

Health Care Complaints Commission

Report on an investigation of
incidents in the
Operating Theatre at

Canterbury Hospital
8 February - 7 June 1999

3 September 1999



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1. Executive Summary

On 08 June 1999 , the Commissioner met with the Chief Executive Officer and Chairman of the Central Sydney Area Health Service about an incident at Canterbury Hospital.

On 09 June 1999 the Health Care Complaints Commission assessed a complaint against Canterbury Hospital and the VMO physician, for investigation.

1.2 Investigation of the systemic problems

A number of systemic problems have been identified that relate to the supply of a solution containing phenol to the operating theatres. The Commission has found that:

- 1.2.1 The computerised requisition system, Oracle, was inadequate;
- 1.2.2 The staff in the hospital pharmacy had inadequate training in the use of Oracle;
- 1.2.3 There was no feedback loop in the requisition system, to detect a significant change in a pattern of requisition over time.
- 1.2.4 A contrast medium in a 20ml vial costing \$7.50 was replaced with a solution containing phenol in a 5ml vial at a cost of \$21. There was no system to detect a requisition which caused a cost increase, repeated over a five month period.
- 1.2.5 A contrast medium was replaced with a caustic solution and no health professional in the operating theatre adequately checked the solution before it was injected into the patient.

1.3 Recommendations to the Director-General to address the systemic problems

The Commission has proposed the following recommendations to Central Sydney Area Health Service to address the problems identified in this investigation:

- 1.3.1 that Canterbury Hospital develop as a matter of priority policies protocols or guidelines to address the deficiencies in the requisition and supply of goods in the Pharmacy Department and the Operating Theatre;
- 1.3.2 that processes be developed to ensure that unusual orders for goods, (such as first time use of a special purpose product, increased use of a product or increased cost) are flagged and followed up by the supply service;
- 1.3.3 that Canterbury Hospital review the roles and responsibilities of nursing staff in the Operating Theatre, including the checking of solutions in use in the Operating Theatre, and involve all staff in mandatory in-service education about these responsibilities;
- 1.3.4 that Canterbury Hospital develop and implement a review program for surgeon's preference sheets and guidelines for operative procedures;
- 1.3.5 that Canterbury Hospital develop a comprehensive annual rotating education program to include appropriate documentation in the operating theatre, roles and responsibilities of the nurse, and practice standards to maintain patient safety;
- 1.3.6 that a system is in place to monitor costs in the operating theatre, to detect at an early stage deviations from expected expenditure, and take appropriate action to identify the problem.

In view of the broader systemic similarities to another investigation, the Commission is making the following state wide recommendations to the Director-General of Health:

1. Establish a multi-disciplinary working party with the following terms of reference:
 - A. Review and develop requisition and supply systems for use by all Area Health Services and facilities to make them consistent, accurate efficient and fail-safe.
 - B. Review on a state-wide basis the professional services supplied by Hospital Pharmacy Departments to Theatres. The review should address the assessment of the suitability of products used in Theatres. State-wide protocols should be developed after this review.
 - C. Develop a written protocol for all health care facilities for the checking of solutions and other pharmaceuticals before use in Theatres.

(The working party should include a representative of the Australian Confederation of Operating Room Nurses in respect of the last term of reference.)
2. Review current department publications, including Circulars, Policies and Protocols, relating to documentation of operative procedures to ensure that all significant data is recorded accurately in medical records and that there is an effective ongoing audit process in each facility so that the quality of records is maintained.
3. Establish a working party to review the current practices for developing and disseminating Department Circulars, Area and Hospital Policies and Protocols to ensure they are consistent and implemented.

1.4 Investigation of the medical practitioner

The investigation of the standard of care provided by the medical practitioner who performed the twenty-eight (28) procedures has been finalised. The findings and outcome of the investigation are subject to consultation with the NSW Medical Board, pursuant to s38 and s39(2) of the Health Care Complaints Act. The Commission will consult with the NSW Medical Board about the outcome of the investigation in September.

1.5 Investigation of individual nursing practitioners

The investigation of the standard of care provided by the nursing staff in the operating suite is being finalised. The Commission will provide the practitioners with the opportunity to make a submission before consulting with the NSW Nurses Registration Board about the outcome of the investigation. The findings and outcome of the investigation are subject to consultation with the NSW Nurses Registration Board, pursuant to s38 and s39(2) of the Health Care Complaints Act.

To assist your understanding of the factual material, please refer to the glossary at the end of the report.

2. Preface

The Health Care Complaints Commission (the Commission) is a statutory body that acts in the public interest by investigating, monitoring, reviewing and resolving complaints about health care with a view to maintaining and improving the quality of health care services in New South Wales.

The Health Care Complaints Act 1993 (the Act) requires the Commission to investigate a complaint if the complaint raises a significant issue of public health and safety. This complaint involves a trail of errors that raise serious concerns about existing mechanisms established to keep patients safe.

At the conclusion of the investigation, the Commission must, under the Act, do certain things: each respondent, the health facility and any individual health practitioner must be given the opportunity to provide a submission about the proposed outcome of the investigation, as required by s43 and s40 of the Act.

Before the parties to a complaint are advised of the outcome, the Commission must consult with the relevant registration board, pursuant to ss 38 and 39(2) of the Act.

The Commission must provide a report to the Director-General of NSW Health about adverse comments made about the standard of care at a health facility, pursuant to s42 of the Act.

In summary, owing to the requirements of the Health Care Complaints Act, this report does not address any aspects of the complaint concerning individual health practitioners. This report addresses the problems raised at Canterbury Hospital and which are believed to be state-wide, requiring immediate action by the NSW Department of Health to reduce the likelihood that further patients will be exposed to an incorrect solution during an operative procedure.

The Commission would like to acknowledge the following assistance provided by:

Mallinckrodt Australia Pty Ltd, 11 Corporate Avenue, Rowville Vic (Mallinckrodt Medical Pty Ltd until July 1999) for the supply of exhibits and information about Conray 280

Ophthalmic Laboratories Pty Ltd 41 Sydenham Road, Brookvale NSW for the information about Phenol 10% in 60% Conray 280

NSW Police for the production of digital forensic photographs.

3. Sources of Information

On 09 June 1999, the Commission obtained copies of the patient records and ERCP films. Information was obtained from interviews with staff directly involved in the requisition and receipt of goods and with the handling of the solutions in the operating theatre. The Commission also obtained written reports from key medical and nursing staff.

The Witness List gives the sources of information by interview or report. In addition the Commission obtained a number of reports on the facts from the Central Sydney Area Health Service.

Witness List

1. RN, Operating Theatres, Canterbury Hospital (scout)
2. RN, Operating Theatres, Canterbury Hospital (scout)
3. RN, Agency (scout)
4. RN, Recovery, Canterbury Hospital
5. RN, Agency (scout)
6. Medical practitioner (endoscopist)
7. Managing Director, Ophthalmic Laboratories
8. Chief Pharmacist, Canterbury Hospital
9. RN, Operating Theatres, resigned April (scout)
10. RN, Operating Theatres, Canterbury Hospital (**instrument**)
11. Manager, Operating Theatres, Canterbury
12. Medical Registrar, Canterbury Hospital
13. RN, Operating Theatres, Canterbury Hospital (**instrument**)
14. RN, Operating Theatres, Canterbury Hospital (NUM)
15. RN, Recovery, Canterbury Hospital
16. RN, Operating Theatres, Canterbury Hospital (**instrument**)
17. RN, Operating Theatres, Canterbury Hospital, Acting Clinical Nurse Educator
18. RN, Anaesthetic nurse, Canterbury Hospital
19. RN, Operating Theatres, Canterbury Hospital (**instrument**)
20. RN, Agency (scout)
21. Manager, Central Sterile Supply Services
22. RN, Operating Theatres, Canterbury Hospital (scout)
23. RN, Recovery, Canterbury Hospital
24. RN, Recovery, Canterbury Hospital
25. Pharmacy Clerk
26. RN, Agency
27. Pharmacy Assistant
28. RN, Agency (scout)
29. Manager, Pharmaceutical Supply Services (PSS)
30. RN, Operating Theatres, Canterbury Hospital (scout)
31. VMO Anaesthetist, Canterbury Hospital

RN = Registered Nurse, NUM = Nursing Unit Manager, VMO = Visiting Medical Officer

4. The Complaint

The Central Sydney Area Health Service reported an incident to the Director-General of NSW Health on 08 June 1999. The incident concerned the injection of a solution containing phenol, a caustic substance, into the biliary tree and / or pancreatic duct of patients undergoing endoscopic procedures at the Canterbury Hospital operating theatres in the period between 04 February and 07 June 1999.

The Central Sydney Area Health Service also made a complaint to the Health Care Complaints Commission and identified the health professionals who were directly involved in the use of a solution containing phenol during Endoscopic Retrograde Cholangio Pancreatography (ERCP) procedures at Canterbury Hospital.

On 07 June 1999, on completion of an ERCP (Endoscopic Retrograde Cholangio-Pancreatography) in the Operating Theatres at Canterbury Hospital, it was noted by a scout nurse that the solution used as contrast medium during the procedure was the caustic solution, Phenol 10% in 60% Conray 280. The contrast medium intended for this procedure at Canterbury Hospital was Conray 280, 20ml.

The matter was reported by the health professionals in the operating theatre to Canterbury Hospital management and subsequently, the Central Sydney Area Health Service. It appeared that from 01 February 1999, supplies of Conray 280, 20ml, at Canterbury Hospital had been substituted with 5ml bottles of a diluted form of 'Conray 280' which also contained 10% Phenol, a product clearly labelled 'use under strict medical supervision - caustic substance' and 'single dose vial'.

Central Sydney Area Health Service identified 24 patients who had a total of 28 procedures (some patients had two ERCPs between 04 February 1999 and 07 June 1999.) Most of these patients were exposed to the incorrect solution containing Phenol during ERCP procedures.

4.1 The hospital

Canterbury Hospital is a district level hospital serving almost 200,000 people living in Canterbury and parts of Marrickville and Ashfield. The facility opened in 1929 and serves the most ethnically diverse population in NSW, with 44 to 48 per cent from a non-English speaking background.

Canterbury Hospital is part of the Central Sydney Area Health Service. The hospital was redeveloped from June 1996 to July 1998. The new Operating Theatre Suite has five operating rooms, and no designated endoscopy room. Over the period 01 February to 07 June 1999, all operating rooms were used for ERCP procedures.

