Southern Cross Hospitals Limited

A Report by the
Health and Disability Commissioner

(Case 18HDC01370)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This case highlights the importance of ensuring that sterility processes and policies are complied with fully in an operating theatre, and of having appropriate follow-up after an incident.

2. On 18 May 2018, an unsterilised drill bit was used during a woman's orthopaedic surgery at a Southern Cross Hospital. As a result, the woman was put at risk of infection and had to undergo additional testing.

Findings

3. The Commissioner identified a number of factors that contributed to the private hospital's systems failure in this case, including the way it stored unsterile instruments; the time pressure resulting from the woman being in theatre by the time it was discovered that equipment was missing; the scrub nurse being under pressure because he was acting in two nursing roles; and non-compliance with its Checking of Sterile Packaging Procedure.

4. The Commissioner concluded that the services provided to the woman were seriously inadequate and put the woman at risk of infection. In addition, the Commissioner considered that the private hospital's follow-up with the woman did not comply with its open disclosure guidelines. Accordingly, the Commissioner found that Southern Cross Hospitals Limited (SCHL) failed to provide services to the woman with reasonable care and skill and breached Right 4(1) of the Code.

Recommendations

5. The Commissioner recommended that SCHL conduct a further audit of all surgical equipment to check whether it has been sterilised and stored appropriately; conduct an audit of 15 perioperative clinical records to check whether there was a leader in each theatre for each surgical case, and whether a "huddle" was conducted prior to the commencement of the list on each day; develop or include in an existing policy further clarification about opening and checking equipment; provide evidence of recent training for all theatre staff on the Checking of Sterile Packaging Procedure and the Open Disclosure Guidelines; review its Open Disclosure Guidelines; and apologise to the woman.

6. The Commissioner also suggested that SCHL engage with the loan surgical equipment company to improve the process for sourcing loan equipment to ensure that the correct equipment is supplied and can be easily checked off in advance of planned surgery.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her by Southern Cross Hospitals Limited (SCHL). The following issue was identified for investigation:

- *Whether Southern Cross Hospitals Limited provided Mrs A with an appropriate standard of care in May 2018.*

8. The parties directly involved in the investigation were:

Mrs A	Consumer/complainant
Private hospital	
Registered Nurse (RN) B	Registered nurse
RN C	Registered nurse
Dr D	Orthopaedic surgeon
Ms E	Company representative
Equipment loan company	

9. Independent expert advice was obtained from RN Rosalind Jackson (Appendix A).

Information gathered during investigation

Introduction

10. This opinion concerns the use of an unsterile drill bit during Mrs A's orthopaedic surgery at a private hospital[1] on 18 May 2018.

11. The operating surgeon was orthopaedic consultant Dr D. Dr D had ordered equipment for Mrs A's procedure from an equipment loan company. A company representative, Ms E, was present in the operating theatre for part of the operation.

12. SCHL stated that a company representative is invited to be present by either the surgeon or nursing staff, depending on who is intending to seek assistance. In this case, Dr D requested the presence of Ms E for assistance with the loaned equipment.

Roles of nurses

13. RN C was the circulating nurse. SCHL said that the role of the circulating nurse is to confirm sterility of equipment using the external indicator prior to opening the packs, and then the scrub nurse confirms the sterility using the internal indicator strip, prior to the items entering the sterile field.

[1] The private hospital is owned and operated by SCHL.

14. RN B was the scrub nurse. The scrub nurse is required to check and verbalise the presence of the internal indicator strip prior to equipment being added to the sterile trolley.

15. Initially SCHL told HDC that the clinical resource nurse (CRN)[2] in theatre or their designee had overall responsibility for the company representative during surgery. In response to the provisional opinion, SCHL stated that although the CRN has overall responsibility for the theatre environment, they are not individually tasked with supervising everybody in that theatre environment in every task that they do.

16. RN B, in addition to being the scrub nurse, was also the designated CRN in theatre that day. SCHL stated: "Regrettably, occupation of that position, as well as being the scrub nurse is not ideal."

Role of company representative

17. Ms E stated that she is a registered nurse, and her role is to educate the private hospital employees about medical devices from the equipment loan company. Her role requires her to be present in theatre during surgery to educate the hospital medical staff about, or answer questions about, the medical devices from the equipment loan company that are being used. She said that she understands that the sterile/unsterile protocols at the private hospital are Australasian Guideline Standard.[3]

18. SCHL told HDC that Ms E was present in an "advisory role" to provide specialist advice to health professionals, and was not involved in the patient's care.

19. SCHL said that it is not uncommon for a loan instrument to be unavailable,[4] and if an instrument is unavailable for a surgical procedure, then the company representative has the responsibility to locate and provide a suitable instrument or suggest an alternative option. SCHL stated:

> "Those matters are completely outside the knowledge and control of Southern Cross Hospitals Limited. Only the company representative and the associated company knows the whereabouts of the instruments, and they are the experts on what would be suitable, and where it is located. Southern Cross Hospitals Limited has no involvement in that process of locating and supplying a further instrument."

20. However, SCHL said that it does have expectations around what occurs once an instrument has been located, including the confirmation of sterility of the instrument before it enters the sterile operating field.

[2] A specialist senior nurse who supports the delivery of surgical services within the operating theatre suite.
[3] Ms E referenced the AS/NZ 418[7]:2003 standard. The standard was updated in 2014.
[4] SCHL told HDC that an instrument could be unavailable for several reasons, including the instrument losing sterility during the procedure, or an instrument breaking. It stated that in most circumstances the alternative loan instrument will not be available at the SCHL premises where the operation is occurring. There is then a need to locate that instrument somewhere outside the hospital and arrange its urgent transport to the hospital.

21. SCHL submitted to HDC that Ms E did not have a legal relationship with SCHL. It explained that the company representative is required to read and sign the guidelines for medical representatives as part of the orientation process prior to having access to the operating theatres.

22. Ms E said that she had received no orientation or training on the private hospital's policies and protocols. She stated that when she first attended the private hospital in her current position, she was given a document to read that detailed her role as a company representative within the private hospital, and she read and signed the document.

Process for ordering equipment for patient's surgical procedure

23. SCHL said that the surgeon's rooms send an operation list to the hospital bookings team. The hospital bookings clerk then gives a copy of those bookings to the orthopaedic CRN. The CRN then contacts the loan company to let them know the procedure that is being carried out, the date on which it is being carried out, and the surgeon who is performing the operation. The equipment loan company supplies the relevant loan set[5] for the procedure that has been notified to them. When the sets arrive from the company, the loan coordinator checks the contents of the sets against a checklist provided by the company.

