A Private Hospital

Plastic Surgeon, Dr B

A Report by the

Health and Disability Commissioner

(Case 06HDC00096)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Dr B	Provider/Plastic Surgeon
A Private Hospital	Provider
Mr C	Hospital Manager, the Hospital
Ms D	Theatre Services Manager, the Hospital
Dr E	Ear nose and throat surgeon
Dr F	Ophthalmologist

Complaint

On 9 January 2006 the Commissioner received a complaint from Mrs A about the services provided by Dr B and a private hospital. The following issues were identified for investigation:

Dr B

- *Whether Dr B provided Mrs A with surgical services of an appropriate standard on 20 October 2005.*

- *Whether Dr B provided Mrs A with adequate information, and appropriate care after her surgery on 20 October 2005.*

The Private Hospital

- *Whether the private hospital (the Hospital) staff took appropriate steps to ensure the correct solution was used to soak the eye shields.*

- *Whether the Hospital staff took appropriate steps to alert Dr B that the eye shields were soaking in chlorhexidine and alcohol.*

An investigation was commenced on 27 January 2006. It has taken over 12 months to complete the investigation because it became necessary to issue a second provisional opinion upon receipt of new information supplied in response to the first. It was also necessary to obtain advice from a second independent plastic surgeon.

Information reviewed

Information provided by:

- Mrs A
- Dr B
- Mr C
- Dr F

Independent expert advice was obtained from Dr Mary Seddon, an expert in quality improvement, root cause analysis and hospital system issues, and independent plastic surgeon Dr David Glasson.

Information gathered during investigation

Blepharoplasty
Blepharoplasty is cosmetic eyelid surgery (eye lift). It involves the removal of redundant (wrinkled) skin, muscle and fat around the upper and lower lids to make the eyes appear wider open, and it is said to have a rejuvenating effect on the face.[1]

Eye shields
When the surgeon has completed surgery to the upper eyelids, plastic eye shields are inserted under the upper and lower lids to protect the eye from abrasions while the lower lid surgery is performed. These eye shields need to be sterilised before they are used in surgery. Care should be taken when inserting the eye shields because injury may occur. The manufacturer advises that to prevent corneal abrasion, antibiotic ointment should be applied to the concave surface of the shield.

The Hospital used re-useable eye shields that could not be high-heat sterilised. At the time of the incident, the Hospital did not have a low temperature autoclave available, and instead used an alcohol and chlorhexidine solution to disinfect the shields. The shields were soaked in a bowl and the solution rinsed off with sterile water before use. Mr C, the Hospital Manager, explained the procedure:

> "At no time was the Chlorhexidine 0.5% in 70% spirit (soaking solution) on the 'sterile tray' (the scrub nurse's instrument trolley used during surgery). The shields were placed in the soaking solution in a dish away from the sterile trolley and removed from the soaking solution by the scrub nurse using forceps prior to use. Once out of the soaking solution, they were to be rinsed in sterile water on the scrub nurse's trolley."

Dr E

[1] Barnes, Lyn. *A Consumer's Guide to Cosmetic Plastic Surgery in New Zealand* (1997).

Dr E was Mrs A's employer at the time of the events giving rise to this complaint. Dr E said that Mrs A had approached him to perform the surgery. He was an ear, nose and throat surgeon but had done blepharoplasty overseas and wanted to develop skill in this area of plastic surgery. He was not well practised in surgery to the lower eyelid but had observed the procedure performed by other surgeons. In his opinion, Dr B had a good reputation and he advised Mrs A to consult him. When she proved suitable for the procedure, Dr E arranged to assist Dr B to perform the lower lid surgery.

Dr B

Dr B is a plastic surgeon and a visiting practitioner holding clinical privileges at the Hospital. He performs plastic surgery, including blepharoplasty, using the equipment, facilities and nursing support at the Hospital. As a visiting practitioner Dr B is subject to the "the Hospitals' Registration Guide" (discussed below).

Mrs A

Dr B first saw Mrs A on 12 October 2005, to assess her suitability for upper and lower lid blepharoplasty. He advised her that she would be a good candidate for the procedure and outlined his "standard explanation of the risks and complications associated with Blepharoplasty, namely bleeding, infection, bad scars, asymmetry, blindness, the need for second surgery, ectropion". Mrs A decided to proceed and the surgery was scheduled for 20 October 2005.

Theatre incident

On 20 October 2005, Dr B performed blepharoplasty surgery on Mrs A at the Hospital.

Dr B explained that after completing surgery to Mrs A's upper lids, he picked up the eye shields, placed them in her eyes, and commenced surgery on her lower lids. However, the nurse assisting him immediately told him that the shields had not been rinsed. He took them out, rinsed them, rinsed Mrs A's eyes with saline, and then replaced the shields before continuing surgery.

The Manager for Theatre Services at the Hospital, Ms D, later provided more details about the incident. Ms D explained to Mrs A that the eye shields had been pre-soaked in a solution made up of chlorhexidine and alcohol. The circulating nurse delivered the eye shields to the scrub nurse and went to get some sterile water so she could rinse them. In the interim, Dr B, who was unaware that the items were not ready for use and wanted to press on with the surgery, took the eye shields from the trolley and placed them in Mrs A's eyes. The scrub nurse quickly alerted him that they had not been rinsed and they were removed. However, the incident was not documented in either the nursing notes or the operation record.

Dr B said that some months before Mrs A's surgery, he had asked the theatre staff what solution was used for disinfecting eye shields, and had been told "chlorhexidine". At the time of Mrs A's surgery, Dr B said that he was "blissfully unaware the solution also contained alcohol".

The Hospital Manager, Mr C, confirmed that "unless the specialist has provided specific standing orders it is not standard practice for medical specialists to be told how items have been sterilised or disinfected".

The Hospital provided a copy of its standard "Clinical Intra Operative Form", which included a category for site sterilisation. Chlorhexidine is included as a subcategory on the form, with options for the nursing staff to tick alcohol, cetrimide, aqueous, saline, adhesive or other. On the form used for Mrs A's surgery and dated 20 October 2005, the aqueous option was ticked. the Hospital later advised that "site sterilisation" on this form meant sterilisation of the outer skin.

Dr B noted that in his experience it is reasonably common for small amounts of chlorhexidine to dribble into the eyes during facial surgery, and that he simply rinses it out. Dr B stated:

> "… [P]ersonally I have never seen any sort of significant reaction to this. This clearly explains why it never occurred to me that any significant untoward event had occurred, as I was unaware that there was alcohol in the solution. I thought it was simply a matter of brief contact of the conjunctiva with chlorhexidine solution which had been taken care of with the saline wash. It certainly never occurred to me that this was something worth noting or mentioning in the operative record or certainly to the recovery nurse."

Dr E had arranged to be in the theatre to observe the blepharoplasty as a support person for Mrs A. He was scrubbing up when Dr B inserted the eye shields. Dr E heard the nurse tell Dr B "that the eye shields may not have been rinsed prior to insertion", although he could not recall the specifics of the conversation. He confirmed that the eye shields were removed and rinsed. Dr E said that both he and Dr B examined Mrs A's cornea and conjunctiva, which appeared normal, and then her eyes were rinsed. Dr E said he was unaware of the sterilisation procedures used to clean the eye shields.

Dr F, ophthalmologist, later told the Hospital investigation team that "chlorhexidine is known to be an extreme irritant to the cornea and causes extraordinary discomfort in proportion to the injury. The damage caused by the solution may not have been visible at time of incident."

Recovery room

Mrs A's surgery appeared to have gone well but while she was recovering from the anaesthetic she experienced extreme pain in both eyes, rather than at the operation site as she had expected. Mrs A told the recovery room nurse who, she said, was very abrupt and spoke to her aggressively. Mrs A was given pethidine, which made her feel light-headed and sick, but had little effect on her pain level. When the anaesthetist came to check Mrs A's recovery, he prescribed Voltaren, but this also proved ineffective. The recovery room nurse attempted to rinse Mrs A's eyes but her pain was excruciating and she could barely open her eyes. She told the nurse that the pain was improving because she wanted to go home. Mrs A was surprised that Dr B did

not come to see her before she was discharged. She was given a steroid cream, Maxitrol, and instructed to commence using the cream the following day.

The recovery room record has a section to record pain. This score is based on a pain level assessment that has a range of 1–5, 1 being low and 5 being severe. Mrs A was assessed as having a pain level of 2 (which is low).

Dr B said that he does not usually visit patients after simple routine surgery such as blepharoplasty but relies on nursing staff to report any problems. Once Mrs A was taken to the recovery room, he continued with the next case and was not advised of Mrs A's extreme pain by the recovery room staff.

Postoperative care

Mrs A was discharged from the Hospital that afternoon. Dr E said that he was surprised she was discharged. He thought that she would remain in hospital overnight but, when he rang the ward, Mrs A had been discharged at her own request. Later that evening, Dr E telephoned Mrs A to ask about her recovery. She believes she told him she could not understand why she was still in such pain, and asked him about the surgery. Mrs A said Dr E gave her a detailed account but said nothing about the incident with the eye shields. Mrs A said that she told Dr E that she could not open her eyes because of the pain, and if she forced a small opening in one lid at a time, all she could see was a "dark haze".

Dr E recalls that they talked for some time. He did not get the impression that she was in "extreme pain" — she seemed "reasonably cheerful and upbeat though she did say her eyes were sore". He explained to her that Dr B had used diathermy[2] on the lower lids and thought this could be the cause of the pain. Dr E said that at no time did he consider a corneal injury because she had no obvious injury to the cornea at the time. He had no previous experience with this type of surgery and had no idea of the level of pain expected.

The following morning (21 October 2005), Mrs A was still in a lot of pain. She was unable to open her eyes. She telephoned Dr B but was only able to talk with his nurse. Mrs A complained of a burning pain inside her eyes, and was told by the nurse that she would inform Dr B.

Dr B explained that he told his nurse that "postoperative burning after Blepharoplasty was uncommon and definitely not normal and I felt like I needed to see her or she needed to be referred to an eye specialist". This was the first he knew of any problem.

Dr E confirmed that he was in contact with Mrs A the day after her surgery. She had told him that her eyes were still sore and it felt like it was coming from within the eye, rather than at the surgery site. Dr E said "that doesn't sound right; you might have had some damage, maybe with the eye shields they used".

[2] The use of high frequency electric current to make an incision.

Dr E said that when it became obvious that Mrs A was suffering complications the day after her surgery, he rang Dr B to check whether this was normal. Dr B confirmed that it was not. They agreed that a review by an ophthalmologist would be a good idea. As it was Friday, Dr E told Dr B that he might be able to get Mrs A seen urgently by a colleague ophthalmologist, Dr F, rather than going through the normal referral process.

Dr B confirmed that he received a phone call from Dr E shortly after Mrs A's call. Dr B said that Dr E told him that "[Mrs A] had had a terrible night and he had already arranged an appointment with an ophthalmologist [Dr F]". Dr B agreed with this course of action.

Dr E telephoned Dr F and was able to arrange an urgent appointment for Mrs A the next morning. Dr E said that Dr F agreed to see Mrs A as a favour for a colleague. It would have been difficult to obtain a specialist appointment at such short notice on a Saturday morning. Dr E said that he explained the surgery to Dr F, including the use of eye shields and the possibility that Mrs A might have had a chemical injury to the cornea. Dr E told Dr F that Mrs A had been using eye pads with antibiotic and steroid ointment since the surgery. Dr F confirmed this to be appropriate treatment even if there was a chemical injury.

Mrs A said that Dr B telephoned her that night to ask her to see him the following week, but Dr E had telephoned her with Dr F's appointment, so she did not see Dr B.

On Saturday 22 October 2005, Dr F examined Mrs A's eyes. Dr B said that he telephoned Dr F, who reported that "she did have healing corneal abrasions secondary to cleaning solution … it should heal within 24–48 hours and that he would continue her on Maxitrol ointment". This assessment was confirmed in a handwritten note from Dr F to Dr B dated 22 October 2005. Dr B said that he "was most reassured by this and felt that with several days' treatment it would be the end of the matter". Dr B noted "at this time I merely thought she had had a corneal abrasion due to the chlorhexidine solution alone and was unaware of any alcohol in the solution".

Unfortunately, Mrs A's eyes did not improve as predicted. She reported having to remain in bed for the remainder of the week; required analgesia every four hours; and applied Maxitrol steroid cream regularly in an effort to control the pain.

On 25 October, Mrs A had an appointment with Dr B's nurse to have her stitches removed. Dr B recalls that he spoke to her that day and told her about his conversation with Dr F. He reassured her that Dr F had said that her eyes would clear up quickly. From a plastic surgery point of view her eyes were healing and, because she felt nauseated, the antibiotics were stopped.

Mrs A said that she did not see Dr B, only his nurse, that day. Mrs A said that Dr B's nurse spoke to Dr B by telephone, and he stopped the antibiotics. Dr B's clinical records for 25 October confirm that Mrs A was seen by the nurse.

On 31 October Mrs A returned to work. She had been unable to drive since her surgery and had had to be driven to work by a friend. She was still in pain, had extreme photophobia, and her vision remained affected. She could not work at her computer and needed sunglasses to control the glare.

On 1 November Mrs A spoke to Dr B's nurse, asking her to tell him that she had "been back to Dr F" and it would take another two weeks for the cornea to heal. Apparently she had also suffered some visual changes, which were improving. On 2 November Dr B received Dr F's letter advising him of the problems Mrs A continued to have with her eyes.

On 3 November, Mrs A had a postoperative appointment with Dr B. However, Dr B was accompanying his wife to an appointment to see Dr E and thought it would be convenient to see Mrs A at the same time. Dr B said that "rather than have Mrs A make an extra trip to the rooms, I simply took her into their coffee room to look at her result and to hear what had been happening".

Dr B said he assured Mrs A that, from a plastic surgery point of view, the blepharoplasty looked fine and that Dr F was taking care of the corneal injury. Dr B said that because Mrs A was improving and her problems appeared to be related to ongoing discomfort rather than the plastic surgery portion of the procedure, he planned to see her again for a final check in three weeks' time. He said he apologised for the problems she had had after the surgery. Mrs A said that when she reported she was still in pain, he said, "I have no idea how that happened and I have asked my staff this morning at [the Hospital] to look into this."

Dr B confirmed that he did have a conversation with the Director of Nursing at the Hospital after his discussion with Mrs A on 3 November 2005. Dr B became aware at that point that the solution had contained alcohol and that Mrs A had complained of severe pain to the recovery nurse. Dr B said he learned that the Theatre Services Manager, Ms D, was to meet with Mrs A in the next few days.

Over the following days, Mrs A's pain did not subside, even though she had finished the steroid cream and obtained another prescription. She telephoned Dr F on 7 November and saw him on 9 November. He told her that her eyes appeared to have healed but she might have "suffered nerve damage". Mrs A said she found this reassuring because, until then, she thought no one believed the level of her pain.

Mrs A called Dr B after her appointment with Dr F on 9 November 2005 and was offered another appointment with Dr B by his nurse. Mrs A declined but asked that Dr B call her. Dr B said he spoke to Mrs A later that day and again expressed his disappointment about her complications. Dr B noted that he asked Mrs A to keep him informed of her progress. Mrs A cannot recall speaking to Dr B that day.

The Hospital
On 3 November Mrs A made a complaint to the Hospital. On 28 November, the Theatre Services Manager, Ms D, reported her investigation findings to Mrs A. Ms D stated:

> "The impression I have initially, on receipt of your complaint, was that a Registered Nurse in our Recovery Area had not managed your care and post operative pain appropriately, in addition her attitude and behaviour could have been perceived as being quite rude and abrupt. I have followed up the issues you raised with the nurse concerned, so that she has had the opportunity to comment, she has been able to reflect upon her nursing practice and the ways in which her behaviour and actions may have been negatively received by you. She is absolutely devastated that you had such an unpleasant experience in the recovery room, and as part of our ongoing nurse education she has agreed to complete an up-date in post-operative pain management including the provision of adequate analgesia and appropriate post operative management.
>
> However, she is a very competent Recovery Nurse, and in support of her I believe there were other contributing factors, related to your corneal burn, [of] which I have only just become aware, and I would like to provide the following details.
>
> During blepharoplasty surgery, some surgeons use eye shields, which are placed in the eyes to reduce the risk of damage i.e. corneal abrasion, which could occur during the surgery, as this occurs in such close proximity to the eyes.
>
> These re-usable eye shields are purchased in an unsterile condition (sterile disposable eye shields are not available). The instructions for the sterilisation of these shields state they cannot be autoclaved at the routine temperature, and a low temperature programme should be used. We do not have Validation for a suitable low temperature programme in our autoclaves; therefore the Team Leader for Plastic Surgery chose to soak the eye shields in a preparation solution of chlorhexidine and alcohol to disinfect them in preparation for the sterile surgical field.
>
> On the day of your procedure, as the theatre nurses prepared the operating theatre, instruments and equipment for your operation, this process was followed by the circulating nurse and the eye shields were pre-soaked for a period of time in this solution. She delivered them to the scrub nurse, who took them aseptically on to her sterile field and placed them in a gallipot. Then, the circulating nurse went to get sterile water to rinse the items, and unfortunately while she waited [Dr B] (who was unaware that the items were not ready for use) took the eye shields from the sterile trolley, and placed them in your eyes. Quickly, as soon as the scrub nurse realised this had happened, she alerted [Dr B] immediately and the eye shields were removed, your eyes were thoroughly washed out with an appropriate ophthalmic Balanced Salt Solution (BSS). At that stage your eyes were checked and they appeared to be normal with no obvious injury incurred.