4.2 The procedure

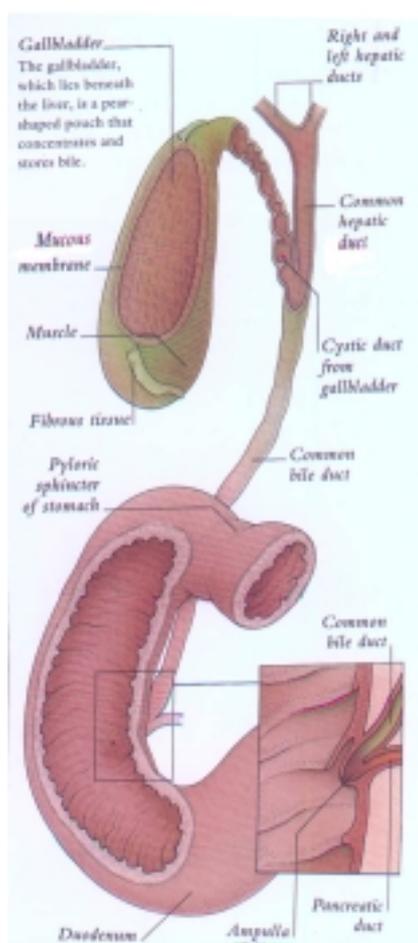


DIAGRAM 1A: THE BILIARY SYSTEM
Smith T(Ed) *The Human Body* p.161

ERCP is a diagnostic procedure performed where there is a suspected disorder of the gallbladder. A fiberoptic duodenoscope, a type of endoscope, is inserted by the medical practitioner conducting the procedure into the patient's mouth and guided through the oesophagus to the duodenum. Cannulas are then directed through the duodenoscope and placed in the common bile duct. A contrast medium is injected through the cannulas into the ducts so that x-ray films can be taken.

Diagram 1A shows the structure of the biliary system. Diagram 1B the location of the fiberoptic duodenoscope during an ERCP, and Diagram 1C the position of the duodenoscope and cannula during an ERCP.

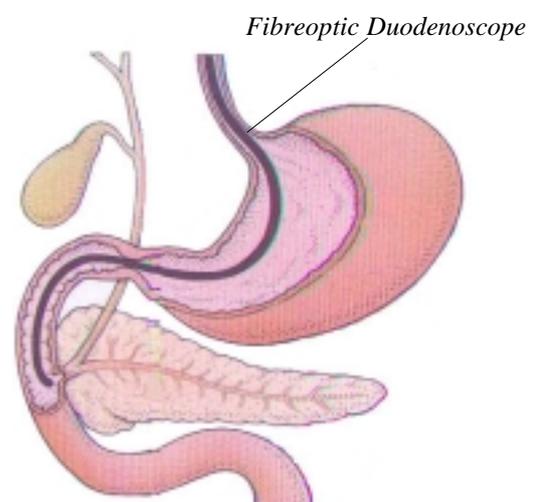


DIAGRAM 1B: POSITION OF THE DUODENOSCOPE
Smith T(Ed) *The Human Body* p.151

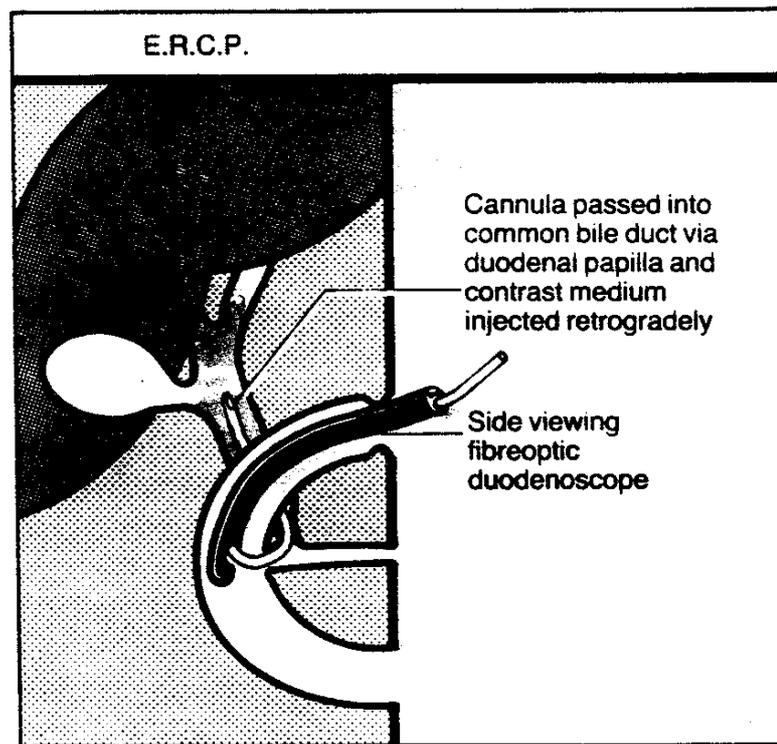


DIAGRAM 1C: POSITION OF THE CANNULA
 Burkitt, Quick and Gatt, p.43

The procedure is performed by a medical officer with specialist qualifications as a surgeon or physician. ERCP is a complex procedure which involves a team approach to enable the smooth coordination between nurses and doctors who are both using a wide variety of equipment. It is not a sterile procedure but Department of Health infection control guidelines are followed to prevent transmission of infection from patient to patient when the contrast medium is injected into human tissue.

ERCP is performed in an Endoscopy Unit, Radiology Department or Operating Theatre. At Canterbury Hospital, the procedure of ERCP had been carried out in the Operating Theatres since 1996. The last ERCP procedure performed in the Radiology Department of Canterbury Hospital was on 25 March 1996. During the redevelopment of Canterbury Hospital, the hospital used Concord Hospital Theatres for ERCP from 21 June 1996, and the last ERCP was performed there on 23 June 1998.

The first ERCP performed in the new theatres at Canterbury Hospital was on 6 July 1998 and the last on 7 June 1999.

At Canterbury Hospital, an anaesthetist was present in the operating theatre for all procedures to monitor cardiopulmonary complications, the most common complication of endoscopy.¹ The role of the anaesthetist is to monitor the patient's level of consciousness and cardiorespiratory status during sedation when the patient remains conscious for the procedure.

But most of the ERCP patients were under a general anaesthetic during the procedure, requiring close supervision by an anaesthetist while the patient was unconscious.

Table 1 shows the proportion of the 28 procedures where the patient was sedated or under general anaesthetic during the procedure. There were four anaesthetists involved, labelled a,b,c,d.

Table 1
list of 28 ERCP procedures at Canterbury Hospital:
anaesthetist present / type of anaesthetic
Intravenous sedation (IV): general anaesthetic (GA)

Patient	Date of Procedure	Anaesthetist	Type of Anaesthetic
1	01 February	a	IV
2	08 February	a	IV
3	01 March	a	GA
4	01 March	a	GA
5	08 March	a	GA
6a	08 March	a	GA
6b	15 March	a	GA
7	22 March	a	GA
8a	22 March	a	GA
8b	29 March	a	GA
9	29 March	a	GA
10	29 March	a	GA
11a	12 April	b	GA
11b	19 April	c	GA
12	19 April	c	GA
13a	03 May	c	GA
13b	31 May	c	GA
14	03 May	c	GA
15	03 May	c	GA
16	03 May	c	GA
17	10 May	b	IV — GA
18	10 May	b	IV
19	10 May	b	IV
20	24 May	b	GA
21	24 May	b	GA
22	31 May	c	GA
23	04 June	d	GA
24	07 June	b	GA
Total = 24 patients 28 procedures	01 February to 07 June	anaesthetists = 4	IV : GA = 4 : 24 RATIO 1:6

During the procedure, there would be at least three nurses present: an instrument (scrub) nurse, a scout (circulating) nurse, and an anaesthetic nurse. The instrument nurse assists the medical officer with the procedure by preparing the equipment including the duodenoscope, the solutions for injection and injects the solutions into human tissue during the procedure.

The nursing staff present in the operating theatre, and their functions are identified in Table 2. In addition, some procedures had an additional nurses listed on the Operating Suite Nurses Report.¹

There were 24 nurses (identified by letter of the alphabet in **(Table 2)**) involved in 28 procedures with one nurse the Team Leader (TL) for 27 of the 28 procedures. The four instrument nurses were hospital employees, while eight of the scout nurses were from an agency that supplies temporary nurses. Some of the scout nurses had also worked in the role of anaesthetic nurse.

Table 2
List of RN witnesses in the Theatre

Source: Operating Suite Nurse Report & Theatre Allocation Sheet

Patient	Date 1999	Instrument RN	Scout RN	other RN	Anaesthetic RN	Procedure start	Procedure finish
1.	01/02	TL = A	E		R	(start 13 50)	14 08
2.	08/02	TL = B	A		S	(start 14 35)	14 30
3.	01/03	TL = A	F	I	S	(start 14 05)	14 30
4.	01/03	TL = A	F	I	S	(start 15 30)	15 47
5.	08/03	TL = A	G		T	(start 16 55)	17 10
6a.	08/03	TL = A	B	H	S	(start 14 20)	15 05
6b.	15/03	TL = A	G		U	(start 13 54)	14 34
7.	22/03	TL = A	C		S	(start 14 15)	14 55
8a.	22/03	TL = A (C)	I		B	(start 15 50)	17 53
8b.	29/03	TL = A	J	F	S	(start 17 23)	18 24
9.	29/03	TL = A	J		S	(start 14 00)	16 25
10.	29/03	TL = A	J		S	(start 16 10)	16 39
11a.	12/04	TL = A	K	B	V	(start 14 43)	15 23
11b.	19/04	TL = A	L		W	(start 14 56)	16 01
12.	19/04	TL = A	L		W	(start 14 00)	14 13
13a.	03/05	TL = A	C		X	(start 14 00)	14 25
13b.	31/05	TL = A	M		V	(start 15 40)	16 15
14.	03/05	TL = A	C		X	(start 14 45)	15 08
15.	03/05	TL = A	D		X	(start 15 30)	15 57
16.	03/05	TL = A	C		X	(start 16 15)	16 50
17.	10/05	TL = A	N		Q	(start 14 10)	14 58
18.	10/05	TL = A	N		Q	(start 15 54)	16 07
19.	10/05	TL = A (D)	N	Y	Q	(start 17 10)	17 45
20.	24/05	TL = A	O		Z	(start 15 40)	16 10
21.	24/05	TL = A	O		Z	(start 13 55)	14 30
22.	31/05	TL = A	M		X	(start 13 47)	14 37
23.	04/06	TL = A	P		Z	(start 1707)	17 53
24.	07/06	TL = A	Q		V	(start 14 00)	15 38
Total Procedures = 28			Agency Scout RN = 08				

4.3 The patients

Central Sydney Area Health Service identified 24 patients who had a total of 28 procedures (some patients had two ERCPs between 04 February 1999 and 07 June 1999.) Most patients had been exposed to the incorrect solution containing Phenol during ERCP procedures. The medical records for all patients related to the ERCP were examined by the Commission. **Table 3** describes the demographics of the patients who had ERCP procedures. See **Document 1** for a copy of a pro forma letter sent to 22 of the 24 patients about the investigation.