24. A set[6] was requested for Mrs A's surgery. SCHL said that three loan sets arrived at the private hospital for Mrs A's surgery, but the sets did not contain all the instruments required (the missing pieces of equipment were a patella drill bit, calipher, and drill guide). However, the loan coordinator was not aware of this because the checklist sent from the company did not list the missing items. Rather, for each of the three instrument sets that the company supplied, the items inside the instrument sets matched what was on the checklist that the company also supplied. SCHL told HDC: "There was therefore no indication to any SCHL employee that there would be insufficient instruments for the procedure."

25. SCHL said that at the time of the incident, owing to the large volume of loan instruments and space constraints, loan items that had undergone cleaning, disinfection, and packing in preparation for sterilisation were stored in a room outside the Sterile Services Department (SSD). When the equipment was required for an operation, the SSD staff would obtain it from the store room and it would be sterilised. An indicator strip in each sterilised set of equipment shows that the set has been sterilised, and the tray contains an external indicator strip.

26. Once sterilised, the set would be released for use and taken to the sterile storage room. The equipment supplied for Mrs A's procedure was duly checked in and sterilised in preparation for her surgery.

[5] Sets will vary depending on the kind of surgery, and will usually contain instruments and tools needed for the surgery. For knee replacement surgery, this will include metal or plastic replacement parts.
[6] A replacement knee system.

Surgery 18 May 2018

27. On 18 May 2018, Mrs A was admitted to the private hospital for knee surgery — a right patella resurfacing[7] and a change of polyethylene liner.

28. Mrs A was taken into theatre at 9.06am (she was the second patient on Dr D's theatre list), and the anaesthetic was administered. RN B said that he first identified that an instrument was missing when he was scrubbed and setting up for Mrs A's surgery, and he made Ms E and RN C aware of the issue.

29. RN B stated that Ms E confirmed that his assessment was correct, and said that she would ring a colleague who was a product specialist. She then left the theatre.

30. Ms E told HDC that an entire tray had either not been ordered or not been sent. In response to the provisional opinion, SCHL stated that Ms E's account that the tray had either not been ordered or sent is correct. However, SCHL clarified that it does not order a specific tray. SCHL stated:

> "[Rather,] it notifies the loan company of what the procedure being performed is and who the surgeon performing it is. The company then selects what the appropriate trays are to supply. SCHL's reference to three instruments was on the understanding these were missing from the supplied sets, however, it has now been determined that it was an entirely different set that the company should have advised SCHL was required for the surgery."

31. Ms E initially told HDC that she asked an offsite product specialist what could be done, as the patient was already on the operating table, and the product specialist recommended that she open another set[8] and use the lug drill from that set. However, in her later response to the provisional opinion, Ms E told HDC that the product specialist did not answer her call, so she discussed this with Dr D, who agreed to obtain the drill from the other set.

32. In response to the provisional opinion, Ms E also stated: "I informed [RN B] what [Dr D] and I had discussed and as [RN C] was busy with [Mrs A], [Dr D] asked me to collect it."

33. In response to the provisional opinion, SCHL told HDC that if the company representative knew, or was informed, that the alternative instruments were located at the same hospital, SCHL would expect that company representative to tell the SCHL employees that fact. SCHL would then expect those SCHL employees to source that instrument through the sterile supply department so that sterility was ensured before the instruments reached the sterile surgical field.

34. Ms E went to the storage area beside a ward and selected a tray that contained the equipment needed. SCHL said that Ms E's action in venturing into the area where she located the tray was unexpected and inappropriate. SCHL told HDC that the normal

[7] Patella resurfacing is a procedure that removes the layer of cartilage at the back of the knee cap.
[8] A knee system used in cases where collateral ligaments are deficient.

process when sourcing something at short notice would be to obtain the instrument from the sterile storage room, as that is where the equipment to use in theatre is stored.

35. SCHL said that Ms E was not directed to the storage area (which is located outside the theatre department) by anyone at the private hospital, and the theatre staff had no indication that Ms E had gone there.

36. SCHL told HDC that it is unclear exactly why Ms E went to the storage area, which involves going out through double doors and into a carpeted ward area, but SCHL presumed that she was informed of the location of this loan pack by her colleague, who was also not employed by SCHL.

37. The private hospital said that the equipment in the storage area had been cleaned and wrapped in preparation for being sterilised. It was placed in the storage area beside the ward because there is a lack of storage in theatre. Sterilised equipment cannot be left in the storage area beside the ward because of the air flow, but there was no signage to alert staff that the equipment had not been sterilised.

38. RN B said that he carried on setting up the theatre within his sterile field and, because he was focused on his job, he had no knowledge of what RN C was doing during this time. RN C said that she was helping to insert a catheter, and did not see Ms E return or witness her opening anything for RN B.

39. RN B stated that after 15–20 minutes, Ms E returned to the theatre with a tray of instruments. In response to the provisional opinion, Ms E told HDC that she was gone for "no longer than 2 minutes".

40. Ms E stated that RN B asked her to open the tray because there was no "floor nurse"[9] to assist him. She said that she proceeded to open the tray for him on a separate trolley.

41. Regarding Ms E's statement that she believes she was asked to open the equipment, SCHL stated that it is "firm in its position" that Ms E was never asked to open the equipment. SCHL said: "In fact, [Ms E] was so quick to open the equipment that the circulating nurse present did not have the opportunity to assist or take over that step." RN B recalls that Ms E opened the pack of instruments and placed them on a trolley. He stated:

> "I was not in a position to know whether she had checked the sterility tag on the outside of the tray, or whether she had had the circulating nurse, or another member of staff do this. However, in hindsight I think that because I knew that she was a nurse familiar with Southern Cross' operating procedures, which I understand are standard across the hospitals, and in fact are relatively standard in all hospital operating theatres, she knew to check for the sterility on the outside of the pack."

42. RN B said that the indicator strips would have been clearly evident to anybody carrying the pack, before they opened it, because the strips are on top, "right in front of your eyes". He

[9] Another name for a circulating nurse.

said that anyone familiar with operating environments would be well aware of this, and the absence of the strips should be immediately noticeable to them. He stated:

> "It would not have made any sense for [Ms E], who was familiar with operating theatres, and sterility requirements, to pass me a tray when I was in the sterile field, without having first confirmed it was sterile. Once she opened the pack the external indicator strips were not visible to me."

43. RN B said that he omitted to check the indicator strip on the inside of the pack. He stated that it is his routine practice to check the indicator strip, but a combination of his understanding of Ms E's familiarity at the private hospital, the fact that he had not seen the check done, and also that he was in a rush given that there had been a 15–20 minute delay while the instruments were sourced, led him to omit his usual check of the indicator strip.