> Then the eye shields were thoroughly rinsed in sterile water, and re-placed in your eyes, and your operation proceeded without further event.
>
> When you were transferred to Recovery, inexplicably, this event was not communicated to the Recovery Nurse, and I was not informed of the event. I firmly believe that had the Recovery Nurse been aware that you may have had a suspected corneal burn reaction to this disinfectant solution, she would have been able to understand your symptoms, and deliver care to effectively manage your pain more adequately and appropriately.
>
> I have had in-depth discussions and debrief with the Theatre Registered Nurses concerning their failure to follow policy and procedure in the following areas:
>
> 1. Reporting of untoward Incidents/events
> 2. Documentation and record keeping
> 3. Timely and appropriate communication
> 4. Management of sterile surgical field.
>
> They are well aware that their performance has fallen short of [the Hospital's] quality standards and services delivery expectations, and they have agreed to undertake training and education so that they are reminded of their responsibilities and to ensure that this sort of event does not happen again.
>
> I have requested the Recovery Team Leader conveys to all recovery room nursing staff, the need to carefully assess patients with unexplained pain, signs and symptoms which do not seem to follow the routine postoperative care pathways. They have also been reminded of the importance to ensure that information is communicated promptly to the surgeon or anaesthetist, in order to seek further advice, to best manage and care for our patients."

The Hospital investigation into Mrs A's complaint noted that when Dr B took the eye shields off the scrub nurse's trolley this was contrary to accepted practice. Ms D explained:

> "I refer to the Guidelines 'Role of the Scrub Nurse' it is the scrub nurse's absolute responsibility to 'maintain strict control of all swabs, needles and instruments at all times'. Also it is generally understood and is accepted practice that the surgeon (or any other surgical assistant) does not help himself/herself to any item on the scrub trolley without first checking with the scrub nurse. This has been known and widely accepted theatre practice in my experience."

Subsequent events

Mrs A asked Dr E why he did not tell her about the incident. He said that he did not see it happen as he was not in theatre at the time. Mrs A's frustration about the injury and her complaint against Dr B caused tension in the employment relationship between Mrs A and Dr E and she eventually resigned.

On 1 December Mrs A asked Dr B about the accident. He replied that he thought he was "only dealing with chlorhexidine". Dr B indicated that he was unaware that the cleaning solution contained alcohol and that chlorhexidine in the eyes would not have constituted an adverse event during surgery. Mrs A told Dr B that she thought there had been "some elaborate cover-up involved in not telling her what the problem was".

Mrs A recalls that she was becoming very angry with Dr B and Dr E because no one would give her an explanation about the cause of her eye problems, and because Dr B did not record the event in her notes. The recovery room nurse had no idea that Mrs A had suffered an injury to her eyes, was unaware of the burns, and did not report Mrs A's pain to Dr B. Mrs A said that, had everyone been informed, "my postoperative recovery may have been a lot more pleasant and I could have had proper postoperative care frequent wash outs to soothe them and stop the continuing burning". Mrs A waited five weeks for an explanation from the Hospital but was "grateful to [the Hospital] for being so honest".

Dr B advised me:

> "At every step of the post operative course I did discuss with [Mrs A] what I felt was her progress and prognosis, mostly based on information given to me by the ophthalmologist. Unfortunately this particular problem needed the almost exclusive management of another consultant and I was heavily dependant on his evaluation and advice. I did note initially that the outcome was expected to be favourable and as during the immediate post operative period she seemed to be improving, I had no reason to believe that it would be otherwise.
>
> … [T]here was little in the way of active treatment I could personally provide after learning about the burns. I certainly stayed in contact with [Mrs A] and followed her progress …
>
> On a personal note this has been a very sobering experience for me and I do sincerely regret any injury that may have been caused to [Mrs A]."

The Hospital Visiting Practitioners Guide

Specialists, such as Dr B, hold clinical privileges at the Hospital. Visiting practitioners must apply to hold such privileges and applicants are screened by members of the Hospital Audit Review Committee. The Hospital controls its relationship with approved visiting practitioners through its "[The Hospitals'] Registration Guide" (the Guide).

The Guide sets out the conditions for registration on page 10 and requires visiting practitioners to be "familiar with and observe the policies and procedures contained in the [Hospital] Health and Safety System Handbook".

Incident Reports are canvassed on page 23, which states: "It is essential that a fully detailed report of any incident or untoward event is provided immediately, in writing to the Hospital Manager."

In relation to Operating Theatre Procedures, page 24 of the Guide states:

> "In the event of any out of the ordinary occurrence such as a count or clinical incident, or an innocuous object not being removed from the operating site, it is the surgeon's responsibility to inform the patient of this fact. Documentation is an essential activity to be carried out by Visiting Practitioners and our own nursing team. Please ensure that you write explicit intra-operative notes within the clinical records."

The Hospital incident reporting systems
The Hospital supplied its Incident Reporting Policies and Procedures, dated July 2005 (Policies 1.1 and 2.1, see **Appendix Five**).

In the section headed "Reporting and Management Procedures" (2.1) a reportable incident is defined as "an adverse or unplanned outcome, accident, untoward event, near miss and also includes complaints". Ms D explained that reportable events include those that result in harm, or have the potential to harm patients.

According to Ms D, the policy operates on "the underlying premise that every person has a responsibility to identify and report incidents ...:

> In this situation the surgeon (as the primary medical carer and admitting doctor) is responsible for reporting and recording any untoward event in the Surgeons Operation Record. The Operation Record is the central component of the handover of operative events (the operation details and any other matters to handover e.g.: an untoward event) for the recovery room and ward staff ..."

The surgeon is responsible for reporting the incident in the Operation Note, and for informing the patient.

Ms D said that the circulating and scrub nurses also have clear responsibilities. They are responsible for completing an incident form as soon as practicable. In support of this, the role description for a scrub nurse at the Hospital states that the nurse is: "Responsible for ensuring documentation of actual operative procedure, personnel present, specimens, count process and status are documented".

The circulating nurse's role is described similarly. The description includes: "Documentation is complete/accurate/legible … OR [operating room] record maintained and completed according to expectations".

Ms D said it had been discussed with the nurses that it would have been appropriate for them to record the incident in the Nursing Intra-operative record; however, there was a clear expectation that the surgeon would record details in his record. This did not occur.

Section "1.1 Incident Reporting and Management Policy" of the Hospital's policy makes the following general comment:

> "The Incident Reporting and Management System contributes to maintaining a safe environment for patients, visitors, employees and Medical Specialists. It does this through the reporting and immediate management of incidents, including subsequent sharing of information to enable learning, improvement in service delivery and the retention of institutional knowledge.
>
> [The Hospitals] foster a culture of safety that is supported by a continuous cycle of quality improvement. The 'no blame' culture within the hospitals ensures employees and Medical Specialists feel supported when incidents are being managed, without diminishing their professional accountability. Patients and doctors are fully informed regarding any incident that may affect them directly …"

Ms D said that all staff, visitors and patients were made aware of the Hospital policies through the orientation process.

When asked whether Dr B had taken part in orientation, Ms D stated:

> "I can confirm that as with all new Medical Specialists, [Dr B] would have had an orientation to the hospital. Typically the first meeting involves a discussion with the Hospital Manager, when he would be informed of our requirements to become a Visiting Practitioner, and be given or sent the Hospital Visiting Practitioners Registration Guide. Also the Hospital Manager provides a general overview and orientation of the hospital business and the hospital's operational abilities and activities, including the appropriate referral and admission of patients to the hospital. At this time suitable operating theatre sessions are discussed, most often in liaison with the Theatre Manager.
>
> The Medical Specialists are also given a guided tour of the hospital and operating theatres, with introductions to key personnel, walking and talking through systems and processes providing information and answering questions as we go. At this stage we normally request standing orders for patients, and ask if they have any special requirements regarding equipment or instrumentation etc.
>
> During the first list in theatre this orientation continues and they work with our personnel, are provided with support and guidance operationally, and as they use our documentation and clinical records. They also are provided with direction and guidance by their own anaesthetists on patient clinical pathways, and any other relevant patient management information they need to know. This is an ongoing process, with informal familiarisation towards the Hospitals systems, processes and routines at each visit to the hospital."

Independent advice to Commissioner

This complaint has raised issues in relation to the open disclosure and reporting of adverse events. It has been necessary to seek expert advice on both the incident reporting and surgical systems that were in place at the Hospital, and the appropriateness of Dr B's response to the incident.

Systems Advice
Systems advice was obtained from Dr Mary Seddon, general physician and Senior Lecturer in Quality Improvement, Epidemiology and Biostatistics. Dr Seddon's advice is attached as **Appendix One**.

Plastic surgery advice
I initially sought verbal advice from an independent plastic surgeon, and this was incorporated in my first provisional opinion. However, this advisor was subsequently contacted by Dr B and aspects of his advice were amended. In my view the expert's amended advice was contradictory. I was also concerned that the independence of the expert advisor had been compromised through direct contact with one of the parties, and decided to seek advice from a second independent plastic surgeon.

I obtained expert advice from independent plastic surgeon Dr David Glasson. Dr Glasson's advice was included in my second provisional opinion (attached as **Appendix Two**).

In response to my second provisional opinion, Dr B sought his own advice from plastic surgeon Dr Stephen Gilbert. Dr Gilbert's report is attached as **Appendix Three**.

I asked Dr Glasson to comment on Dr Gilbert's report. Dr Glasson's comments are attached as **Appendix Four.**

Response to Second Provisional Opinion

Mrs A responded to my first provisional opinion to clarify some factual matters. She remains upset by what she describes as Dr B's "arrogance and neglect of patient care", which for her is "the key to the whole issue". Mrs A believes that Dr B "wiped his hands of any blame during the operation and continued to ignore [her] from the moment the operation finished". She did not provide any further response following the issuance of my second provisional opinion.

On 3 May 2007 the Hospital provided the following response to the second provisional opinion:

> "Thank you for the opportunity to comment on your second provisional report dated 27 March 2007. And for the consideration given to our response to your

initial provisional opinion in November last year. We do wish to take this second opportunity to make further comment though please.

Firstly [the Hospital] accepts your breach finding against [it]. As you will be aware [the Hospital] was not aware there had been any breakdown in our systems and processes until we received the initial request for information and subsequent complaint from [Mrs A]. At that time we were extremely disappointed to learn what had happened and for our part in it we remain extremely sorry for the painful disability and disruption to [Mrs A's] life. At that time we had met and communicated with [Mrs A], unreservedly apologised and will apologise unreservedly again via your office.

In relation to our orientation and communication of operating reporting policies and procedures to the visiting medical practitioners who have access rights to provide patient care, a comprehensive review of [the Hospital] Clinical Governance credentialing and defining scope of practice is in its final consultation stages. The revised system for external medical practitioners to gain and maintain access rights includes a Practice Guide and Agreement which reinforces orientation, communication and practice expectations between the hospital and the visiting medical practitioner. Additionally we have included on our annual conference plan a significant teaching and learning session on root cause analysis and the provision of expert resource and support for management leading this key step in incident investigation and management is also available through the national office.

[The Hospital] would like to clarify two points raised in your second opinion.

1. Relationship between medical specialists and private hospitals

The second provisional opinion continues to use the phrase 'contracted surgeons'. [The Hospital] does not represent to the public that doctors who have access to its hospitals are contracted. It correctly informs patients that their doctors are independent from the hospital. [The Hospital] does not accept that doctors using its facilities are its agents.

2. Accountability

In our initial comments we corrected facts relating to [Mrs A's] care in the Recovery Room which do not appear to be included in the second provisional report. The practice of recovery room nurses is that if problems arise during the immediate recovery phase it is typically the anaesthetist who attends as the surgeon will be scrubbed and performing the next operation. A recovery room nurse is not permitted to leave recovery room as the patients there are under continuous direct nursing monitoring and the nurse will call through to the theatre for medical input as required. In [Mrs A's] situation the anaesthetist attended to [Mrs A] at the request of the Recovery Room Nurse. The anaesthetist assessed [Mrs A's] abnormal level of pain and made an analgesic medical prescription and the Recovery Room Nurse administered the medication. We presume the anaesthetist was completely aware of the eye shields incident which was not

communicated to the Recovery Room nurse and we further point out that it would be normal and good practice for the anaesthetist on returning to the theatre to communicate the abnormal symptom, extreme pain in both eyes, to the surgeon particularly given the eye shields incident and relative to the operative area. A further point of note and in further defence of the Recovery Room nurse's care was the admission by [Mrs A] herself that she 'told the nurse the pain was improving because she wanted to go home'."

On 14 June 2007 Dr B provided the report from Dr Gilbert (Appendix Three) as his response to the second provisional opinion.

Code of Health and Disability Services Consumers' Rights

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

RIGHT 4
Right to Services of an Appropriate Standard

(1) Every consumer has the right to have services provided with reasonable care and skill.
(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

…

(4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.
(5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 6
Right to be Fully Informed

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

(a) An explanation of his or her condition; …

Other relevant standards

The Medical Council of New Zealand *Guidelines for the maintenance and retention of patient records* (October 2001) states:

> "Introduction
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> Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any further dispute or investigation.
>
> 1. Maintaining patient records
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> (a) Records must be legible and should contain all information that is relevant to the patient's care.
>
> (b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory."

The Medical Council of New Zealand *Disclosure of Harm 'Good Medical Practice'* (August 2004) states:

> "When a patient is harmed while receiving medical treatment the Medical Council expects that the patient's doctor will advise the patient of the facts of the harm in the interests of an open, honest and accountable professional relationship. Disclosure should be based on the patient's interests and information should not be withheld to protect the interests of the doctor."

Opinion: Breach — the Hospital

As a provider of health services, the Hospital is bound by the Code of Health and Disability Services Consumers' Rights (the Code), and had a duty to provide Mrs A with a safe theatre environment. Under the Code Mrs A had the right to services provided in a manner that minimised potential harm (Right 4(4)) and to cooperation between providers to ensure consistency and quality of care (Right 4(5)). She also had the right to have the services provided to her documented in accordance with professional standards (Right 4(2)).

Sterilisation of eye shields
It has been said that "all systems are perfectly designed to achieve the results they get".[3] That appears to have been the case here. In purchasing reusable eye shields that could not be high-heat sterilised, and instead using a manual sterilisation option in the operating theatre, the Hospital set the scene for what ultimately transpired.

My expert systems advisor, Dr Seddon, noted that the decision by the Hospital to disinfect the eye shields on the theatre trolley at the time of the surgery set in train a series of events that led to this accident. She explained:

> "On the manufacturer's advice sheet — in bold letters are the autoclaving instructions: 'Corneal Eyeshield is steam autoclavable up to 250°F (121°C) for not more than 15 minutes and not more that 5 sterilisation cycles'. In small print in the bottom right hand corner it does state that the 'shell should be sterilised with a disinfectant solution for 15 minutes.' It does not describe what is the correct solution for such sterilisation.
>
> However, soaking the eye shields in concentrated chlorhexidine and alcohol, and doing this on the sterile trolley was a risky procedure. So at the time of the incident, it would appear that [the Hospital] did not take appropriate steps to ensure safe sterilisation of the eye-shields. [The Hospital] could've used the sterad process earlier or invested in disposable eye shields."

[The Hospital] responded that the eye shields were not sterilised on the scrub nurse's trolley. The shields were soaked in the chlorhexidine solution in the preparation room, removed from the solution and brought into theatre by the circulating nurse. The scrub nurse removed the eye shields and placed them in a bowl on the trolley. The circulating nurse then returned to the preparation room for water to rinse the shields, readying them for use.

While I accept my (and Dr Seddon's) misunderstanding of the exact location of the sterilising solution, the fundamental principle stands. Equipment that was not patient ready was placed on the sterile trolley with other equipment with no means of identifying which equipment was safe for patient use. The fact that the eye shields were not rinsed before being placed on the scrub nurse's trolley meant that this was an

[3] Dr Don Berwick, CEO, Institute for Healthcare Improvement.

accident waiting to happen. The staff at the Hospital had a number of options when deciding how to sterilise the re-useable eye shields. When they were considering those options, they should have identified the inherent risks for each option and the steps necessary to minimise the risks for the patient.

While the decision to disinfect the eye shields in chlorhexidine and alcohol was not unreasonable per se, the solution should have been rinsed off in the preparation room before the eye shields were brought into the operating theatre. This procedure carried a significant level of risk that the solution would be in close proximity to the patient. At a minimum, the composition of the solution should have been explained to the other theatre staff so that everyone involved in the surgery knew the solution was harmful and that the eye shields could not be used without rinsing.

