A Public Hospital

A Report by the

Health and Disability Commissioner

(Case 01/01818)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer
Ms B	Customer Services Manager, a Public Hospital
Dr C	Registrar, a Public Hospital
Dr D	Registrar, a Public Hospital

Independent expert advice was obtained from Dr Geoff Hughes, emergency medicine specialist.

Complaint

On 14 February 2001 the Commissioner received a complaint from Mr A concerning the services provided to him at a Public Hospital. The complaint is summarised as follows:

On 4 February 2001, a sigmoidoscope was used on Mr A that was contaminated by a previous patient's blood.

An investigation was commenced on 2 July 2001.

Information reviewed

- Complaint letter from Mr A, dated 13 February 2001;
- Mr A's medical records from the Public Hospital;
- Details of the Public Hospital investigation of this matter and subsequent action;
- Report completed on the incident by Dr C, completed on 9 February 2001;
- Report completed on this incident by Dr D on 9 February 2001;
- Independent expert advice provided by Dr Geoff Hughes, Emergency Medicine Specialist.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Information gathered during investigation

Summary
On 4 February 2001, Dr D, registrar, performed a diagnostic examination with a sigmoidoscope on Mr A at the Public Hospital. After the scope was withdrawn from Mr A following the examination, Dr D noticed blood on the floor and surrounds. Dr D examined the sigmoidoscope and found the bulb contained blood. Later investigation revealed the blood was from a previous patient examined by Dr C, registrar.

Information gathered during the investigation
Sigmoidoscopes have been used at the Public Hospital since 1995. They are used in a number of different departments for the purpose of examining the interior of the rectum and the sigmoid colon. The device consists of a tube, which is inserted through the anus, an eyepiece and a unit consisting of a light source and bellows, which are used to inflate the colon. The manufacturer's instructions advise that between uses the tube should be disposed of and replaced, the eyepiece sterilised, and the bellows unit cleaned with mild detergent. It appears that staff at the hospital followed these instructions, although copies do not appear to have been distributed and the Public Hospital never formally incorporated them into company manuals.

During the course of normal use the bellows unit does not come into contact with body fluids and cleaning the unit with mild detergent is entirely appropriate. However, on rare occasions fluids can enter the tubing and contaminate the bellows unit. When this occurs, the bellow unit itself must be sterilised or disposed of. These instructions do not appear to have been distributed and the Public Hospital never formally incorporated them into company manuals.

In 1997 the manufacturer of the sigmoidoscope, Welch Allyn, introduced filters designed to prevent bodily fluids from entering the bellows. In August 1999 a representative of USL, the company distributing Welch Allyn products in the city, approached the Public Hospital to discuss the use of filters. The representative was advised to talk to staff at the Outpatients, Emergency, Central Sterilising and Supply and Infection Control departments. Only one meeting was arranged and this was with the Outpatients Department. At this meeting the USL representative explained the use of filters and was informed that this information would be passed on to the Infection Control Department and incorporated into the Hospital's procedures. In August 1999 the Outpatients Department began purchasing filters but it appears that their use was limited to that part of the hospital until after the incident involving Mr A occurred. There is no evidence that instructions for their use went beyond the Outpatients Department during this time.

On 3 February 2001, Dr C, registrar, examined a patient with a sigmoidoscope at the Emergency Department of the Public Hospital. The device was used without a filter. During the examination blood filled the sigmoidoscope with some hitting the eyepiece. Dr C was aware that the whole device (and not just tube) now required sterilising or disposal and so did not put the device away as usual. Dr C cannot recall discussing the need for the

device to be cleaned with nursing staff, but advised that as the device was covered with so much blood that it could not have been used before cleaning. Dr C left the sigmoidoscope out and accompanied her patient from the room.

It appears that sometime after this occurred, someone dissembled the sigmoidoscope, disposed of the tube, put the eyepiece aside for sterilisation and wiped the bellows unit before placing this part of the device back on the equipment trolley. As noted above, this is normal procedure for use of the sigmoidoscope, but should not have occurred in this case because the bellows were contaminated.