44. SCHL stated:

> "Had [RN B] been available without being preoccupied with his duties as scrub nurse, he may have been able to pay closer attention to [Ms E] and identify that no one had checked the outer sterility of the tray."

45. SCHL also stated that a 15–20 minute delay while instruments are being sourced is not extraordinary and that delay should not result in pressure to shortcut essential sterility standards. It said: "Theatre staff are also used to working under pressurised situations, and this unfortunate failure to check sterility cannot be fully explained by time pressure."

46. Dr D told HDC that he is unable to comment on whether the systems in place at the time of the incident were followed, as he was not in the operating theatre when the unsterile equipment was opened and placed into the surgical field.

47. The surgery proceeded using the equipment that Ms E had brought to theatre.

Events following surgery

48. Following the procedure, the used equipment was sent to the SSD for cleaning in accordance with normal procedures. At 2.30pm, the loan coordinator informed RN B that the loan equipment used during Mrs A's procedure had probably been taken from the unsterile trolley in the storage area beside the ward, and that while the equipment had undergone a fully validated, automated cleaning and washer disinfection process prior to packing in a "clean room", it had not been sterilised.

49. At 3pm, RN B completed an incident form. It noted: "[S]urgical Rep — [Ms E] opened crate without on floor staff supervision — label not checked properly … Surgeon and theatre manager advised immediately."

50. RN B and the theatre manager went to the recycling bin in the basement and located the label that confirmed that the crate involved had not gone through the sterile processing system.

51. The failings identified on the incident form are:

> "1. Outer wrapper not identified as being unsterile by [Ms E]
>
> 2. Circulating staff not involved with checking and opening crate to ensure it was sterile
>
> 3. Scrub Nurse in rush not checking indicator label as required …"

Open disclosure to Mrs A

52. SCHL told HDC that it considered that Dr D would be the most appropriate person to provide open disclosure of the events that had occurred to Mrs A. At 4.45pm, Dr D explained to Mrs A that the patella drill bit used in the surgery had been found not to have been sterile, and that this could cause long-term infection.

53. Dr D discussed the situation with an infectious diseases specialist physician and then developed a plan for Mrs A to have intravenous (IV) and oral antibiotics, as well as HIV and hepatitis B and C testing. Dr D stated that he discussed the plan with Mrs A, and recorded that she understood the plan and the risks. Dr D sought further advice from a microbiologist to ascertain the level of risk of infection.

54. Initially SCHL told HDC that following Dr D's discussion with Mrs A, the ward manager and clinical duty manager also spoke to Mrs A to ascertain whether she required any further information about the event.

55. In response to the provisional opinion, Mrs A told HDC that no representative from SCHL spoke to her about the incident. She stated:

> "… SCHL abdicated all responsibility of informing me and further discussions to the surgeon. [Dr D] is not an employee of SCHL, and he was not in theatre during the setup. Nor is he responsible for the instruments and checks. So why SCHL decided the total disclosure and further discussions regarding this matter should fall solely to [Dr D] is dubious."

56. SCHL responded to Mrs A's comments and accepts that Mrs A's recollection is correct. SCHL explained that after Dr D spoke to Mrs A, he spoke to the clinical duty manager and reported that he had discussed the incident with Mrs A and that she was happy with his explanation. On that basis, SCHL did not send anyone else to discuss the event further. Later that evening, the clinical duty manager discussed the event and Dr D's instructions with the ward manager by telephone. SCHL told HDC that it acknowledges and deeply regrets that Mrs A was not spoken to by a representative from SCHL management.

57. In response to the provisional opinion, SCHL accepted that "its own expectations around open disclosure in this case were not met".

58. SCHL stated that the afternoon nurse was informed of the event, and prophylactic antibiotics were commenced as charted, and all clinical duty managers and nurses involved

in Mrs A's care were informed of the event. SCHL told HDC that information about the incident was conveyed at nursing handovers and in the clinical record.

59. Mrs A disputes that all nurses involved in her care were informed of the event. She stated:

> "While discharging me [the nurse] presented me with the incomplete discharge letter and when I questioned the omission of the incident … [s]he clearly stated she had no knowledge of the situation."

60. Dr D stated that he personally observed Mrs A's surgical wound every day during her admission at the private hospital.

Discharge

61. Mrs A said that when she was being discharged on 20 May 2018, the nurse discharging her told her that the discharge summary contained no information about the incident. Mrs A said that she had to "push" to get the information included, in order to inform her GP about the risk of infection. SCHL stated: "We acknowledge that this was disappointing and that our expectation would have been that this detail would have been included without prompting."

62. On discharge, Mrs A was provided with a prescription for antibiotics, a copy of her serology results, and the discharge paperwork. SCHL said that it was agreed that she would provide these to her GP herself.

63. Dr D said that he provided Mrs A with his mobile telephone number when she was discharged from hospital, so that she could contact him directly if she had any further concerns regarding her knee. On 27 May 2018, Mrs A contacted Dr D with concerns regarding potential cellulitis.[10] He arranged for her to meet him at the Emergency Department at a public hospital.

64. Mrs A had a slightly elevated inflammatory marker with a CRP[11] of 14,[12] and was diagnosed with cellulitis. Dr D said that given the risk of a prosthetic joint infection, he discussed the case with the infectious diseases consultant on call, and it was decided to treat Mrs A with IV flucloxacillin (an antibiotic). She completed two days of IV antibiotics and was discharged home with a normal wound and no persisting cellulitis.

65. A private hospital nurse made a follow-up telephone call to Mrs A on 21 June 2018. The nurse did not discuss the adverse event that had occurred, and documented:

> "The wound dressing was intact with nil ooze. The patient reported feeling very tired but managing ok with pain. No concerns follow up as arranged in 2 weeks' time mobilising with crutches."

[10] A potentially serious bacterial skin infection.
[11] C-reactive protein (CRP) is produced by the liver. Its level rises when there is inflammation in the body.
[12] For a standard CRP test, a normal reading is less than 10 milligrams per litre (mg/L).

66. Mrs A told HDC that she felt that a call from a clinical nurse manager would have been more appropriate to allow for more detailed questions about the wound and signs of infection.

67. Mrs A experienced no further symptoms of infection. Dr D said that her inflammatory markers remained normal, and repeat serology for HIV and hepatitis were also normal.

Policies

68. The details of SCHL's relevant policies in place at the time of the events are included as Appendix B.

Event review report

69. The private hospital conducted an investigation into the events that occurred. The event review report concluded that staff did not follow the expected standard of practice either in sourcing the missing equipment or checking the sterility of equipment prior to it being placed on the sterile trolley, and that Ms E sourced the missing equipment without supervision.