The Hospital's own root cause analysis acknowledged that, at the outset, the best practice for sterilising the eye shields was not identified and followed. However, Ms D went on to say that Dr B departed from accepted practice in taking the eye shields directly from the trolley rather than having them passed to him by the scrub nurse who is responsible for ensuring items are fit for use on a patient. The internal investigation by the Hospital identified this as the cause of the error.

I note the advice of my plastic surgeon expert, Dr Glasson, that there will be situations where the surgeon may need to take items directly from the trolley. Dr Gilbert commented that "surgeons often have to help themselves to items on the trolley to ensure the efficient running of an operation". This advice suggests that there was no established practice on the handover of equipment.

Dr B said that he had asked about the solution some months earlier and had been told that the solution was just chlorhexidine. He was "blissfully unaware" that the solution also contained alcohol. Dr Seddon also advised that the communication between Dr B and the theatre staff "was poor when it came to the eye shields and their sterilisation" and that it is unclear how Dr B would have been aware of any protocols about removing equipment from the trolley. Mr C confirmed that it is not "standard practice for medical specialists to be told how items have been sterilised or disinfected".

The clinical intra-operative form used on the day of Mrs A's surgery recorded that "aqueous chlorhexidine" would be used during the surgery. However, the Hospital and Dr Gilbert have confirmed that this referred to the solution that is used for cleaning the skin around the eye, rather than the sterilising solution. It is therefore not relevant to the issue of whether the Hospital took adequate steps to inform Dr B about the nature of the sterilising solution.

The Hospital submits that it is a well-established practice that the scrub nurse is responsible for the control of all instrumentation on the trolley, which includes handing equipment to the surgeon as needed, except in cases of necessity. The Hospital policies on theatre equipment clearly state that it is the scrub nurse's responsibility to manage the sterile surgical field. In my view, reasonable management includes the responsibility for ensuring that the equipment is ready for

use (such as rinsing the shields in the preparation room) and alerting the surgeon to any issues with the equipment.

This complaint highlights the importance of each person in the operating theatre taking responsibility for identifying the nature of the substances that are used. The same issue was highlighted when a similar incident occurred at Dubbo Base Hospital in New South Wales on 8 February 1999. While carrying out cataract surgery, the theatre staff thought they were using balanced salt solution to irrigate patients' eyes when they were actually using a solution called "eyestream", which contained benzalkonium chloride. Several patients who underwent surgery that day suffered injuries to their corneas. The New South Wales Health Care Complaints Commission investigated the matter and found that there were no protocols for the identification of substances used during surgery. It recommended that the hospital develop a protocol setting out the responsibilities of each of the nursing and surgical team for identifying substances used during surgery, including an assessment of the product for its intended purpose.[4]

Similar principles apply in this case. In a private hospital where different visiting practitioners are using the surgical facilities and there is less opportunity for team meetings and information sharing, staff should inform the surgeon of any issues with the equipment before each episode of surgery.

In my view, Dr B's response to the incident during surgery was consistent with his belief that the solution was chlorhexidine and water (although his belief that chlorhexidine would not cause any injury was misguided, as discussed below). Dr B said he had not been adequately informed about the sterilisation systems being used by the theatre staff.

I agree with Dr Seddon that:

> "The use of their sterilisation technique (concentrated chlorhexidine and alcohol which requires rinsing before use), coupled with the fact that [the rinsing] was done in the operation theatre … and the fact that the surgeon was not aware of the process led to the incident taking place."

I am satisfied that the Hospital did not take appropriate steps to minimise the harm posed by the chlorhexidine sterilisation technique. In failing to provide a safe environment for Mrs A's surgery, the Hospital breached Right 4(4) of the Code.

If Dr B had known about the composition of the solution, it is most unlikely that he would have placed the eye shields in Mrs A's eyes. The lack of communication between theatre staff and Dr B about those risks therefore constitutes a breach of Right 4(5) on the part of the Hospital.

[4] The full report is available at http://www.hccc.nsw.gov.au/downloads/dubbo.pdf

Documentation
The Hospital provided a copy of its "Reporting and Management Procedures" (2.1) where a reportable incident is defined as "an adverse or unplanned outcome, accident, untoward event, near miss and also includes complaints". Ms D explained that reportable events include those that result in, or have the potential to, harm patients and said the policy operates on "the underlying premise that every person has a responsibility to identify and report incidents ..."

While I acknowledge that Dr B had a responsibility to document the incident with the eye shields (discussed below), the circulating and scrub nurses also had clear responsibilities in relation to incident reporting. They were responsible for completing an incident form as soon as was practicable. The job descriptions for both roles require complete and accurate documentation. I note that the recovery nurse also did not make a note of Mrs A's atypical pain after the surgery.

In response to my second provisional opinion, the Hospital noted that the recovery nurse requested a medical assessment of Mrs A's abnormal pain and that the anaesthetist prescribed her pain relief. The Hospital noted that the anaesthetist, who was presumably aware of the incident that occurred in theatre with the eye shields, did not identify the incident with the eye shields as being the possible cause for Mrs A's postoperative pain. I agree that it would have been prudent for the anaesthetist to note Mrs A's pain and to inform Dr B. The fact that the anaesthetist failed to do so may be evidence of a general failure by nursing staff and visiting practitioners to report incidents in line with policy. I will, however, bring this matter to the attention of the anaesthetist.

I am satisfied that the incident reporting systems in place at the Hospital were comprehensive and appropriate. However, even the best policies are of little use if they are not followed. On 20 October 2005, the incident with the eye shields was not reported by the two nurses in theatre and, consequently, there was a breakdown in the chain of communication between the theatre staff and the recovery nurse. If the adverse event had been properly noted in the Nursing Intra-operative record, Mrs A's unusual pain may have been managed differently in recovery.

Addressing this issue in her response to Mrs A, Ms D acknowledged that there was a departure from the Hospital's usual systems and confirmed:

> "[The nurses] are well aware that their performance has fallen short of [the Hospital's] quality standards and services delivery expectations, and they have agreed to undertake training and education so that they are reminded of their responsibilities and to ensure that this sort of event does not happen again."

Ms D confirmed that all staff are oriented on the Hospital policies and procedures when they commence employment. However, a responsible private hospital needs to have systems in place to monitor that its policies are being followed. The Hospital reported on the steps it takes to monitor compliance:

> " … Dr Seddon may not have had sufficient information for her to appreciate the high level of monitoring that is undertaken at [the Hospital]. The comment from independent auditors, DAA Group Ltd during their February 2006 Certification Audit evidenced 'Excellent systems exist. The staff are reporting a wide variety of incident and near miss situations that are then collated and [monitored] as part of the systems for quality improvement linked to the Safety, Quality and Risk Management committee. KPIs have been built into the monitoring programme as has benchmarking against the other hospitals in the group.'"

Notwithstanding these laudatory audit comments, the Hospital theatre nurses neglected to follow the incident reporting policy, and the recovery nurse did not recognise the need to note Mrs A's unusual postoperative pain. The simple fact is that no one involved recognised the significance of the incident which, at the very least, should have been reported as a "near miss". The necessary policies were in place but, on this occasion, they were not followed by the staff involved with Mrs A's surgery. In these circumstances the Hospital failed to follow its own "relevant standards", and thereby breached Right 4(2) of the Code.

Opinion: Breach — Dr B

When Dr B performed eye surgery on Mrs A on 20 October 2005, he took eye shields that were sitting in a gallipot on the theatre nurse's trolley. The eye shields had previously been soaking in a sterilising solution and had not been rinsed. Not realising that they were unrinsed, Dr B placed them in Mrs A's eyes. As soon as Dr B was told that the eye shields had not been rinsed, he took immediate remedial action by removing the shields and irrigating Mrs A's eyes. Despite this, Mrs A suffered corneal burns to both eyes.

These facts are not disputed. They were not the main focus of Mrs A's complaint. She stated that her "complaint is regarding [Dr B's] concealment of the truth during and following the accident and his judgement to not record the fact in my medical notes". This investigation has focused on why the incident occurred and Dr B's actions in response to the incident. It highlights the important role incident reporting plays in ensuring that adverse events are promptly recorded and openly disclosed to the consumer.

Incident in theatre

There is no doubt that the incident with the eye shields was accidental — Dr B thought the eye shields had been rinsed when he took them from the trolley. However, as soon as they were placed in Mrs A's eyes, Dr B became aware that they had not been rinsed. The issue I need to determine is whether Dr B took appropriate action from that point onwards.

The first responsibility was for Dr B to take appropriate clinical action. When the nurse told him the eye shields had not been rinsed, he removed the eye shields immediately, and rinsed Mrs A's eyes and the shields, before replacing them and continuing with the surgery. Dr B therefore recognised that there was the potential for harm and that remedial action was necessary.

Dr B sought the advice of a peer, Dr Gilbert, in responding to my second provisional opinion. Dr Gilbert confirmed that it is appropriate to rinse with saline when aqueous chlorhexidine enters the eyes during surgery.

My expert advisor, Dr Glasson, advised that, according to the manufacturer's instructions, Dr B should also have applied an antibiotic ointment to the eye shields before they were placed in Mrs A's eyes. The usual practice is to put ointment on the concave surface of the shield, as it provides protection for the eyes. Dr Glasson advised that ointment should also have been applied to the shields both before the first insertion of the eye shields and again when the shields were re-inserted.

Dr Gilbert advised that, while he has not seen these instructions, "it could have been helpful to put antibiotic ointment in the eyes when the eye shields were rinsed and replaced". However, Dr Glasson noted that the manufacturer's instructions were provided by the Hospital so must have been available to Dr B.

Dr Glasson acknowledged that "it would have been helpful for the staff to inform [Dr B] about the sterilising solution" but advised that Dr B could also have asked to confirm what the solution was, as that would have guided him in deciding what clinical action was necessary. Dr Glasson advised that eyes should be irrigated for 15 minutes if they have come into contact with chlorhexidine and alcohol.

Dr Glasson further advised that aqueous chlorhexidine is not generally used for sterilisation as alcohol solutions are more effective. He also noted that it is common practice to avoid the use of chlorhexidine solutions near the eyes, with many surgeons preferring aqueous iodine-based solutions.

I agree with Dr Gilbert that when Dr B was informed that the eye shields had not been rinsed, he did take some measures to reverse the effect of contact with chlorhexidine solution by irrigating the eyes. However, I also agree with Dr Glasson that Dr B could have done more. It would have been prudent for Dr B to apply antibiotic ointment to protect the eyes both initially, when the eye shields were first inserted, and then a second time, when the eye shields were rinsed and re-used. It would also have been common sense to ask about the nature of the solution to guide any necessary remedial action. Dr B assumed the eye shields had been sterilised in aqueous chlorhexidine on the basis of a conversation he had had some months earlier. However, as Dr Glasson noted, it should have seemed unusual that the hospital was using aqueous chlorhexidine for sterilising and it was risky to be using it in equipment that would be near the patient's eyes.

In my view, a reasonable surgeon would have asked what the solution was so that appropriate action could be taken. As noted above, in relation to the Dubbo Hospital Inquiry, it is incumbent on every person in the theatre environment to identify the nature of the substances that are used.

The next issue is whether Dr B should have recorded the incident in the operation notes as an adverse event.

Dr B said that he did not record it because it is not unusual for some chlorhexidine to dribble into a patient's eye during facial surgery without any adverse consequences:

> "…[P]ersonally I have never seen any sort of significant reaction to this. This clearly explains why it never occurred to me that any significant untoward event had occurred, as I was unaware that there was alcohol in the solution. I thought it was simply a matter of brief contact of the conjunctiva with chlorhexidine solution which had been taken care of with the saline wash. It certainly never occurred to me that this was something worth noting or mentioning in the operative record or certainly to the recovery nurse."

Dr Gilbert commented that Dr B's failure to note the incident was understandable because Dr B thought the solution was innocuous:

> "One of the Chlorhexidine solutions commonly used to clean the skin is Savlon which has a concentration of 0.0 15% Chlorhexidine. Another stronger solution is

> aqueous Chlorhexidine having a concentration of 0.05% Chlorhexidine but in the sterilizing solution with alcohol the concentration of Chlorhexidine is 0.5%. References quoted refer to Chlorhexidine toxicity at far greater strengths than the 0.0 15% or 0.05% percentages and greater exposure time. It is not clear if Chlorhexidine 0.5% in contact with the cornea briefly and then washed out with saline would in fact have caused much damage."

However, Dr F noted that "chlorhexidine is known to be an extreme irritant to the cornea and causes extraordinary discomfort". The Hospital reported that chlorhexidine (in water or alcohol) are both recognised as irritants to the eye and are not recommended for cleansing the periorbital area. It should be used only as a skin preparation or for the sterilisation of equipment. This is documented by the manufacturer on the container. Dr Glasson confirmed that aqueous Chlorhexidine is considered toxic to the cornea and all contact, even with Savlon, should be avoided around the eyes.

Dr Gilbert was concerned that I had misinterpreted Dr B's clinical response as suggesting that he must have known that the sterilising solution consisted of chlorhexidine and alcohol. For the sake of clarity, I accept that Dr B thought he was responding to a solution of chlorhexidine and water. I also accept that the risk posed by aqueous chlorhexidine will depend on the level of dilution that has been used and the amount that enters the eye. However, as noted above, Dr B did recognise that there was at least some potential for harm arising from this event as this is why he irrigated Mrs A's eyes. As Dr Glasson noted, "why do it otherwise?" I also consider that this was more than a simple case of chlorhexidine dribbling into the eyes. Unrinsed eye shields were placed squarely in Mrs A's eyes and covered her cornea.

Defending Dr B's failure to record the incident, Dr Gilbert said:

> "Seldom does an operation go totally ideally as planned but minor variances which are not harmful are not documented and reported to the patient. The issue is identifying which matters are of sufficient seriousness and concern to require documentation."

Dr Glasson agreed that this is the usual approach to incident reporting but noted that Dr B would have recognised that it was an incident that warranted reporting if he had asked about the nature of the solution.

The Code confirms that the Commissioner as decision-maker is expected to form an independent opinion on the reasonableness of the care provided. While I accept that there can often be a legitimate range of responsible opinion and practice, I am also conscious of my responsibility, as an independent guardian of patients' rights, to distinguish between mediocre and good practice.

In this case, Drs Gilbert and Glasson have both suggested that the accidental insertion of eye shields soaked in aqueous chlorhexidine would be unlikely to reach the threshold for reporting. However, in my view, even if non-reporting of such incidents

is a commonly accepted practice, given the pressured environment of the operating theatre where such minor variances are not infrequent, reasonable care demands that surgeons have a very low threshold for incident reporting. A patient is unconscious during surgery and entirely reliant on those providing care to recognise and report any deviations from the usual course. Any incident that deviates from standard surgical procedures, particularly when it involves the entry of a foreign object or solution, should be documented and explained to the patient, whether or not the patient suffers injury as a result. As this case illustrates, seemingly minor events during surgery have the potential to cause postoperative complications. Appropriate documentation is essential for coordination between providers and to ensure consistency and quality of care. It is also a professional obligation to ensure complete and accurate records are kept, as stated by the Medical Council.

In addition to his general duty to comply with professional standards, Dr B was also required, as a visiting practitioner, to comply with "[The Hospitals'] Registration Guide". In relation to Operating Theatre Procedures, page 24 of the Guide states:

> "In the event of any out of the ordinary occurrence such as a count or clinical incident, or an innocuous object not being removed from the operating site, it is the surgeon's responsibility to inform the patient of this fact. Documentation is an essential activity to be carried out by Visiting Practitioners and our own nursing team. Please ensure that you write explicit intra-operative notes within the clinical records."

The Guide also required Dr B to be "familiar with and observe the policies and procedures contained in [the Hospital] Health and Safety System Handbook". Dr B was therefore subject to the incident reporting policies in place at the Hospital. As discussed above, this included the responsibility to report "an adverse or unplanned outcome, accident, untoward event [or] near miss".

Dr B did not see Mrs A in recovery. He said that it was not his normal practice to do so, and he relied on nursing staff to alert him of any problems. In this case, that was not done and the first he was aware of any problem was when Mrs A called his rooms the following day.

Dr B appears to take this stance on the basis that a blepharoplasty is not a high-risk procedure and that the recovery nurse will report any concerns. However, I note that when Dr B saw Mrs A preoperatively he listed a significant number of risks, including "bleeding, infection, bad scars, asymmetry, blindness, the need for second surgery, ectropion".

Dr Glasson noted that Dr B had recorded on the operation note that he did not need to see Mrs A before discharge. Dr Glasson advised that a reasonable plastic surgeon would review the patient prior to discharge to check on the absence of complications, for example haematoma or visual disturbance. A review by the surgeon would be especially indicated if there was a possibility of an eye injury, or there were any

unexpected symptoms. Dr Glasson noted that Dr B was not alerted to Mrs A's symptoms by the recovery staff.

Dr Gilbert said that it is not always possible for a surgeon to review a patient in recovery and that he is reliant on the recovery room staff to report any unusual findings before discharging the patient.