Table 3
List of Subjects booked for an ERCP at Canterbury Hospital

Patient	Age	Sex	Date and time of procedure	Theatre
1.	>60	M	01 February 1999 at 13 50hrs	(OT 5)
2.	>80	F	08 February 1999 at 14 35	(OT 5)
3.	>60	M	01 March 1999 at 14 05	(OT 4)
4.	>70	F	01 March 1999 at 15 30	(OT 4)
5.	>80	F	08 March 1999 at 16 55	(OT 2)
6.	>40	F	08 and 15 March 1999 at 14 20 / 13 54	(OT 2 / 5)
7.	>40	F	22 March 1999 at 14 15	(OT 2)
8.	>60	F	22 and 29 March 1999 at 15 50 / 17 23	(OT 2 / 5)
9.	>80	F	29 March 1999 at 14 00	(OT 5)
10.	>50	M	29 March 1999 at 16 10	(OT 5)
11.	>50	M	12 and 19 April 1999 at 14 43 / 14 56	(OT 1 / 2)
12.	>40	F	19 April 1999 at 14 00	(OT 1)
13.	>30	F	03 and 31 May 1999 at 14 00 / 1540	(OT 3)
14.	>70	M	03 May 1999 at 14 45	(OT 3)
15.	>50	F	03 May 1999 at 15 30	(OT 3)
16.	>30	F	03 May 1999 at 16 15	(OT 3)
17.	>80	F	10 May 1999 at 14 10	(OT 4)
18.	>40	M	10 May 1999 at 15 54	(OT 4)
19.	>60	F	10 May 1999 at 17 10	(OT 4)
20.	>60	M	24 May 1999 at 15 40	(OT 1)
21.	>70	M	24 May 1999 at 13 55	(OT 1)
22.	>60	F	31 May 1999 at 13 47	(OT 3)
23.	>30	F	04 June 1999 at 17 07	(OT 1)
24.	>60	F	07 June 1999 at 14 00	(OT 1)

SUMMARY: 24 PATIENTS age range over 30 to over 80
28 PROCEDURES of which there was one emergency
All theatres used for an ERCP (1-5)
One patient was recovered in the theatre, not in the Recovery Room, owing to the presence of Methicillin Resistant Staphylococcus Aureus (MRSA)

4.4 The contrast medium

Conray 280 is an iodine based contrast medium. Contrast media increase the absorption of x-rays as they pass through the body and are used to delineate body structures on x-ray.

Contrast media are not “pharmaceutical” products. Conray 280 is imported from Canada and supplied in Australia in 50 ml and 20 ml bottles (vials) by Mallinckrodt Medical Pty Ltd. (Now Mallinckrodt Australia Pty Ltd)

In 1998, the vial size requisitioned by Canterbury Hospital was 20mls. (Photograph 1)



PHOTOGRAPH 1: CONRAY 280, 20ML VIAL

The contrast medium Conray 280 has been used during ERCP procedures at Canterbury Hospital since 1996. Until 1998, the vial size requisitioned was 50mls (see photograph 2) However, to comply with departmental guidelines to avoid using multi-use vials to reduce the risk of patient to patient transmission of infection, only 20ml vials were requisitioned from 1998.



PHOTOGRAPH 2: CONRAY 280, 50ML

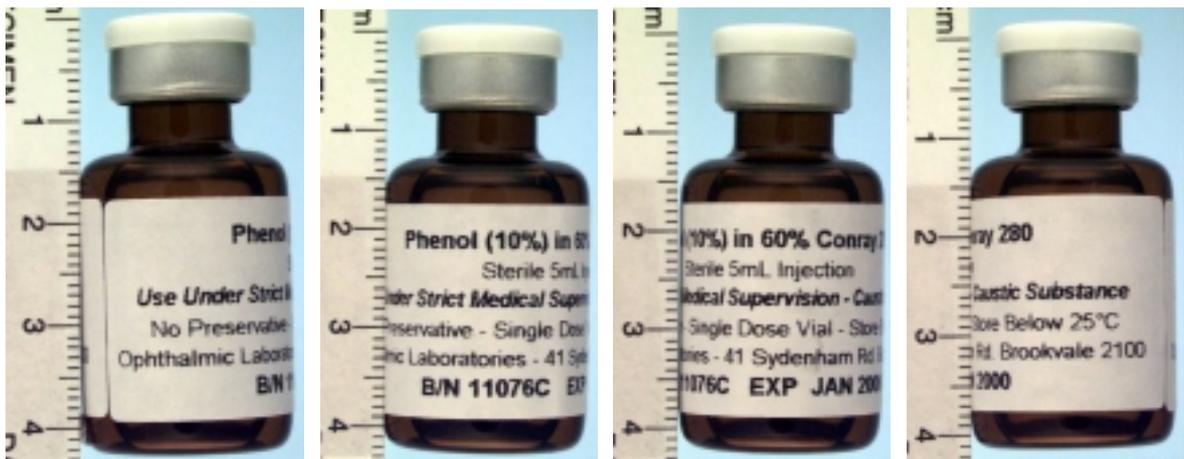
4.5 The solution containing phenol

Phenol is a crystalline compound derived from coal tar or plant tars. It is an antiseptic and disinfectant active against a wide range of micro-organisms. It is a caustic, corrosive substance and has been used therapeutically as a sclerosing agent (causing hardening of tissue). For example, Operating Theatres at Canterbury Hospital stock the product Phenol 5% in Almond Oil, which is used to sclerose haemorrhoids.

Phenol 10% in 60% Conray 280 is not a registered pharmaceutical product but is made appropriately under a special exemption clause provided for by the Therapeutic Goods Act, by a company licenced under the Act. It is made in limited amounts on receipt of an appropriate order and for a specific documented purpose. The purpose for which the product is to be used is stated on the order form (DEB9 form, **Document 2**), as required by the Therapeutic Goods Act. Phenol 10% in 60% Conray 280 is designed to cause scarring of tissues under radiographic control for purposes such as nerve blocks in pain management. The Conray 280 in the solution enables that radiographic control.

The photographs below (photograph 3) show the 05ml vial being turned so the full label may be read.

Note the warning *Use Under Strict Medical Supervision - Caustic Substance*



PHOTOGRAPH 3: PHENOL 10% IN 60% CONRAY 280, 05ML VIAL

5. Two Central Questions

How was the correct solution, Conray 280, a contrast medium, replaced by an incorrect solution containing phenol, Phenol 10% in 60% Conray 280, a caustic solution, at Canterbury Hospital?

How did the incorrect solution, Phenol 10% in 60% Conray 280, a caustic substance, come to be used during ERCP procedures at Canterbury Hospital during the period 01 February 1999 to 07 June 1999?

6. Analysis - the Answers

6.1 How was the correct solution, Conray 280, the contrast medium, replaced with an incorrect solution containing Phenol and 60% Conray 280.

The usual procedures for requisition and supply of solutions described by staff provided a number of opportunities to check that the product requisitioned was the correct product and that the product received was the same as the product requisitioned. These procedures are described in **Table 4** and outlined in the flowchart below (Diagram 2).

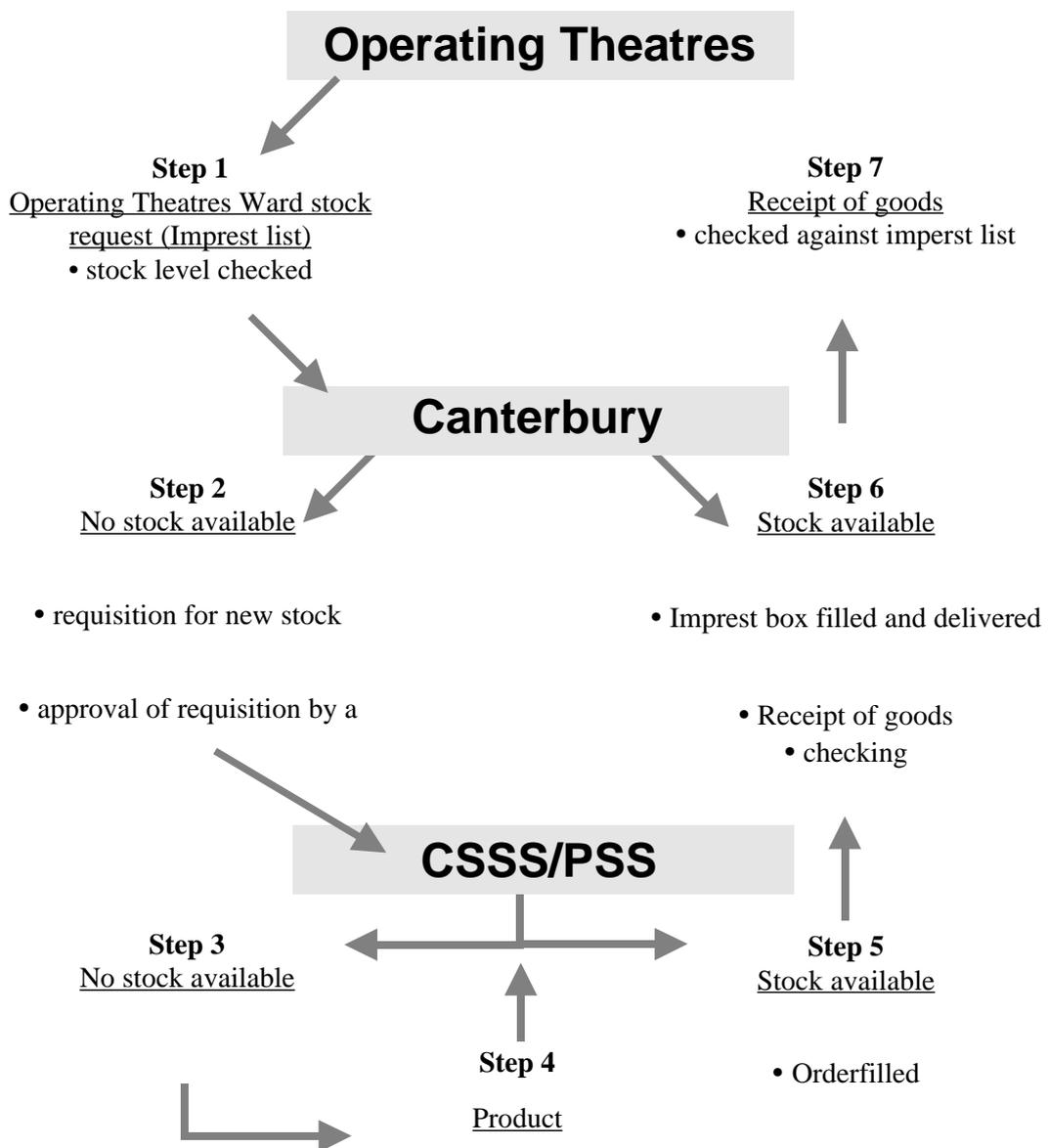


Diagram 2: Flowchart summarising the usual procedure at Canterbury hospital for requisition and receipt of Conray 280

Analysis of the requisition and supply of Conray 280 to Operating Theatres at Canterbury Hospital from 05 January 1999 to 07 June 1999:

Table 4
Procedure for requisition and receipt of solutions in use
in the Operating Theatres.

