Health Care Complaints Commission

Report on an investigation into adverse outcomes following cataract surgery at

Dubbo Base Hospital

on 8 February 1999

3 September 1999

HCCC
HEALTH CARE COMPLAINTS COMMISSION

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Executive Summary

- The Commission has investigated the circumstances surrounding a high number of adverse outcomes following cataract surgery at Dubbo Base Hospital on 8 February 1999. The Commission is also investigating the Hospital's response to notification about those adverse outcomes.
- The Commission's investigation includes the actions of individuals and it is inappropriate to express opinions on the conduct of particular health care practitioners in this report. A separate confidential report will cover this aspect of the investigation.
- 12 out of 19 patients who underwent surgery on 8 February 1999 experienced significant permanent damage to their corneas and visual impairment.
- A solution named "Eyestream" was introduced into the surgical procedures during the course of the Surgical List. The box and bottle containing this solution bear warnings to the effect that it is not to be used for intra ocular surgery.
- On the evidence available, the use of this solution caused the adverse outcomes.
- The following systemic issues warrant review and rectification. The Commission recommends that:

  1. Protocols and procedures be developed for

     i. acquisition of stock for use in Theatres

     ii. verification of receipt of materials used in operating rooms, particularly in unusual circumstances.

  2. The role and function of the Hospital Pharmacy be reviewed to ensure the correct use of products in Theatres.

  3. Protocols for nursing and surgical team members be developed to specify the procedures to follow when identifying drugs, solutions and other substances in Theatre.

  4. The critical incidents policy of the Hospital and Area Health Service be reviewed to ensure the policy is widely disseminated and that staff understand and act on their obligations under the policy.

Recommendations

1. The Hospital and the Area Health Service conduct a review and develop the current policy and practice for the ordering of surgical stores. The policy should include the following:
   - Documents should show the actual date the materials are required .
   - Order documents should be able to identify the status of the requisition, in particular, whether it is urgent or non-urgent.
   - Order documents should show the actual address to which the stores are delivered.

2 Relationships with suppliers be developed by the Hospital and Area Health Service to ensure that any ambiguity or variation in the Order form is capable of being clarified informally prior to supply.

3 The Hospital and Area Health Service ensure that a full and detailed description of the processes involved in the acquisition of stores is available to those primarily responsible for ordering stores.

4(a) Clear procedures be set in place to check and record the physical receipt of goods at both Area Supply Service and Hospital, irrespective of when the goods are delivered or where they are delivered.

4(b) The above procedure should include a process whereby the nursing staff for the Theatre for which the goods are ordered are advised as early as possible of the receipt and adequacy of the goods supplied.

5 The Hospital develop a written protocol for the proper identification of substances introduced into Theatres. Identification should include the assessment of the suitability of the product for its intended purpose. The protocol should also identify the individual responsibilities of each of the Surgical and Nursing Team members.

6 The Hospital review and develop its Quality Assurance Operating Rooms Skills Test to ensure it fully examines the competence of the person in respect of each of the key processes involved in identifying the suitability of substances for surgical purposes.

7 The Hospital review and develop the Hospital Policy entitled “Handling of Medications” to ensure that it includes the identification and asssessment of pharmaceutical items and to ensure that it is clearly applicable to Theatres and all relevant professional groups involved.

8 The Area Health Service conduct an audit of the adherence by the Hospital to Departmental Circular No. 95/37, titled “ Guidelines for the handling of medication in New South Wales Public Hospitals”, and take steps to ensure future adherence with the policy.

9 The Hospital Pharmacy policy be reviewed to ensure that the same involvement and consultation provided by pharmacists to the Wards is provided to Theatres.

10 The Hospital and Area Health Service review the appropriateness and effectiveness of the current Critical Incident Policy and identify the means to ensure the policy is widely disseminated and staff understand and act on their obligations under the policy.

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:

11 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 failsafe.

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 the 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 the a representative of Australian Confederation of Operating Room Nurses in respect of the last term of reference.)

12 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.

13 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. The Complaint

The Chief Health Officer of the NSW Department of Health advised the Commissioner on 23 June 1999 of an incident concerning a cataract extraction and intra ocular lens implantation surgery list at Dubbo Hospital. The Commission was told that more than 50% of patients in the list were found to have suffered corneal damage following that surgery. The incident in question occurred on 8 February 1999.

The Chief Executive Officer of the Macquarie Area Health Service subsequently made a complaint related to the incident in the form of a statutory declaration to the Commission dated 29 June 1999.

The complaint was assessed for investigation by the Commission's Assessment Committee on 30 June 1999.

2. Background

In early February it was decided to conduct an additional cataract surgical list at Dubbo Base Hospital.

A surgical list of 20 patients was developed by the hospital. Surgery was scheduled for 8 February 1999.

It appears that on 8 February 1999 supplies of the usual irrigating and intra ocular agent, BSS[1] a balanced salt solution, were low due to errors in ordering and/or delivery and that the solution "Eyestream"[2] was used as a substitute for the usual solution.

On 12 March 1999 the Ophthalmologist who performed the surgery wrote to the Director of Medical Services at Dubbo Base Hospital advising that follow-up examinations found 11 patients with "marked corneal decompensation". The letter postulated that the balanced salt solution "Eyestream" may have been responsible for the adverse outcomes on the basis that it contained a preservative, Benzalkonium chloride, which is not present in BSS.

3. Sources of Information

Interviews have been conducted with the following:

1 Scout Nurse
2 Phaco emulsifier machine operator
3 Scrub nurses (3)
4 Anaesthetist
5 Chief Pharmacist
6 Pharmacist
7 Stores Officers (2)
8 Hospital Manager
9 Hospital Business Manager
10 Hospital Manager of Nursing Services
11 Hospital Acting Director of Medical Services
12 Hospital Infection Control Consultant
13 Acting Manager of Nursing Services

Reports

Reports have been received from the Opthalmologist and both Surgical Assistants.

Advice

Advice as to the general matters relating to the surgery has been obtained from a practicing Ophthalmologist and further advice from a Ophthalmologist who examined the patients in respect of the current condition of the patients.

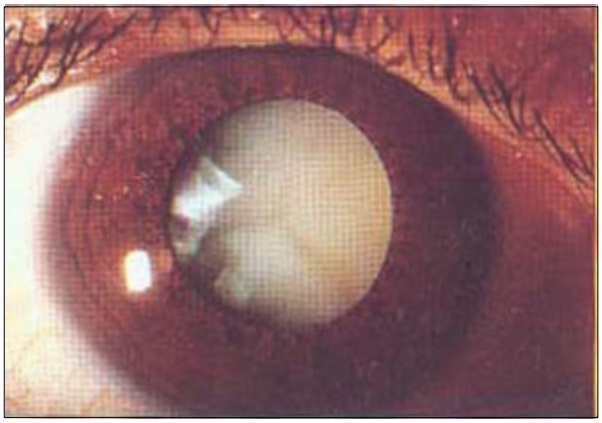
Documentation

A significant volume of information, including patient records, copies of policies, rules, by-laws and other documents have been acquired from both the Hospital and the Area Health Service. Information has also been supplied by the product manufacturer.