70. Incidental findings were that there was inadequate signage to alert staff of unsterile equipment in storage areas, and inadequate storage available to accommodate loan sets not in regular use.

Further information

71. The Chief Executive Officer at SCHL stated:

> "… I would like to extend my sincere apologies to [Mrs A] for her experience whilst in our care. I acknowledge how distressing and impactful this has been for her. Patient safety, the quality of our care and positive consumer experiences are central to our values. Whilst we cannot change the event that occurred for [Mrs A], we can and have made every effort to mitigate a recurrence. I would like to reassure her of the organisation's commitment to improving our services based on learnings from this event."

72. SCHL told HDC:

> "[SCHL] accepts that this situation should not have been able to occur within its theatre, but it does not escape the situation that [Ms E], being aware of Southern Cross' expectations acted contrary to them. In making this point, Southern Cross has no hesitation in also accepting that [Ms E] did this with the best of intentions. She was the medical representative present who was in a difficult position when her employer had supplied an incomplete instrument set and would have felt the need to rectify that situation as soon as possible. Her actions would also have been informed by her familiarity with Southern Cross having worked at a different Southern Cross hospital for a considerable length of time. She was also well known to staff inside the theatre. This level of familiarity has been identified as a contributing factor."

73. In relation to the Checking and Sterile Packaging Guidelines and Loan Guidelines being out of date, SCHL told HDC:

> "Southern Cross has checked the status of those procedures and guidelines, as it was also surprised that any policy or guidelines could go for seven years without further review. What that enquiry has revealed is that the procedures and guidelines were reviewed in September 2014 and were confirmed as fit for a further period of five years without change as evidenced in the network notification that is enclosed. Unfortunately, the footer of the document was not updated to indicate that this review occurred in 2014. Southern Cross believes that with this further information these policies are within the accepted standard."

Responses to provisional opinion

Mrs A

74. Mrs A provided a detailed response to the "information gathered" section of the provisional report and expert advice. Where appropriate, her comments have been included in the "information gathered" section above or are detailed below.

75. Mrs A said that her main complaint is the lack of treatment and follow-up care provided by SCHL, and the lack of any official apology offered directly from SCHL prior to the apologies she received after she complained. She stated:

> "SCHL did not approach me while I was in [the private hospital] to have any discussion, apologise or offer ongoing support. Written apologies were only received after I placed a complaint and following other complaints concerning their conduct around privacy of information. No offer was made of meeting with me or ongoing support."

76. Mrs A appreciated the care and apology Dr D provided after the incident. She also acknowledges and accepts the apologies she received from RN B (via Dr D) and the discharge nurse.

77. Mrs A reiterated the significant impact and ongoing consequences this incident had on her personal life. The incident required her to take extra health precautions with her husband and family, and undergo further treatment and testing, and she and her husband had to cancel an overseas holiday.

SCHL

78. SCHL responded to the provisional opinion. Where appropriate, its comments have been included in the report or are detailed below.

79. SCHL told HDC that it agrees that the system in place to check the loan equipment was defective in this instance, and submitted that the system is not SCHL's system but that of the equipment loan company.

80. In relation to the orientation of the company representative, initially it submitted:

> "While SCHL accepts that it was responsible for ensuring appropriate services were provided to [Mrs A] through its systems and its employees, and it also accepts that it was required to familiarise [Ms E] with the relevant policies and protocols, it cannot be held liable for [Ms E's] nor her employer's actions outside of this."

81. In a further response to the provisional opinion, SCHL submitted:

> "[I]t is not realistic to orientate the medical technology representative on the private hospital's policies and protocols that have nothing to do with her role. The key point is that [Ms E], by nature of her expertise and position, understood sterility requirements and was an expert on the product being used."

82. As part of its submissions, SCHL provided an expert opinion from a registered nurse and a letter from the New Zealand Private Surgical Hospitals Association Inc.

83. Ms E was given an opportunity to comment on the relevant sections of the provisional opinion relating to her. Where appropriate, her comments have been included in the report.

Opinion: Southern Cross Hospitals Limited — breach

Introduction

84. An unsterilised drill bit was used during Mrs A's orthopaedic surgery at the private hospital on 18 May 2018. This very concerning event resulted from a number of system failures at the private hospital. Although the private hospital had in place policies that my nursing advisor, RN Rosalind Jackson, considers were generally robust, there was a lack of compliance with the policies.

85. It was the responsibility of SCHL to ensure that Mrs A received services of an appropriate standard, that it had an appropriate quality management system, and provided an environment that encouraged good practice.

86. My assessment of whether Mrs A received care of an appropriate standard has in part been informed by independent expert advice from RN Rosalind Jackson.

Sourcing equipment

87. The process for sourcing loan equipment involved the private hospital CRN contacting the loan company to let it know the procedure that was being carried out, the date on which it was being carried out, and that Dr D was performing the operation. The equipment loan company then supplied the relevant loan set for the procedure. When the sets arrived, the loan coordinator checked the contents of the sets against the checklist provided by the company.

88. Three loan sets arrived at the private hospital for Mrs A's surgery but did not contain all the instruments required (patella drill bit, calipher, and drill guide). However, the fact that three pieces of equipment were missing was not evident because the checklist provided by the loan company did not list the missing items. SCHL said that for each of the three sets that were supplied, the items inside the instrument sets matched what was on the checklist. SCHL told HDC: "There was therefore no indication to any SCHL employee that there would be insufficient instruments for the procedure."

89. The consequence of this was that it was not discovered that the items were missing until Mrs A was already in theatre. It then became a matter of urgency to locate replacement items and, during that time, Mrs A's surgery was delayed. I acknowledge SCHL's submission that its staff were used to pressurised situations and that this time delay was not uncommon. However, I note that RN B told HDC that he felt rushed owing to the delay caused by locating the equipment needed.

90. This system was defective, as the loan company's list showed what had been sent rather than the equipment that was required for the surgery. SCHL agrees that this system was defective in this instance, and submits that the system is not SCHL's system but that of the loan company, and that this is the common system that operates around New Zealand. In the context of this case and SCHL's acknowledgement of the pitfalls of the system, I encourage SCHL to engage with the loan company to improve this system to ensure that the correct equipment is supplied and can be easily checked off in advance of the planned surgery.

Compliance with sterile procedure

91. While preparing for the surgery, RN B discovered that the loan set did not contain all the equipment required. SCHL said that if an instrument required for a procedure is unavailable, then the company representative has a responsibility to locate and provide a suitable instrument or suggest an alternative option. SCHL stated that these matters are completely outside the knowledge and control of SCHL, as only the company representative and the loan company know the whereabouts of the instruments, and they are the experts in what would be suitable and where it is located.