However, Dr Seddon was critical of Dr B's failure to see Mrs A in recovery:

> "[Dr B] did not see [Mrs A] after the operation and states that it is not his usual practice to do so. However, from a non-surgeon's point of view it would seem unsatisfactory that [Dr B] did not see [Mrs A] — had he done so he might have realised that her pain was out of proportion to her operation and ensured better pain relief and earlier referral to the ophthalmologist.
>
> If we take it that 'surgical services' encompasses more that the actual operation, then this lack of review in the postoperative period would not seem to be of an appropriate standard."

In this case an untoward incident occurred during Mrs A's surgery. I agree with Dr Seddon that it would have been prudent for Dr B to have checked on Mrs A in recovery and to have told her about the adverse event at that early stage. A reasonable patient would expect no less. Dr B's failure to record the incident and to share this information with Mrs A was, in my view, a breach of Rights 4(2) and 6(1) of the Code.

Referral to Dr F

As a result of the incident with the eye shields during her surgery on 20 October 2005, Mrs A experienced pain and complications for a further five weeks. During that time, ophthalmologist Dr F provided treatment for the corneal injury but Dr B, as the surgeon, remained responsible for postoperative care. It is therefore necessary to consider whether Dr B provided that care appropriately.

Mrs A advised that the pain following the surgery was excruciating. She called Dr B the next morning to report her symptoms and spoke to his nurse. Mrs A also spoke to Dr E when he called to check on her. Dr E told Mrs A that her pain might have been caused by the eye shields and suggested a referral to an ophthalmologist, Dr F.

Dr B advised me that his nurse reported Mrs A's burning symptoms and he was about to telephone her when he received a call from Dr E. Dr E told Dr B that he had already spoken to Mrs A and recommended a referral to Dr F. Dr B agreed with this suggestion. Dr E then telephoned Dr F to make the referral, explaining the surgery, the use of the eye shields and the possibility that Mrs A might have had a chemical injury to the cornea. Dr F accepted the referral and agreed to an urgent appointment for Mrs A. It is clear that Drs E and F were colleagues and that the referral occurred on an informal basis. Dr E said that Dr F saw Mrs A as a favour to him; otherwise, it is unlikely she would have obtained a specialist appointment so quickly.

Once Dr F had examined Mrs A's eyes on 22 October, he reported to Dr B that "she did have healing corneal abrasions secondary to cleaning solution … it should heal within 24–48 hours and that he would continue her on Maxitrol ointment". This assessment was confirmed in a handwritten note from Dr F to Dr B dated 22 October 2005.

I accept that it is appropriate to refer a patient to an ophthalmologist if a patient is experiencing pain or a possible injury to the eyes following surgery. A corneal injury would have been outside Dr B's area of expertise, and it was appropriate to refer this aspect of Mrs A's care to Dr F. The issue, however, is whether that referral was made appropriately.

To comply with Right 4(5) of the Code, a referral should be made in such a way that it ensures quality and continuity of care. At a minimum, the referring practitioner should explain the reason for the referral and include any background information that may be relevant to the patient's ongoing care. A patient is usually sent a copy of the referral so that she is kept informed of the decisions regarding her care.

Dr Glasson advised that in this situation a reasonable plastic surgeon would contact the patient directly to clarify the problems and discuss diagnosis and management with the ophthalmologist. However, the referral to Dr F occurred before Dr B was able to see Mrs A.

In this case, Dr B had performed the surgical procedure and was in the best position to make the referral. I agree with Dr Glasson that a reasonable surgeon would have telephoned or met with Mrs A to review her symptoms and to discuss the possible causes, including the incident with the eye shields. However, in this case, Dr B did not have an opportunity to review Mrs A's injuries before she was referred to Dr F for prompt treatment. Dr B then liaised appropriately with Dr F two days later. This course of action enabled Mrs A to get appropriate care that might otherwise have been delayed. Dr F clearly recognised that the primary responsibility for Mrs A's postoperative care lay with Dr B when he reported the results of his assessment.

I am satisfied that Mrs A was referred to Dr F quickly and appropriately and that Dr B did not breach Right 4(5) of the Code by allowing an informal referral to Dr F to occur.

Ongoing postoperative care

Dr B said that he did not link Mrs A's corneal damage to the incident with the eye shields, yet two days after surgery Dr F told him of the corneal abrasion from the cleaning solution. I find it curious that both Drs B and E were aware that Mrs A could have suffered chemical burns to her eyes but Dr B did not tell her.

Even if Dr B did not recognise the significance of the incident on the day of the surgery, he knew by 22 October that Mrs A had suffered burns that were most likely caused by cleaning solution. Dr Glasson advised that a reasonable plastic surgeon would have contacted Mrs A directly "to clarify and discuss diagnosis and

management with the ophthalmologist". I do not find it credible that Dr B did not connect the corneal damage to the incident in theatre. The responsibility to tell Mrs A of the possible link between the incident in theatre and the corneal burn lay with Dr B.

Dr B advised me that he did telephone Mrs A after he learnt of her symptoms on 21 October and offered to see her the following week. However, Mrs A declined this offer as she had already made the appointment with Dr F.

On 25 October, Mrs A had an appointment with Dr B's nurse to have her stitches removed. Dr B thought that he spoke to her that day and told her about his conversation with Dr F. However, Mrs A said that she did not see Dr B that day, but only his nurse. Mrs A said that Dr B's nurse spoke to him by telephone and he stopped the antibiotics. Dr B's clinical records for 25 October confirm that Mrs A was seen by the nurse.

I am surprised that Dr B did not take the opportunity to personally review Mrs A's injury and discuss the possible causes at the five-day check. While it was appropriate for Dr F to take over the treatment of Mrs A's corneal injury, Dr B remained responsible for oversight of her postoperative care. Dr B was aware that Mrs A had been experiencing significant pain since the surgery, and this would have provided him with an opportunity to remain actively involved in her care.

Dr Seddon advised:

> "As [Dr B] did not see [Mrs A] in the postoperative period he was not able to give her any information about the incident, and indeed he did not realise the seriousness of the incident itself. It is however odd that at her day 5 check-up, at [Dr B's] rooms, [Mrs A] was only seen by the nurse — [Dr B] did not make the time to see her. In fact her only postoperative contact with [Dr B] seems to be on day 15 when she was at her work and [Dr B] was visiting with his wife. [Dr B] probably thought that he was doing her a favour — saving her coming to his rooms — but it was probably inappropriate as she was only seen briefly and may have felt inhibited about speaking about her concerns in her work 'tea-room'."

Dr Gilbert has suggested that Dr B was unable to act on his duty to follow up with Mrs A as her care was transferred to Dr F and she declined the opportunity for Dr B's review. However, I do not accept that these circumstances absolved Dr B of responsibility. From 22 October 2005 onwards, Dr B knew that Mrs A had suffered a corneal burn from cleaning solution. Even if he thought that this was an unusual reaction to aqueous solution, he had an obligation to tell her about the incident in theatre so that she could understand how the injury occurred. When Mrs A declined the opportunity for a review on 21 October, Dr B should have explained the situation by telephone or made a point of discussing it at the scheduled appointment on 25 October.

Dr Gilbert has suggested that Mrs A's management and recovery would not have been different had she known about the incident earlier. I disagree. Full information about

the incident would have allowed Mrs A to understand why she was in so much pain and how this would impact on her recovery. It would also have allowed her to seek support from ACC when she required more time off work.

The Medical Council of New Zealand encourages open disclosure when an adverse event occurs. Its guidelines on the disclosure of harm in *Good Medical Practice* state:

> "When a patient is harmed while receiving medical treatment the Medical Council expects that the patient's doctor will advise the patient of the facts of the harm in the inte should be based on the patient's interests and information should not be withheld to protect the interests of the doctor."

In case 02HDC14836 (24 March 2004), I considered a provider's broader duty of open disclosure in relation to the Code and stated:

> "The Code of Health and Disability Services Consumers' Rights is based on the fundamental right of patients to be fully informed in order to make informed choices. The test in Right 6 is whether the patient has received the information that a reasonable patient, in that patient's circumstances, would expect to receive. Such information not only enables patients to make informed choices about their health care but also provides them with information about their condition. Doctors have a duty of candour and patients have a right to full disclosure when something goes wrong. Such action is underpinned by a respect for autonomy and promotes trust in the medical profession. Disclosure of adverse events also serves to minimise the potential harm of unknown conditions going untreated."

So the issue is what information a reasonable patient, in Mrs A's circumstances, would have expected to receive from her surgeon about the incident.

Regardless of whether Dr B knew the solution contained alcohol, he knew Mrs A was not following the normal path of recovery and was suffering some adverse event. In my view, Dr B should have made more effort to see Mrs A earlier in the postoperative period, particularly when he learned that she had corneal ulcerations, to explain what had happened, ensure she received appropriate care and refer her to ACC. I accept Dr Glasson's summation of Dr B's omissions:

> "In my opinion, when an event occurs with the potential for patient injury, the practitioner should document it, inform the patient and relevant staff, get expert management advice as soon as possible, and follow up.
>
> Considering this, [Dr B] did not meet all the standards of care and skill reasonably expected of a plastic surgeon in these circumstances. It is my opinion that the conduct of [Dr B] would incur the disapproval of peers and that this disapproval would be moderate."

Dr Gilbert acknowledges that "in retrospect, it would have been appropriate for [Dr B] to have discussed the incident of the eye shields with [Mrs A] earlier in the piece

when he realised that the opthalmological opinion was that [Mrs A] had received a chemical burn from Chlorhexidine in the sterilising fluid".

Postoperative care continues until such time as the surgeon discharges the patient from his care. Dr B performed surgery on 20 October and did not see Mrs A again until 3 November 2005 (in the tea room at her work), despite reports about her corneal damage from Dr F. In the interim she suffered significant complications. While I acknowledge that the immediate postoperative care was complicated by the referral to Dr F, Dr B remained responsible for ensuring that Mrs A received adequate information about what had occurred. Research suggests that what most patients want is an honest explanation of what happened and, if appropriate, an apology.[5] Instead of taking steps to provide Mrs A with this information, Dr B took a passive approach to her postoperative care and relied on Dr E, Dr F and the practice nurse to keep him informed of her progress. It would have been comforting for Mrs A to know that her surgeon was maintaining some oversight of her care.

In my view, Dr B did not manage Mrs A's postoperative care appropriately. He should have provided Mrs A with full information about the incident with the eye shields as soon as he became aware of her injuries. This failure to do so constitutes a breach of Right 4(1) and Right 6(1) of the Code.

Opinion: No Breach — The Hospital

Vicarious liability
Under section 72 of the Health and Disability Act 1994 ("the Act") an employing authority may be liable for acts or omissions by an employee, an agent or a member.

Section 72(1) of the Act states that the term "employing authority" means a health care provider or a disability services provider. Section 3(a) of the Act states that a health care provider includes a person for the time being in charge of providing health care services within the meaning of the Health and Disability Services (Safety) Act 2001. the Hospital provides health care services within the provisions of the Health and Disability Services (Safety) Act 2001.

Dr B is a consultant plastic surgeon at the Hospital. He performs plastic surgery using the equipment, facilities and nursing support at the Hospital. As a visiting practitioner, Dr B is subject to the "[The Hospitals'] Registration Guide" (discussed below).

The Hospital does not accept that doctors using its facilities are "agents" and points out that the public are told the doctors are independent from the hospital.

[5] A Wu, "Handling hospital errors: is disclosure the best defence?" (1999) 131 (12) *Annals of Internal Medicine* 970 (21 December 1999).

In a previous case,[6] I have taken the view that, notwithstanding the arms-length "visiting privileges" arrangement, specialists may be agents of the private hospitals where they provide services. Ostensibly, such practitioners are represented to the public as being associated with these hospitals where they work, and the private hospitals retain some degree of control over the practitioners, including the ultimate sanction of not renewing clinical privileges. In my view, visiting practitioners may be agents of the private hospitals where they provide services within the meaning of section 72(3) of the Act.

Section 72(3) provides that anything done or omitted by a person as the agent of an employing authority shall, for the purposes of this Act, be treated as done or omitted by that employing authority as well as by the first-mentioned person, unless it is done or omitted without that employing authority's express or implied authority, precedent or subsequent. Under section 72(5) it is a defence for an employing authority to prove it took such steps as were reasonably practicable to prevent the employee from acting or omitting to act in breach of the Code. Section 72(5) can also be applied as a defence to liability under section 72(3).

The Hospital allowed Dr B to provide services under the conditions for registration set out in the "the Hospitals' Registration Guide" (the Guide). The Guide sets out the conditions for registration on page 10 and requires visiting practitioners to be "familiar with and observe the policies and procedures contained in [the Hospital] Health and Safety System Handbook". Incident Reports are canvassed on page 23, which states: "It is essential that a fully detailed report of any incident or untoward event is provided immediately, in writing to the Hospital Manager."

Dr B's breach of Right 4(2) of the Code related to his failure to document in the operation note the incident involving the eye shields. However, the Hospitals' Registration Guide and its operating policies clearly outline the expectation that adverse events will be documented and reported by visiting practitioners.

Incident reporting and analysis is a vital tool in ensuring good practice and improving the quality of care, and its educative value should not be underestimated. In order for staff to learn from incidents, all those involved in the incident (including the surgeon) must be given an opportunity to discuss the events in a learning forum, with the focus on patient safety. Incidents should not be allowed to become personalised since individual blame does not foster trust in the reporting process. "Understanding the nature, causes and incidents of failures is a vital component of prevention."[7]

Having reviewed the incident reporting systems, and the conditions placed on the registration of visiting practitioners, I am satisfied that the Hospital took reasonable steps to prevent Dr B from breaching the Code in relation to documentation and incident reporting. The Hospital is therefore not vicariously liable for Dr B's breach of Right 4(2) of the Code.

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[6] 99HDC06799 (24 May 2002).
[7] *Gisborne Hospital 1999–2000*: *A Report by the Health and Disability Commissioner (2001)* p 60.

I have also formed the opinion that Dr B breached the Code by his failure to manage Mrs A's postoperative care appropriately and to provide her with adequate information postoperatively. In my view, these omissions were attributable to individual clinical decisions by Dr B and could not have been prevented by the Hospital imposing any conditions on his registration. The Hospital is therefore not vicariously liable for Dr B's breaches of Rights 4(1) and 6(1) of the Code.

Other comments

Root cause analysis
Although it may appear that one particular act or omission caused the accident, closer inspection often reveals that a series of interlinking failures by a number of people resulted in the accident. To ensure that accidents such as this do not happen again, all systems faults must be addressed.

I am reassured to learn that the Hospital has decided to discontinue chlorhexidine/alcohol soaks for eye shields and to adopt the Sterad processing system. However, I recommend that the Hospital management team review how it undertakes the root cause analysis in light of the following comments by Dr Seddon:

> "The documentation supplied with the RCA is very brief and it does not appear that a full Root Cause Analysis has been done. Having said that, the vulnerability of the sterilisation process was at least recognised and [the Hospital] looks to have made progress in changing this. The rest of the recommended actions are weak in that they almost all refer to individuals reading protocols and policies. These are unlikely to affect future error rates. The vulnerability of running a surgical Hospital with only visiting surgeons and anaesthetists is not touched on in the RCA; however, most systems analysts would recognise that such a set-up would not support teamwork and communication."

The Hospital has reviewed its policies and procedures in relation to the orientation and communication of operating reporting policies and procedures to visiting practitioners. It has also reviewed and updated the Hospital Clinical Governance credentialling and defining scope of practice. The Hospital advised:

> "The revised system for external medical practitioners to gain and maintain access rights includes a Practice Guide and Agreement which reinforces orientation, communication and practice expectations between the hospital and the visiting medical practitioner. Additionally we have included on our annual conference plan a significant teaching and learning session on root cause analysis and the provision of expert resource and support for management leading this key step in incident investigation and management is also available through the national office."

I commend the Hospital for identifying the opportunities for quality improvement presented by this case and for taking such prompt and comprehensive action to review its systems.

Pain management
Mrs A suffered a high level of pain once the anaesthetic had worn off, and it was unrelieved by pethidine and Voltaren. It would appear that this level of pain was out of the ordinary. Not only was the pain extreme, it was not at the surgical site, but within the eye itself. No one investigated the pain or informed Dr B about it.

Dr Seddon commented:

> "[Mrs A] was obviously in severe pain postoperatively but as this was unusual for such an operation her symptoms were dismissed. She did not get adequate analgesia, was given pethidine without an anti-emetic which caused her nausea, and she was not assessed to determine why her pain was out of the normal range for this operation. Whether or not the incident had been written in the notes (as it should have been) the management of [Mrs A's] pain was poorly managed."

In response to my second provisional opinion, the Hospital noted that the recovery nurse called for a medical assessment of Mrs A's postoperative pain and that Mrs A later "told the nurse the pain was improving because she wanted to go home".