Step1	<p>Operating Theatres Ward Stock Request Form (Imprest list) <i>(Document 3)</i></p>	<p>The imprest list is a hard copy checklist of items regularly used in the Operating Theatres at Canterbury Hospital and requisitioned from the Canterbury Hospital Pharmacy. A working supply of each item is stored in the Operating Theatres for ease of access. The common name of the product and the number and size of packs or items kept in stock are documented on the imprest list. The form is multi-use with 13 columns provided for ongoing checks over a period of time.</p> <p>The imprest list form is provided to Operating Theatres by Canterbury Hospital Pharmacy. If the supply of stock changes, the imprest list may be amended by hand, but it is updated on the computer before the new form is printed once the 13 columns are filled.</p>
	<p>Checking Operating Theatres stock levels</p>	<p>The Nursing Unit Manager in Operating Theatres allocated the task of checking the stock levels of the items on the imprest list to Recovery nursing staff.</p> <p>Recovery nursing staff check the stock levels on Tuesday and Thursday each week. The number of units or packs of each imprest list item remaining in stock is counted. There is no set stock level at which new stock is requisitioned. If the nurse checking the stock considers that additional stock is required, the number of packs or items required is recorded on the imprest list. On completion, the nurse initials the form for the appropriate date.</p>
	<p>Requisition of stock by Operating Theatres</p>	<p>The completed imprest list, with notation of the numbers of items requisitioned, is then returned to Pharmacy.</p>

Step 2

Requisition of stock by Pharmacy

The Canterbury Hospital Pharmacy stored items that are frequently requisitioned. When the imprest list from Operating Theatres is received, the requisition is filled by the pharmacy assistants, where possible, from existing stock.

The Canterbury Hospital Pharmacy uses a “working ordering sheet”. Whenever a member of the Pharmacy staff picks an item from the shelves to fill a requisition, if stock is running low, this item will be written on the “working ordering sheet”.

This “working ordering sheet” is used to make an online requisition through the Central Sydney Area Health Service.

This computerised system, ‘**Oracle**’, is used throughout Central Sydney Area Health Service. It allows orders to be sent on-line from hospitals to Central Sydney Supply Service (CSSS) and Pharmacy Supply Service (PSS).

The Central Sydney Area Health Service catalogues goods so that the prefix will indicate if the item is to be requisitioned as a pharmaceutical (prefix ‘P’ or ‘X’ for a narcotic), and ordered through PSS, while the number ‘1’ indicates that the item is non-pharmaceutical and may be ordered through CSSS.

Access to the Oracle system is by **password**. Each staff member required to use the system is issued with a password. The staff member is provided with the level of access necessary to their position.

The Canterbury Hospital pharmacy clerk completes a **requisition form** using the Oracle system. Items, catalogued on the system as ‘**inventory items**’,² can be located and added to the requisition list by a number of methods including by catalogue number. Where a catalogue number is not known, a ‘**search**’ or ‘**query**’ can be initiated using the item name, or part of the item name to locate the full name, catalogue number and description of the item to be requisitioned. Where part of the item name is used in the search, all items with the search phrase, or ‘colloquial’ included in the full product name will be listed.

The clerk can then select the appropriate item from the list.

However, not all items requisitioned by Canterbury Hospital Pharmacy are catalogued by the Central Sydney Area Health Service.

Such non-catalogued items could be requisitioned as a **miscellaneous** item. Conray 280 is requisitioned as a miscellaneous item.

In this case, the Canterbury Hospital pharmacy clerk would type in the full name of the product on the requisition form.

Once the electronic requisition form is completed with the orders on the screen, the Canterbury Hospital pharmacy clerk requests approval from a pharmacist. The electronic approval is attached to passwords of the pharmacists who authorise the requisition by inserting their password, and the requisition is electronically dispatched to PSS.

Step 3 Requisition by the Pharmacy Supply Service (**PSS**)

When a requisition is received by PSS, if items are not already held in stock, PSS requisitions stock from the manufacturer or distributor. The appropriate buyer arranges purchase of new stock.

In the case of Conray 280, 20ml, PSS last requisitioned the product from Mallinckrodt Medical in October 1998.

When stock is received at PSS, delivery to the Canterbury Hospital Pharmacy is arranged. A **pick slip** generated by the Oracle system from the original approved requisition is used to select appropriate items.

This pick slip becomes the **delivery receipt** which accompanies the items on despatch from PSS.

Step 4 Delivery to the Pharmacy Department, Canterbury Hospital

The stores provided by PSS are **signed for** by the person taking delivery at Canterbury Hospital.

The **pharmacy assistant/clerk** prepares an imprest delivery for Operating Theatres, **checks the items** selected against the imprest list, ticks (✓) each item selected and packs for despatch to operating theatres.

If an item is out of stock, the pharmacy assistant/clerk writes the letters "os" next to the number of items requisitioned. The item is delivered when new stock is available.

Step 5 Delivery to **Operating Theatres**, Canterbury Hospital

The **imprest list** is returned to operating theatres with the stock delivery. A **delivery receipt** also accompanies the requisition provided by the Pharmacy Department to Operating Theatres.

Step 6 Receipt of goods by recovery staff
(**Document 4**)

Recovery staff check the items received against the imprest list and delivery receipt. Items are then placed in the appropriate stock cupboard in operating theatres for use. If any item delivered is found to be incorrect in any way, the nurse contacts Pharmacy.

The circumstances outlined in **Table 4** which resulted in Phenol 10% in 60% Conray 280 being supplied instead of Conray 280 are analysed in more detail below. Further detailed information is also available in **Document 5**.

Step 1. The Ward Stock Request Form (imprest list):

At the beginning of 1999, the imprest list for Operating Theatres included the item Conray 280, **50ml**. The number of packs listed as being kept in stock by Operating Theatres was one (1) and the pack size listed was ten (10) items.

Although the imprest list said the item was Conray 280 **50mls**, the solution in stock in 1998 was Conray 280, **20ml**.

Conray 280 was requisitioned by Operating Theatres a total of 18 times from 01 February 1999 to 07 June 1999, with a total of 27 packs delivered by Pharmacy³. For the same period, the PSS record indicates that 126 vials of the wrong solution, Phenol 10% in 60% Conray 280, 05ml were delivered to Canterbury Hospital Pharmacy.

When the Recovery nurse requisitioned stock using the imprest list, the nurse counted the amount of the product in stock on the shelf of the cupboard in the Sterile Stock Room⁴ and made a decision regarding how many extra vials or packs of the product were required to maintain a satisfactory stock level for the next few days. Copies of the imprest lists demonstrate that such checks occurred twice weekly.

Even though checks were made, it was **not** noted at any time, or by any person, that the product being counted as Conray 280 was a completely different solution.

Phenol 10% in 60% Conray 280, 5ml, was not delivered to Canterbury Hospital pharmacy before 05 January 1999, or the Operating Theatres prior to 04 February 1999. It is likely, therefore, that there were some bottles of Conray 280, 20ml, on the shelf in the stock cupboard in Operating Theatres on 01 February 1999, when the first ERCP for 1999 was performed. It appears that there was no recognition by the staff member/s checking the stock level on or around this date, that the product Phenol 10% in 60% Conray 280 received on 04 February 1999, was different to the product Conray 280, 20ml, previously supplied by Canterbury Hospital Pharmacy in 1998.

Since there is no independent recollection held by Recovery nursing staff of seeing a 05 ml vial and a 20ml vial in the cupboard space occupied by Conray 280, it is not possible to say with certainty that there was any Conray 280, 20ml, on the shelf after the procedure on 01 February 1999.

Nursing staff interviewed by the Commission, said it was their habit when cleaning the shelves in the stock cupboard or checking the stock, to note the expiry date and rotate stock as required to ensure that stock due to expire first was used. The expiry date for Phenol 10% in 60% Conray 280 is printed on the label along with the name of the solution and the warning that the solution is caustic. If the expiry date was checked, as stated, there was no recognition that the product was:

- significantly different to that being used previously;
- different to the name printed on the imprest list;
- different to the name printed on the shelf of the stock cupboard in the Sterile Stock Room, Operating Theatres;
- different to the name printed on the Solutions List (**Document 6**) attached to the stock cupboard door located in the Sterile Stock Room (**Document 7**).

The following are photographs of the vials showing the labels of Phenol 10% in 60% Conray 280, 5ml and Conray 280, 20ml. It is obvious that the labels of the two products are significantly different.

Nursing staff who requisitioned stock on the imprest list twice weekly from 08 February 1999 to 03 June 1999, failed to recognise that the product stored in the sterile stock room in 05 ml vials was not the correct contrast medium Conray 280 identified on the imprest list.



PHOTOGRAPH 4: COMPARISON OF THE LABELS OF CONRAY 280 AND PHENOL 10% IN 60% CONRAY 280 (ACTUAL SIZE)

Step 2. Requisition of Conray 280 by the Pharmacy Department:

The contrast medium Conray 280 was a stock item at Canterbury Pharmacy which means that it would be requisitioned by a pharmacy clerk if the stock level was low, regardless of whether it was requested by Operating Theatre or not.

The Pharmacy staff used a “*working ordering sheet*”. Whenever a member of the Pharmacy staff picked an item from the shelf and observed stock was low, the item was written on the “*working ordering sheet*”. The sheet was used to requisition items using the on line requisition system.

The last ERCP procedure performed at Canterbury Hospital in 1998 was on 21 December and the last requisition by the Pharmacy Department for Conray 280, 20mls x 20 units, was on 19 October 1998 with delivery on 20 October 1998.

The next requisition by Canterbury Hospital Pharmacy Department was on 05 January 1999 and the product requisitioned was Phenol 10% in 60% Conray 280.

