tip of the endoscope to check water flow. There is also a protocol for weekly microbiological testing of endoscopes which includes a requirement that results are copied to both the Clinical Director and Clinical Charge Nurse, who must sign that they have received and read these results (Procedures Manual, 4.6 Microbiological Testing of Endoscopes, July 1999).

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Advice to the Commissioner

Gastroenterology Infection Control Advice

Dr Alistair Cowen, the international expert brought to Christchurch by the Ministry of Health, advised the Commissioner that:

It is always easier in hindsight and I think they did not know in the beginning what was going to be necessary. They probably didn't know how to contact people like me in the beginning and the people involved may not have known of the appropriate action to take. The question is what has been lost by the delay? Nothing. They spent time consulting with people internally and that was appropriate. Although it could have been done faster, nothing in the end was lost by the delay. Imagine if it was delayed by two or three years.

In answer to a question from the Commissioner about the percentage chances of a consumer contracting a virus from an endoscope after manual cleaning processes and a soak in glutaraldehyde, Dr Cowen replied that it was not possible to put a figure on it because there have been no reported cases of viral infection transmitted this way in the world.

An Ethicist's View

The Commissioner also received advice from an ethicist. In response to a question on whether it was appropriate for Canterbury Health to notify the 1331 consumers about possible exposure to infection during their endoscopy procedure, the ethicist gave the following reply:

Proceeding on the assumption that ethics finds much of its basis in what a society at a particular time generally regards as at least tolerable and at best what fits in with its ideal perception of itself (but without wishing to subscribe entirely to the relativist point of view), I would come down on the side of disclosure, truth-telling and autonomous decision making on the basis of full information as far as that is possible to ascertain. I am influenced in this conclusion by the misleading credence so often given to the mathematical calculation of risk. I think we should acknowledge that we are easily convinced by what appears to be hard fact in this regard. A further influencing factor is a current trend in some sectors of society which I see as limiting, that is, to understand and explain value only in dollar terms. My answer to the question is that it was appropriate for Canterbury Health to notify 1331 consumers about possible exposure to infection during their endoscopy procedure.

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Advice to the Commissioner *continued*

The Ministry of Health's Investigation

The Ministry of Health released its report, "*Result of an inquiry undertaken on behalf of the Director-General into possible contravention of Regulation 19(b) of the Hospitals Regulations 1993"* on 23 July 1999. The Commissioner took the Ministry's findings of the report into consideration and accordingly did not investigate in any detail the matters contained in this report, which made the following recommendations:

The Endoscopy Unit

The inquiry team recommends that:

- *The Gastrointestinal Investigation Unit Procedures Manual, first drafted on 8 July 1999 be peer-reviewed by a multidisciplinary group, confirmed and re-issued with full document control, ensuring that it makes reference to any manuals staff may refer to and is complete (e.g. states the strength of solutions to be used).*
- *Training requirement in the unit be documented and individuals have their training recorded, as already required in the Corporate Human Resource manuals.*
- *All manuals and written instructions from the equipment manufacturers be reviewed so as to achieve consistency between process and manufacturer's recommendations.*
- *'Infection Control' should check the rationale for having 5, 10 and 15 minute glutaraldehyde irrigation cycles for disinfection, in order to minimise the number of times operators have to re-set the automated machine. This could reduce the potential for having an incorrect setting used on the next pair of endoscopes.*
- *'Infection Control' should review the recommendation that certain endoscopes should be considered "more likely to be contaminated" than others and receive longer disinfection, when current thinking is that all equipment should be considered as potentially contaminated.*
- *The Autoscope manufacturer be consulted about decommissioning the single/double rocker switches to reduce risk of unwittingly interrupting the disinfection irrigation.*
- *Canterbury Health Limited* [CHL] *investigate whether having the print-out option fitted to the machine would be cost-effective as an extra safeguard.*
- [CHL] *urgently complete the plumbing work required to control and monitor the water supply to the Autoscope machine.*

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Advice to the Commissioner *continued*

Canterbury Health Limited

The inquiry team recommends that Canterbury Health Limited:

- *Monitor progress on recommendations made to the endoscopy unit.*
- *Review compliance with the following Quality Assurance procedures, most of which are covered generically in the Corporate Quality Document:*
  - *involvement of Technical Services in equipment purchase decisions and installation*
  - *operators manuals are supplied with new equipment at the time of installation and are immediately document-controlled*
  - *initial training on new equipment is recorded and the training material retained*
  - *staff training/orientation is formalised, and recorded and signed off for each individual*
  - *the endoscopy-users group be reconstituted to consider whether lessons can be learned by other endoscopy providers within the hospital.*

Scientific and Technical (NZ) Limited

The inquiry team recommends that:

- *A copy of this report be provided to Labcaire Systems Limited for their consideration.*
- *That Sci-Tech reviews it's service documentation to ensure that all modifications (such as affixing of warning stickers) are recorded and dated.*
- *That Sci-Tech urgently arranges for review of the manuals and operating instructions for the Autoscope and progressively for other equipment it sells and services, but only replaces documents held by it's customers as a controlled procedure, with full explanation to the responsible person in the customers organisation.*

Health Funding Authority

The inquiry team recommends that:

A copy of the report be provided to the HFA's Quality Team, to be referenced during their on-site quality systems audit of Canterbury Health Limited and in preparing their report.

Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Code of Health and Disability Services Consumers' Rights

The following Rights are applicable to this investigation:

RIGHT 4
Right to Services of an Appropriate Standard

1) Every consumer has the right to have services provided with reasonable care and skill.
2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

RIGHT 5
Right to Effective Communication

1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

RIGHT 6
Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.

Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Opinion: No Breach Canterbury Health Ltd

In my opinion Canterbury Health did not breach the Code of Health and Disability Services Consumers' Rights in respect of the following matters:

Rights 4(1) and 4(4)

Endoscopy Cleaning

Canterbury Health's Gastroenterology Department is to be commended for its thorough cleaning of endoscopes. When one of the four pumps in their Labcaire machines failed for an unknown length of time between 29 January and 27 April 1999, the potential risk of infection transmission was reduced because of the Department's meticulous routine cleaning and maintenance of the equipment. Furthermore each endoscope is named so that it was possible to follow its washing cycles and note any problems that might be occurring.

The nurses who worked in the Department when the LabCaire machines were first installed in 1996 state they were not given instructions to lift the tip to check the irrigation flow through the endoscopes during the first cycle of the automatic wash. Nurses who began work in the Department after this time also state they were at no time given instructions to lift the end of the endoscope to check the pump flow.

The manufacturers of the equipment strongly deny this and state that when the machine was first installed, the product specialist gave the appropriate instructions. In the absence of any documentation from the supplier stating what written materials were supplied and specifically, what training was given at the time, the issue of what instructions were given remains unclear. In respect to the prompt cards which were attached to the machine giving operating instructions to nurses, I received conflicting evidence. I am therefore unable to determine the date on which these cards were replaced to reflect the need to check the flow. However I accept that SciTech service staff reminded nursing staff of the importance of completely immersing the endoscopes in the fluid.

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Opinion: No Breach Canterbury Health Ltd *continued*

With respect to the nurse training, I accept the signed statements made by the nurses as accurate. In my opinion the unusual step of performing a manual procedure during an automatic process, which results in a warning alarm sound, would have been remembered by the nursing staff.

The Ministry of Health report stated that "*staff of the endoscopy unit carried out the procedures that they had been taught to prevent cross-infection and consistently maintained the same standard throughout.*"

In my opinion Canterbury Health did not breach Right 4(1) of the Code. Services were provided with reasonable care and skill. In the absence of firm evidence to the contrary, in my opinion correct protocols were followed. No examples of bacterial infection were found that could be related to the use of the endoscopes during this period.

Further, in my opinion Canterbury Health did not breach Right 4(4) of the Code. The overall process of infection control was thorough and minimised potential harm to consumers.

Timeframes for Testing and Clinical Involvement

I saw no evidence that there was a deliberate campaign to keep information from clinical colleagues. A standard procedure of risk management was followed and while the Gastroenterology Department's minutes were amended, the revised minutes still reflect the issue and that ongoing testing and analysis was taking place to ascertain the extent of any potential harm. Clinical staff within the Department were not prevented from asking for information, following up or discussing the issue with their colleagues. The matter was simply not seen as a high risk problem because the ongoing quality process had been corrected immediately by fixing the pump, and analysis was occurring which continued to show no consumer risk.