4. The Hospital

Dubbo Base Hospital is located in central western New South Wales and is classified as a major non metropolitan health care facility with approximately 144 available beds. The Hospital is under the authority of the Macquarie Area Health Service and provides acute specialist and referral services for a large geographic area. It has four operating rooms, and the relevant surgical list was conducted in operating room 3.

5. The Procedure



Photograph 1 - Cataract[3]
Smith T (Ed) The Human Body

A cataract is an opacity of the crystalline lens of the eye (see Photograph 1). Minor lens opacity is extremely common but more extensive lens opacity interferes with light passing through the crystalline lens and therefore reduces vision.[4] The criteria for diagnosis of cataract are a history of progressive loss of vision and an absence of, or remarkedly diminished, red reflex from the fundus of the eye, as viewed with an ophthalmoscope. The only treatment for cataract is surgical extraction of the opacified lens and the introduction of an artificial intra-ocular lens (see Diagram 1). There are a number of different procedures available for use in cataract extraction. The procedure employed on 8 February is described below.

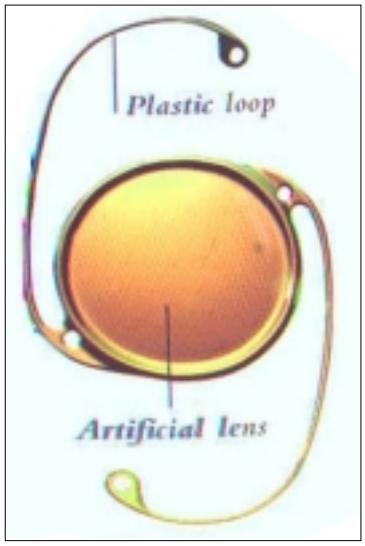


Diagram 1 - Intra-Ocular Lens[3]
Smith T (Ed) The Human Body

The surgical site was prepared by swabbing the area with a solution of Betadine and Hartmans solution. Pre-operative medication was administered and local anaesthesia, involving a combination of Naropin or Lignocaine, Clonidine, Hyalase and Adrenalin, was injected conjunctively.

The technique employed by the ophthalmic surgeon involved extra capsular cataract extraction where the cataract is aspirated (extracted) while leaving the lens capsule intact (see Diagram 2). An intra-ocular lens is then placed in the empty lens capsule in the posterior chamber, substituting for the natural lens. This usually leads to the rapid recovery of sight[6].

The operative procedure involves the use of a phaco emulisfier machine as the primary surgical tool (see photograph 2).

This device is operated through a handset through which a metal probe is inserted into the opaque lens. The lens is broken up through the application of high frequency (ultra-sonic) vibrations. The probe also carries with it two tubes. One is used to pump BSS into the

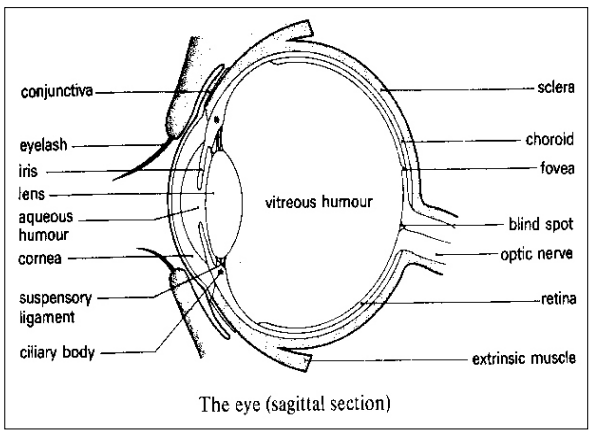
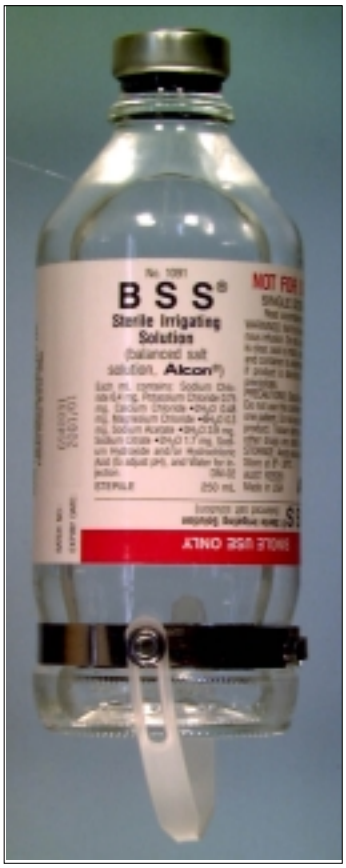


Diagram 2 - Basic Structures of the Eye[4]
Cook et al, General Surgery at District Hospital

Photograph 2 - Alcon Universal, phaco emulsifier machine used on 8 February 1999

anterior chamber and one is used to evacuate the BSS and the fragments of the lens. The BSS is introduced to the machine via a tube connected to a 250 ml bottle of the solution (see Photograph 3).

"BSS" is a product name for a balanced salt solution. This solution is sold to hospitals and is used for irrigation during surgery of the eyes, ears, nose and throat. It is suitable for intra ocular use.



Where a cataract is particularly dense additional BSS may be required. In such cases a 500ml bottle is used, subject to availability.

In addition to the phaco emulsifier BSS can be introduced to the anterior chamber of the eye through the use of a Binkhorst cannula and a Rycroft cannula, both of which are attached to 5ml syringes. Both cannulae may be used as required to assist in the dislodgement of the lens. It is not always necessary to use either or both cannulae in an operation

The solution is also used in a 20ml syringe to irrigate the corneal surface during surgery, refilled as necessary, and a further 5ml syringe is available to administer BSS to the anterior chamber prior to insertion of the intra ocular lens to separate the walls of the lens capsule permitting free passage of the lens.

The solution was drawn up into the syringes by the scrub nurse from small "galley-pots" filled with the solution by the Scout Nurse.

It should be noted that other substances, in particular Miochol[7], were also introduced into the operation site, via cannula, as required.

Photograph 3 - 250ml Bottle BSS Solution

6. Operation Team

The operation team consisted of the following personnel:

(1) The Ophthalmologist who performed the surgical procedures

(2) Two surgical assistants (each present for part of the list)

(3) A phaco emulsifier operator, a specially trained nurse

(4) A scout nurse, whose role is to ensure the availability of adequate supplies and support the scrub nurses.

(5) 2 scrub or instrument nurses, who alternated between patients and whose role is to prepare the instruments, drugs and solutions required during surgery and support the surgeon as required. Replacement Scrub Nurses commenced duty on the afternoon shift.