From 04 February to 07 June 1999, further product requisitions by Canterbury Hospital Pharmacy Department in response to the imprest requisition from Operating Theatres for Conray 280 resulted in the requisition of the incorrect solution containing Conray 280 and a caustic solution: Phenol 10% in 60% Conray 280.

When the ward stock request form (imprest list) was received in the Pharmacy Department, the Pharmacy Clerk or Pharmacy Assistant would pack the imprest box for delivery to theatres. If there was no stock of Conray 280 on the shelf, a “*working ordering sheet*” would be completed and a requisition made to PSS (Pharmacy Supply Service).

A new employee commenced as pharmacy clerk in November 1998. This staff member had no previous pharmacy experience but had undergone a merit selection process for the position. The new pharmacy clerk was orientated to the duties of the position by the previous pharmacy clerk who had resigned and returned two days a week for training purposes. The orientation period was

two days per week for two weeks. The Chief Pharmacist told the Commission that following the orientation period all pharmacists contributed to supervising the pharmacy clerk in her new role.

Products can be requisitioned on the Oracle system by catalogue number. The catalogue number is assigned to all items on the inventory for Central Sydney Area Health Service. Even though Phenol 10% in 60% Conray 280 had not been requisitioned by Canterbury Hospital pharmacy before 05 January 1999, the product had a catalogue number because it had been catalogued by the Central Sydney Area Health Service. Table 5 describes the categories used within the Central Sydney Area Health Service for the requisition of products.

Table 5

Categories used by Hospitals in the Central Sydney Area Health Service for the Requisition of Products

INVENTORY ITEM	<p>Inventory items abbreviated as I or INV. Catalogue numbers for the inventory items includes one of the following prefixes:</p> <p>“P” indicating that the item is a pharmaceutical and requisitioned through the PSS</p> <p><i>Phenol, meglumine iothalamate, liquid, 10%-60%, 5ml was catalogued by CSSS as an inventory item with the catalogue number P83035. The “P” prefix means that it was a pharmaceutical and requisitioned by PSS.</i></p> <p>“X” flags the pharmaceutical item as a narcotic</p> <p>“1” indicates the item is a stores item requisitioned through CSSS</p>
PURCHASE ITEMS	<p>catalogued by CSSS are abbreviated as “P” or “PUR” are catalogued but not held in stock</p>
MISCELLANEOUS ITEMS	<p>abbreviated as “M” may be requisitioned on line or by hard copy. Full details of the product must be provided with the requisition.</p> <p>A miscellaneous item does not appear in the catalogue.</p> <p><i>Conray 280 was a miscellaneous item, ie it was not catalogued.</i></p>

A hospital pharmacist said the PSS catalogue number for each inventory item in stock in the Canterbury Hospital Pharmacy appeared on the pharmacy stock shelf where the product was kept. A pharmacy clerk said the PSS catalogue numbers required for requisitioning items on the Oracle system were not on the shelf at the time of the events, but had subsequently been placed on the shelves. The Commission understands that the PSS catalogue numbers have been placed on the shelves during the period from January 1999. However, there would have been no catalogue number for the contrast medium Conray 280 because it was not catalogued. The Commission understands that there was nothing on the shelf where Conray 280 was stored to indicate to inexperienced pharmacy staff that it was a miscellaneous item.

The Oracle system includes a number of cross references for each item. In circumstances where the catalogue number was not known, to raise a requisition, the pharmacy clerk entered “%Conray%” via the keyboard to initiate a query or search for catalogued or inventory items incorporating the term “Conray” in their name. The only item located as a result of this search on the Oracle system was Phenol 10% in 60% Conray 280. Consequently, this product was entered onto the Oracle generated computer requisition. This process was repeated on each occasion that Conray 280 was

requisitioned by Pharmacy from 04 February to 07 June 1999. The pharmacy clerk demonstrated this procedure for Commission officers on 09 June 1999.

Conray 280 was not listed by the Oracle system as a result of the search using the colloquial “%Conray%”, because Conray 280 was not an inventory item, but a “miscellaneous” or one-off purchase. Conray 280 was requisitioned prior to 1999 by typing the full name, Conray 280, onto the requisition form. The new pharmacy clerk, however, was not aware that the product was a miscellaneous item or that it had been requisitioned in this manner previously. Since the last requisition in 1998 for Conray was on 19 October 1998, (before the pharmacy clerk commenced work in the Pharmacy Department in November 1998), the pharmacy clerk would not have been involved in the previous requisition or receipt of Conray in 20mls vials.

Therefore, the Pharmacy Clerk had no basis for comparison when the incorrect solution was first received in the Pharmacy Department.

At Canterbury Hospital, those authorised to approve pharmacy orders were the Chief Pharmacist and one other Hospital Pharmacist. On each occasion the order for the product Phenol, meglumine iothalamate (10%-60%), 5ml (10% Phenol in 60% Conray 280 in a 5 ml vial), appeared on a requisition for stock, from January to June 1999. Its purchase was approved by the Chief Pharmacist. Documentation provided by Central Sydney Supply Service (CSSS) indicates that this product had not previously been requisitioned by Canterbury Hospital before January 1999.

With regard to password access to the Oracle system, it was found during the investigation that the new pharmacy clerk had not been issued with a password allowing an appropriate level of access to complete requisitions. The pharmacy clerk accessed the system by using the password of the Chief Pharmacist. The other hospital pharmacist had been issued with a password which, the Commission was advised, had expired due to infrequent use. Therefore, when this pharmacist required access to Oracle, again the Chief Pharmacist’s password was used.

The Chief Pharmacist approved a requisition once 20 items were on screen. The information available to the Chief Pharmacist on the screen was limited to the first seven characters of the product name. Therefore the view of the product “*Phenol, meglumine iothalamate, liquid, 10%-60%, 5ml, #INJ 018, bottle*”,⁵ was limited to “*Phenol,..*”.

Since the Operating Theatre would routinely requisition a product containing Phenol, (Phenol in Almond Oil, used for haemorrhoids) there would be nothing on the screen requisition to alert the approver. The limited amount of information available to the approver is one of the limitations of the Oracle system.

If the approver required more than seven characters of information, they would have to search through the lower part of the screen. This is very cumbersome with up to 20 line items. The approver can do a further query of the order using Oracle, if required. However, problems observed with the use of the Oracle system in this case involve the complexity of the system of catalogued and non-catalogued items and the paucity of information available to the approving pharmacist. Once approved, the requisition was forwarded electronically to the centralised Pharmacy Supply Service (PSS).

Commission officers visited the Canterbury Hospital Pharmacy Department on 22 June 1999 for a second time and viewed the manner in which the product in question was requisitioned using the Oracle system. The pharmacy clerk demonstrated the query function used by entering the colloquial “%Conray%”. Again the only product listed was Phenol 10% in 60% Conray 280, 5ml. The Commissioner brought this continuing situation to the attention of the Director-General of NSW Health, and changes were made to the “Oracle” system to ensure that the product Phenol 10% in 60% Conray 280 was no longer listed by Oracle in response to any query using the colloquial “Conray”. Further, an alert was issued from the office of the Director-General on 24 June 1999 to all users of Oracle and other computerised stock control and ordering systems to ensure that a similar situation did not occur in the future (**Document 8**).

The requisition system in place using ORACLE was extremely complex for a new member of Pharmacy staff to master and it provided the name of a special purpose product with Conray 280 as a component, but not the main component, in response to a query using the term “Conray” as the basis of the query;

There was no catalogue number for the item Conray 280, and no warning or direction on the Pharmacy shelf, or elsewhere, to alert an inexperienced staff member that the product was a “miscellaneous” item and ordered in a different manner to an inventory item;

The ORACLE system provides very limited information on screen for viewing by the person approving the item for purchase. To view more than the first seven characters of any product name requires scrolling to the end of a twenty line product list where the remainder of each item description is shown. This process would need to be repeated for each listed item.

The ORACLE system failed to provide a full description of a product to the approver that would alert the approver to query the requisition.

Step 3. Requisition by Central Sydney Supply Service (CSSS) / Pharmacy Supply Service (PSS)

Once PSS received a requisition for the product Phenol 10% in 60% Conray 280, 05ml vial, a requisition was appropriately made to the manufacturer for supply of the product. Phenol 10% in 60% Conray 280, 05ml vial, is a special purpose solution prepared under Section 5 of the Therapeutic Goods Act. The Act requires a DEB9 form, setting out the details of manufacture and the reason for its preparation to be completed for each batch of the solution requested and prepared (**Document 2**). This form is completed in part by the manufacturer. The remainder of the form, namely the intended use of the solution, is completed by the ordering facility, in this case the Area Pharmacy Supply Service. The hospital who requests it determines the use is appropriate and specified the route of administration. No product information is supplied with the product as it is requested by the hospital for the specific use stated in the DEB9 contract. In this case it is stated on the completed form that the product is to be used for chemical sympathectomy for the relief of chronic pain. This is an appropriate use for this solution.

Reports provided by CSSS indicate that the Phenol 10% in 60% Conray 280, 05ml, was requisitioned by two services other than Canterbury Hospital in the first half of 1999. The total number of vials provided to services other than Canterbury Hospital was 36, while 177 vials of the product were supplied to Canterbury Hospital. From 05 January 1999, Canterbury Hospital pharmacy requisitioned more than four times the amount of Phenol 10% in 60% Conray 280, 05ml, documented for all the other facilities combined in the Central Sydney Area Health Service. The other facilities included Royal Prince Alfred Hospital and Concord Hospital.

There was not at the time a system in place at CSSS/PSS to ‘flag’ an order for a product that was:

- not usually used at a particular hospital;
- requisitioned in unusually large amounts;
- a special purpose item not usually used at a particular facility or provided only under certain conditions.

The Manager, Central Sydney Supply Service, confirmed that there was no system in place at the time to flag such product orders.

The central requisition system for the Central Sydney Area Health Service:

- failed to flag the first time a special order product, used in limited clinical circumstances, was requisitioned by a health facility;
- failed to flag the high level usage of a special order product by a health facility;
- failed to query the high level usage of a special order product.

Step 4. The delivery of the product to Canterbury Hospital Pharmacy:

Phenol 10% in 60% Conray 280 was delivered on each occasion to Canterbury Hospital Pharmacy with an accompanying delivery receipt stating the name of the product requisitioned, Phenol 10% in 60% Conray 280, 5ml.

No Conray 280 (the correct solution) was delivered to Canterbury Hospital after October 1998, and stock of Conray in the Pharmacy Department was sufficiently low to warrant an order being placed on 05 January 1999, when the Operating Theatres at Canterbury Hospital were closed. It would appear that Phenol 10% in 60% Conray 280 was accepted as Conray 280 on delivery to the Pharmacy Department in 1999. It would then have been placed on the stock shelf in the section where Conray 280 had been stored, and selected for delivery to Operating Theatres each time replacement stocks of Conray 280 were requisitioned.