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Opinion: No Breach Canterbury Health Ltd ***continued***

I do not accept that international data was available which would have quickly alerted Canterbury Health to immediately take action to inform all consumers. I reviewed the literature and found no evidence on which the Infection Control Investigations Team should have acted differently. Rather, the literature supported their actions. In addition, I accept the advice of the International Expert Gastroenterologist that there are no reported incidents so far on viral transmission where manual cleaning processes have been carried out to the standard maintained by Canterbury Health's Gastroenterology Department.

Canterbury Health's response to the possible infection was carefully considered. A methodical inquiry to narrow risk factors was followed. Until the outcome of such processes was determined it was not appropriate to widely discuss the issues because the problem could not be quantified and speculation would not have assisted the scientific review being undertaken.

Finally, I note that the bacteriological testing found no transmission of any infection, that the viral infection testing showed fragments only and such fragments have never been identified as transferring a virus. These fragments only occurred after live virus was injected into the endoscope. This is recognised as creating a higher risk of viral infection than would have been introduced by a person carrying such a virus. Furthermore only one in four of the pumps was not functioning, the maximum timeframe over which this pump failure could have occurred was analysed and appropriate action taken. Canterbury Health's processes were so thorough that they were able to determine which named endoscope had been used on particular consumers and therefore carefully consider whether to notify consumers next using that actual endoscope.

In my opinion while the timeframes could have been shortened, the process followed and the decision to inform the 1331 consumers was correct in the circumstances and did not breach Rights 4(1) or 4(4) of the Code. The methodology of analysis, followed by information preparation and execution of plans to ensure a smooth rollout of planning and testing of consumers was of a high standard.

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Opinion: No Breach Canterbury Health Ltd *continued*

Rights 5(1) and 6(1)

Timeframes for Communication to Consumers

Once Canterbury Health discovered viral fragments were present in the endoscopes, a decision was made to notify all consumers who had endoscopies during the period of possible pump failure from 29 January to 27 April 1999. This required strategic planning and the involvement of a large number of staff working long hours to ensure the success of such large scale notification.

Canterbury Health has been forthcoming with documentation on how this decision was made. While there have been criticisms about the delay in reaching this decision, I accept the explanation that notification of all 1331 consumers was not at first thought necessary. Canterbury Health went to considerable lengths to determine exactly what the level of risk was and this process has been fully documented. The Clinical Director of Infection Control, who led the microbiological investigation, reported that she only became concerned about potential viral transmission when she heard of a consumer with HIV who had had an endoscope during this period and bled a lot. While international literature may have been available on potential viral transmission, in my opinion, Canterbury Health was correct in undertaking an investigation that took into account the specific circumstances of the Gastroenterology Department and the consumers that used its facilities.

Furthermore I accept the Independent Gastroenterologist's advice that Canterbury Health's actions were appropriate in the circumstances and that no harm was caused by the delay in notifying consumers.

Once the decision was made to notify consumers, considerable effort was made to ensure that consumers were notified in the best possible way. For example, couriers were used, an 0800 number set up, an explanatory video was made available and all General Practitioners were involved in this process. Although such a large-scale notification exercise involved considerable expense, when the risks were negligible, Canterbury Health appropriately decided to ensure consumers were fully informed.

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Opinion – Case 99HDC07727/AM, continued

Opinion: No Breach Canterbury Health Ltd ***continued***

In answer to the criticism of Canterbury Health from both internal and external sources for not involving certain individuals and groups in the early period when the pump failure was first discovered, in my opinion Canterbury Health needed to exercise discretion in managing the incident before the decision was made to notify consumers. If such information was known publicly before procedures and systems were in place to respond to affected consumers, anxiety and distress would have occurred.

Furthermore, Canterbury Health used a number of appropriately qualified staff to investigate the matters in an efficient way, allowing ongoing services to continue providing healthcare without disruptions.

After the notification I received no complaints from any consumer relating to this matter. Further my random survey of consumers did not signal significant dissatisfaction with Canterbury Heath's processes. While I have been advised there are a small number of consumers who are considering taking a class action for the distress caused, in my opinion the communication process was full and clear and did not breach Right 5(1) of the Code.