(6) Anaesthetist

(7) Anaesthetic nurse

7. The Patients

Dubbo Base Hospital identified that 20 patients were initially scheduled for the ophthalmic list, however only 19 attended for surgery, 14 female and 5 male. Medical records for all these patients were reviewed by the Commission. Ages ranged from 59 years to 84 years. 6 patients had operations to their left eye and 13 had operations to the right eye. The List was organised so that left eye operations were performed first then right eye operations. This was because the various equipment and personnel in the operating room have to be re-located depending on which eye is being operated on.

Of the patients subsequently identified as suffering corneal damage the first, in order of operation, was at number 5 and thereafter each patient suffered damage, other than patients 9, 13 and 16. A total of 12 patients have been identified as suffering corneal damage. On the information currently available to the Commission it is extremely rare for more than 1 patient in such a List to experience adverse outcomes.

Two patients presented to the hospital within one week of the operation, complaining of poor vision and discomfort. The first presented with severe right-eye pain. She was admitted two days post operatively with a provisional diagnosis of glaucoma. It was noted that her right eye cornea was cloudy. She was given medication and discharged after five days. The second was seen five days post operatively and reviewed by the ophthalmologist and his registrar. It is noted in a letter from the registrar that the patient was diagnosed at that time as having "plasmoid iritis[8] secondary to intraoperative miochol". She was given medication and discharged.

Document 1 is a copy of the surgical list with those suffering adverse outcomes identified. All patients were subsequently reviewed by an ophthalmic surgeon engaged by the Area Health Service in mid July 1999. His findings support the observations of the treating doctors.

Damage to either the epithelium or endothelium will cause corneal oedema which may be transient, or permanent if the endothelium is mechanically or chemically destroyed. As adult endothelium cells do not regenerate they cannot sustain insult without incurring permanent damage (reference *Means et al.* See diagram 3). Such damage may lead to mild or significant visual impairment.

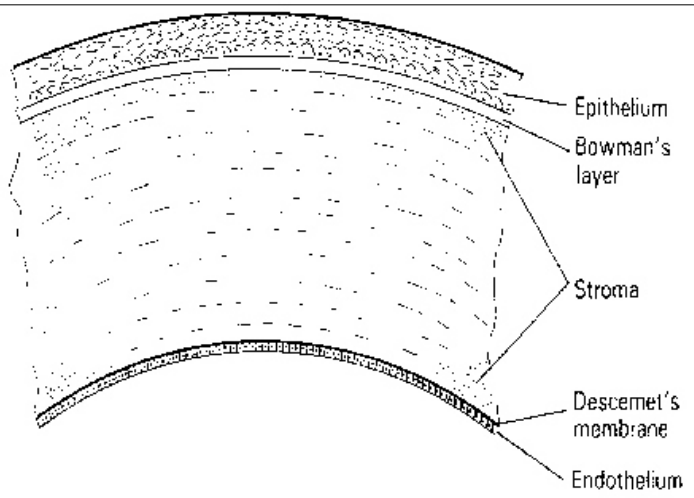


Fig. 24.1 The cornea is composed of five layers. The epithelium is the non-keratinized surface composed of four to six cell layers. Bowman's layer is in contact with the basement membrane of the basal epithelial cells and continuous with the corneal stroma posteriorly. The stroma is composed of lamellar layers of collagen in a glycosaminoglycan matrix. Descemet's membrane is the basement membrane of the endothelial cells. The endothelium is a single cell layer which does not display mitotic activity in adults.

Diagram 3 - The Structure of the Cornea[9]

8. Possible Causes of Corneal Decompensation

The cornea functions as the major refractive surface of the eye. It refracts the light entering the eye into the lens. To do this effectively, the cornea requires a smooth surface and transparent structure. It is a highly sensitive structure and is liable to be damaged, (decompensate) in surgery for a number of reasons. Research available to the Commission so far shows the following possible causes of decompensation associated with surgery:

- **Pre-existing conditions**
    - diseases such as uveitis, Fuchs' endothelial dystrophy, previous trauma or surgery or glaucoma.
    - chronic inflammation
    - previous eye surgery
    - contact lens use
    - dry eye syndrome/eye medications

- **Intraoperative factors**
    - surgical technique. Preparation for surgery including prolonged contact with topical solutions may damage the corneal epithelium. Surgical instruments may strip the endothelium and/or Descement's membrane if misdirected.
    - "difficult cases" are associated with a higher endothelial cell loss
    - insertion and properties of intraocular lenses
    - exposure to irrigating solutions may traumatise the endothelium particularly when the composition of the solution does not resemble the aqueous solution.

9. The Role of Benzalkonium Chloride

Benzalkonium chloride is primarily used as an opthalmic preservative and a germicidal cleaning solution for contact lenses. The literature notes that the agent is toxic to the corneal endothilium when introduced into the eye[10]. An article by *Means et al* found that extremely low levels of Benzalkonium chloride when used in an intraocular solution caused immediate corneal swelling and destruction of corneal endothelial cells.

As noted earlier in the report the product Eyestream, which contains Benzalkonium chloride, was introduced into the intra ocular environment of some patients on 8 February 1999. Eyestream is widely available and was used in the Emergency Department for first aid purposes.

The technique used by the surgeon is recognised as an acceptable approach to cataract removal and intra ocular lens insertion. A video recording of a number of the operations on the list has been reviewed by a peer and the technique was found to be unremarkable. There is similarly no evidence that the insertion and properties of intra ocular lenses previously caused adverse outcomes to the extent experienced in this instance. There is no evidence to suggest that those patients who suffered an adverse outcome were particularly 'difficult cases'.

A number of the substances used during cataract surgery can cause adverse reactions of the kind experienced in this list. All of these substances were used, as required, throughout the list. There is no prior history at Dubbo of these substances causing such a high number of adverse outcomes so far as the Commission is aware.

Each of the above possible causes still requires further examination. The Commission has identified that the introduction of Eyestream was the only departure from normal surgical practice. The extent and number of adverse outcomes was unexpectedly high. The Commission has considered the available factual information, expert opinion and literature on the effects of Benzalkonium chloride and concludes that the use of Eyestream was the most probable cause of the adverse outcomes arising from the surgical procedures on 8 February 1999.

10. Identification of Systemic Issues

The following issues warrant attention:

- Procedures and Protocols for the acquisition of substances and materials required for operating room use.
- Role and function of Hospital pharmacy in ensuring the safety of substances used in theatres.
- Role of the surgical and nursing team in determining the safety of substances used in the operating rooms.
- Protocols for identifying substances used during surgery.
- Protocols for introducing new or substitute substances prior to or during the course of surgery.
- Identification and reporting of critical incidents by operating team members.
- Hospital management's obligations and actions for unexplained adverse surgical outcomes.

11. Investigation

11.1 Checking and ordering stock

11.1.1 Actions prior to 8 February 1999

Preliminary information suggested Eyestream was associated with the adverse outcomes. For this reason, information was obtained on stock control and ordering mechanisms.