92. I acknowledge SCHL's limited involvement in locating the appropriate instruments in this case. However, it was the private hospital's responsibility to have processes and practices in place to ensure that the instruments brought into the operating theatre were confirmed as being sterile before being placed in the sterile operating field. The system clearly failed in this respect, and I outline contributors to that failure below.

93. On 18 May 2018, RN B was the scrub nurse in theatre. He was also the CRN with overall responsibility for the theatre environment. He was focused on the task of preparing the instruments for the surgery and, as such, he had limited ability to undertake the dual role of leadership and scrub nurse.

94. When RN B identified that an instrument was missing, he was already scrubbed and setting up for Mrs A's surgery. Mrs A was in the operating theatre and had been prepared

for the surgery. RN B told Ms E and RN C about the missing equipment. After ascertaining a recommendation for an alternate drill, Ms E went to the storage area beside a ward and selected a tray that contained the equipment that was needed. The equipment in the storage area had been cleaned and wrapped in preparation for being sterilised, but it was not sterile.

95. SCHL said that Ms E's actions were unexpected and inappropriate, and that the normal process would have been to obtain the instrument from the sterile storage room, which is where the equipment for use in theatre is stored.

96. Ms E returned to the operating theatre with the tray of instruments. The Checking of Sterile Packaging Procedure was for the circulating nurse to confirm sterility using the external indicator prior to opening the pack, and for the scrub nurse to confirm the sterility using the internal indicator strip prior to the items entering the sterile field. The scrub nurse was required to check and verbalise the presence of the internal indicator strip prior to the equipment being added to the sterile trolley.

97. However, in this case neither nurse complied with the procedure. The circulating nurse, RN C, said that she was helping a nurse to insert a catheter, and did not see Ms E return or witness her opening anything for RN B. RN B did not check the sterility of the equipment. It appears that RN B was busy, and relied on Ms E's experience with SCHL's operating procedures and her general nursing knowledge, and so he failed to check the indicator strip on the inside of the pack.

98. Ms E had not been orientated or trained on the private hospital's policies and protocols, although she had read and signed the Medical Representative Guideline. The Medical Representative Guideline states that the medical representative/technical support personnel must not open any instrumentation or implant, or use any private hospital equipment, unless requested to do so by private hospital staff. Ms E stated that RN B asked her to open the equipment, whereas SCHL stated that Ms E was never asked to open the equipment, and that Ms E opened it quickly and RN C did not have the opportunity to assist or take over the task.

99. Owing to RN B's and Ms E's conflicting accounts, and the absence of other witnesses to the conversation or to the equipment being opened, I am unable to make a finding as to whether Ms E proceeded to open the tray of her own volition or whether she was asked to do so. However, it is clear that whatever transpired in terms of the basis upon which the pack was opened by Ms E, both Ms E and RN B failed to check the sterility of items entered into the sterile field adequately. This was undoubtedly caused in part by the pressure to source the equipment quickly, as Mrs A was already in theatre and had been prepared for her surgery, together with the occupation of RN B on other tasks, and his familiarity with Ms E's experience.

100. My expert advisor, RN Jackson, advised that it was appropriate for Ms E to retrieve the missing equipment. However, RN Jackson noted that, ideally, Ms E should not have opened the equipment, because she was then undertaking a role normally carried out by the circulating nurse. RN Jackson noted that if Ms E was asked to open the instruments,

she was working within the guidelines. However, RN Jackson advised that even if Ms E was not asked to open the instruments, she was still under pressure because the company had provided an incomplete set of loan instruments.

101. RN Jackson considered that Ms E was doing all she could in a pressured situation to resolve the issue of the missing equipment, and that through no fault of her own, the equipment she obtained was not sterile, and the usual checks of sterility failed.

102. I agree that Ms E was acting with the best intentions. However, it is concerning that, as a registered nurse with experience in operating theatres, she did not check the sterility of the instruments before opening the pack, and she should have done so.

103. RN Jackson noted that RN B failed in his responsibility to check the sterility of the instruments before placing them on the trolley, which is a breach of the standards expected of a scrub nurse. RN Jackson stated that it would be a severe departure from accepted standards of practice for unsterile instruments to enter the sterile field. However, she considers that multiple mitigating system errors affected RN B's performance.

104. RN Jackson stated that the direct causative factor/issue was that the instrument was not sterile, and she noted that all instruments are now sterilised before being placed in storage. She considers this to be an appropriate action because it will eliminate, rather than minimise the risk of non-sterile equipment entering the theatre. She stated that all equipment should be sterile ready for use, and that a process should be in place to monitor the sterility expiry dates, following which date the items should be re-sterilised and/or considered for return to the company, or retired from use.

Open disclosure

105. Once RN B had confirmed that non-sterile equipment had been used during the surgery, it was decided that Dr D would carry out the process of open disclosure and inform Mrs A of what had happened. Dr D discussed the situation with an infectious diseases specialist, and a plan was formulated for Mrs A to be administered IV vancomycin followed by five days of oral ciprofloxacin. HIV and hepatitis B and C serology was also carried out.

106. SCHL deeply regrets that Mrs A was not spoken to by a representative from SCHL management, and has accepted that its own expectations around open disclosure were not met.

107. RN Jackson advised that it was appropriate for Dr D to discuss the event with Mrs A because they already had a relationship, and Dr D was able to inform Mrs A of the event, risks, and follow-up process. However, RN Jackson noted that the private hospital failed to comply with its open disclosure guidelines fully in the following respects:

a) There were no arrangements for further meetings with Mrs A.

b) The information about the event was included in the discharge summary only at Mrs A's insistence.

c) Mrs A does not appear to have received an apology from the private hospital within 24 hours of the event.

108. RN Jackson was critical that SCHL did not arrange for one person to be a single point of contact for Mrs A, to keep in touch with her during the 12-month period in which she was at risk. RN Jackson stated that an event of this nature is a surgical "never event",[13] and the private hospital could have been more proactive in working in partnership with Mrs A. RN Jackson said that the failure by the private hospital to follow its own standards of open disclosure would be considered a moderate departure from accepted standards. I agree with this advice.

Conclusions

109. Overall I am satisfied that, notwithstanding the responsibilities of individuals in this matter, the exposure of Mrs A to the risk of infection by the introduction of a non-sterile instrument into the sterile field, and the failure of its open disclosure policy is primarily attributable to a failure of the private hospital's systems. The system did not support the individuals involved in making appropriate decisions.