Delivery receipts for the order of Conray 280 indicate that all the stock delivered to Operating Theatres from the Pharmacy Department after 05 January 1999, were:

- in 05ml vials;
- invoiced at a cost of \$20 or \$21, the cost of a 5ml vial of Phenol 10% in 60% Conray 280.

It appears there was no stock of Conray 280, 20ml, in Pharmacy when the requisition for the incorrect solution was placed on 05 January 1999. The last order for Conray 280 from the supplier was in October 1998. In these circumstances, it is likely that the new Pharmacy clerk, who commenced work in November 1998, had never seen the 20ml vial of Conray 280, when the 05ml vial of Phenol 10% in 60% Conray 280 was delivered to Pharmacy. Therefore, the Pharmacy Clerk would not have been able to compare the correct product with the incorrect product when unpacking the supplies.

There was a failure to recognise that the product delivered was not the correct product, Conray 280;

There was a failure to question the change in size of the vial delivered to that used previously;

There was a failure to question the need for revision of the amounts ordered in view of the change from a 20ml to a 5ml vial;

There was a lack of any protocol regarding the receipt of goods into the pharmacy and guidelines for dealing with any discrepancies regarding goods received.

Step 5. The delivery of Phenol 10% in 60% Conray 280 to Operating Theatres at Canterbury Hospital:

Commencing 04 February 1999, Phenol 10% in 60% Conray 280 was delivered to Canterbury Hospital Operating Theatres from Canterbury Hospital Pharmacy in response to imprest requisitions for Conray 280.

The documentation accompanying deliveries (the imprest list and a delivery receipt) generated in Canterbury Hospital Pharmacy rather than from Oracle, stated that the product delivered was Conray 280, 5ml. The name of the product delivered after 05 January 1999 was clearly different to the name of the product requisitioned by Operating Theatres on the imprest list and that stated on the delivery docket.

The Chief Pharmacist provided a history of the devolution of responsibility from Pharmacy to nursing staff at Canterbury Hospital, following an audit of Canterbury Hospital pharmacy in 1995. The background to this initiative is found in **Document 9**, which includes, a memorandum to nursing staff dated 1 December 1995 from the then Acting Director of Nursing and Clinical

Support Services regarding pharmaceutical supply and segregation of functions. Attached to the memorandum was a Procedure for Ordering Pharmaceuticals from the Pharmacy. That procedure states:

- the person responsible for ordering pharmaceuticals from the pharmacy is the nursing unit manager or department head;
- the imprest list should be signed to acknowledge receipt;
- it is the responsibility of the nursing unit manager to check goods received and quantities charged in the invoices.

A requisition and receipt history compiled by the Health Care Complaints Commission is appended as **Document 5**.

There was no system in place in pharmacy to ensure that the name, strength, and volume of the goods was adequately checked against the requisition prior to despatch

Step 6. Receipt of goods

A. The Pharmacy Department

The invoice cost of the orders of Phenol 10% in 60% Conray 280, 05ml, for Canterbury Hospital was significantly higher than the invoice cost of Conray 280, 20ml:

From Oracle reports provided by CSSS, in 1997, Conray 280 was requisitioned by Canterbury Hospital in 50ml vials, at a cost of \$15 per vial. There was a change in 1998 to ordering Conray 280 in 20ml vials, at a cost of \$7.50 per vial.

In 1998, Conray 280 was delivered to Canterbury Hospital Pharmacy 6 times, a total of 107 vials of 20ml each, invoiced at \$7.50 per 20ml vial. (Information from CSSS indicates that Canterbury Hospital was invoiced a cost of \$7.50 per 20ml vial during 1998. Internal Canterbury Hospital delivery receipts, however, continue to show delivery of 50ml vials at a cost of \$15 per vial to Operating Theatres.)

From 05 January 1999 to 28 May 1999, CSSS records show that 177 vials of Phenol 10% in 60% Conray 280, 5ml, were provided to Canterbury Hospital Pharmacy. The cost per 5ml vial from the manufacturers invoices, was \$21 which would have resulted in a total cost of \$3,717 to the Pharmacy Department for the five month period stated. Receipts from Canterbury Hospital Pharmacy to Operating Theatres invoice the cost at \$20 - \$21, a total of \$2,604. See **Table 7** for the increased cost invoiced to Theatre in 1999.

There was no system in place to flag the apparent increased cost of an item from \$7.50 to \$21 with a decrease in volume from 20ml to 5ml.

Table 7
Comparison of the Cost of Contrast Solution over 6 Months

1998	1999
Cost of Conray 280	Cost of Replacement Product
\$577.50	\$2604

B. Operating Theatres



PHOTOGRAPH 4: COMPARISON OF THE LABELS OF CONRAY 280 AND PHENOL 10% IN 60% CONRAY 280 (ACTUAL SIZE)

The Nurse Manager 2 of Operating Theatres advised that responsibility had been given to Recovery nursing staff to check each delivery and to store it appropriately in the stock cupboard in the Sterile Stock Room. The Nurse Manager advised that this change took place in 1996 at the time of the relocation of Canterbury Hospital Operating Theatres to Concord during the redevelopment of Canterbury Hospital. There is no documentation relating to this decision.

Recovery nursing staff advised at interview, if any item on the order was found to be incorrect on delivery, it was usual for the nursing staff to telephone Pharmacy to advise of the error. From the copies of delivery dockets obtained from the Operating Theatres, there was one occasion when it is noted on the delivery receipt that a particular item delivered was incorrect, that Pharmacy was advised of the error and the product returned to Pharmacy. This appears on a delivery receipt for 21 December 1998. However, with regard to Phenol 10% in 60% Conray 280, there has been no documentation or verbal advice obtained from

Recovery nursing staff to indicate that the nature of this product was ever questioned on receipt in Operating Theatres.

Apart from the name of the item delivered, Phenol 10% in 60% Conray 280, there were other visible differences in the product delivered from Conray 280:

Table 8
Comparison of the vial containing Phenol 10% in 60% Conray 280 / with Conray 280

PHYSICAL FEATURE	Phenol 10% in 60% Conray 280	Conray 280
size of the vial	05ml	20ml
colour of the vial	brown glass	clear glass
colour of the label	black print on white	light blue print on white
contents on the label	Phenol was part of the mixture	Conray 280 alone
strength on the label	diluted form of Conray 280 (60%);	Conray 280 hypertonic solution
nature of the solution	contains a caustic substance	radiopaque contrast agent for intravascular use
directions for use	use under strict medical supervision	

Delivery receipts show that deliveries of Phenol 10% in 60% Conray 280 were made on thirteen occasions from 04 February 1999 to 03 June 1999. (**Document 5**) A number of Recovery nursing staff were involved with checking stock delivered to Operating Theatres during that time period. There is evidence that the goods received were checked on receipt in Operating Theatres:

- ticks (✓) appear on a number of the delivery receipts indicating that the order was checked, including the product listed on the receipt as Conray 280, 5ml.
- on the imprest lists, a second tick (✓✓) has been placed alongside or over that made by the pharmacy assistant/clerk when the order was packed. Recovery nursing staff advised that this was the usual method of documenting that the items had been delivered and checked. (Refer **Document 3**)

An examination of the imprest list and delivery receipts confirm the lack of any notation that might indicate the product had been questioned. Given the differences noted in Table 8, goods received were not appropriately checked for contents, volume, strength the imprest list and delivery receipt to verify the correct solution had been received. The only check consistently carried out was the expiry date. There was no written procedure to guide recovery staff in this activity.

One of the delivery receipts had been signed and dated by the staff member checking it (03 June 1999). There is no designated place on the imprest list for the person checking the delivery to sign.

One nurse reported to the Commission that she had queried the nature of the product being used during ERCP procedures. This enquiry, the nurse stated, was made inside the operating theatre. Commission officers found no verification from any other staff member interviewed that such an enquiry was made or that any contact was made with the Pharmacy Department regarding the nature of the product.

Three nursing staff have verified to the Commission that an enquiry was made about the changed size of the vial provided (5ml rather than 20ml) and whether a larger vial size could be obtained. Pharmacy staff confirmed that such an enquiry was made to Pharmacy. The response was that 5ml was the only size available, which is correct in relation to the product Phenol 10% in 60% Conray 280. It should be noted that the Pharmacy staff dealing with this enquiry were not pharmacists.

No one in the operating theatre queried the apparent increase in price of a solution which reduced in size from 20ml to 5 ml. The cost to theatres of purchasing Phenol 10% in 60% Conray 280, 5ml, in place of Conray 280, 20ml, increased the cost per procedure by \$76, given 20ml of contrast / procedure.⁸ There was no system in place to flag an increase in cost of an imprest item used regularly in the operating theatres.

Interviews with nursing staff confirm that Phenol 10% in 60% Conray 280 was stored in operating theatres in place of Conray 280. A list on the door of the solutions cupboard in Operating Theatres (**Document 6**) listing those items stored, still listed the product in the cupboard was Conray 280, 20ml, as of 22 June 1999, when the Commission visited the department. **Document 7** shows the location of sterile stock room in the operating theatre)

It was from this solutions cupboard that staff setting up for ERCP procedures would obtain the contrast medium, and where the incorrect solution Phenol 10% in 60% Conray 280 was stored by nursing staff.

There was no system in place at Canterbury Hospital Pharmacy and/or Operating Theatres to monitor costs of goods received.

There was no system in place Operating Theatres to flag a sudden increase in solution cost which would increase the cost of the procedure by \$76.

Goods received were not appropriately checked for contents, volume, strength and correctness against the imprest list and delivery receipt. The only check consistently carried out was the expiry date. There was no written procedure to guide staff.

All staff failed to recognise significant differences between the correct contrast medium, Conray 280, and the incorrect substitute, Phenol 10% in 60% Conray 280.

6.2. How did Phenol 10% in 60% Conray 280, 05mls, a caustic solution, come to be used during ERCP procedures at Canterbury Hospital during the period 01 February 1999 to 07 June 1999?

6.2.1 Role of nursing staff in the operating theatre

A number of nursing staff were involved in twenty eight (28) ERCP procedures during the period from 01 February 1999 to 07 June 1999. On each of these occasions there was an opportunity for the contrast solution used to be identified and questioned before, during and after the procedure.

It was usual for nursing staff to prepare the necessary equipment in readiness for ERCP procedures. A “*surgeon’s preference list*” (Document 10) compiled by nursing staff, listed equipment and solutions used for this procedure at Canterbury Hospital. The name “Conray” appears on that list under the heading “Drugs - Cream - Miscellaneous”. There are no details on the list regarding any dilution required or the amount to be drawn up for the procedure.