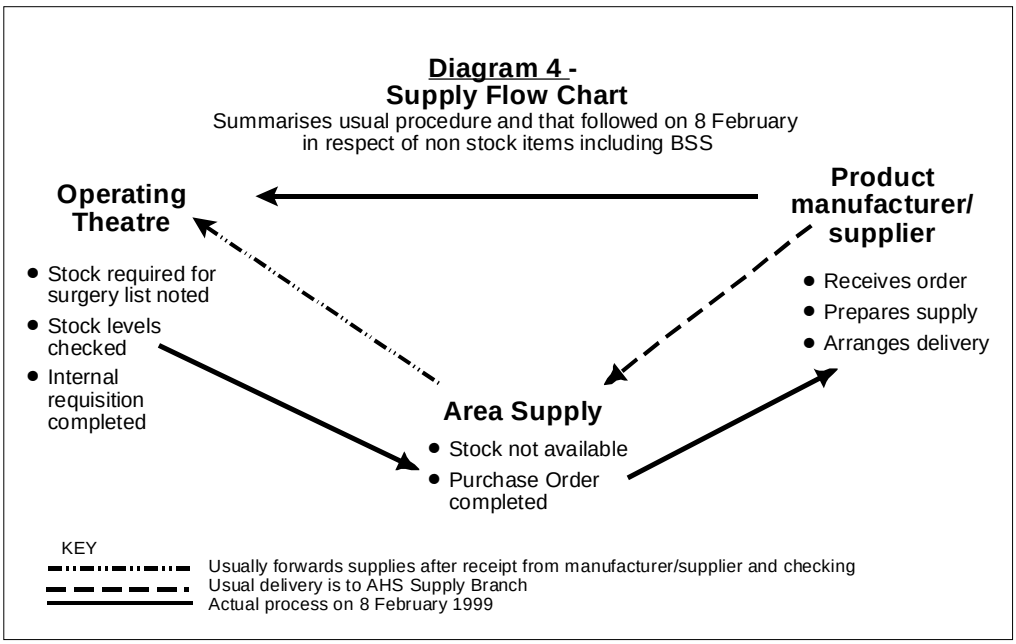
Interviews with the relevant staff at the Area Health Service Supply Service, administrative staff at Dubbo Base Hospital and the Nursing Team members involved in the ordering of substances for the surgical list have established the following:

- In early February 1999 it was decided that an additional cataract list would be conducted at Dubbo Base Hospital.
- A Surgery list of 20 patients was developed by the Hospital to take place on 8 February 1999.
- On Wednesday 3 February 1999 a check was conducted on the available supplies of the substances necessary for the surgical list to proceed. Following this check an internal purchase requisition form was completed by a member of the nursing Team **(Document 2)** and forwarded to the Macquarie Area Purchase and Supply Service. Amongst the substances requested was 10 boxes of 250ml BSS, 60 bottles in all, and 3 boxes of 500 ml BSS, 18 bottles in all. As noted previously, BSS is a balanced salt solution.
- A Purchase Order **(Document 3)** was completed by the Acting Order Officer in the Supply Service of the Area Health Service and forwarded to the product supplier. The Purchase Order form does not have a field to record the status of the Order, for example, urgent or routine. It is noted that the Purchase Order is dated 4.2.99 and requested for delivery on the same day. The Commission understands that delivery was not, in fact, required that day. However the document does not record an actual date for delivery, which in this instance is understood to have been 8 February. Delivery was initially arranged for Monday morning 8 February, however after it was realized that this would be too late, delivery was re-arranged for Saturday morning, 6 February. Arrangements were made for the BSS to be delivered to the Theatres, rather than the AHS Supply Service.
- A physical check was made during the week-end by the same member of the nursing team who placed the order. It was discovered that only 3 boxes of BSS had been delivered however, the contents of the 3 boxes were not checked.
- The Invoice **(Document 4)** shows only 10 bottles of 250ml BSS and 3 bottles of 500ml BSS were in fact delivered. There appears to be a discrepancy between the Order date on the Purchase Order, 4/2 and the Order date recorded on the Invoice, 5/2. See Diagram 4.

11.1.2 Actions on 8 February prior to surgery

Interviews with members of the Nursing Team have established that:

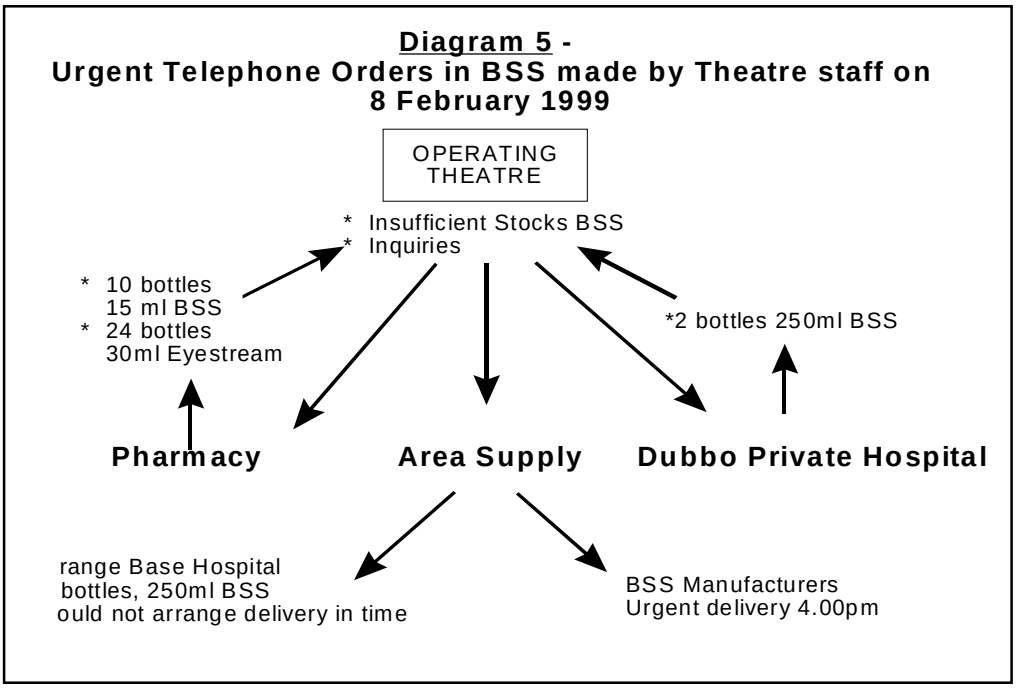
- The 3 boxes were opened at around 7.30 a.m. on Monday morning on 8 February 1999 in the course of preparing for the surgical list. At that time the deficiency was discovered.
- A further 7 bottles of 250 ml BSS were already in stock and arrangements were made to borrow a further 2 or 3 250ml bottles of the solution from the local Private Hospital. This meant there was sufficient BSS for use in the phaco emulsifier machine. (See Diagram 5). However there would still be a shortage of the solution for use in the syringes, and for other purposes.