The following night, 4 February 2001, Dr D, registrar, performed a diagnostic examination on Mr A using a sigmoidoscope, which included the same bellows unit, at the Emergency Department of the hospital. Dr D advised that he did not observe any blood in assembling the device or during its use on Mr A. However, after the scope was withdrawn from Mr A following the examination, Dr D noticed blood on the floor and surrounds. Dr D advised that his first thought on observing this was that either he or Mr A were bleeding. After establishing that this was not the case, Dr D examined the sigmoidoscope and found that the bellows contained blood which he was sure had not come from his patient. Dr D informed Mr A that there had been blood in the bellows and assured the patient that he did not believe any had reached him. Dr D handed Mr A back to the care of nursing staff and informed them what had happened.

Nursing notes indicate that in the hours following this incident, surgical and nursing staff spent a significant amount of time with Mr A and counselling was offered. Blood tests were conducted to ensure that the patient whose blood contaminated the bellows did not have any contagious illnesses and further tests were conducted on Mr A to ensure that he had not contracted any illnesses from the incident.

Once alerted, the Public Hospital immediately apologised to Mr A. In addition, a review of sigmoidoscope use at the hospital was conducted. On 20 February 2001 a memo was circulated to clinical directors, clinical charge nurses, resident medical officers, the Chief of Medicine, Director of Nursing and Assistant Director of Nursing. This memo advised of changes to the use of sigmoidoscopes and included the following:

> "1. Filters that prevent the flow of bodily fluids into the tubing of the sigmoidoscope are to be used. These are single use items. Refer to the attached policy document for an explanatory diagram.
> 2. A label identifying clean equipment is to be introduced. An example is attached. Nursing staff will be trained in the introduction of this item in the areas utilising such scopes. Scopes that do not have this sticker intact on the tubing ought to be regarded as dirty and the tubing should be cleaned as per Step 4 on the attached protocol before use.
> 3. After use the non-disposable equipment should be taken to the dirty area of the ward/department for cleaning. E.g. Sluice room. Please do not neglect to do this as this minimises the potential for inappropriate misuse.

4. A number of new eyepieces will be purchased to enable these to be sent to CSSD [Central Sterilising and Supply Department] for sterilisation after use. If the availability of eyepieces is an issue, please ensure the CCN [Clinical Charge Nurse] is aware of this. CCNs should communicate this to [the Quality Manager and her extension number] who will monitor whether we have purchased a sufficient number of additional eye pieces."

Attached to this memo were instructions published by Welch Allyn on the use of filters and an example clean equipment sticker. On 28 February 2001 the following was incorporated into the Public Hospital's Infection Control Manual:

"***Infection control recommendation for care of sigmoidoscopy equipment***

1. Sigmoidoscopy Equipment

Purpose
To ensure staff involved in performing Sigmoidoscopies adhere to a standardised process, which protects the safety of the patient and the personnel involved.

Scope
Medical Staff
Registered Nurses
Enrolled Nurses
Student Nurses under the supervision of a registered nurse
Hospital Aides

Associated Documents

Procedure
The following steps must be followed by all staff involved in the Sigmoidoscopy procedure:

Step	Action
1	**Obtain the equipment:** • Sigmoidoscopy rubber tubing with bulb and light source which is labelled with a "cleaned" label. • CSSD packaged eyepiece (exception Gastro Day Ward, Theatre and Outpatients Departments where an eyepiece which has been sterilised with the unit is obtained). • Disposable scope, filter and luer cap. • Lubricant. • Tissues. • Non sterile gloves.