110. The private hospital's systems failed in this case as a result of a combination of factors, including:

a) The way unsterile instruments were stored;

b) The time pressure resulting from Mrs A being in theatre by the time it was discovered that the equipment was missing, and the need to source the missing instrument;

c) RN B being under pressure because he was acting in two nursing roles; and

d) Non-compliance with the Checking of Sterile Packaging Procedure.

111. As a consequence of these failures, unsterilised instruments were brought into theatre and used during Mrs A's surgery. The services provided to Mrs A were seriously inadequate and put her at risk of infection.

112. The private hospital has accepted that it did not follow up with Mrs A following Dr D's initial disclosure of the incident, and that it did not comply with its open disclosure guidelines.

113. For the above reasons, I consider that SCHL failed to provide services to Mrs A with reasonable care and skill and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights.

114. I acknowledge SCHL's acceptance that it breached Right 4(1) in the circumstances.

[13] "Never Events" are defined as serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available and should have been implemented by all healthcare providers.

Changes made

115. SCHL told HDC that to eliminate the risk of recurrence:

a) The CRN is now responsible for allocating roles to theatre staff in their respective theatres each day. Staff will be given their allocations at the huddle each morning. When the CRN/nurse in charge is out of the theatre for a significant period of time, they will hand over the leadership role to the circulating nurse.

b) The SSD process has changed so that loan equipment is packed only if there is sterile storage available and if it can be sterilised immediately. The sterile storage room has also been rearranged to accommodate the high volume of sterilised loan equipment. There is no longer non-sterile equipment stored elsewhere.

c) It shared the events that occurred (on an anonymous basis) throughout its network at the quality managers', theatre managers' and sterilisation managers' annual workshop on 4 September 2019. An open book learning will also be distributed throughout the network to capture all SCHL staff, medical specialists, and those with special purpose credentialling to ensure that an event like this does not occur again. An education session on the roles and responsibilities of the theatre team and perioperative practice sterile technique has been provided.

d) All theatre staff were required to have a peer audit review of sterility checks to confirm compliance with its Checking of Sterile Packaging Procedure. The findings were discussed at the monthly theatre meetings and Safety Quality and Risk meeting. SCHL stated that the observational audits will remain ongoing, as will the peer audits, to ensure that standards of practice are maintained.

116. SCHL also made the following changes to its service:

a) The General Manager or a delegated senior team member routinely visits a patient as part of an event investigation to ensure that the appropriate support from the hospital is offered at the earliest opportunity.

b) Further enhancements to the new national theatre nursing roles and responsibilities document have been considered.

c) The Medical Representative Guidelines were reviewed, and the hospital confirmed that the document remained current and it saw no benefit from changing it. Nonetheless, given the events that occurred, SCHL considered it appropriate to implement a national document dealing with the issue.

d) Further improvements to the Loan Guideline were made. It was updated in December 2019 and has been renamed "Management of instruments on loan or evaluation". The document refers to the management of hospital-owned and loan instruments.

e) It updated its Sterile Packaging Procedure (2011) to include roles and responsibilities for checking.

117. SCHL stated that the move to national documents recognises that there has been some variance between different Southern Cross hospitals around the country, and standardisation has been attempted to ensure the continuation of high-quality care.

118. The updated documentation and policies were provided to HDC.

119. The loan company confirmed that Ms E was required to retake Operating Theatre Protocol training as set out by the Medical Technology Association New Zealand. The protocol clearly defines the role of clinical support in theatre from medical device companies.

120. The loan company also notified all of its representatives who access the hospital of this event, and reiterated their roles and responsibilities while in the theatre environment.

Recommendations

121. I recommend that within three months of the date of this report, SCHL undertake the following and report back to HDC:

a) Conduct a further audit of all surgical equipment to check whether it has been sterilised and stored appropriately.

b) Conduct an audit of 15 perioperative clinical records to check whether there was a leader in each theatre for each surgical case, and whether a "huddle" was conducted prior to the commencement of the list on each day.

c) Develop or include in an existing policy:

   i. the requirement to ensure that loan sets are opened and checked before the patient is taken to theatre and/or anaesthetised; and

   ii. the requirement for a registered nurse to be responsible for checking the sterility of an instrument in a situation where the company representative has been requested to open an instrument by SCHL staff, or amend the Medical Representative Guidelines to remove the option of the company representative being able to open an instrument on the request of its staff.

d) Provide evidence of recent training for all theatre staff on the Checking of Sterile Packaging Procedure and the Open Disclosure Guidelines.

e) Review its Open Disclosure Guidelines and give consideration to allocating responsibility for follow-up to a single staff member.

122. I also recommend that SCHL provide a formal written apology to Mrs A for the breach of the Code identified in this report, within three weeks of the date of this report. The apology is to be sent to HDC for forwarding to Mrs A.

Suggestion

123. In addition to the recommendations made above, I suggest that SCHL engage with the equipment loan company to improve the process for sourcing loan equipment to ensure that the correct equipment is supplied and can be easily checked off in advance of planned surgery.

Follow-up actions

124. A copy of this report with details identifying the parties removed, except the expert who advised on this case and Southern Cross Hospitals Limited, will be sent to the Health Quality & Safety Commission, the New Zealand Private Surgical Hospitals Association, the Medical Technology Association of New Zealand, the equipment loan company, and the New Zealand Nursing Council, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from RN Rosalind Jackson:

"Thank you for the opportunity to provide opinion to the Commissioner on this case, number **C18HDC01370**. I confirm that I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. By reviewing this case I confirm that I have identified no conflict of interest.

My name is Rosalind Clare Jackson and I am a New Zealand trained Registered Nurse (NZRN comp, reg 120875) and hold a Master's Degree in Health Science. Since 2006 I worked full time as a Nurse Service Leader (Anaesthesia and Surgical Services) with responsibility and accountability for operational management and professional leadership to nursing in the surgical setting, including the Perioperative Department, in a larger secondary hospital and neighbouring smaller hospital site. In November 2017 I was seconded to programme manager role responsible for organisational development of our staff engagement and culture programme. In February 2019 I was appointed into the permanent role as Associate Director of Nursing which includes responsibility for the nursing practice development team.

Other training that I have completed that is relevant to the role of an Independent Advisor includes,

- Institute for Healthcare Improvement (IHI) — Patient Safety Programme
- **New Zealand Incident Management System** — Root Cause Analysis Training (Clinical event/investigation review)
- **IHI Open School (completed)** — six modules on quality improvement methodology

The Commissioner is seeking my opinion on the care provided by [the private hospital] to [Mrs A] on 18th May 2018.

1.0 Background

[Mrs A] was admitted to Southern Cross Hospitals Limited trading as [the private hospital] on 18 May 2018 for right knee patella resurfacing and change of polyethylene liner procedure. Equipment had been ordered for the procedure from [an equipment loan company]. The loan set was missing three instruments required for the procedure.