- Contact was also made with Orange Base Hospital by Supplies Branch. There were supplies of the solution at the Hospital however delivery could not be arranged for use in the List.
- Information from the various members of the Nursing Team, corroborated to some extent by information provided by the Ophthalmologist, establishes that a discussion took place between some members of the surgical and nursing teams as to whether there was sufficient solution to enable the proposed surgical list to proceed. It was decided that the surgical list could commence, and that care would be taken to limit, as far as possible, the use of the solution.

Analysis

The Hospital and Area Health Services policies for the requisition and acquisition of surgical stores need to be reviewed in a number of areas, namely the need to specify the materials required-by date and the need to establish the degree of urgency. Physical checks of material received should be conducted prior to the date of surgery. The Order Forms should also specify any special requirements.



There were deficiencies in the procedures by which the ordering and checking of the supplies were conducted. It is acknowledged that this was an "extra" list and therefore placed unexpected demands on Theatre stock, procedures and staff. Given however that the supplies were essential to the conduct of the list, it would seem highly desirable to verify that sufficient supplies were in fact available to permit the list to proceed. The Commission is not aware of any protocol which exists to ensure that the supplies are actually checked on receipt against the internal order form, at least in respect of weekends. There appears to be no obligation or responsibility to report to the surgical/ nursing team on whether adequate supplies exist to permit the list to proceed.

There is considerable inconvenience to patients and additional expense to the hospital if surgical lists are cancelled at the last minute. Also, once patients are being prepared for surgery and the surgical/nursing team assembled the temptation to press on with inadequate supplies exists. For these reasons it is desirable that a protocol be developed which identifies responsibility for receiving, checking on supplies and also for identifying and implementing appropriate procedures should there be a shortfall between the amount ordered and supplied. This issue is particularly significant where facilities do not have proximate access to suppliers and therefore deficiencies in stock cannot easily be rectified.

Recommendations

1 The Hospital and the Area Health Service conduct a review and develop the current policy and practice for the ordering of surgical stores. The policy should include the following:
- Documents should show the actual date the materials are required
- Order documents should be able to identify the status of the requisition, in particular, whether it is urgent or non-urgent.
- Order documents should show the actual address to which the stores are delivered.

2 Relationships with suppliers be developed by the Hospital and Area Health Service to ensure that any ambiguity or variation in the Order form is capable of being clarified informally prior to supply.

3 The Hospital and Area Health Service ensure that a full and detailed description of the processes involved in the acquisition of stores is available to those primarily responsible for ordering stores.

4(a) Clear procedures be established to check and record the physical receipt of goods at both Area Supply Service and Hospital, irrespective of when the goods are delivered or where they are delivered.

4(b) The above procedure should include a process whereby the nursing staff for the Theatre for which the goods are ordered are advised as early as possible of the receipt and adequacy of the goods supplied.

11.2 Introduction of Eyestream into surgery

The surgical procedures commenced using the available BSS. At an early stage in the list the stocks of the solution available for use in the syringes became depleted. It is noted that operations on patients numbers 3 and 4 took 29 minutes and 26 minutes respectively. This is significantly longer than the operation time for the majority of the patients. Additional BSS may have been required by the phaco emulsifier machine in these operations and therefore the available stock for use by the scrub nurses in filling the syringes may have been exhausted at that time. A schedule of the operation times with patients suffering adverse outcomes indicated by an asterisk is set out in Table 1.

The medical records do not assist the Commission to determine when the Eyestream was introduced, as the records fail to record all pharmaceuticals used during the procedures eg BSS, Eyestream, Viscoat, Miochol.

The Commission found the records did not accurately identify the members of the surgical/nursing team and who performed each function in respect if each operation.

Table 1
Duration of procedures by patient

Patient	Time (mins)	Patient	Time (mins)
1	20	10*	16
2	10	11*	19
3	29	12*	14
4	26	13	13
5*	28	14*	17
6*	17	15*	20
7*	17	16	22
8*	20	17*	24
9	21	18*	15
		19*	20

The Commission has evidence to show that the Pharmacy Department was contacted by a member of the Nursing Team and requested to supply eye solutions. The exact terms of the request are in dispute, however, there is evidence that the Pharmacy Department initially provided some 10 x15ml bottles of BSS (Photographs 4 & 5), and, shortly thereafter, 24 X 30ml bottles of a balanced salt solution known as "Eyestream". **(Document 5)**.

Photograph 4

Photograph 5

When the boxes of "Eyestream" were delivered to the Nurse, no inquiry or discussion as to the suitability of the product for intra ocular surgery took place with the Pharmacist who delivered the product. Each bottle of Eyestream is individually boxed and one side of the box bears the warning: "Not for injection or intra ocular use". Each bottle bears the warning "not for injection or intra ocular surgery". It is a balanced salt solution and chemically identical to the BSS product other than for the additional component of 0.13mg per ml. of Benzalkonium chloride, a preservative.

Photographs 6-9 - Product information including warning on 30ml Eyestream packaging

The Nursing Team and the Surgical Team are in conflict as to whether the Eyestream was identified when it was introduced into the Theatre. This matter is the subject of ongoing investigation. It is clear that the Eyestream was introduced into the operative procedures by emptying bottles of the solution into the galley pots in lieu of the BSS. The solution was then drawn up into the syringes in the manner described in Section 4 **(The Procedure)**. The syringes were used by the Ophthalmologist or the surgical assistant (if present) as required to assist in eye irrigation, cataract extraction and the insertion of the artificial lens. Not all patients required the use of all the syringes which were drawn from the galley pots. The Eyestream solution was not used in the phaco emulsifier machine as there was adequate supply of 250ml bottles for that machine.

Photographs 10-13 - Product information including warning on 30ml bottles of Eyestream.

Irrespective of which version of events is accepted, it is clear that the warnings on the box and bottle were not read. The Commission has been unable to identify any written protocol within the Hospital's policy which deals directly with the introduction of substances to the surgical field. A Clinical Nurse Educator specialising in Theatres, has set out a suggested protocol in respect of the identification of drugs and other substances introduced into Theatre. **(Document 6).** The protocol in place on the 8 February differed from the suggested protocol. The full extent of the difference is still being investigated.

Review of policies

The Commission has examined the Hospital's Nursing Policy Manual in relation to the handling of medications. The Commission has been advised that the procedures outlined in Policy No. 3.1.09 **(Document 7)** are identical for both familiar and unfamiliar products. Neither that policy, nor any other policy sets out or refers to any protocol for substance identification from the delivery point into Theatres and its introduction and use in the surgical procedures.

One element of product identification is included in the Quality Assurance Operating Room Skills Test **(Document 8)** under the Topic "Aseptic Technique as a Scout Nurse". This is not an adequate approach to what is a critical process involving a number of persons of different specialities and professions.

The Policy titled "Handling of Medications" **(Document 7)** identifies safeguards for medications applicable for wards however no such safeguards appear to have been developed for use in Theatres. The Policy also appears to focus on Schedule 8 Drugs and to a lesser extent I.V. fluids. Little guidance is provided in respect of other pharmaceutical products.This policy refers to a "Medication Incident Policy", whereby Nursing staff are required to report "all medication incidents" via an approved form.