The nurse preparing equipment for the ERCP would collect the solutions required, including the contrast medium to be used, from the stock cupboard in the Sterile Stock Room of the Operating Theatres.

Those staff present during ERCP procedures, who have verified that they actually saw the vials containing Phenol 10% in 60% Conray 280, 05 mls, during ERCP procedures prior to 07 June 1999 are few. Of the scout nurses who say they saw the product, all say that they questioned the product while in the operating theatre for the procedure and that they were reassured that the product was appropriate for the procedure by the instrument nurse. Two staff members also noted that there was no information leaflet inside the box of Phenol 10% in 60% Conray 280.

Phenol 10% in 60% Conray 280 is documented as being used in 11 of the 28 ERCP’s performed from 01 February 1999 and 07 June 1999. This documentation appears on the Operating Suite Nurses report form which is filled out for each procedure in the operating theatre and forms part of the medical record for the patient.

On examining the requisition records in conjunction with the dates and numbers of procedures performed, it is likely however, that Phenol 10% in 60% Conray 280, 05ml, was used during procedures for which there is no documentation of the product used. The use of Phenol 10% in 60% Conray 280, 05ml, during ERCP procedures at Canterbury Hospital is first documented on 22 March 1999. An examination of the documentation provided about the supply of Conray 280, 20mls and Phenol 10% in 60% Conray 280, 05ml, shows that it is most likely, that the product with phenol was used for all ERCP procedures performed after 22 March 1999, but there was incomplete documentation on the Operating Suite Nurses Report.

6.2.2 Documentation of the solution by operating theatre nursing staff

The following table illustrates the dates of ERCP procedures and the solution used as documented by nursing staff. The reorder pattern for Conray 280 and the delivery pattern for Phenol 10% in 60% Conray 280 is included.

Table 9
Documentation of the solution used, and the solution delivered, to the Operating Theatre

ERCP Date	Solution used in procedure (Operating Suite nurses report)	Theatre Imprest Order date	No. to order	Vials delivered by pharmacy	
01.02.1999	Conray 280 15mls	04.02.1999	1	2	5ml
08.02.1999	Conray 280 20mls	08.02.1999	1	10	5ml
		11.02.1999	2	1	5ml
		15.02.1999	1	1	5ml
		25.02.1999	6	2	5ml
01.03.1999	Conray 280				
01.03.1999	Conray 280				
08.03.1999	Water irrigation				
08.03.1999	Conray 280	11.03.1999	2		
15.03.1999	Conray 280mg	15.03.1999	1		
22.03.1999	Phenol 10% in 60% Conray 280	22.03.1999	1		
22.03.1999	Phenol 10% in 60% Conray 280	25.03.1999	1	10	5ml
29.03.1999	Conray 280				
29.03.1999	Conray 280				
29.03.1999	Conray 280	01.04.1999	1	10	5ml
12.04.1999	Water for irrigation	15.04.1999	1	10	5ml
19.04.1999	40ml Conray	20.04.1999	-	20	5ml
19.04.1999	20mls Conray	22.04.1999	1		
		27.04.1999	2		
03.05.1999	Phenol 10% in 60% Conray 280				
03.05.1999	(blank)				
03.05.1999	Phenol 10% in 60% Conray				
03.05.1999	Phenol 10% in 60% Conray 280	06.05.1999	2	20	5ml
10.05.1999	Phenol (10%) in 60% Conray 280 15mls				
10.05.1999	Phenol (10%) in 60% Conray 280 20mls				
10.05.1999	Phenol (10%) in 60% Conray 280	13.05.1999	1	10	5ml
24.05.1999	Conray 60% Phenol 10% 15ml				
24.05.1999	Conray 280 with Phenol 10% 30mls	27.05.1999	2	20	5ml
31.05.1999	Xylocaine spray	03.06.1999	1		
31.05.1999	Conray				
04.06.1999	Xylocaine Spray, Conray 20mls			10	5ml
07.06.1999	Conray with Phenol, Urograffin 15mls				
TOTAL		18 orders	27	126 vials	

While there may have been some stock of Conray 280, 20ml, remaining in Operating Theatres when the first ERCP for 1999 took place on 01 February 1999, from the ordering patterns summarised above, it would not be expected that any stock remained when Phenol 10% in 60% Conray 280 was documented as being the product used on 22 March 1999.

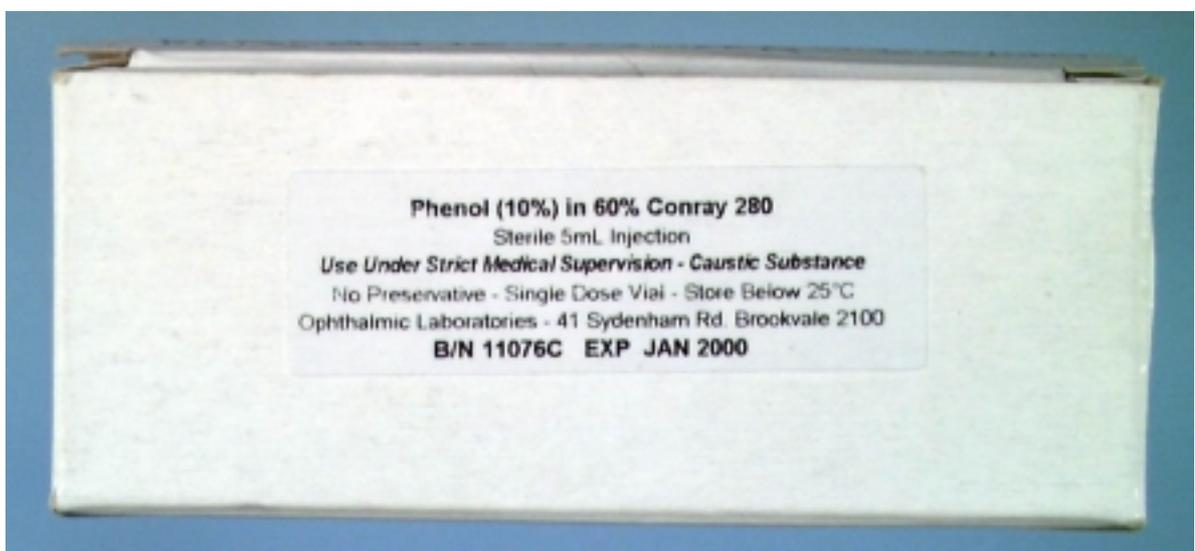
However, there are occasions after 22 March 1999 where Conray is documented as the product used. The evidence shows that the documentation of the product used on 29 March 1999, 19 April 1999, one procedure on 03 May 1999, 31 May 1999 and 04 June 1999, was inaccurate.

The following information provided by nursing staff at interview supports the finding regarding incorrect entries on the Operating Suite Nurses Report:

- one registered nurse advised during interview that the contrast medium had been placed in syringes prior to her arrival in Operating Theatres, sufficient for the three ERCPs listed for that day, 29 March 1999, and that she saw the syringes in 3 kidney dishes but did not see or check the labels on the vials. Prior to documentation of the name of the solution used during two of those procedures she stated she asked the other registered nurse whether Conray 280 was being used. When the other registered nurse agreed that was correct, she documented the use of Conray on the Operating Suite Nurses Report.
- another registered nurse stated that the contrast solution had already been drawn up (placed in a syringe ready for injection), sufficient for the two procedures booked, when she arrived in the Operating Theatre on 31 May 1999. This nurse looked at the vial but did not document the name of the product on the Operating Suite Nurses Report. This nurse described the vials being in a small box with the vials wrapped in plastic. This description is consistent with the product Phenol 10% in 60% Conray 280. However, the solution documented on the Operating Suite Nurses Report is **Conray**.



PHOTOGRAPH 5: PHENOL 10% IN 60% CONRAY 280 5ML VIALS WRAPPED IN PLASTIC



PHOTOGRAPH 6: WHITE BOX CONTAINING PHENOL 10% IN 60% CONRAY 280

6.2.3 Documentation of the procedure by operating theatre nursing staff

At the time of the investigation there was no current protocol or guideline to help nursing staff set-up for the procedure of ERCP at Canterbury Hospital (see **Documents 10 & 11**). The only document that was dated was dated 1992 and was prepared when ERCP procedures were performed in the Radiology Department at Canterbury Hospital. Urograffin is listed as the contrast medium, with details regarding its preparation. (**Document 11**). The review date on the document was 1995, and it was acknowledged that this review did not take place.

The Commission did not locate any documents setting out the role and responsibilities of the instrument nurse, scout nurse and anaesthetic nurse during operative procedures at Canterbury Hospital. Role descriptions were prepared following a request from the Commission. The Commission was told that these reflected usual practice at the time of these events. These documents state that the scout nurse should “*check with the instrument nurse drug preparation*”.

Australian Confederation of Operating Room Nurses (ACORN) standards clearly state the accountability of the perioperative nurse and consider that a scout nurse should “*be familiar with the operative procedure*” and possess a sound body of knowledge including knowledge of the “*legal and ethical aspects of perioperative nursing*”.

The documents provided by Canterbury Hospital describe the role of the instrument nurse, with regard to drugs required for the procedure - the instrument nurse “*draws up required amount specified by performing Medical Officer. Vials are retained for Medical Officers viewing*”.

No Operating Theatre policies existed in relation to the role of nursing staff in checking solutions used in an operative procedure. In addition, there is no written standard published by the NSW Health Department, or ACORN, that specifically addresses the practice for checking solutions.

6.2.4 How contrast medium was injected into the patients

One of the roles of nursing staff in theatre is to provide a safe environment for the patient. This is particularly important once the patient is unconscious.

The nursing staff prepare all the equipment for the procedure, including any solutions to be injected. Care is taken to ensure that the set-up for the procedure reflects the medical order, and that all equipment is free of any contamination that might cause patient infection.

The Surgeon’s preference list and any policy and procedures developed by the hospital from departmental guidelines are used as a guide to set up for the procedure. The contrast medium was taken from the solutions cupboard in the sterile stock room. The standard procedure in Operating Theatres in NSW, is for the instrument nurse to check the solution to be used with the scout nurse or the medical practitioner. It is nursing practice that the solution is checked by saying the name of the solution out loud before it is injected into the patient.

In this case, the nurses understood the contrast medium was “Conray”. While some nurses documented the solution as *Phenol 10% in 60% Conray 280*, no one said this name out loud in the operating room, during the procedure, before the solution was injected into the patient.

During the procedure the nurse injects the solution under the direction of the medical practitioner.