In my opinion Canterbury Health did not breach Rights 5(1) or 6(1) of the Code of Health and Disability Services Consumers' Rights.

Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Opinion: Breach Canterbury Health Ltd

Right 4(2)

In my opinion Canterbury Health breached Right 4(2) of the Code. While the endoscopy cleaning, timeframes for testing and clinical involvement, and communication to consumers, met the obligations of Right 4(1), there were a number of actions that, while not major departures from standards, were not reasonable in the circumstances. These are as follows:

Failure to Meet Standards

Until December 1998 routine bacteriological testing of the endoscopes was undertaken at least once a week. In January 1999 the testing occurred at irregular intervals. I have received no satisfactory answer from Canterbury Health on why this occurred and conclude there were no adequate checks in place to ensure the regularity of this procedure.

The Infection Control Team, responsible for reviewing these quality checks on the endoscopes, had no protocols which picked up when these tests did not occur continuously. During this period, there was no written documentation or quality assurance checks in place that would alert the Clinical Director and Charge Nurse that this procedure was being neglected. As noted in the Ministry of Health's report:

There is no evidence of a conscious decision to stop bacteriological monitoring of the processed endoscopes in December 1998, which would have provided reassurance about the disinfecting process.

Appropriate Administrative Management

In my opinion the staffing in the Gastroenterology Department was insufficient to enable administration, quality assurance and training functions to occur adequately. These important tasks were given a lower priority than attending to the clinical work of the Department in order to process as many endoscopies as possible. In these circumstances the individuals managing the Department were not able to provide a reasonable standard and Canterbury Health must accept responsibility for this.

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Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Opinion: Breach Canterbury Health Ltd ***continued***

At the time of the incident there was a Quality Assurance folder in the Department which was accessible to staff but there were no checks in place on whether it was read or not.

In my opinion the Department had insufficient time available for administrative duties by both the Clinical Director and Charge Nurse. This led to the inadequacy of training, the lack of documentation, inadequate control over manuals and quality assurance, resulting in Canterbury Health's failure to meet its own standards.

I note that the Department has since introduced a new Procedures Manual that specifies the need to lift the tips of the endoscopes. Signs to this effect have also been placed on the machine and nurses responsible for cleaning must sign a statement to the effect that they have followed this protocol.

Quality Co-ordination

With regard to its Incident Reporting practise, Canterbury Health adhered to its policy except for the delay in referring the incident on to the appropriate personnel. For example, the Quality Manager was informed of the incident ten days after it had occurred whereas the policy recommends five days. The Corporate Quality and Risk Manager was informed on 11 May 1999, 14 days after the incident, and the Corporate Solicitor was informed on 12 May 1999, 15 days after the incident. The current policy states that all serious incidents must be brought to the immediate attention of the Corporate Solicitor.

I am advised that the Quality Team is working towards having all quality manuals in the Hospital updated in anticipation of accreditation. While "top level" policy and procedure manuals were revised as part of this process, in some smaller clinical departments, such as the Gastroenterology Department, this did not occur. I note that the Department now has an updated Procedures Manual which was issued on 27 July 1999. This manual is comprehensive, detailed and easily understood.

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Opinion: Breach Canterbury Health Ltd ***continued***

There is also a lack of understanding of committee purposes throughout the Hospital. In particular the clinical staff did not understand why the Infection Control Committee was not involved in the incident. A separate Infection Control Investigations Team was established to work under the leadership of the Clinical Director of Infection Control and the Corporate Quality and Risk Manager on this particular matter. As the Infection Control Committee which meets monthly to discuss policy issues did not meet in June, the matter did not come to its members' attention. While the terms of reference of this Committee are clear, many clinical staff do not understand its policy and advisory, rather than practical, role. This is also relevant to the CPPC which is a policy and advisory committee, although in my opinion the CPPC's Terms of Reference are open to misinterpretation.

Lastly I note that the Gastroenterology Department advised they were unable to spend sufficient time on administration as they could not justify more clinical staff were needed. The Department said justification was not possible as they received inadequate prices by the Health Funding Authority (HFA) and were not paid for acute procedures. My investigation revealed that the Department only received income on elective procedures. The HFA prices paid for elective procedures were comparable to that paid to other hospitals but an internal recharging process has not been introduced at Christchurch Hospital. Consequently no contribution towards acute procedures is received by the Department, and these acute procedures, undertaken for other departments, comprise 35% of the department's workload. In my opinion this lack of information and understanding of the real revenue and costs of procedures contributed to the Department's inability to manage administrative tasks, as it could not justify these resource issues to management.