	• Trolley with rubbish bag attached.
2	**Procedure is performed by medical staff.**
3	**At Completion of the Procedure:** • The person performing the procedure is to ensure that they dispose of or assign another staff member to dispose of the disposable equipment into a biohazard rubbish bag, i.e. scope, filter, luer cap, tissues and gloves. • Ensure the "cleaned" label is removed off the remaining equipment and ensure this equipment is taken to the "dirty" area of the ward/department, e.g. sluice room.
4	**Cleaning of the equipment** in the "dirty" area of the ward/department: • Ensure disposable equipment has been discarded, i.e. scope, filter and luer cap. • Arrange for the eyepiece to be sent to CSSD for cleaning (exception Gastro Day ward, Theatre and Outpatient Departments where the eyepiece is sterilised in the department steriliser). • Wipe the light source, rubber tubing and bulb with Prephen. If rubber tubing and bulb is heavily contaminated, wipe with Prephen and send to CSSD for sterilisation. If this equipment is cleaned in the ward/department, ensure a "cleaned' label is placed around the equipment to signify to users that the equipment has been cleaned.
Note:	String bags around the tubing balloon should not be in use as they are a potential risk for infection.

The use of this policy was audited and it was amended and incorporated into the equipment procedures for outpatients, operating theatre, paediatric outpatients and the emergency department the following month. After further audit and review the following procedure was included in the infection control manual on 7 January 2002:

"***Infection control recommendation for care of sigmoidoscopy equipment***

1. Sigmoidoscopy Equipment (preparation and cleaning procedures)

Purpose
To ensure staff involved in performing Sigmoidoscopies adhere to a standardised process, which protects the safety of the patient and the personnel involved.

Scope
Medical Staff
Registered Nurses
Enrolled Nurses
Student Nurses under the supervision of a registered nurse
Hospital Aides

Associated Documents
Outpatients Department Sigmoidoscopy Equipment Procedure
Operating Theatre, Sigmoidoscopy Equipment Procedure
Paediatric Outpatients Sigmoidoscopy Equipment Procedure
Emergency Department Sigmoidoscopy Procedure

Procedure
The following steps must be followed by all staff involved in the Sigmoidoscopy procedure:

Step	Action
1	**Obtain the equipment:** • Sigmoidoscopy light source. • Sterile Supply Department packaged eyepiece and rubber tubing with bulb (exception Outpatients Department where equipment, which has been sterilised within the unit, is obtained). • Disposable scope (exception Paediatric Outpatients), filter and luer cap. • Lubricant. • Tissues. • Non sterile gloves. • Trolley with rubbish bag attached.
2	**Procedure is performed by medical staff.** **Note: The emergency Department protocol states that all patients undergoing sigmoidoscopy in the ED/EOA are to have a nurse chaperone present.**
3	**At Completion of the Procedure:** • The person performing the procedure us to ensure they dispose of or assign another staff member to dispose the disposable equipment into a biohazard rubbish bag, i.e. scope (exception Paediatric Outpatients), filter, luer cap, tissues and gloves. • Ensure the remaining equipment is taken to the "dirty" area of the ward/department, e.g. sluice room.
4	**Cleaning of the equipment** in the "dirty" area of the ward/department: • Protective clothing is worn • Ensure disposable equipment has been discarded, i.e. scope (exception Paediatric Outpatients), filter and luer cap. • Arrange for the eyepiece and rubber tubing with bulb, to be sent to Sterile Services for cleaning (exception Theatre and Outpatient Departments where the equipment is cleaned within the department). **Note:** Ensure the ward/department is identified to allow the equipment to be sent back to the same area.

	• Wipe the light source with Prephen.
Note:	String bags around the tubing balloon should not be in use as they are a potential risk for infection.

Independent advice to Commissioner

The following expert advice was obtained from Dr Geoff Hughes, an independent emergency medicine specialist:

"**Purpose of report**

I, Dr Geoffrey Hughes am employed as a consultant in emergency medicine and clinical director of Clinical Support Services at Wellington Hospital Capital Coast Health District Health Board. I am also chair of the Quality Improvement Group (committee) in the DHB and have a role as Director of Quality.