The relationship of this Policy to the Critical Incident Policy document is unclear and the role of the Medical Practitioner reporting incidents via this Policy is also unclear.

The absence of a policy or protocol in a written form does not mean no such protocol exists. Protocols are taught in nursing training and are the subject of comment in textbooks. The absence of a written protocol however, means there is no written standard against which individual nurses and medical practitioners practices can be evaluated and improved if necessary.

The absence of a written protocol also enables unsafe practices to develop, both within surgical/ nursing teams and with the surgical procedures being undertaken. For example, taking short cuts in protocol and making assumptions are unsafe practices which may arise from the absence of a written protocol. A mandatory written protocol should be developed for use in identifying medications and solutions used in surgical procedures at Dubbo Base Hospital. That protocol should establish the responsibility of each relevant member of the surgical/nursing team in the identification process. Consideration should be given to developing a system where members of the surgical and nursing team sign some acknowledgement where new pharmaceuticals are introduced to a surgical procedure.

Recommendations

5. The Hospital develop a written protocol for the proper identification of substances introduced into Theatres. Identification should include the assessment of the suitability of the product for its intended purpose. The protocol should also identify the individual responsibilities of each of the Surgical and Nursing Team members.

6. The Hospital should review and develop its Quality Assurance Operating Rooms Skills Test to ensure it fully examines the competence of the person in respect of each of the key processes involved in identifying the suitability of substances for surgical purposes.

7. The Hospital should review and develop the Hospital Policy entitled "Handling of Medications" to ensure that it includes the identification and asssessment of pharmaceutical items and to ensure that it applies to Theatres and all relevant professional groups involved.

11.3 The role of Pharmacy Department

Interviews with nursing team members and Hospital pharmacists have established that:

- The Theatre obtains pharmaceuticals from either the Pharmacy Department or the Area Health Supply Service. In this instance the BSS solutions were obtained from the Supply Service which is consistent with normal practice.
- Theatres acquire some pharmaceutical products from the Pharmacy Department. There is an imprest system for regularly used pharmaceuticals. In addition there is an internal requisition process whereby pharmaceutical products can be acquired on a "as required" basis.
- In this instance the information currently available shows that a member of the nursing team contacted a pharmacist by telephone and requested an urgent delivery, without completing an internal requisition form. The pharmacist completed an undated requisition form to ensure a record was kept of the substances he provided **(Document 5)**.
- On the evidence available it appears there was an initial verbal request for any balanced salt solution, which was supplied. There was a further verbal request (the details are in dispute), which resulted in the supply of 24 boxes of the solution known as "Eyestream". The product was kept in the Pharmacy Department as it was frequently used in the Emergency Department for first aid purposes.
- The Hospital Pharmacists have, as part of their professional responsibility, a monitoring role in respect of drugs and other pharmaceutical products used in the various wards of the hospital.

The responsibilities of Pharmacists in the public health system are set out in Circular 95/37 'Guidelines for handling of medications in NSW public hospitals' issued by the Department of Health, May 1995. The Policy covers any department of the hospital including Theatres.

Section 4.4 of the Policy deals with supply and specifies in part:

> Medications may only be supplied to a ward: "on the written requisition of a medical officer or dentist or of the nurse in charge of the ward in which the drug is to be used or stored".

This does not preclude the use of the Imprest system (see below).

A review of internal requisition forms issued by Theatres dated between 2 February to 23 March 1999 found the following omissions:

- schedule 8 drug ordered without signature by the authorising officer
- drugs ordered without the designation of the person completing the form nor a signature by the authorising officer
- one order lacked any signature
- the majority of drugs were ordered without the signature of the nurse in charge as specified in the policy.

- the majority of forms lacked the name or signature of the receiving officer
- one Imprest order for schedule 4 drugs was made by an enrolled nurse.

Circular 95/37 outlines the requirement to have a mechanism in place for medication incident reporting. Such incidents would be considered by the institution's Drug Committee. Dubbo Base Hospital has a Drug Committee with a policy for nursing staff to report medication incidents. The policy does not have a definition of medication.

The Hospital was requested to provide guidelines and policies concerning ordering and checking pharmaceuticals by Theatre staff. The documents provided were attached to a cover sheet entitled 'Ophthalmic Ordering System'. The documents included a list of contact names and number for suppliers and an order form. There is no outline of any ordering system in the documentation.

The Hospital's policy on 'Fluids' advises that common IV fluids and irrigations 500 ml and over are handled by Area Supply, with the remainder handled by the Pharmacy Department [11]. The Pharmacy Department advises that it is not consulted on which fluids are currently handled by stores.

There is an absence of any pharmacy policy dealing with the dispensing and monitoring of pharmaceuticals to Theatres.

The Pharmacy Department at Dubbo Base Hospital consists of a Chief Pharmacist, another pharmacist and 2-3 pharmacy assistants. The Chief Pharmacist has duties outside Dubbo Base Hospital on a regular basis. The Pharmacy Department covers other Hospitals in the area, which do not have their own pharmacy. The Chief Pharmacist deals with pharmacy supplies for Dubbo and those hospitals.

The procedure for the requisition and supply of pharmaceuticals to wards at Dubbo Base Hospital is via the Imprest and Requisition systems. A computerised list of regularly used pharmaceuticals is developed by the pharmacist and the head nurse of the relevant ward. The stock is checked by the pharmacist on a regular basis. The type of pharmaceutical and the amount to be supplied is agreed between the pharmacist and the head nurse. Once the supply list for the day is established, the Imprest cupboard is then restocked by either the pharmacist or the pharmacy assistant. Irrespective of who has performed the restock, the Pharmacist checks the list against the stock and signs off the restocking list. This procedure is followed in all wards of Dubbo Base Hospital but not in Theatres.

In Theatres, the Imprest List is still used but not in consultation with the pharmacists. The Imprest List is checked by staff in Theatres and an Order forwarded to the Pharmacy Department. There is no consultation regarding the products supplied. Occasionally the Pharmacy Department might query the amount supplied but this is not a common occurrence. If new drugs are added to the Theatres Imprest List, the Pharmacist would check the Pharmacopeia[12] before supply.

The Chief Pharmacist believes the Imprest List in Theatres was developed with a previous Chief Pharmacist but is not aware of when this occurred. Neither is the current Chief Pharmacist aware of any ad hoc review of the Imprest List nor any system of review of the List.

On receipt of an Order from Theatres the Pharmacy Assistant places the requested stock onto a trolley which is then either collected by a member of the Theatre staff or delivered by the Pharmacy Assistant to the office of the Manager, Nursing Services, Operating Theatres. The Pharmacy Assistant does not deliver directly to the Imprest cupboard since it is within the sterile area and there is a requirement to gown before entering that area.