I accept that it may not have been obvious to the recovery nurse that Mrs A's pain remained severe after Voltaren had been administered. I nevertheless consider that Dr Seddon makes an important point. Patients may experience pain levels beyond what a health professional considers "normal", and the degree of pain the patient is experiencing may be underestimated. Pain is a subjective measure of discomfort. Hence the use of pain scales (1 to 10) to introduce an element of objectivity. There is a danger that patients reporting extreme pain can be thought to be over-reacting. In this instance Mrs A said that she thought this level of pain must have been expected with this type of surgery, particularly when the recovery room nurse was so abrupt. She reported diminishing pain levels because she thought she must have been over-reacting. The lesson is that patients reporting postoperative pain levels that require the administration of reasonably strong medication, need to be closely monitored and encouraged to describe their pain accurately.

Dr E — appropriate boundaries
Dr E practises as an ear nose and throat surgeon but, in this instance, was involved in Mrs A's care as a support person, rather than as a clinician. Because he knew Dr B personally, Dr E recommended Dr B to Mrs A when she expressed some interest in a blepharoplasty, and later attended the surgery. When complications arose after the surgery, Dr E referred Mrs A to another colleague, Dr F.

Dr E obviously intended to act in Mrs A's best interests. However, his intervention created unnecessary complications in Mrs A's relationship with her clinicians. The informal referrals to colleagues meant that Mrs A did not receive adequate

information about her condition and was not involved in the decisions being made about her care. This case is a good example of the pitfalls of allowing formalities to lapse when dealing with friends and colleagues. I draw these comments to Dr E's attention.

Recommendations

The Hospital
I recommend that the Hospital:

- apologise to Mrs A for breaching the Code of Health and Disability Services Consumers' Rights. This apology is to be sent to my Office where it will be forwarded to Mrs A;

- review how it undertakes root cause analysis in light of this report.

Dr B
I recommend that Dr B:

- apologise to Mrs A for breaching the Code of Health and Disability Services Consumers' Rights. This apology is to be sent to my Office and it will be forwarded to Mrs A;

- review his practice in light of this report.

Follow-up actions

- A copy of my final report will be sent to the Medical Council of New Zealand, the Royal Australasian College of Surgeons, and ACC (to consider Mrs A's entitlement to compensation for a treatment injury).

- A copy of my final report, with details identifying the parties removed, will be sent to the Theatre Nurses Group, New Zealand Nurses Organisation, and the New Zealand Private Hospitals Association and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix One — Expert advice from Dr Mary Seddon

The following expert advice was obtained from Dr Mary Seddon, general physician and Senior Lecturer in Quality Improvement, Epidemiology and Biostatistics:

> "I have been asked to provide an opinion to the Commissioner on case number 06/00096 [Mrs A], and I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.
>
> Qualifications: MBChB, FRACP, MPH, FAFPHM.
> Training: Graduated Otago Medical School 1987, MPH (Auckland) 1999.
> Experience: Medical Registrar appointments in Auckland and Tauranga 1990–1995.
>
> General Physician Middlemore Hospital 2000–2002.
> Senior Lecturer in Quality Improvement, Epidemiology and Biostatistics, School of Population Health, University of Auckland, 2000–2004.
>
> **Referral instructions: Expert Advice Required**
>
> [Dr B]:
>
> (6) Whether [Dr B] provided [Mrs A] with surgical services of an appropriate standard on 20 October 2005.
>
> (7) Whether [Dr B] provided [Mrs A] with adequate information and appropriate care after her surgery on 20 October 2005.
>
> [The Hospital]:
>
> (8) Whether [the Hospital] staff took appropriate steps to ensure the correct solution was used to soak the eye shields.
>
> (9) Whether [the Hospital] staff took appropriate steps to alert [Dr B] that the eye shields were soaking in chlorhexidine and alcohol.
>
> **The following documentation was received and reviewed.**
>
> 1. Complainant's letter dated 9th Jan 2006.
> 2. Clinic letter from [Dr F] (Ophthalmologist).
> 3. Statements from:
>
> i. [Dr B] (Plastic Surgeon)
> ii. [Mr C] (Hospital Manager)
> iii. [Ms D] (Manager Theatre Services)

4. [The Hospital] polices and guidelines:
    i. Outlines of specific nursing roles (Circulating Nurse and Scrub Nurse)
    ii. [The Hospital] guideline on 'Cleaning, disinfection and sterilisation'
5. Information sheet on Corneal Eye shields (Ellman International product).
6. Clinical notes.
7. Discharge letter and post-discharge recovery general information.
8. Root Cause Analysis carried out by [the Hospital].

Brief synopsis of case:
[Mrs A] was referred by her employer (ENT surgeon [Dr E]) to [Dr B] (plastic surgeon) for upper and lower lid blepharoplasty.

During the operation (20th October 2005) eye shields were placed over both eyes to prevent inadvertent damage during the operation. Prior to placement the eye shields had been soaking in a 'sterilising' solution (alcohol and chlorhexidine) put there by the scrub nurse on the sterile trolley. A 'circulating nurse' went to collect sterile water to rinse the eye shields before they were applied to the eyes, however, [Dr B] who was unaware that the eye shields needed to be rinsed, took them off the sterile trolley and placed them over [Mrs A's] eyes. The nurses alerted [Dr B] to the problem and the eyes were rinsed with normal saline before the rinsed eye pads were once again placed in the eyes.

No mention was made in the clinical notes of this incident. [Mrs A] suffered severe postoperative pain in her eyes, well outside the normal limits of pain to be expected with blepharoplasty, however, the recovery nurse was not aware of the incident and [Dr B] did not review her after the operation.

[Mrs A] continued to have severe pain and two days later [Dr E] referred her to an ophthalmologist ([Dr F]), who diagnosed corneal burns. Despite treatment [Mrs A] continued to have pain for six weeks. It affected her ability to cope, led to distress and she eventually resigned her job.

Systems issues highlighted by the case:
1. [The Hospital] had purchased re-useable eye shields that could not be high heat-sterilised and at the time of the incident [the Hospital] did not have a low temperature autoclave available. They were instead using an alcohol & chlorhexidine sterilisation technique. The alternatives were:

    a) To use a process called 'Sterad' — a low temperature sterilising cycle — exposing the eye pads to hydrogen peroxide, U.V. light and plasma. This would be done in the central sterile supply unit, not in the operating theatre.
    b) Purchase disposable eye shields.

The use of their sterilisation technique (concentrated chlorhexidine and alcohol which requires rinsing before use), coupled with the fact that it was done in the operation theatre (on the sterile tray), and the fact that the surgeon was not aware of the process led to the incident taking place.

The Root Cause Analysis (RCA) done by [the Hospital] suggested the following actions, to be completed by [Mr C] by the 28th of November 2005:

a) Discontinue chlorhexidine/alcohol soaks for eye shields
b) Adopt the Sterad processing system,

2. Communication within the operating theatre
The communication between the visiting surgeon and the theatre staff was poor when it came to the eye shields and their sterilisation. [Dr B] states that he was 'blissfully unaware that the solution also contained alcohol.'

[Dr B] states that he 'believed that [Mrs A] had an uncommon reaction to the disinfecting solution.' He notes in his statement that it is common in other operations for a 'small amount of chlorhexidine to get into the patient's conjunctival sac. We simply irrigate the eyes when this happens and personally I have never seen any sort of significant reaction to this.' However, the ophthalmologist states that 'chlorhexidine is known to be an extreme irritant to the cornea and causes extraordinary discomfort'.

3. Orientation of staff
It is stated that [Dr B] acted 'contrary to standard protocol'[8] by removing the eye shields from the sterile trolley himself. It is unclear how [Dr B] would have been made aware of such a protocol. Elsewhere in the same statement it is stated that 'all staff working at [the Hospital] participate in an orientation programme on commencing employment'. Again it does not appear that such orientation programmes apply to the contracted surgeons — they would appear to apply only to the employed staff (e.g. nurses). Such a system where the work-force is divided into those who are part of the organisation and those who are independent contractors — with different orientations for both — is likely to lead to misunderstandings.

In the RCA, an 'error' is identified as one of the root-causes — that is [Dr B] was guilty of non-standard practice by accessing the eye shields directly off the sterile trolley. However, according to the standard teaching of RCA, 'each human error must have a preceding cause' and the reasons for [Dr B's] error in accessing the eye-shields is not explored adequately. It is stated that he was in a hurry because of a busy list, but does not go into why the list was busy, nor does it delve into whether he knew of the operating protocol. Did

[8] Statement from [Mr C] dated 20th February 2006.

he not know of the protocols because contracted surgeons were not required to attend an orientation and up-dates?

4. Pain relief management.
[Mrs A] was obviously in severe pain postoperatively but as this was unusual for such an operation her symptoms were dismissed. She did not get adequate analgesia, was given pethidine without an anti-emetic which caused her nausea, and she was not assessed to determine why her pain was out of the normal range for this operation. Whether or not the incident had been written in the notes (as it should have been) the management of [Mrs A's] pain was poorly managed.

5. Handover
The severity of the mistake with the eye-shields was under-appreciated and was not written in the notes by the surgeon, the anaesthetist or the nurses. The nurse who wrote the discharge summary did not know of the mistake and it was therefore not communicated to [Mrs A's] General Practitioner.

6. Incident reporting
This information was therefore not communicated to the recovery nurse. An incident form was not completed until [Mrs A] wrote her letter.

7. RCA
The documentation supplied with the RCA is very brief and it does not appear that a full Root Cause Analysis has been done. Having said that, the vulnerability of the sterilisation process was at least recognised and [the Hospital] looks to have made progress in changing this. The rest of the recommended actions are weak in that they almost all refer to individuals reading protocols and policies. These are unlikely to affect future error rates. The vulnerability of running a surgical Hospital with only contracted surgeons and anaesthetists is not touched on in the RCA, however, most systems analysts would recognise that such a set-up would not support teamwork and communication.

Specific questions
[Dr B]:

1. Whether [Dr B] provided [Mrs A] with surgical services of an appropriate standard on 20 October 2005.

   I am not qualified to comment on the standard of the actual operation. The preoperative check appeared to be of an appropriate standard. [Dr B] did not see [Mrs A] after the operation and states that it is not his usual practice to do so. However, from a non-surgeon's point of view it would seem unsatisfactory that [Dr B] did not see [Mrs A] — had he done so he might have realised that her pain was out of proportion to her operation and ensured better pain relief and earlier referral to the ophthalmologist.

If we take it that 'surgical services' encompasses more that the actual operation, then this lack of review in the post-operative period would not seem to be of an appropriate standard. [Dr B] himself appears to have reflected on his standard of postoperative care as in his statement dated 14th February 2006 he notes that now he 'rings all patients who have had blepharoplasty on the evening of their operation to be sure that there are no substantial complaints or problems regarding the procedure'.

2. Whether [Dr B] provided [Mrs A] with adequate information and appropriate care after her surgery on 20 October 2005.

   As [Dr B] did not see [Mrs A] in the postoperative period he was not able to give her any information about the incident, and indeed he did not realise the seriousness of the incident itself. It is however odd that at her day 5 check-up, at [Dr B's] rooms, [Mrs A] was only seen by the nurse — [Dr B] did not make the time to see her [[Dr B] said that he did see her that day]. In fact her only postoperative contact with [Dr B] seems to be on day 15 when she was at her work and [Dr B] was visiting with his wife. [Dr B] probably thought that he was doing her a favour — saving her coming to his rooms — but it was probably inappropriate as she was only seen briefly and may have felt inhibited about speaking about her concerns in her work 'tea-room'.

   [Mrs A] received information about the extent of her corneal damage from [Dr F]. And [Dr B] appeared to defer to [Dr F] as the expert in the area. However [Mrs A] had to wait 5 weeks to get an adequate explanation of what had actually happened in the operating theatre.

[The Hospital]

3. Whether [the Hospital] staff took appropriate steps to ensure the correct solution was used to soak the eye shields.

   On the manufacturer's advice sheet — in bold letters are the autoclaving instructions: 'Corneal Eyeshield is steam autoclavable up to 250°F (121°C) for not more than 15 minutes and not more that 5 sterilisation cycles.' In small print in the bottom right hand corner it does state that the 'shell should be sterilised with a disinfectant solution for 15 minutes.' It does not describe what is the correct solution for such serialisation.

   However, soaking the eye shields in concentrated chlorhexidine and alcohol, and doing this on the sterile trolley was a risky procedure. So at the time of the incident, it would appear that [the Hospital] did not take appropriate steps to ensure safe sterilisation of the eye-shields. [the Hospital] could've used the sterad process earlier or invested in disposable eye shields.

4. Whether [the Hospital] staff took appropriate steps to alert [Dr B] that the eye shields were soaking in chlorhexidine and alcohol.

[The Hospital] staff in the operating theatre did not inform [Dr B] that they were soaking the eye shields in concentrated chlorhexidine and alcohol. As stated in [Mr C's] letter dated 20 February 2006 'Unless the specialist has provided specific standing orders it is not standard practice for medical specialists to be told how items have been sterilised or disinfected'. [Mr C] goes on to say that 'Medical specialists' knowledge is usually irrelevant because the scrub nurse passes the specialist any items he or she needs. [Mr C] does not seem to understand that this is a risky procedure as demonstrated by the incident at hand.

If [Dr B] had known the sterilising practice then it is unlikely that he would have placed the un-rinsed eye shields in [Mrs A's] eyes. [Mr C] states later in his report that 'we know that [Dr B] was aware that eye shields were soaked in a disinfectant solution prior to use because he had previously discussed this issues with [one of the theatre nurses]'. We do not know when this discussion took place and whether it included the crucial fact that they were soaked in concentrated chlorhexidine and alcohol which then needed to be rinsed.

It would appear that [the Hospital] did not take appropriate steps to alert [Dr B] as to the risks associated with their sterilisation technique at the time of the incident. They have now changed to a safer technique which should prevent further incidents of this type."

Appendix Two — Expert advice from Dr David Glasson

I obtained a second opinion from independent plastic surgeon Dr David Glasson. Dr Glasson provided the following written advice:

> "I am a registered specialist Plastic and Reconstructive Surgeon. I obtained my MBChB in 1978, my FRACS in Plastic and Reconstructive Surgery in 1987, and became a registered specialist in plastic surgery with the Medical Council of New Zealand in 1988. I worked in combined public and private practice until mid 2005 and since then have been in full time private practice. My practice includes a broad range of reconstructive and cosmetic surgery".
>
> **Complaint**
>
> - Whether [Dr B] provided [Mrs A] with surgical services of an appropriate standard on 20 October 2005
>
> - Whether [Dr B] provided [Mrs A] with adequate information and appropriate care after her surgery on 20 October 2005.
>
> **Expert advice required**
>
> In your opinion, did [Dr B] provide postoperative services of an appropriate standard and, in addition, answer the following:
>
> 1. Is it reasonable for a surgeon to take equipment directly from the scrub nurse's trolley. If not, please explain?
>
> 2. If a plastic surgeon accidentally placed eye shields soaked in chlorhexidine in a patient's eyes, is this an 'adverse incident' that should be noted in the operation note?
>
> 3. Would a reasonable plastic surgeon usually follow up personally with a patient in postoperative recovery following a blepharoplasty?
>
> 4. If a patient experienced unusual pain following a blepharoplasty and self-referred to an ophthalmologist, what steps would a reasonable plastic surgeon take to follow up on the patient's progress?
>
> If, in answering the above, you believe that [Dr B] did not provide an appropriate standard of care, please indicate the severity of their departure from that standard.
>
> To assist you on this last point, I note that some experts approach the question by considering whether the providers' peers would view the conduct with mild, moderate, or severe disapproval.

Supporting information

- [Mrs A's] letter to the Commissioner dated 19 November 2005, marked 'A'. (Pages 1–13).
- Notification letters to [Dr B] and [the Hospital] dated 27 January 2006, marked 'B'. (Pages 14–19).
- [Dr B's] response to the Commissioner dated 14 February 2006, marked 'C'. (Pages 20–31).
- [The Hospital's] response to the Commissioner dated 20 February 2006, including the position descriptions for circulating and scrub nurses (pages 37–42), cleaning, disinfection and sterilisation guidelines (pages 43–51) and information on corneal eye shields (52), marked 'D'.
- Incident report and report of [the Hospital] investigation to [Mrs A] (page 53–55) and medical records (pages 56–106) marked 'E'.

Factual Summary

20th October 2005, [the Hospital]. [Mrs A] had surgery performed by plastic surgeon [Dr B] which included upper and lower blepharoplasty (cosmetic eyelid surgery) and excision of a naevus (mole) from the left side of her neck. Notes provided by [the Hospital] refer to 'pressure of time with overbooked list'. At the beginning of the surgery [Dr B] used eye shields to protect the eyes. These eye shields were soaking in a disinfectant solution of chlorhexidine and alcohol on the scrub nurse's trolley. The usual practice was for the nurse to rinse the eye shields with water to remove the disinfectant solution before the eye shields were placed on the patient's eyes. On this occasion, while the scrub nurse was distracted waiting for the rinsing solution, [Dr B] took the eye shields from the scrub table without rinsing them and placed them on the patient's eyes to protect the corneas. The nurse alerted [Dr B] who removed the eye shields and irrigated the patient's eyes with balanced salt solution. [Dr B] checked the eyes which 'appeared normal'. The shields were replaced and the surgery completed.