The Health & Disability Commissioner (HDC) has asked for independent emergency medicine advice to allow him to form an opinion on whether the care provided by various staff at the Public Hospital was provided with reasonable care and skill.

Background that has led to this request

On 4 February 2001, Mr A underwent diagnostic examination with a sigmoidoscope at the hands of Dr D, registrar, at the hospital. After the scope was withdrawn from Mr A following the examination, Dr D noticed blood on the floor and surrounds. Dr D examined the sigmoidoscope and found the bulb contained blood. Later investigation revealed the blood was from a previous patient examined by Dr C, registrar.

Consumers complaint

The patient (consumer) directly affected, Mr A, has written to the HDC complaining that on February 4 2001, a sigmoidoscope was used on him that was contaminated by a previous patient's blood.

Supporting information

The HDC has given me the following documents:-

- Complaint letter, labelled 'A'
- Mr A's medical notes, labelled 'B'
- Response from the Public Hospital, dated 18 March 2002, labelled 'C'
- Additional information provided by the Public Hospital, dated 23 May 2002, labelled 'D'

Questions asked

The HDC has asked me the following questions.

1. **In my opinion, did the use of a contaminated sigmoidoscope on Mr A occur as a result of substandard care and skill by the staff involved, or as a result of a systemic problem?**

2. **Is it usual practice for a hospital such as the Public Hospital to have a policy in relation to infection control for sigmoidoscope use and cleaning?**

3. **Should the procedures introduced by the Public Hospital after this incident prevent a reoccurence?**

Comment and opinion

The background to this case is briefly described above and is also well described and documented in the clinical notes. I do not feel the need to repeat all the details of the incident here.

The documents sent to me also detail the processes that occurred after the incident happened.

Before answering the questions put to me by the HDC I will start by making some general comments.

Quite clearly this incident should not have happened. It is axiomatic that any patient who is being treated or investigated with any piece of medical equipment should expect that the equipment is clean and not soiled with body fluids from another patient.

Medical equipment may be new and disposed of after each usage or it is reused. If it is reused then it can be 'prepared' for the next patient or usage in many ways. The details of this preparation will vary, depending on exactly what the equipment is. Some equipment will come with instructions from the manufacturer on how it is to be cleaned.

It is reasonable to expect an organisation such as a hospital to have guidelines to help staff maintain and clean equipment to the required standard. Within a hospital different departments may use a similar (or the same) piece of equipment. For example a sigmoidoscope may be used in an operating theatre, an outpatient clinic and a ward. Within these areas it may be used by doctors from different specialties. The guidelines should cover all the different areas in which the equipment is used, to ensure consistency.

Reusable equipment may be 'prepared' for next usage 'locally' in the area in which it used or be returned to a centralised cleaning and sterilisation service. The exact path that a piece of equipment follows will depend on what it is and 'local' guidelines.

I will now answer the specific questions from the HDC.

1. In my opinion, did the use of a contaminated sigmoidoscope on Mr A occur as a result of substandard care and skill by the staff involved, or as a result of a systemic problem?

I believe the incident occurred as a result of a systemic problem. Although the reality is that the failure to clean the sigmoidoscope properly after its previous usage may be due to the failure of one or two individuals to do the cleaning or send it to a centralised cleaning service, the other reality is that there do not appear to have been any guidelines in place. Any individuals involved are really nothing more than victims of a systemic error.

The confidential Quality Assurance Report under paragraph 2.1.1 notes that one of the actions to be taken following the incident is the preparation of guidelines for the cleaning of all parts of such equipment. This responsibility was delegated to the infection control team. The very fact that this is reported as an action to be taken suggests that no existing policy, protocol or guidelines for the cleaning of such equipment was in place at the time of the incident. This implies a systemic error rather than specific individual error.

2. Is it usual practice for a hospital such as the Public Hospital to have a policy in relation to infection control for sigmoidoscope use and cleaning?