Replacement instruments were located however following surgery, it was discovered that the drill bit used was cleaned but not sterilised. Shortly after the issue was discovered, open disclosure was made to [Mrs A] by the operating surgeon.

The Commissioner is seeking my advice on whether the care provided to [Mrs A] by [the private hospital] was reasonable under the circumstances, and why. In particular,

- The appropriateness of [the private hospital's] policies and procedures in place at the time of events.

- The appropriateness of the actions taken by the company representative, [Ms E], in retrieving and opening the equipment packet.
- The appropriateness of the actions taken by the scrub nurse, [RN B], in particular his supervision of [Ms E].
- The appropriateness of [the private hospital's] actions taken once it became aware an unsterilized drill bit had been used.
- Any comment I wish to make about [the private hospital's] internal review.
- Any other matters in this case that I consider warrant comment.

For each question I will consider and advise,

- What is the standard of care/accepted practice?
- If there has been a departure from the standard of care or accepted practice, how significant a departure do I consider this to be (mild, moderate or severe departure)?
- How would it be viewed by my peers?
- Recommendations for improvement that may help to prevent a similar occurrence in the future.

In forming my opinion on the matters requested I have reviewed the following documents provided by the Commissioner,

- Letter of complaint dated 25 July 2018
- [The private hospital's] response dated 19 September 2018 including clinical notes
- [The private hospital's] response dated 13 November 2018 including appendices
- [The private hospital's] response dated 17 May 2019 including staff statements and appendices
- [Ms E's] statement dated 6 May 2019
- [The private hospital's] response dated 7 May 2019

2.0 The appropriateness of [the private hospital's] policies and procedures in place at the time of events.

The policies and procedures included in the review documents are, in the main, appropriate and consistent with expected standards found in the highly technical and process orientated environment of a Perioperative Department and CSU. However, in the event of an adverse event there are often improvements to be recommended. Therefore, in addition to changes made or to be made to policies and procedures by Southern Cross, I have made further comment and suggested amendments.

The policies and procedures reviewed included,

2.1 Scrub nurse role (March 2018)

The scrub nurse is part of the checking procedure process, i.e. required to check (and verbalise) the internal indicator strip prior to equipment being added to the sterile trolley. Consideration should be given to reviewing the document to add this responsibility in section 'procedure before each case'.

2.2 Guidelines for medical representative or technical support person in the operating room (March 2015)

This document does not appear to have been reviewed as recommended in the internal review action plan. Update of review outcomes document of 12 September 2018–April 2019 states that this guideline KB16178 is to be reviewed however an updated version was not provided or this has not yet occurred.

For this event, it appears that the performance of the representative has been overly focused on. The current guideline states,

'Must not Open any instrumentation or implant or use any of [the private hospital's] equipment, unless requested to do so by [private hospital] staff.'

Therefore, if a representative is asked to open instruments then they are working within the guideline. Consequently, in this instance and based on the information provided, the performance of the representative should not be framed in a way that implied that the error was theirs.

It is at Southern Cross's discretion to alter the guidelines as they see fit and in partnership with the loan companies. However, in my view it is not the fault of the company representative that this event occurred so adding additional steps and pink hats that further limit the representative's scope in theatre feels punitive and does not address the core issue — that the equipment was not sterile and checks of sterility failed.

As stated, this document does not yet appear to have been reviewed as recommended in the internal review action plan.

2.3 Circulating nurse — role in theatre (April 2013 and July 2018)

At the time of this event the circulating nurse was operating within the parameters of the current guideline. That is, the circulating nurse was helping another staff member with setting up for catheterisation (which is included in the list of requirements in the event that a 'third nurse' is unavailable) and like [RN B] was focused on this task.

I note the change made to the circulating nurse role description (2018) that has removed additional responsibilities in the event that a third nurse/assist is unavailable.

2.4 Checking of sterile packaging procedure (2011)

Consider updating this procedure document to cross reference links to include 'who' is required to check as well as 'how' to check. Specific to this case is to cross reference the role of checking sterile instruments to the role of circulating nurse and role of scrub nurse.

The currency date for this document is 2011 and by contemporary standards would be considered old. It is not clear what Southern Cross's internal policy is for review of controlled documents and when this should occur however review of this document to refresh currency is recommended. As it stands, reference to a controlled document that was nine years old would be considered a **minor** departure from accepted standards.

2.5 Instruments on loan guidelines (2011)

This guideline is focused on loan equipment that regularly comes in and out of the hospital. In this case, the loan equipment was appropriately cleaned and sterilised. The unsterile equipment used in this case was on consignment (items belong to an external company however are stored on site for the hospital's use). Any other guidelines for Southern Cross owned or consignment equipment/instrumentation were not included in the case documentation therefore, I recommend [the private hospital] reviews their documentation around management of owned and consignment stock to ensure standards of management across all equipment is consistent.

The currency date for this document is 2011 and by contemporary standards would be considered old. It is not clear what Southern Cross's internal policy is for review of controlled documents and when this should occur however review of this document to refresh currency is recommended. As it stands, reference to a controlled document that was nine years old would be considered a **minor** departure from accepted standards.

2.6 Open disclosure: Fully informing patients and patient right to know guideline (November 2016)

This is a comprehensive document that outlines the process for open disclosure in the event of any adverse, unplanned and untoward event or circumstances that relate to a patient's care. Reflecting on this case, of note, I note the statement,

'open disclosure is a process of ongoing communication, not a one-off communication. It must be appropriate the nature of the disclosure, the patient and their family's individual needs at different times and provid(es) updates as new information becomes available'

Referring to 'the process of open disclosure' section, other than clinical follow up two weeks following discharge, there was no other arrangements for, or offer of a further meeting with [Mrs A].

There is no evidence that a verbal and sincere apology 'we are sorry this has happened to you' occurred within 24 hours of the incident.

The discharge summary did eventually include details of the event and clinical follow up however this appears to have occurred at [Mrs A's] insistence.

The impact on [Mrs A] of this guideline not being followed is explored further below in question 5.0.

In summary, the policies and procedures included in the review documents appear appropriate and consistent with expected standards found in the highly technical and process orientated environment of a Perioperative Department and CSU. Four recommendations have been made for further review.

3.0 The appropriateness of the actions taken by the company representative, [Ms E], in retrieving and opening the equipment packet.

In my opinion it was appropriate for [Ms E] to retrieve the equipment. It was her responsibility to source alternative equipment and [Ms E] was responsive in this regard. In [RN B's] statement (point 12) he refers to his experience that over previous years he has observed company representatives opening gowns and instrumentation, therefore it is possible that [Ms E] has been in other situations and in other hospitals whereby from time to time this practice has occurred and deemed acceptable.