[Dr E], an ENT surgeon, and employer of [Mrs A], was present in the theatre as an observer.

This event was not recorded in the operation note by [Dr B]. On [the Hospital] surgeon's operation record [Dr B] noted that he did not need to see the patient prior to discharge.

[Mrs A] was transferred to the recovery area. The recovery staff were not alerted to the incident in theatre.

In recovery, [Mrs A] complained of severe pain in her eyes and received analgesic medication.

The recovery room record has a section to record pain. This shows a score '2', which is the lowest level of pain, with '5' being severe pain. [This score is based on a pain level assessment which has range of 1–5, 1 being low and 5 being

severe. The score also allows for the patient's description of their level of comfort. [Mrs A] was assessed as having a pain level of 1–2 (which is low) within a range of 1–5, or that she stated she was comfortable.] [Mrs A's] own account would indicate severe pain, [requiring] a score of '5'.

The recovery staff did not record any distress and there were no specific comments made on the recovery sheet. [Dr B] was not alerted of [Mrs A's] symptoms. She was discharged from recovery without review by [Dr B].

21st October 2005. [Mrs A] phoned [Dr B's] rooms complaining of a burning sensation in her eyes. [Dr B's] nurse called him and he explained to his nurse that these symptoms were not normal and that he needed to see her or she needed to be seen by an eye specialist. Shortly after this [Dr E] phoned [Dr B] to say that he had arranged an appointment with an ophthalmologist [Dr F].

22nd October 2005. [Mrs A] saw [Dr F] whose letter to [Dr B] records healing corneal abrasions, possibly secondary to cleaning solution. He noted that these should heal within 24–48 hours and he prescribed some topical treatment.

[Dr B] reports that he spoke to [Dr F] that day. He felt reassured by [Dr F's] report and anticipated that 'with several days treatment it would be the end of the matter'.

25th October 2005. [Mrs A] reports that she attended [Dr B's] rooms so the nurse could take the stitches out. She explained her recovery course and the visit to the eye specialist and the nurse advised that she would tell [Dr B]. [Dr B's] report states that he saw [Mrs A] himself and talked to her about his conversation with [Dr F]. He advised that this would be a temporary problem and would clear up quickly.

26th October 2005. [Dr B] wrote to Dr F thanking him for evaluating Mrs A.

2nd November 2005. [Mrs A] had a further appointment with [Dr F] reporting ongoing symptoms of photophobia (light sensitivity). He reported that the abrasions had healed over and prescribed a change in her topical treatment.

3rd November 2005. [Mrs A] had a scheduled appointment with [Dr B] that day but coincidentally [Dr B] attended [Dr E's] office where [Mrs A] works. A review of her surgery occurred there when [Dr B] reported a satisfactory outcome from an aesthetic point of view, and that he was assured by [Dr F] that a complete recovery was expected. He apologised for all the problems that she had had after the surgery. [Mrs A] reports that [Dr B] said 'I have no idea how that happened and I have asked my staff this morning at [the Hospital] to look into this'.

7th November 2005. [Mrs A] phoned [Dr F] complaining of persistent pain. He advised the use of some different eye drops.

9th November 2005. [Mrs A] saw [Dr F], and she reports that he advised the eyes were healed, but a further six weeks may be required for her symptoms to settle, and that she may have suffered nerve damage.

28th November 2005. [Mrs A] received a letter from [the Hospital] with a full explanation of the events in theatre.

1st December 2005. [Dr B] met with [Mrs A] and her son. [Mrs A] states that [Dr B] said he was unaware there was alcohol in the disinfectant solution and that he thought he was only dealing with chlorhexidine in the eyes 'which is a common event in theatre'.

13th December 2005. [Mrs A] was seen by [an Optometrist]. He notes the history of chemical burn contracted during surgery. He records the compromised visual acuities that were first measured by [Dr F] had resolved but that there was a definite alteration in the corneal curves. This had resulted in a left refraction that was 'substantially different'. He noted that 'this eye has definitely been affected by the chemical burn …'

[The Hospital] Response

Included in [the Hospital] response is information that the disinfectant solution was made up on chlorhexidine (presumably 0.5%), and 70% alcohol. This is the usual concentration of this sterilising solution.

There is an information sheet, page 051, about the Ellman corneal eye shields. This explained that the shields should be sterilised with a disinfectant solution for fifteen minutes. The concave side of the shell should be coated with antibiotic ointment before placing the shield on the cornea.

[The Hospital] did not have the necessary low temperature steam sterilisation equipment to sterilize the shields, and therefore used disinfectant solution.

Key points

At surgery, the eye shields were being soaked in disinfectant solution as recommended. [Dr B] removed the eye shields directly from the disinfectant solution, without rinsing them, and placed them on the patient's eyes. No antibiotic ointment was applied to the concave surface of the eye shields.

After being informed that the eye shields had not been rinsed, [Dr B] removed them and the eyes were irrigated with balanced salt solution. The eye shields were replaced and the operation completed.

The operation note contains no record to show that the surgery was anything other than routine. No incident report was done.

The recovery staff were not alerted to any potential problem. [Mrs A] reports severe pain in recovery. The recovery record reports that patient was comfortable

and makes no special comment about her symptoms. [Dr B] was not alerted to anything unusual by the recovery staff. [Dr B] did not review [Mrs A] prior to discharge.

[Dr B] wrote in his report that it is not unusual for chlorhexidine to make contact with the eye during preparation of the skin for surgery, and that it is his understanding that the alcohol content of the disinfectant caused the injury. Both chlorhexidine and alcohol are toxic to the cornea.

See attached references obtained from the National Pesticide Information Center www.npic.orst.edu/RMPP/rmpp_ch19.pdf — section on chlorhexidine in a chapter on disinfectants. Also see 'Mediflex answers chlorhexidine question' and specifically the section on ocular toxicity by Cynthia T Crosby. This is on the Anaesthesia Patient Safety Foundation site at www.apsf.org/resource_center/newsletter/2003/summer/letters.htm.

Specific questions

1. Is it reasonable for a surgeon to take equipment directly from the scrub nurse's trolley. If not, please explain?

In some circumstances, for example if the scrub nurse is involved with assisting at the surgery, it may be expeditious for the surgeon to take items directly from the scrub nurse's trolley. If an item is soaking in a solution, it is prudent to check what that solution is.

2. If a plastic surgeon accidentally placed eye shields soaked in chlorhexidine in a patient's eyes, is this an 'adverse incident' that should be noted in the operation note?

Yes. This event is a deviation from a routine procedure. Measures were taken to reverse the effect of contact with chlorhexidine and alcohol solution by irrigating the eyes. Such a deviation from standard procedure should be recorded in the operation note.

3. Would a reasonable plastic surgeon usually follow up personally with a patient in postoperative recovery following a blepharoplasty?

Yes. A reasonable plastic surgeon would review the patient prior to discharge to check on the absence of complications, e.g. haematoma, visual disturbance. A review by the surgeon would be especially indicated if there was the possibility of an eye injury, or there were any unexpected symptoms. However, [Mrs A's] symptoms were not reported to [Dr B] by the recovery staff who did not interpret her symptoms as severe. On [the Hospital] surgeon's operation record [Dr B] had noted that the patient did not have to be seen by him prior to discharge.

4. If a patient experienced unusual pain following a blepharoplasty and self-referred to an ophthalmologist, what steps would a reasonable plastic surgeon take to follow up on the patient's progress?

In this situation a reasonable plastic surgeon would contact the patient directly to clarify the problems and discuss diagnosis and management with the ophthalmologist.

Note that [Mrs A] had contacted [Dr B's] rooms on the day following surgery complaining of a burning sensation. [Dr B's] nurse had contacted him and he had advised his nurse that he should see her and that she would need to be seen by an eye specialist. This is appropriate.

However, it seems from the information supplied that before [Dr B] could arrange to see her, [Mrs A] and [Dr E] had pre-empted him and arranged to see [Dr F] already.

[Dr B] did liaise with [Dr F] on 22nd October, 2 days after the surgery, and was reassured by his comments.

5. If, in answering the above, you believe that [Dr B] did not provide an appropriate standard of care, please indicate the severity of their departure from that standard.

…

To answer this question, the events are summarised:
[Mrs A] sustained a corneal injury from the application of chlorhexidine and alcohol solution when [Dr B] applied eye shields soaking in that solution to her eyes.

[Dr B] did not check with the scrub nurse what solution the eye shields were soaking in.

[Dr B] did not appreciate the potential harm of the disinfectant solution near the eyes. Chlorhexidine can be toxic to the cornea without the addition of alcohol, and alcohol at that concentration will also damage the cornea. Chlorhexidine and alcohol can both cause corneal injury.

The eye shields were removed and the eyes irrigated but the injury had been done.

The eye shields were not used as recommended by the manufacturer who advises that the concave side of the shield should be coated with antibiotic ointment.

The incident was not documented in the operation record and an official incident report was not initiated.

The recovery room staff were not alerted to any potential problem.

The recovery room record is at variance with the patient's recollection.

Recovery room staff did not report anything unusual to [Dr B].

[Mrs A] was not reviewed by [Dr B] in the recovery area before discharge and was not informed about possible injury.

[Dr B] did not seek expert advice or management at, or shortly after, the time of injury to assess whether any injury had occurred.

When his nurse informed him the following day about his patient's symptoms he planned to see her and arrange an eye specialist review. However, the patient self referred to an ophthalmologist the day following surgery before [Dr B] had the opportunity to do so.

This has been an unpleasant experience for [Mrs A]. Fortunately the corneal burns healed completely with some refractive change requiring new glasses.

In my opinion, when an event occurs with the potential for patient injury, the practitioner should document it, inform the patient and relevant staff, get expert management advice as soon as possible, and follow up.

Considering this, [Dr B] did not meet all the standards of care and skill reasonably expected of a plastic surgeon in these circumstances. It is my opinion that the conduct of [Dr B] would incur the disapproval of peers and that this disapproval would be moderate."

Appendix Three — Report from Dr Stephen Gilbert

"Thank you for asking me to comment on the criticisms made of [Dr B] in the Health and Disability Commissioner's opinion and whether or not I concur with the opinion expressed by [the Commissioner's first expert advisor].

You have supplied me with:

i. A copy of [Dr B's] response to the Health and Disability Commissioner

ii. A copy of the first Health and Disability Commissioner's provisional opinion

iii. A copy of the second Health and Disability Commissioner's provisional opinion

iv. A copy of the opinion of [the Commissioner's first expert advisor]

v. A copy of the Health Practitioners Disability Tribunal's practice note relating to expert witnesses. (This is applicable to expert witnesses appearing before the Tribunal and enclosed as a general guide)

[Dr B] also has provided me with a copy of his clinical notes by fax.

I am a plastic and reconstructive surgeon vocationally registered with the Medical Council with Fellowship from the Royal College of Surgeons, England and a Fellowship in Plastic Surgery from the Royal Australasian College of Surgeons. I am in full time private plastic surgical practice in Auckland, having been a part time visiting plastic surgical specialist at Middlemore Hospital until about ten years ago. I now specialise in aesthetic facial plastic surgery. I confirm that I have read the Code of Conduct for expert witnesses and agree to comply with its terms.

1) From reviewing the above documents it is clear that the Health and Disability Commissioner's main criticism of [Dr B] is based on the belief that [Dr B] was told by theatre nursing staff that the sterilizing solution contained Chlorhexidine and alcohol (page 32). However in the papers I have been given there is no evidence that he was told anything more than that the eye shields had not been rinsed after being placed in a sterilizing solution. In particular [Ms D], [the Hospital] theatre services manager, in her report to [Mrs A] reported that the scrub nurse, as soon as she had realised that [Dr B] had taken the eye shields from the trolley and put them in her eyes, alerted [Dr B] immediately that the shields had not been rinsed but she did not say that [Dr B] was told what the sterilizing solution had been.

   [Dr B] himself states that he was unaware the solution contained alcohol until he was told so by the Director of Nursing about mid November, some time after [Mrs A] had made her complaint.

   Had [Dr B] been told in theatre that the solution contained alcohol rather than what he thought was dilute (and innocuous) Chlorhexidine then he

should have documented it. This would have ensured that appropriate care would have been instituted in Recovery.

A prudent surgeon, on learning that the shields had not been rinsed, should adopt a cautious approach and wash out the eyes. The fact that this was done by [Dr B] seems to have been taken to imply he knew the solution was toxic to the cornea. I do not agree with this interpretation. What he did was consistent with what I would expect a careful surgeon to do and what I would expect a reasonable surgeon to have done if face cleaning Chlorhexidine had got in the eyes.

It would have been helpful if [the Hospital] theatre staff who were aware of the contents of the sterilizing solution had advised [Dr B] of this. I would expect such information to have resulted in appropriate documentation being made both by the nursing staff and [Dr B] resulting in Recovery being alerted to a possible injury.

To be criticised for any shortcomings in documentation for possible injury, [Dr B] needed to be aware that injury might have occurred.

2) This leads to the next criticism that [Dr B] did not inform [Mrs A] that an incident had occurred in theatre that might have affected her post operative recovery.

He couldn't do this initially as it appears he was unaware that such an incident had occurred.

From my analysis of the timing of this matter, it appears that at the first opportunity after hearing from [the Hospital] that the solution contained alcohol he did discuss it with [Mrs A] when he phoned her and she came to his office on 1/12/05. But by this time, [the Hospital] had received a complaint from [Mrs A] and communicated with her about the matter in a way critical of [Dr B], apparently without the involvement of [Dr B]. The process used could lead to misunderstandings and grievances as has occurred here.

3) [Dr B's] postoperative management is criticized.
From the information available, it appears that [Mrs A] reported pain in her eyes to [Dr E] next day when he phoned her to find out how she was progressing. [Dr B's] nurse also telephoned her and discussed her condition with [Dr B] who advised that she should come to his office to be seen but by that time [Dr E] had arranged an urgent ophthalmological appointment for her with [Dr F] and so she did not come to [Dr B's] rooms. [Dr E] had given [Dr F] a full report of the operation and the information about the eye shields. [Dr B] had discussed this referral with [Dr E] and approved of it and was from the reports provided fully in touch with the ophthalmologist on [Mrs A's] progress from there on.

Therefore [Mrs A] was receiving appropriate care as soon as a problem was recognised.

4) [Dr B] is also criticized for not seeing [Mrs A] appropriately for follow-up. It appears that [Dr B] wanted to see [Mrs A] the day after surgery but an appointment had already been made for her to see the ophthalmologist urgently. It is understandable he didn't intervene when appropriate care had been instituted. On day five her sutures were removed by [Dr B's] nurse who discussed her condition with him.

Surgeons are not necessarily present when sutures are being removed and often give advice on the telephone if there is a problem. [Dr B] appears to have reassured himself that she was getting appropriate care from the ophthalmologist at that time. He did see her in [Dr E's] rooms on 3/11/05 and she was offered an appointment to see him in his rooms on 9/11/05 but opted for a telephone conversation instead. She then came to his office on 1/12/05 at [Dr B's] request and discussed the issues including the accidental placing of the unrinsed eye shields in her eyes, now known to have been sterilised in Chlorhexidine and alcohol.

In my opinion [Dr B] made reasonable attempts to see [Mrs A] after surgery at his rooms but was forestalled by her urgent appointment to see [Dr F] and then by the coincidence of meeting her in [Dr E's] rooms. She declined to come in to see him on 9/11/05 and only came on 1/12/05 after receiving [the Hospital] report. [Dr B's] nurse was also in touch with her during this time, and [Dr B] was constantly in touch with [Dr F].

In these circumstances I do not think [Dr B's] standard of care was wanting and had he discussed the incident with the eye shields with her earlier I do not believe this would have changed her management or the medical outcome.

In my view, in retrospect it would have been appropriate for him to have discussed the incident of the eye shields with [Mrs A] earlier in the piece when he realised that the ophthalmological opinion was that [Mrs A] had received a chemical burn from Chlorhexidine in the sterilizing fluid.

While I agree with Mr Glasson's opinion that "when an event occurs with the potential for patient injury the practitioner should document it, inform the patient and relevant staff, get expert management advice as soon as possible and follow up" this requires knowledge on the part of the surgeon that there is something to document. It appears that once aware of the issue, appropriate care had been initiated by another doctor with an appropriate specialist from another specialty, namely ophthalmology

I would like to comment on several inconsistencies that appear in the HDC report.

i. The eye shields on the trolley. Mr Glasson assumed [Dr B] had taken the eye shields from sterilizing solution on the trolley. As I read the material, this was not so, he took them from an empty galley pot. Had the galley pot been filled with a solution he would have been alerted to the need to enquire what this solution was as a prudent surgeon would have done. Mr Glasson was under the misapprehension that [Dr B] took the eye shields directly from a solution on the trolley without checking what the solution was and therefore acted imprudently.

He partly based his opinion of [Dr B's] performance on this. I agree with [the Commissioner's first expert advisor] and Mr Glasson that surgeons often have to help themselves to items on the trolley to ensure the efficient running of an operation. In fact during a six hour face lift operation it is only me and one nurse scrubbed and we share the use of the trolley. An extra assistant would often get in the way, be inadequately utilised and increase the risk of procedural error.