I think it is reasonable to expect that a hospital such as the Public Hospital would have a policy in place in relation to the cleaning of a sigmoidoscope. As stated earlier in my general introductory comments this should be in place. This policy may be part of a generic policy relating to the cleaning of other 'hollow tube' investigation devices (such as endoscopes) or it may be a specific policy written for a sigmoidoscope.

It would normally be expected that such a policy would be part of an organisation policy manual. Such a manual may be available as a hard copy or electronic copy, or both.

A policy and procedures manual would be developed or overseen by an organisational quality committee. The actual name of the quality committee may vary from organisation to organisation. Such a manual forms the backbone to consistency of practice in a hospital and also forms a key framework to the accreditation of an organisation by an external accreditation agency.

3. Should the procedures introduced by the Public Hospital after this incident prevent a reoccurence?

It is quite clear from the investigation and work done following the incident that the organisation responded very quickly and appropriately. They appeared to have acted with due sensitivity. It is my opinion that the work they have done to formalise and document future procedures should go a long way to preventing a reoccurence of an incident like this. I don't think it is possible to say it will NEVER happen again (because of the nature of human frailty and human involvement) but it is extremely unlikely it will ever happen again.

I think they can be congratulated on the way they have responded.

Summary

Mr A has been the unfortunate sufferer of an unusual but preventable incident. Although specific individuals may have failed to complete some standard and routine processes the reality is that they were victims of a failure of a policy/guidelines vacuum in the Public Hospital.

The organisation has responded quickly and appropriately since the incident. Their new policy should go a long way to reducing the risk of a similar event happening again. I do not think it is possible to say that it will NEVER happen again."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

1) Every consumer has the right to have services provided with reasonable care and skill.

…

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.

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Opinion: Breach – The Public Hospital

Right 4(1) and 4(4)

Mr A had an invasive procedure conducted with a device that was contaminated with someone else's blood. As my emergency medicine advisor, Dr Hughes, stated "it is axiomatic that any patient who is being treated or investigated with any piece of medical equipment should expect that the equipment is clean and not soiled with bodily fluids from another patient. Although no physical injury resulted, this incident would have resulted in considerable unnecessary distress and anxiety for Mr A.

It could be argued that the individuals involved should bear some responsibility for what happened to Mr A. However Dr Hughes advised me that the staff members involved were effectively victims of a systemic error that resulted from a lack of guidance by the Public Hospital.

Although sigmoidoscopes had been in use at the hospital since 1995, there were no policies, protocols or guidelines for cleaning the equipment at the time of this incident. Dr Hughes advised me that he would have expected there to have been a section of the the Public Hospital policy manual that dealt with either the cleaning of sigmoidoscopes specifically, or a generic policy that dealt with all 'hollow tube' investigation devices.

I also note that in August 1999 the hospital had been approached by a USL representative who offered to give instructions on the use of filters specifically designed to prevent contamination of the bellows unit. While the offer was taken up, the representative only gave one lesson (to the Outpatients Department) before being told that her instructions would be circulated and incorporated into the company manual. Although practice in the Outpatients Department did change to incorporate filter use after this lesson, other departments were not advised on the use of filters and no policy was incorporated into the company manual.

I accept the advice of my advisor. In my opinion, the Public Hospital's failure to have an appropriate policy in place to cover the use and cleaning of sigmoidoscopes amounted to a failure to provide services with reasonable care and skill and in manner that minimised the potential harm to Mr A and is a breach of Right 4(1) and Right 4(4) of the Code.

Actions

I have no recommendations to make to the Public Hospital in light of the prompt and appropriate action it has already undertaken, in particular to apologise to Mr A and to develop and implement procedures to prevent a recurrence.

A copy of my opinion will be sent to the Medical Council of New Zealand.

Copies of my opinion with all identifying details removed will be sent to the Chief Executive Officers of all District Health Boards, the Royal Australasian College of Physicians, the Nursing Council of New Zealand and placed on the Health and Disability Commissioner's website, www.hdc.org.nz, for educational purposes.

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