The Chief Pharmacist told the Commission that the Pharmacy Department at Dubbo Base Hospital is not involved in the Theatres as it is in the wards. This has been the case since at least 1991 when the Chief Pharmacist employed at the Hospital commenced working for Dubbo Base Hospital as a

Pharmacist. The chief pharmacist advised that a change of procedures would involve resource considerations as there are only two pharmacists in the Department.

Analysis

Whilst the request was unusual, the evidence is that the product "Eyestream" was supplied to Theatres without any consultation between the Surgical/Nursing Team and the Pharmacist.

The processes set out in the Department of Health Policy as set out in Circular 95/37 (see page 18) are designed to ensure the safe and accountable supply of pharmaceuticals to Theatres. The pharmaceutical requisition system at Dubbo Base Hospital does not appear to comply with the Policy in relation to the supply of non Imprest medication to Theatres.

BSS may arguably be a specialist irrigation fluid, yet it is handled by Area Supply. The lack of involvement of the Pharmacy Department in determining which fluids come under its purview and which do not is of concern.

No protocols involve the Hospital Pharmacy Department in any professional oversight of the pharmaceutical products used in Theatres. In practice, the Pharmacy Department is not informed of the nature of the surgical procedures to be carried out by Theatres and is not consulted by Theatre staff. The absence of such a protocol denies Theatres access to the pharmacists' specialized knowledge. In this instance the lack of information and consultation resulted in the pharmacist being unaware of the use to which the substance was put and unable, therefore, to provide any advice in relation to such use. The practice in Theatres should be consistent with the practice in the wards. The lack of consultation between Theatre and Pharmacy Department contributed to the events that occurred on 8 February 1999.

The Commission recommends that the Pharmacy Department and Theatre procedures at Dubbo Base Hospital be reviewed to ensure that pharmacist involvement in the assessment of the suitability of a new product is the same for items requested by Theatres as it is for items requested for use by the various Hospital wards.

Recommendations

8. The Area Health Service conduct an audit of the adherence by the Hospital to Departmental Circular No. 95/37, titled " Guidelines for the handling of medication in New South Wales Public Hospitals", and take whatever steps are appropriate to ensure future adherence with the policy.

9. The Hospital Pharmacy policy be reviewed to ensure the same involvement and consultation provided by pharmacists to the Wards is provided to Theatres.

11.4 Critical Incident Reporting and Management

The evidence suggests that Hospital management was first notified about the adverse outcomes experienced by the patients when the letter from the Ophthalmologist dated 12 March 1999 was received on or around 23 March.

The Hospital has adopted the Critical Incident Policy of the Macquarie Area Health Service (Diagram 6). This policy though, does not translate well into the Hospital environment. In particular the policy defines responsibilities by position descriptions which are not directly analogous to Hospital positions. It is also not clear at which point the Hospital policy and responsibilities overlap with those of the Area. These matters should be addressed. The critical incident Policy **(Document 10)** provides, in part, that:

- The term "Critical Incident" is defined , partly by example. *(It is noted that no example refers to unexplained or unusual adverse outcomes being suffered by patients.)*
- All Critical Incidents must be reported by staff as soon as they occur.
- Managers and supervisors are to review all such incidents with staff as soon as reported and to make a judgement about the seriousness of the incident.
- If the incident is judged to be critical then the Manager is to give the matter priority attention.
- The Manager determines who will be the co-ordinator of the critical incident handling process.

There are detailed steps identified in the Policy as to what should occur in the course of the process. (Diagram 6).

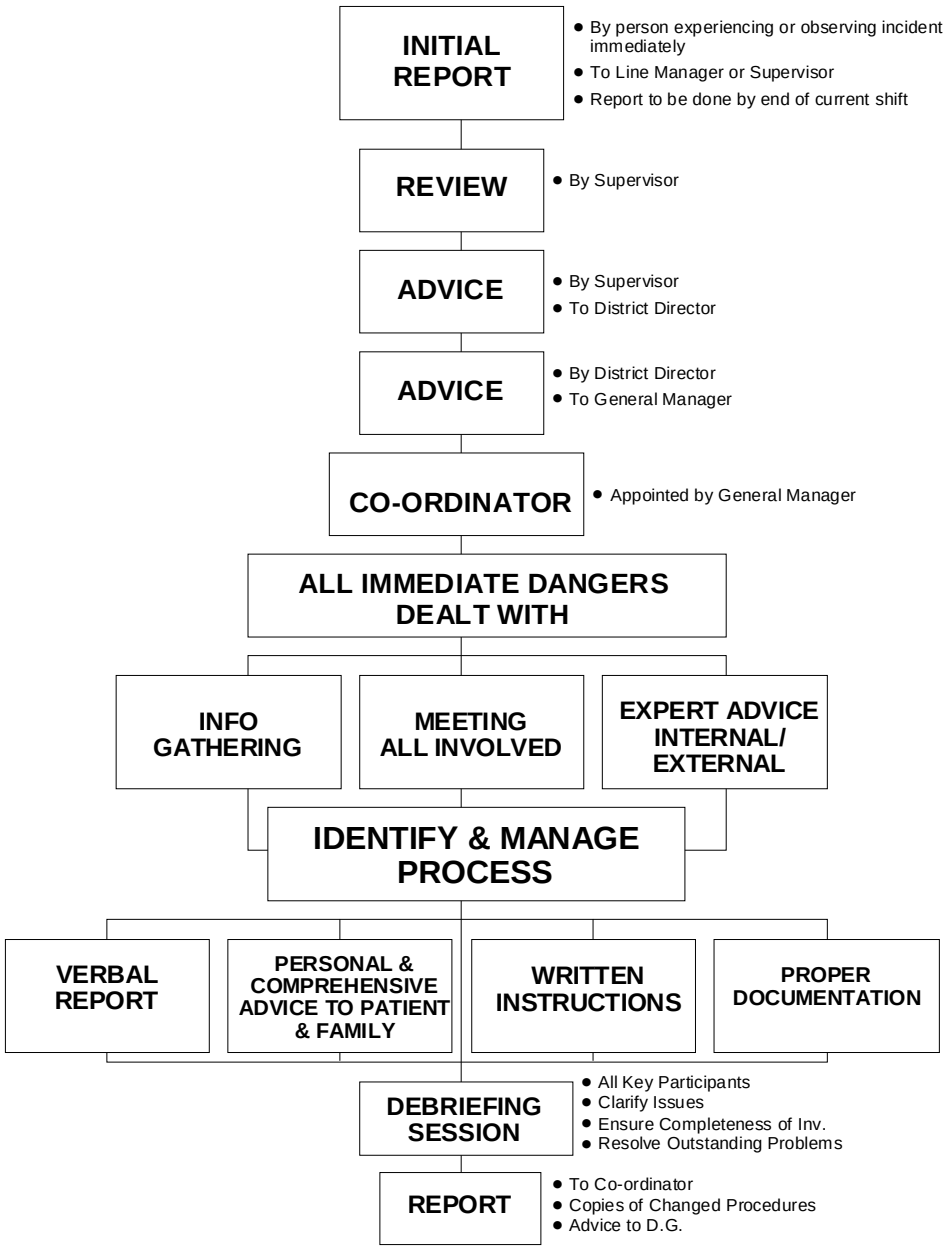
The Commission is satisfied that on any reasonable reading of the Critical Incident Policy, the situation described in the letter of 12 March 1999 constitutes a Critical Incident. The policy, as noted above, directs staff to report incidents as soon as they occur. The adverse effects arising from the incident on 8 February were not apparent on that date. The Commission therefore suggests the words *"or as soon as the incident is discovered"* be added in order to ensure that incidents not discovered until some time after the event are still identified as Critical Incidents.