Recommended use of the eye shields. Mr Glasson says that the eye shields were not used as recommended by the manufacturer who advised that the concave side of the shield should be coated with antibiotic ointment. Most surgeons would put some lubricating solution into the eyes under the shields. I have never seen the instructions that recommend that antibiotic ointment should be used. It is the responsibility of theatre staff to ensure that surgical equipment provided by them is being used as recommended by the manufacturer. It could have been helpful to put antibiotic ointment in the eyes when the eye shields were rinsed and replaced.

ii. Chlorhexidine. In the HDC report there is a comment that the nurses had recorded that aqueous Chlorhexidine was used whereas it should have been Chlorhexidine with alcohol. I expect this is incorrect because the nurses would have been recording the solution used to wash the face which would have been a mixture of Chlorhexidine and water, never Chlorhexidine with alcohol.

This Chlorhexidine is what [Dr B] had commented did not harm the eyes when it accidentally got into them and is not the Chlorhexidine in which the eye shields were soaked.

[Dr B] reports that he had previously been told by [the Hospital] that the sterilizing solution contained Chlorhexidine and not Chlorhexidine and alcohol. One of the Chlorhexidine solutions commonly used to clean the skin is Savlon which has a concentration of 0.0 15% Chlorhexidine. Another stronger solution is aqueous Chlorhexidine having a concentration of 0.05% Chlorhexidine but in the sterilizing solution with alcohol the concentration of Chlorhexidine is 0.5%. References quoted refer to Chlorhexidine toxicity at far greater strengths than the 0.0 15% or 0.05% percentages and greater exposure time. It is not clear if Chlorhexidine 0.5% in contact with the

cornea briefly and then washed out with saline would in fact have caused much damage.

iii. Documentation. Because, as reported by [Dr B], he thought that the aqueous Chlorhexidine solution he assumed the eye shield had been soaked in was innocuous to the cornea, especially if rinsed out immediately with saline (which is what is done if Chlorhexidine being used to clean the skin accidentally gets into the eyes), he understandably therefore did not see this as an incident with potential harm to the patient and did not document it or report it to the patient afterwards. Seldom does an operation go totally ideally as planned but minor variances which are not harmful are not documented and reported to the patient. The issue is identifying which matters are of sufficient seriousness and concern to require documentation.

iv. Recovery and pain relief. In this case the method of scoring pain as recorded in the HDC report is confusing. It is usual to score the pain level on an ascending level from 1–5 or 1–10 as assessed by the patient at the nurses' request. It does not make any sense to say the highest level is 0 as referred to in the HDC report. It should be 5 or 10. In this case 2 was recorded and this would indicate that the patient gave the impression to the nurse that her pain was relatively mild or that the nurse misinterpreted the scoring system.

It is surprising that when she was checked in Recovery by the anaesthetist that he did not recognise a high level of pain as she subsequently reported and treat her appropriately. Also she discharged herself early from Recovery. This appears to have resulted in a missed opportunity for early assistance. Had she not done so but discussed the pain level with the nurse this is likely to have been reported to [Dr B], who would have investigated and instituted early management.

I agree with [the Commissioner's first expert advisor] that it is not always possible for a surgeon to see patients in Recovery before they are discharged because the surgeon may still be operating on the next case. Then the surgeon has to rely on the Recovery room staff reporting any unusual findings before discharging the patient. If the recovery team had been aware of the high level of pain reported by [Mrs A] this circumstance would have required the Recovery room staff to come to the theatre to discuss the patient's condition with the surgeon

Conclusion — I would agree with [the Commissioner's first expert advisor's] opinions in his letter dated 7/12/06 to the Health and Disability Commissioner.

I repeat that the censoring of [Dr B] is partially dependent on unproven evidence in the documents I have been given. The HDC opinion is that [Dr B] was told of the contents of the sterilizing solution in theatre after the incident had happened but nowhere in the documents I reviewed is this stated by any one else. In [Ms D's] report she states that [Dr B] was merely alerted to the fact that the eye shields had not been rinsed after they had been sterilised.

It is inconceivable that any surgeon having been told that the sterilizing solution was a strong concentration of Chlorhexidine and alcohol would not have instituted appropriate management with antibiotic and steroid ointment immediately and documented the incident.

Mr Glasson was under the misapprehension that [Dr B] imprudently took the eye shields out of a fluid filled galley pot and was critical of this.

In the record postoperatively [Dr B] satisfied himself four times that [Mrs A] was being appropriately looked after by the ophthalmologist and asked her to come to his rooms on two occasions but on the first she already had an appointment to see the ophthalmologist and on the second she preferred to have a discussion by telephone.

[Dr B's] actions after he discovered [Mrs A] had a problem in no way interfered with her recovery. In retrospect when [Dr B] found out that the likely problem was a chemical burn from something that had got into her eyes he would have been well advised to check exactly what the content of the sterilizing solution was. Even though he thought the initial problem was due to an unusual reaction to Chlorhexidine, he could have discussed the incident with [Mrs A] and in fact may well have done so had she seen him in his rooms for a follow-up appointment in the normal course of events. It appears that [Dr B's] normal post operative patient involvement has been pre-empted and obscured by [Mrs A's] working relationship with [Dr E]."

Appendix Four — Further comments from Dr David Glasson

"Thank you for sending the report from Stephen Gilbert. I will comment on this and answer your specific questions.

Comments on Mr Gilbert's report

1. Key point: new information to me.

His analysis of events is that the eye shields were removed from an empty galley pot by [Dr B]. They had been soaking in a solution of chlorhexidine and alcohol for sterilization, were then removed by the nurse, and placed in a galley pot, but not rinsed. [Dr B] was not aware they had not been rinsed, and presumed they were ready for use.

He removed them from the galley pot and placed them on the eyes. There is no record of whether ointment was placed on the concave surface as recommended by the manufacturer.

After he was advised they had not been rinsed by the nursing staff (not his fault), he removed the shields, irrigated the eyes, and replaced the shields. There is no record of ointment use.

My impression was that [Dr B] had removed them directly from the solution. Mr Gilbert has provided a clearer description of events.

However, presumably there was residual chlorhexidine and alcohol [because there was] enough to cause injury to the cornea. The alcohol may still have been present, or may have evaporated leaving only residual chlorhexidine.

There is no mention of ointment use on the concave surface of the shields, which would have provided some protection.

Mr Gilbert then states that [Dr B] thought they had been soaked in an innocuous dilution of chlorhexidine and water and therefore would not be likely to cause injury to the cornea. I agree that it would have been helpful for the staff to inform him about the sterilizing solution. But, he could have asked to confirm what the solution was, and such an enquiry may have led to more appropriate measures. (The label on the Chlorhex and alcohol bottle advises the eye should be flushed for 15 minutes if the solution is in the eyes). Ointment on the concave surface may have provided some protection, and there is no record of its use.

[Dr B] did wash out the eyes, and Mr Gilbert states that this is consistent with what a careful surgeon would do if "face cleaning Chlorhexidine had got in the eyes", and that this action does not imply that [Dr B] knew the solution was toxic to the cornea. It remains my opinion that, by taking that action, the surgeon had some awareness that chlorhexidine has the potential to be harmful. Why do it otherwise?

2. Mr Gilbert then explains the lack of information given to the patient on the basis that [Dr B] did not know there could be an injury. As above, he could have asked about the sterilizing solution when advised it had not been rinsed off.

3. Post op management. The patient pre-empted [Dr B] by making her own appointment (with Dr E) to see [Dr F]. I have noted this in my report to HDC.

4. Follow up. No new issues.

5. Recommended use of eye shields. The instructions for use from the manufacturer were provided by [the Hospital]. Mr Gilbert may have not seen them, but they are available. Usual practice is to put ointment on the concave surface — either bland lubricant such as lacrilube, or ophthalmic antibiotic ointment. I agree with his comment that it could have been helpful to use antibiotic ointment in the eyes when the eye shields were rinsed and replaced, but also when the shields were initially placed on the corneas.

6. Chlorhexidine
The concentration in aqueous face prep solution is 0.015%. In the alcohol preparation used for sterilization it is 0.5%.

Mr Gilbert states that [Dr B] believed that aqueous chlorhexidine used to wash the face did not harm the eyes when it accidentally got in to them.

But, I have enquired about this, and an ophthalmologist advised that chlorhexidine is viewed as toxic to the cornea and conjunctiva and contact should be avoided.

7. Documentation
Presuming the chlorhexidine was innocuous, [Dr B] did not record the event. Minor variances from routine practice, which are not harmful, are not generally documented.
Unfortunately harm was done in this case. Had [Dr B] asked what the sterilizing solution was, appropriate measures and documentation could have occurred.

8. Recovery.
The SX pain record is confusing and not the most commonly used pain assessment scale. The patient's recollection of her pain level varies from that recorded, as noted in my report.

If the surgeon does not see the patient in the recovery room, he does rely on the reporting of problems by the recovery room staff. They did not report to him. But [Dr B] had advised he did not need to review her in recovery before discharge. He should have reviewed her before discharge had he suspected risk of injury. Again, he would have known of the risk of injury had he asked about the sterilizing solution.

[Dr F] was managing the complication and [Dr B] maintained liaison with him.

WHAT DID HAPPEN?
Corneal burns occurred.
Presumably these were due to residual sterilizing solution on the eye shields.
The shields were not rinsed by nursing staff.
The unrinsed shields were placed on the eyes — no mention of ointment use.
[Dr B] was advised the shields were not rinsed.
He assumed it was an innocuous solution.
It seems he did not enquire as to the solution used.
The shields were removed and the eyes irrigated (the inference is that the surgeon did therefore identify risk of injury).
Shields were replaced — no mention of ointment use.
No special instruction given to recovery staff to observe for injury.
No decision to review personally in recovery.
No incident recorded in OT note.
Patient not advised early (prior to discharge) about possible problems.

COMMONLY KNOWN RISKS ASSOCIATED WITH A CHLORHEXIDINE USED FOR SURGICAL STERILISATION

Aqueous chlorhexidine would not generally be used for the sterilization of instruments, as alcohol solutions are more effective.

For skin preparation prior to surgery, chlorhexidine in alcohol is commonly used on the trunk and limbs. There are differing surgeon preferences however, and povidone iodine solutions are also commonly used.

For facial surgery, and particularly surgery close to the eyes, common practice is to avoid any alcohol solution and chlorhexidine. I have not surveyed NZ plastic surgeons, but usual practice where I work is for surgeons to use aqueous iodine based solutions as it is known that chlorhexidine may be irritating to the eye. I recall being instructed at registrar level to avoid Savlon around the eyes (it contains chlorhexidine at low concentration).

In this case — it seems to me that the key point is that an assumption was made about the sterilizing solution. [Dr B] assumed it was an aqueous solution containing a low concentration of chlorhexidine which he was familiar with, and considered innocuous. He could have asked the staff at the time what solution had been used, but in the event remained ignorant of it.

Debate about whether chlorhexidine at varying concentrations is injurious or not is not the most relevant point, in my opinion. The surgeon needed to know what had been used. Appropriate measures could then be taken.

HOW DOES A REASONABLE SURGEON DECIDE WHAT NEEDS TO BE DOCUMENTED AND REPORTED TO THE PATIENT AS AN UNEXPECTED AND ADVERSE EVENT?

If the event might cause some deviation from the expected post operative course, I think it should be documented either in [the Hospital] record, and (more likely) in the surgeon's own dictated operation note.

If the event might influence the immediate post operative care, then it would need to be explained immediately in recovery. If of a more minor nature, then explanation at a later time, on the same or following day could be appropriate. If the event could lead to painful symptoms, such as in this case, then an explanation would be given once the patient had recovered enough from the anaesthetic to understand what had happened and the need for special treatment."

Appendix Five — [The Hospital] Incident Reporting Policy

1.1 INCIDENT REPORTING AND MANAGEMENT POLICY

INTRODUCTION

The have a goal of being a leader in private surgical healthcare. This can only be achieved by ensuring operational excellence with appropriate quality, safety and risk management. Strong leadership with consistent processes, systems and information services further supports this goal.

The Incident Reporting and Management Policy and the associated folder of procedures and guidelines, fulfills the requirements for meeting the Health and Disability Sector Standards NZS 8134:2001 *(Organisational Management: Standard 2.3 – Exception Reporting)*.

POLICY STATEMENT

The Incident Reporting and Management System contributes to maintaining a safe environment for patients, visitors, employees and Medical Specialists. It does this through the reporting and immediate management of incidents, including subsequent sharing of information to enable learning, improvement in service delivery and the retention of institutional knowledge.

foster a culture of safety that is supported by a continuous cycle of quality improvement. The "no blame" culture within the hospitals ensures employees and Medical Specialists feel supported when incidents are being managed, without diminishing their professional accountability. Patients and doctors are fully informed regarding any incident that may affect them directly.

An underlying premise is that every person has a responsibility to identify and report incidents. Where appropriate, they should immediately manage the situation to avoid any further problems. Compliance with our insurer's requirements for circumstance notification also provides protection for management, employees, the business and the Southern Cross brand.

APPLICATION

Hospital Managers will ensure that all employees, Medical Specialists, visitors and patients are aware of the requirement to report incidents in a timely manner. In the context of this policy incidents include adverse or unplanned outcomes, accidents, untoward events and near misses and also complaints associated with incidents. Management advice and support may be sought to help manage the process.

The scope of this policy and reporting procedure includes1) events or complaints reported by patients and their families; and additionally these are managed in accordance with the Complaints Management Policy and Folder of procedures and guidelines, 2) restraint situations; and additionally these are managed in accordance with Restraint Minimization and Safe Practice Folder of procedures, and 3) incidents such as accidents affecting employees, health team or visitors; and additionally these are managed in accordance with the Health and Safety in Employment (HASE) Folder of procedures.

All immediate situations must be managed appropriately to avoid escalation of the problem. Where root causes to problems and hazards are identified, the underlying systems and processes, as well as employee performance are addressed to ensure the risk of further incidents occurring is minimised.

Sharing information across the network creates opportunities for continuous quality improvement. Quality improvement initiatives include team and individual teaching and learning for professional development, supervision and coaching, review and improvement to systems, procedures, processes and the maintenance of folders and registers.

Incidents are consolidated nationally through the Incident Summary System to provide data including quality clinical and other indicators to contribute to planning staff development, process improvement and other business activities. Clinical operational oversight of all incidents across the network enables trends to be identified and management support provided. Hospital Managers are responsible for analysing and acting on local data.

The Hospital Manager ensures that there is full disclosure in situations where a patient is harmed or exposed to harm, with the patient being informed in a timely and appropriately caring manner. This reflects the value place on openness and transparency. Where is responsible for an incident, an approved communication is provided, including full explanation and an apology. Hospital Managers must ensure that there is methodical documentation as well as effective internal and external communication and reporting throughout the entire process. They must also ensure that legislative requirements are met for the reporting of specific incidents to external agencies and timely notification internally to senior management and the insurer.

The Incident Reporting and Management Folder provides operational support to assist with interpretation of this policy and details of processes and steps to be followed.

Hospital Managers must ensure that a consistent procedure is undertaken when incidents occur, including the components identified below (and example process is the Plan, Do, Check, Act, [PDCA] cycle):

- Notification
- Analysis and investigation within required timeframe
- Identification of cause and hazards
- Solutions development
- Communication plan and corrective action support
- Authorisation of external correspondence
- Review and final closure

The Incident Reporting and Management System is entirely separate to other quality assurance programmes such as the healthcare professionals' own clinical self-audit reporting (e.g. the Visiting Practitioner Self-Audit Programme [VPSAR]).

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

ASSOCIATED DOCUMENTS

- Annual Business Plan
- Safety, Quality and Risk Management System Folder
- Health and Disability Sector Standards NZS8134 2001 Standards NZ. Wellington
- Health and Safety Folder
- Complaints Management Folder
- Restraint Minimization and Safe Practice Folder
- Reportable Events Guidelines (2001) Ministry of Health Wellington
- Sentinel Events Workbook: Process for Standardized Investigation and Reporting in the Health Sector SNZ HB 8152:2001 Standards NZ Wellington

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

2.1 REPORTING AND MANAGEMENT PROCEDURES

PURPOSE

The purpose of this document is to detail the required steps to be taken when reporting incidents and the standard activities required to manage incidents from the time of the occurrence until resolution, including ongoing safety, quality and risk management.

Definition

An incident is defined as an adverse or unplanned outcome, accident, untoward event, near miss and also includes complaints.

Classification

Incidents are classified, as minor, moderate or major. A major incident may also be identified and defined as a sentinel event. A major or moderate incident may also be identified and defined as an OSH Serious Harm Accident. The detail of the classification is located in Section 3. Appendix A: Classification and Incident Coding. Also refer to Section 4. Workbooks: Reportable Events Guidelines pages 15 & 16.