7. Recommendations

The Commission has investigated the role of the hospital. Once a submission is received about the proposed outcome of the investigation, the Commission will provide a report to the Director-General and make any recommendations to reduce the risk of a repeat incident. The Commission may request the Director-General to notify it of any action taken or proposed as a result of its report.

The proposed recommendations are:

- that Canterbury Hospital develop as a matter of priority policies protocols or guidelines to address the deficiencies in the requisition and supply of goods in the Pharmacy Department and the Operating Theatre;
- that processes be developed to ensure that unusual orders for goods, (such as first time use of a special purpose product, increased use of a product or increased cost) are flagged and followed up by the supply service;
- that Canterbury Hospital review the roles and responsibilities of nursing staff in the Operating Theatre, including the checking of solutions in use in the Operating Theatre, and involve all staff in mandatory in-service education about these responsibilities;
- that Canterbury Hospital develop and implement a review program for surgeon's preference sheets and guidelines for operative procedures;
- that Canterbury Hospital develop a comprehensive annual rotating education program to include appropriate documentation in the operating theatre, roles and responsibilities of the nurse, and practice standards to maintain patient safety;
- that there is a system in place to monitor costs in the operating theatre, to detect at an early stage deviations from expected expenditure, and take appropriate action to identify the problem.

8. The role of the Medical Practitioner

The Commission has investigated the role of the medical practitioner in the 28 procedures. The findings and outcome of the investigation are subject to consultation with the NSW Medical Board, pursuant to s38 and s39(2) of the Health Care Complaints Act.

9. The role of the Nursing Practitioners

The Commission has investigated the role of individual nursing staff directly involved in the 28 procedures. The findings and outcome of the investigation are subject to consultation with the NSW Nurses Registration Board, pursuant to s38 and s39(2) of the Health Care Complaints Act.

10. Conclusion

The Commission has completed the fact finding part of the investigation and found that this complaint involves a trail of errors that raise serious concerns about existing mechanisms established to keep patients safe.

Up to twenty-four patients at a district hospital were exposed to a caustic solution injected into their body tissue. The solution was incorrectly requisitioned and supplied to an operating theatre. All health professionals who checked the solution after receipt in theatre, failed to adequately check the label before the substance was injected into human tissue.

While many health professionals noted the label of the incorrectly requisitioned solution said

“Use Under Strict Medical Supervision - Caustic Substance”

no one recognised the significance of this warning for the patients undergoing ERCP.

The Commission is required to provide all respondents, both individual health professionals and the health facility, with the opportunity to make a submission about the proposed outcome of the investigation.

The Commission will provide a report to the Director-General after the hospital has an opportunity to make a submission.

11 Appendix

11.1 List of photographs

1. Conray 280, 20ml vial
2. Conray 280, 50ml vial
3. Phenol 10% in 60% Conray 280, 05 ml, single vial
4. Photograph comparing Phenol 10% in 60% Conray 280 , 05mls with Conray 280, 20mls
5. Phenol 10% in 60% Conray 280 , 05ml, 05 vials wrapped in plastic
6. White box containing Phenol 10% in 60% Conray 280, 05 mls

11.2 List of tables

1. List of 28 ERCP procedures at Canterbury Hospital Labelled a, b, c, d: anaesthetist present (labelled 1-4) comparison type of anaesthetic: Intravenous sedation: general anaesthetic IV:GA
2. Nurses involved in ERCP procedures as team leader (TL), instrument nurse, scout and anaesthetic nurse in 1999, being 24 nurses in 28 procedures
3. Demographics of 24 patients
4. Procedure for requisition and receipt of solutions in the Operating theatre
5. Categories used by hospitals in the Central Sydney Area Health Service for the requisition of products
6. Requisition and receipt history compiled by the Health Care Complaints Commission (appended)
7. Comparison of the cost of contrast solution received in Operating Theatres in six months 1998 (July to December) and 1999 (January to June)
8. Comparison of the vial containing Phenol with the vial containing Conray 280
9. Documentation of the contrast solution used and the solution delivered to the Operating Theatre, Canterbury Hospital.

11.3 List of diagrams

1. ERCP Procedure
2. Flowchart for the usual procedure at Canterbury Hospital for requisition and receipt of Conray 280

11.4 Document list

1. Commission letter to patients (22 of 24) about the investigation
2. DEB 9 form
3. Imprest list - Operating theatres
4. Receipt provided by the Pharmacy Department
5. Table of information relating to the requisition and supply of solutions containing CONRAY to Operating Theatres
6. List of solutions on the door of the solutions stock cupboard in the Sterile Stock Room
7. Location of the solutions stock cupboard in the Sterile Stock Room, Operating Theatres
8. Alert by the Director-General, NSW Health
9. Memo, Canterbury Hospital, with Appendix: Procedure for ordering pharmaceuticals from the Pharmacy
10. Surgeon's preference list
11. ERCP procedure, Canterbury Hospital, April 1992

11.5 References

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12. Glossary of Terms & Abbreviations

ACORN:	The Australian Confederation of Operating Room Nurses is the body of operating room nurses that set the standards for practice in this speciality of nursing.
biliary tree:	a structure with branches resembling a tree. The structure of the bile ducts resembles the structure of a tree with the two “branches” (the hepatic and cystic ducts) draining into the “trunk” (common bile duct)
cannula:	a tube for insertion into a duct or cavity of the body. In ERCP, cannulas are directed through the endoscope and placed in the common bile duct. Through these cannulas a contrast medium is injected into the ducts so that x-ray films can be taken.
Cardiopulmonary:	pertaining to the heart and lungs.
caustic: burning or corrosive;	destructive to tissue
chemical sympathectomy:	the use of chemical agents to interrupt the transmission of impulses through a nerve (eg for relief of chronic pain).
bile duct:	the human body has three bile ducts: they are canals or passageways that carry bile. Bile is produced in the liver and stored in the gallbladder. Bile flows through the bile ducts into the small intestine when it is needed for digestion
common bile duct:	there are two other bile ducts besides the common bile duct. One of these, the hepatic duct, drains bile from the liver. The other, the cystic duct, conveys bile from the gallbladder. Both of these ducts drain bile into the common bile duct which in turn conveys the bile to the intestine to aid digestion.
Conray 280:	brand name of an iodine based contrast medium. The generic name for this product is meglumine iohalamate.
contrast medium:	a substance introduced into a specific area of the body to increase the absorption of x-rays as they pass through the body. A contrast medium is used to delineate body structures on x-ray.
duodenum:	part of the gastrointestinal tract. The first part of the small intestine. It is important in digestion as both the common bile duct and pancreatic duct empty into it.
Duodenoscope:	an endoscope used for direct visual inspection of the duodenum and surrounding organs
Endoscope:	an instrument used for direct visual inspection of hollow organs or body cavities. The design of an endoscope may vary according to its specific use, however all endoscopes have similar working elements: hollow viewing part or scope that allows viewing in a variety of directions; light source, power cord and power source. A variety of accessories are used for diagnostic and therapeutic purposes.

ERCP:	Endoscopic Retrograde Cholangio-Pancreatography. A diagnostic procedure performed where there is a suspected disorder of the gallbladder. The duodenoscope is inserted into the patient's mouth and guided down to the duodenum. Cannulas are then directed through the hollow duodenoscope and into the common bile duct and or pancreatic duct. A contrast medium is injected through the cannula into the duct so that x-ray films can be taken.
gallbladder:	a pear shaped organ located below the liver. It serves as a storage place for bile.
GSA:	Gastroenterological Society of Australia
hypertonic:	having an osmotic pressure greater than that of the solution with which it is being prepared.
Infection Control Guidelines:	NSW Health Department Infection Control Policy. Circular 95/13.
intravascular:	within a blood vessel or blood vessels
intravenous:	into a vein
MRSA:	methicillin resistant staphylococcus aureus: a bacterial infection with a specific bacteria called staphylococcus aureus. In this case the bacteria is found to be resistant to numerous antibiotics, one of which is methicillin. This resistant bacteria can be transmitted easily from patient to patient. To prevent transmission to any other patient, when a patient who has this resistant infection undergoes a procedure in the operating theatres, the theatre is cleaned immediately after according to a specific cleaning protocol.
oesophagus:	a passage from the throat to the stomach.
pancreatic duct:	the main duct of the pancreas. It carries digestive enzymes, produced in the pancreas, to the intestine. It joins with the common bile duct before entering the duodenum.
Phenol:	This is also called carbolic acid. Phenol is a crystalline compound derived from coal tar or plant tars which can also be produced synthetically. It is an antiseptic and disinfectant and is effective against a wide range of micro-organisms. It is a caustic, corrosive substance. It has been used therapeutically as a sclerosing agent (causing hardening of tissue). For example, the product Phenol 5% in Almond Oil which is used to sclerose haemorrhoids.
Phenol 10% in 60% Conray 280:	Phenol 10% in 60% Conray 280 is a purpose made product, designed to cause scarring of tissues under radiographic control for purposes such as nerve blocks in pain management. The Conray 280 in the solution enables that radiographic control.
radiopaque:	having the quality that will obstruct the passage of x-rays, so that affected areas appear light or white on exposed x-ray film.
sclerose:	to become hardened.
Therapeutic Goods Authority:	the Commonwealth body which regulates the import and marketing of goods and medications in Australia.
vial:	a small bottle
Urograffin:	a contrast medium
Xylocaine spray:	a spray containing a topical anaesthetic. In this case the xylocaine is sprayed in the throat to assist the introduction of the endoscope through the mouth and throat and decrease patient discomfort during this procedure.

13. End Notes

- ¹ Additional nurses may have relieved the instrument nurse or scout nurse for tea breaks or may have acted as a buddy for a nurse new to the role.
- ² An inventory item is a product catalogued by Central Sydney Area Health Service. This means the product has a catalogue number allocated by PSS. To order on-line the catalogue item is used.
- ³ See copies of the completed Operating Theatre imprest lists
- ⁴ See **Document 7**, for the location of the Sterile Stock Room in the Operating Theatre Suite
- ⁵ Phenol 10% in 60% Conray, 5ml
- ⁶ During an investigation, the Commission may seek expert advice on the subject matter of the complaint pursuant to s30 of the Health Care Complaints Act 1993

Contact Details

Health Care Complaints Commission

Level 4, 28--36 Foveaux Street

Surry Hills NSW 2010

Locked Mail Bag 18

Strawberry Hills NSW 2012

Tel: (02) 9219 7444

Toll Free: 1800 043 159

TTY: (02) 9219 7555

Fax: (02) 9281 2585

E-mail: hccc@hccc.nsw.gov.au

Web: www.hccc.nsw.gov.au