Department of Health Circular "Incidents Reportable to the Department" 97/58 issued 20 June 1997 expands the types of incidents which would generally warrant prompt advice to the Department, to include "complications or adverse outcomes in clinical care suggesting an unexpected risk to patients or clients in similar settings in the health system." This covers the type of situation arising from the events of 8 February, 1999. This circular was issued as an attachment to a memorandum from Hospital management to all Department Heads and Nursing Unit Managers on 30 June 1999.

The Hospital management did not identify the matter as a critical incident in terms of the Macquarie Area Health Service Critical Incident Policy or the 1997 Department of Health Policy. Accordingly, the Commission finds that those policies were not followed.

The investigation to date has revealed that a critical incident report has never been prepared by any member of staff at Dubbo Base Hospital. As the report triggers the process, no other action to implement the Policy appears to have occurred. The Commission has no evidence that any investigations were carried out into the conduct of the Surgical List on 8 February until late May 1999, although its inquiries in this regard are continuing. " Eyestream" was not removed from the Hospital until that time (late May). The Commission is not aware of any contact initiated by the Hospital with any patient operated on in the Surgical List of 8 February until July 1999.

Diagram 6
Critical Incident Policy
Flow Chart of Actions



The Hospital informed the Area Health Service of the incident in a letter dated 15 June 1999. The letter indicates that "further developments" will be advised, but there is no indication in this letter that the incident is regarded as a Critical Incident nor of the type of response envisaged by the policy. The letter from the Hospital to the Area Health Service does not amount to a Critical Incident Report. Further, the letter makes no reference to the decision to remove "Eyestream" from hospital stock, although this occurred some time previously.

There were and are fundamental obligations on hospital management, irrespective of the existence of the Critical Incident Policy. These obligations include an assessment of any ongoing risk to future surgical patients, the identification of what actually occured and ensuring the risk, if any, is fully addressed. The central responsbility of the hospital is the welfare of its patients. This means that the hospital should immediately contact those patients identified as having adverse outcomes and minimise, as far as possible, any harm. The information available to the Commission is that none of the above occurred until late May 1999.

The Commission is still investigating the response by management of the Hospital to the advice contained in the letter of 12 March 1999 written by the Ophthalmologist.

Recommendation

10. The Hospital and Area Health Service review the appropriateness and effectiveness of the current Critical Incident Policy and identify the means to ensure the policy is widely disseminated and staff understand and act on their obligations under the policy.

12. Respondents

The Commission is investigating the conduct of a number of health care professionals as part of its investigation of this matter. Those investigations have not been completed and any findings and outcome are subject to consultation with the appropriate Registration Boards pursuant to S.38 and S.39(2) of the Health Care Complaints Act.

The Commission has not formed any final view as to the conduct of any individual and no inference should be drawn from the contents of this Report as to the responsibility of any individual.

It should also be noted that the Commission is not investigating the conduct of the manufacturer of "Eyestream" and "BSS" and this Report should not be viewed as being in any way critical of the conduct of that manufacturer or any of its employees.

Endnotes

1 "BSS" is a product name for a balanced salt solution which is sold to hospitals for surgical use. This solution is used for irrigation during surgery of the eyes, ears, nose and throat.

2 "Eyestream" is a balanced salt irrigation solution for extra-ocular use and is widely available for first aid use.

3 Smith, T (Ed) The Human Body, An Illustrated Guide to its structure, function and disorders Darling Kindersley Ltd London 1997 p. 93.

4 Cook et al, General Surgery at District Hospital p. 64, 1998 Geneva.

5 A Dictionary of Nursing, Majellan T (Ed) p. 164 Oxford University Press, Oxford, 1994.

6 Harrison's "Principles of Internal Medicine" 14th Ed. McGraw Hill N.Y. 1998 (P.168).

7 Miochol consists of Acetylcholine chloride used to constrict the pupil of the eye.

8 Inflammation of the Iris usually marked by pain and congestion in the ciliary region, photophobia and contraction of the pupil and discoloration of the Iris - Dorlands Illustrated Medical Dictionary Ed. 28.

9 Donshik P and Ehlers W, 'Corneal Decompensation following Cataract Surgery: Prevention and Management", in Weinstock FJ Ed (1992), Management and care of the cataract patient. Blackwell Publications, Boston 1992 pp 275-296.

10 See References below, in particular Means et al, Fraunfelder, Jaffe and Liebowitz.

11 Pharmacy Manual Dubbo Base Hospital, Section F, issued January 1999.

12 The Pharmacopeia is a list of pharmaceuticals approved for dispensing by the Pharmacy Services Committee of Dubbo Base Hospital.

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Glossary of Terms & Abbreviations

aseptic:	free from infection or septic material.
aqueous humor:	the fluid produced in the eye occupying the anterior and posterior chambers and diffusing out into the blood.
BSS:	a product name for a sterile balanced salt solution sold to hospitals for use in surgery and used for irrigation during surgery of the eyes, ears, nose and throat.
cannula:	a tube for insertion into a duct or cavity.
cataract:	an opacity of the crystalline lens of the eye.
cornea:	transparent epidermis and connective tissue which forms the front surface of the eye.
decompensation:	a failure to counter balance a defect of structure or function
epithelium:	non keratinized surface of the cornea composed of 4-6 layers of epithelial cells.
Eyestream:	an opthalmic irrigating solution for extra ocular use, widely available for first aid purposes. It is of the same composition as BSS with the addition of benzalkonium chloride.
fundus:	the back part of the inside of the eye.
galley-pot:	small metal bowls.
glaucoma:	a group of eye diseases characterised by an increase in intra ocular pressure which causes pathological changes in the optic disk and typical defects in the field of vision.
intra ocular:	within the eye.
IV:	intravenous.
lens:	transparent refractile tissue of the eye which focuses the image on the retina.
oedema:	swelling due to excess fluid in the tissue.
opthalmologist:	a surgeon specialising in diseases of the eye.
pharmacopeia:	a list of pharmaceuticals approved for dispensing by the Pharmacy Services Committee of Dubbo Base Hospital.
phaco emulsification:	a method of cataract extraction in which the lens is fragmented by ultrasonic vibrations and simultaneously irrigated and aspirated.
syringe:	an instruments for injecting fluids or for irrigating or aspirating cavities.

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