Coding

All incidents are entered into the Incident Summary System (ISS). Managers code incidents into categories to enable identification and management of trends. Incidents can be exported to an Excel spreadsheet action plan for ongoing management and can also be linked through the ISS to specific committees (HARC, HCMC, IC, SQR) and registers (Accidents, Complaints, Restraint, Maintenance). The details of current codes and classifications are located in Section 3, Appendix A.

Reportable incidents include:

- Events that result in or have the potential to harm patients, families, visitors, Medical Specialist or employees that are discovered upon entry to the service, or occur during service provision or following discharge
- Serious harm suffered by employees, visitors or contractors as defined in the Health and Safety in Employment Act 1992
- Events that reflects unsatisfactory quality of practice, management or service delivery systems that managers need to be informed of
- Events that have, or could have, resulted in loss or damage to patient, family, visitor, Medical Specialist, employee, property or our organisation
- Events that have, or could have, resulted in damage to the environment
- An event that could have caused harm, serious harm, damage or loss if:
  The situation had not been rescued in time to prevent harm occurring
  Employees foresee that recurrence of the event could result in harm i.e. 'near-misses'
  (Adapted from the Ministry of Health Reportable Events Guidelines – 2001)

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

Roles and Responsibilities

Any employee, Medical Specialist or person who is party, or witness, to a reportable incident is responsible for ensuring the incident situation is managed by taking immediate action to minimise harm/loss and recover the situation, reporting the incident according to the following procedures and for assisting in the subsequent investigation, management and any quality improvement.

Area Manager or Duty Team Leader

Receives notification of the incident and completed Incident Report Form. Assesses the need for immediate notification to the Hospital Manager and/or any expert assistance, and ensures all appropriate procedures followed.

Hospital Manager

Ensures the reporting and management of entire process is completed. The Hospital Manager may designate an incident manager appropriate to the hospital and specific situation and/or involve experts where appropriate.

Other Involved Parties

Internal experts may include co-ordinators and advisors for Infection Control, Restraint, Health and Safety in Employment and Radiological Services, the Hospital Clinical Medical Committee (HCMC) and/or Hospital Audit Review Committee (HARC) Chair, COO-Hospitals, Clinical Operations/Nurse Advisor/s and the National Office Resource Team, insurer and legal counsel who will provide appropriate advice and support on a case-by-case basis.

Other internal involved parties may include employees or Medical Specialists who perform activities to assist, established committees such as HCMC, SQR and Health and Safety (HASE) including Infection Control, Restraints, Complaints and ad hoc groups to perform clinical post-incident review and sentinel event processes.

External parties may include patient, family / whanau, advocates and experts in risk management, law, public relations, suppliers of goods and services, or public authorities for example.

Nurse Advisor

- Receives reports, seeks pertinent feedback and provides oversight, guidance and referral to resources, and support to ensure investigation and management on a case by case basis
- Advises and supports sentinel event processes
- Keeps Chief Operating Officer (COO) - Hospitals and Clinical Operations Advisor informed as appropriate
- Assists with notification to the insurer and liaison with legal and public relations advisors as needed

Clinical Operations Advisor

- Receives reports and provides oversight, guidance and referral to resources, and support on a case-by-case basis
- Advises and supports sentinel event processes
- Keeps Chief Operating Officer (COO) - Hospitals informed and as appropriate HARC
- Assists with notification to the insurer and liaison with legal and public relations advisors as needed

Chief Operating Office – Hospitals

- Provides management leadership, guidance, referral and support where necessary
- Authorises training and development for Hospital Managers
- Authorises any communication strategy, public relations assistance and implements Media Policy relating to specific incidents
- Reports incidents to Group Chief Executive Officer and Board as appropriate

PROCEDURES

Reporter and /or Involved Party

At the time of the occurrence

1. Take immediate action to minimise harm/loss and recover the situation, follow accepted practice and procedures when an event happens to ensure patients', employees' and others' safety and provide quality care, ensure reporting to Medical Specialist/s as necessary (refer to the flowchart Contacting Doctors / Medical Specialists doc 8.6)

2. Report immediately to the person in charge such as the area manager, duty team leader, senior nurse /Hospital Manager i.e. "on-call manager" (refer to Contacting On-call Manager: Advice and/or Attendance After Hours doc 8.5)

3. Complete documentation in patient clinical records

4. Ensure immediate replenishment of emergency supplies and any equipment, which is out of operation labeled 'out of use', and procedures followed for repair

Prior to going off duty

5. Complete page I of Incident Report Form (refer to doc 5.1) in an objective, factual and accurate manner, provide:

   - A full description of the incident and resulting condition of any injured person
   - Full details of the immediate action taken
   - Full identification details of the subject of the report, including:
     - If a patient, family/whanau or visitor: their name, age, department/clinical area and contact details
     - If an employee: their name, designation and department/clinical area
     - If property, equipment or environment: identifying information such as asset number, physical location, type of equipment and model number

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- The names of all the people involved in the incident, including witnesses, to ensure they can be contacted later as required
- If the incident relates to a patient, family/whanau or visitor, information about whether they are aware of the event at the time the form is completed
- Any breach to safety systems/barriers or control points that enabled the incident to occur
- The date, time and location of the incident
- The date and time the form is completed
- The signature, printed name and designation of the reporter

If the full details of the incident do not fit on the Incident Report Form or if requested by the area manager, duty team leader, senior nurse, Hospital Manager or On-call Manager, a separate report or additional page must be completed (refer to doc 8.3 for Report Writing Guidelines and File Note Taking doc 8.4). This report or additional page/s must be attached to the Incident Report Form so that it is readily recognised as part of the incident report.

6. If the incident affects an individual patient's care or relates to their clinical condition, details must be documented in the patient's clinical record. In some instances it may be appropriate to file a photocopy of the Incident Report Form in the patient's clinical record. Details of where any copies are located are recorded on the Incident Report Form.

7. If another employee or Medical Specialist is named on the Incident Report Form they must be informed, or if the reporter is unable to do this, the reason is documented on the Incident Report Form. Where possible, have them check the report before finalising it.

8. Forward Incident Report Form to the area manager or duty team leader or Hospital Manager prior to going off duty.

Subsequently

9. Provide clarification if sought by the manager who is handling the investigation process.

10. Seek access to support via Hospital Manager such as for activating Professional Indemnity Insurance (refer to docs 8.1 & 8.2), for personal Employee Assistance Programme (EAP) support (refer Section 8.10) and finalisation of any additional reports (refer doc 8.3).

11. Engage in processes such as Critical Incident De-brief for team involved (refer 8.9) and Patient/Clinical Event Review (refer doc 5.2 and also the Emergency Manual pages 36 & 37) meetings and quality assurance including ongoing training and development, or performance planning and review activities.

12. Attend meetings; please note that there is no requirement for any employee to meet with patients, families/whanau, or police (such as associated with an unexpected death situation) or other external parties. If this is proposed you must decline in the first instance and seek advice and support from the Hospital Manager, before attending any meetings with external parties.

13. Receives advice from Hospital Manager of the outcomes and results of actions and closure of the file.

Area Manager or Duty Team Leader (including "On-call Manager)

On verbal and/or written notification of an incident:

1. Classifies the incident (refer to Section 3 Appendix A: Classification of Incident).

2. Notifies the Hospital Manager immediately if a major or sentinel event (refer to Section 3 Appendix A: Sentinel Event Definition or Section 4: Sentinel Event Workbook) or potentially serious situation.

3. Ensures the immediate Incident Reporting and Management Procedure has been appropriately completed by Incident Reporter or Involved Party and that the Incident is entered into the ISS as soon as possible and any additional documents or such as draft reports completed (refer to doc 8.3 Incident Report Writing Procedures and Guidelines). Obtains further information as necessary (also refer to Section 3. Appendix B: Potential/Major Incident Management Process Flow Chart).

4. Where the "On-call Manager" is off site, and where the situation requires, they shall attend. The Hospital Manager ensures there is a system in place recording details so all employees know whom to call and situations that must be reported (refer to Contacting On-call Manager doc 8.5).

5. Where a situation could be classed as a major or sentinel, the Incident Reporter or other Involved Parties may individually need to be asked to write additional draft reports. These reports, labeled 'draft' must be separately written by each person involved and simply provides a summary of the sequence of events (where this additional documentation is required refer Report Writing Guidelines doc 8.3).

6. Ensure follow up with any affected parties e.g. the patient, family/whanau (refer to Section 9 docs), employees or Medical Specialists (also refer to the Complaints Folder).

7. Refers incidents of a complex or sensitive nature for example family, media (doc 8.7) or police enquiries immediately onto the Hospital Manager, or On-call Manager, who may designate an appropriate expert to assist or manage. Carry out actions as instructed by the Hospital Manager or On-call manager. Protect the rights of the Involved Parties ensuring they do not feel pressured into any meetings (refer point 12. page 4 above), management ensures employee advocacy.

8. Ensures all appropriate care and actions undertaken at the time including contact with any patient involved as appropriate and ensuring awareness of patient rights (refer Complaint Folder).

Hospital Manager

(The Hospital Manager may assign activities associated with this responsibility to an incident manager as appropriate to the business and incident situation).

On verbal and/or written notification of an incident:

1. Enters the incident into the ISS including classification of the incident and coding (Refer Section 3 Appendix A: Classification and Coding) immediately.

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It should be noted that where an Incident, including complaints, requires immediate notification to the Insurer a different number (from the ISS number) will also be issued from the National Office file reference numbering system and this or any other numbers is also recorded in the ISS for ease of cross-referencing.

2. Assesses the incident situation. Determines the significance and whether further investigation or action is needed. Not all reported incidents require further investigation.

3. Investigates the incident:
   - Collects the facts, knowledge and physical items related to the incident
   - Determines the sequence of events
   - Identifies the causative/contributory factors, hazards and risks
   - Develops a corrective action plan
   - Seeks advice and authorisation of investigation and action plan as appropriate
   - Implements action plan (refer to SQR 3.5 & 3.6, P-D-C-A, Reportable Event Guidelines Booklet page 26 and Section 3 Safety, Quality and Risk Folder doc 10)

   Recommended investigation timeframes:
   In accordance with the Ministry of Health Reportable Event Guidelines (2001) investigations are commenced as soon as practical after the incident and within the following timeframes:

   Major & Sentinel events: immediately to within 24 hours of the event being reported
   Less-serious events: (moderate/minor): as soon as practicable/immediately to within 3 days of the event being reported
   Complaints: in accordance with the Code of Health and Disability Services Consumers' Rights 1996

   Investigations are completed as soon as practical or within 10 days. If investigations cannot be completed within 10 days, the Hospital Manager negotiates a revised timeframe for completion.

4. Manages the situation.
   Reviews the investigations and actions taken by the Incident Reporter and Involved Parties and Area Manager and takes further action as appropriate or if required. Updates ISS.

5. On the Incident Report Form, (refer Form 5.1)
   - assigns a code number from ISS (this is automated)
   - provides details of the investigation and corrective actions (or an attached extra page), including time frames and people involved
   - indicates in ISS if investigation and actions incomplete at this point, indicate this on the report with timeframes in which completion is anticipated (has a system in place for monitoring activities and timeframes)
   - records notifications
   - records when resolution achieved, completes outcome and sign-off sections

6. Ascertains whether Insurer needs to be notified (refer doc 8.1 Insurer Notification Guidelines) or a claim where material damage has occurred.

7. Notifies the appropriate external agencies in consultation with senior management (Refer doc 10.1 External Agency Notification Requirements and Reportable Events Guidelines booklet pages 28 – 38).

Please Note: Under no circumstances are reports to be given to any external agency or source without being authorised by the Hospital Manager, Clinical Operations Advisor, COO - Hospitals, and legal advisor.

8. Seeks access to support for employees as necessary (refer docs 8.2, 8.3, 8.4, 8.8, 8.9, 8.10 &10.3), including insurer and legal support, finalisation of any reports, critical incident management and employee assistance services.

9. Ensures recognition and notification of a Major or Sentinel Event as follows:
   - Notifies COO - Hospitals and Clinical Operations Advisor/Nurse/HASE Advisor immediately
   - Implements standard processes according to the Sentinel Events Workbook (refer section 4.1) where indicated

   Experience has shown that Sentinel Events are rare occurrences (refer Section 4 Workbooks, Sentinel Events page 4, para 5). Sentinel Events must be authorised by the COO – Hospitals or Clinical Operations Advisor as outlined in the Delegated Authority Policy

10. Manages complaints following standard processes and according to the Complaints Folder

11. Meets standard procedures for managing and reporting by:

    (a) Ensuring a communication plan and strategy is agreed with COO - Hospitals, where patients and family/whanau involved, consults and Clinical Operations Advisor / Nurse Advisor (refer to Section 3. Appendix B: Potentially Serious Clinical Incident Management Process Flowchart)

    (b) Ensuring patient appropriately informed (refer docs 9.1, 9.2 & 9.3), document file notes (refer to doc 8.4) of communications, has external correspondence authorised as appropriate by Clinical Operations/Nurse Advisor and legal advisors

    (c) Ensuring Medical Specialists, and any other parties, appropriately informed (refer doc 8.9) and communications in accord with the HARC policy for hospital management HARC Medical Specialists Folder including external communication and correspondence authorised as appropriate by COO - Hospitals, Clinical Operations and legal advisors. Documents file notes (refer to doc 8.4) of communications

    (d) Seeking assistance for public relations advice from COO - Hospitals where media enquiry or risk (refer Media Policy see doc 8.8). Documents file notes (refer to doc 8.4) of communications

    (e) Ensuring Reportable Events Methodology is followed (refer to Section 4.1 pp. 19 – 26). Assigns actions for investigation, and prepares Action Plans (refer to SQR doc 3.5 & 3.6) and completes. Reviews and monitors progress, ensuring resolution in a timely manner

    (f) Ensuring post incident Patient/Clinical Event Review is conducted by the team (refer to doc 5.2 Forms) and action plans completed.

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(g) Establishing process and timeframes for evaluating implemented recommendations, including systems and process changes as part quality improvement. This will include a practical method for highlighting when evaluations are due. One method of doing this is to file unresolved incidents in a separate folder under the month the evaluation is due. Activities may include training and development and performance management

(h) Ensuring Hazard & Risk List or Register/s (refer Safety, Quality and Risk Folder and Health and Safety Folder) is updated where new issues are identified and Health & Safety Advisor (Risk Management Co-ordinator) informed

(i) Preparing any final reports and notifies the involved and appropriate parties and any committees of outcome and closes off incident and notes as 'closed' on the ISS. Reports to SQR and HCMC as appropriate (refer to SQR doc 5.1.3.1 Clinical Indicators Report and doc 5.1.3.2 Clinical Review of Eventful (Red Dot) Cases.

(j) Retaining and storing records
- Records are stored centrally in a secure location compliant with legal requirements
- Access to these documents is strictly limited by the Hospital Manager
- Archived computer data is retained according Documentation Management
- Files are kept for 10 years
- Where additional copies need to be filed, such as in employee personal files or patient clinical notes and note of this is made on the original and photocopies made

(k) Ensuring all employees aware of procedures and processes during orientation and when there is any change to systems and processes (refer doc 7.1).

(l) Ensuring quality assurance activities (refer doc 6.1).

Clinical Operations Advisor / Nurse /HASE Advisor

On verbal and/or written notification of an incident:

1. On receipt of written summary or verbal notification provides oversight, advice, support and guidance as needed on a case-by-case basis to ensure process and procedures carried out

2. Co-ordinates notification and support from the Hospital Audit Review Committee (HARC), legal, risk and public relations advisors, insurance broker and insurer as required

3. Ensures relevant National Office Advisors and personnel are advised and consulted as appropriate for example, the Human Resource, Clinical/Nurse, Health and Safety Advisor/s, Commercial, Procurement, Technical Services Manager/s.

4. Ensures COO - Hospitals, Chair of HARC and Group CEO informed as appropriate

5. Ensures the appropriate authorities and external agencies have been notified and supports the Hospital Manager with Sentinel Event management

6. Ensures the National Office Incident numbering file-referencing system is maintained and cross-referenced to site specific numbering reference system/s

7. Prepares and distributes a Consolidated Reports from ISS

8. Ensures national Risk Management System Co-ordinator informed and SQR actions undertaken

REFERENCES AND ASSOCIATED DOCUMENTS

- Reportable Events Guidelines 2001 Ministry of Health Wellington
- Sentinel Events Workbook: Process for Standardized Investigation and Reporting in the Health Sector SNZ HB 8152:2001 Standards NZ Wellington
- Delegated Authority Policy
- Health and Safety Folder
- Safety, Quality and Risk Management Folder
- Intranet Performance Planning and Review System
- Health Information Privacy Code 1994 and Privacy Act 1993
- Documentation Management processes
- Complaints Folder
- Health and Disability Commissioner Regulations 1996 (Code of Health and Disability Services Consumers' Rights)
- Professional Development and Recognition Programme
- Emergency Response Folder
- HARC Visiting Practitioner Procedures Folder
- Employee Assistance Programme, EAP Services, pamphlet and booklet
- Media Policy
- Patient Safety Framework, Safety & Clinical Systems Government of South Australia 2003
- Critical Illness Assessment (CIA) Tool

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