In my opinion the above actions demonstrate a failure by Canterbury Health to meet appropriate standards of service as required by Right 4(2).

Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Actions

I recommend Canterbury Health takes the following actions:

1. Ensures quality processes and systems are in place within the Gastroenterology Department, such as on-going staff training on the use of equipment and routine bacteriological testing of the endoscopes. All training must be recorded.

2. Institutes an appropriate replacement policy for endoscopes within the Gastroenterology Department to minimise the numbers on loan at any one time and ensures a full quota of endoscopes are available at all times within the Department.

3. Produces annual and monthly Gastroenterology Department plans, estimating the number of acute and elective procedures expected.

4. Sets specified hours per week in which Clinical Directors and Clinical Charge Nurses are required to attend to administrative work and monitors such administrative functions. Sufficient staff must be available to enable this to be met.

5. Ensures that all Clinical Nurse Practitioners (including the Clinical Charge Nurse in the Gastroenterology Department) has an advisor from whom to obtain appropriate support, supervision and professional development. Such an advisor might be the Director of Nursing or other appropriate nurse.

6. Facilitates regular meetings of the Endoscopy Users Groups so that more functional relationships are developed.

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Opinion – Case 99HDC07727/AM, continued

Actions ***continued***

7. Critically examines whether internal recharging should be introduced within the hospital to ensure its clinical staff understand departmental revenue and costs. Clinical staff will then be able to analyse and where appropriate justify staffing and administration requirements to management. Canterbury Health advised me this is a management issue in which the Commissioner should not interfere and that staff and equipment purchases are based on volumes. However, clinical staff determine the use of resources on a daily basis and if they do not understand costs, they are unlikely to manage them effectively which will affect consumer rights. In examining whether internal charging should be introduced, I recommend Canterbury Health review the systems in place at other Hospitals and Health Services.

8. Records in the minutes of all meetings held in the organisation advice of persons attending as they come and go during the course of the meeting. Where a person is unable to attend a multidisciplinary meeting, an alternative person should be considered to represent that discipline. Additionally, when the date of a monthly multidisciplinary meeting falls on a public holiday, it should be considered whether it is appropriate to assign a new date within that month.

9. Publishes the CPPC and Infection Control Committee's Terms of Reference to ensure they are fully understood by all concerned and if necessary alters the CPPC's Terms of Reference to clarify such understanding.

10. Re-examines the Terms of Reference of the CPPC meeting to consider the Committee's ability to appoint an alternate Chair. This will ensure meetings are not driven by, or rescheduled, due to the individual currently chairing the meeting being unavailable. I understand that the Chief Executive will cease chairing this Committee next year and the Committee has elected his replacement.

11. Seeks advice from an ethicist to assist in decision-making processes where appropriate.

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Actions ***continued***

12. Reviews the new Gastroenterology Department physical layout plans to ensure suitable consumer changing areas are available. Consumer input should be obtained.

13. Sends a letter to all consumers informing them of the availability of the Commissioner's Opinion and offers to distribute a full copy on request.

Canterbury Health Ltd

Opinion – Case 99HDC07727/AM, continued

Other Actions

A copy of this opinion will be sent to the Minister of Health, Ministry of Health, the Health Funding Authority, the Health Select Committee and the Canterbury Ethics Committee. Copies will also be sent to Canterbury Health Medical Staff Association and Science & Technology (NZ) Limited.

The Ministry of Health followed up its recommendations by letter to Canterbury Health on 2 September 1999 and I suggest the Ministry publicly reports on the outcome of all its recommendations.

I suggest the Health Funding Authority distributes this opinion to all public providers of endoscopy services requesting they examine their individual practice to ensure it is of an appropriate standard and distributes the opinion to all regional Ethics Committees for their information.

I support MedSafe's recommendations to manufacturers that they introduce checking systems to document what manuals are provided and what training is given when installing equipment.

This opinion is a matter of public record.