Ideally, [Ms E] should not have opened the equipment because she was then undertaking a role normally carried out by the circulating nurse; however, [Ms E] believes she was asked to open the equipment and has stated that in her response of 6 May 2019. [RN B's] statement does not confirm this point or otherwise therefore actions taken by [Ms E] need to be considered in the alternative.

If, as stated in point 2.6 [Ms E] **was** asked to open the instruments she was working within the Guidelines for medical representative or technical support person in the operating room (March 2015).

If, [Ms E] was **not** asked to open the instruments she was still under pressure, i.e. the company had provided an incomplete set of loan instruments, the patient was on the table and anaesthetic underway. These factors would have been a strong incentive for [Ms E] to do all she could to help get the case underway. Whilst silent in the review that followed, I would have expected that after the event, as company representative, [Ms E] would have followed up why the instrumentation was missing from the loan set in the first place.

In summary, in my opinion focusing on [Ms E] is a 'red herring'. At best, she was doing all that she could, in a pressured situation to resolve the issue of missing equipment so that the procedure could continue. [Ms E] was flexible and responded to immediate need. At worst she was placed in a position whereby she obtained equipment that, through no fault of her own, was unsterile and whereby usual checks of sterility failed.

As per point 2.2, in my opinion it is not the fault of the company representative that this event occurred so adding additional steps and strategies such as 'pink hats' that further limit the representative's scope in theatre feels punitive and does not address the core issue — that the equipment was not sterile and checks of sterility failed.

4.0 The appropriateness of the actions taken by the scrub nurse, [RN B], in particular his supervision of [Ms E].

I note that the initial incident/complaints report and statement was made on 18th May 2018 by [RN B]. In addition, a further statement was provided on 1 May 2019. I wish to acknowledge the evidence of reflection on his practice and variables that contributed to this event. This reporting demonstrates appropriate, transparent and professional responsiveness expected of a senior Registered Nurse.

I agree with the statement made by Southern Cross Chief Executive (7 May 2019) whereby it is regrettable that the scrub nurse was also the designated nurse in charge of the theatre that day. This is because both roles perform different functions that require concentration. On this occasion [RN B] was appropriately focused on completing the tasks required of the scrub role. There was pressure to start the case which was running behind time, missing instruments had to be located at short notice and [Mrs A] was in the theatre and anaesthetic underway.

Whilst it may have been 'his role', as the designated RN in charge of the theatre to oversee events including [Ms E], [RN B], whilst focused on the role of scrub, was simply not in a position to do so.

[RN B] did however fail in his responsibility to check instrument sterility before placing on the trolley which is a breach against standards expected of the scrub nurse role. For reasons already stated, there were mitigating factors that contributed to this system failure.

Considering this further, the unsterile instruments passed by several steps that would normally have occurred,

- they were not already sterile
- they were located at short notice
- both the scrub and circulating nurse thought the other role was checking the instruments
- both the scrub and circulating nurse thought the other role was working alongside [Ms E].

Whilst unsterile instruments entering the sterile field would be considered a **severe** departure from accepted standards of practice, multiple mitigating system errors on that occasion impacted on [RN B's] performance. Therefore, in my opinion it would not be reasonable to apportion fault in any one person's direction. Viewing this event via both a 'human factors' adverse event and 'safety II' lens I believe this view would be supported by my peers.

5.0 The appropriateness of [the private hospital's] actions taken once it became aware an unsterilized drill bit had been used.

[The private hospital] were thorough in their response to suspicions that the drill bit was unsterile. Once confirmed, follow up with [Mrs A] was prompt and a clinical plan for her quickly put into place. The internal review was commenced promptly and initial findings fed back to [Mrs A] in their letter of 12 June 2018. Correspondence between [Mrs A] and [the private hospital] was prompt.

However, with the benefit of hindsight and ability to comment on the entire case to date, opportunities for improvement can be identified when management of the event between parties could have gone better to the extent that, in my opinion, escalation to the Health and Disability Commissioner may have been avoidable. Opportunities for improvement centre around whether [the private hospital] acted according to their own open disclosure policy and the extent that they underestimated the impact this event had on [Mrs A].

5.1 This event was an unexpected outcome for [Mrs A] with consequences of an increased risk of infection or exposure to Hepatitis or HIV. [Mrs A] could not have anticipated that she was at risk of this even occurring. Therefore, she could never be 'happy' with the outcome or explanation. At best she was 'accepting' of the situation because post event, what choice did she have?

Therefore there was a lost opportunity for [the private hospital] to 'front foot' this event with proactive arrangements for follow up post discharge. In the event of this surgical 'never event', [the private hospital] demonstrated an error in judgement to assume that a patient would be 'happy' and that ongoing organisational follow up arranged prior to discharge would be unnecessary.

5.2 I agree that it was appropriate for [Dr D] to discuss the event with [Mrs A]. This is because there is already a relationship between the surgeon and patient and [Dr D] was able to clinically inform [Mrs A] of the event, risks and follow up process. However, reflecting on above point 2.6, [the private hospital] failed to manage this event as outlined in their open disclosure guidelines. That is,

- there does not appear to have been arrangements for offer of further meetings.
- Information provided on discharge was at [Mrs A's] insistence
- [Mrs A] did not appear to have received an apology from [the private hospital] within 24 hours of the event.

Therefore, whilst immediate disclosure was apparent, Southern Cross did not go far enough to proactively support [Mrs A] through the process of the information sinking in, having a single point of contact liaison who would keep in touch with her at agreed intervals — effectively walking alongside her during the 12 month period of risk.

[Mrs A] would not have known what to expect as a result of this event. I acknowledge this may be different for different people however, rather than an exchange of

increasingly frustrated correspondence which took place, Southern Cross could have asked [Mrs A] what she wanted by way of follow up and worked with her in that way.

5.3 In her complaint and subsequent communications, [Mrs A] uses words like (felt) 'dismiss' 'showing no concern', 'brushing off' 'gloss over' 'seeing no ownership', 'belittling' and 'resultant stress related to the possibility of infections and worrying about contracting HIV o[r] Hepatitis'. Whilst, in response to the concerns repeatedly raised, there is prompt correspondence from Southern Cross, they under estimated the impact on [Mrs A] of living with the potential risks of this event. There is no evidence of a 'cover up' that [Mrs A] asserts however because there were no arrangements for further event follow up, the event being omitted initially from the discharge summary and post-operative phone call, I agree with her view that [the private hospital] appear to have 'moved on' from [Mrs A] after the event. In my opinion, unless [Mrs A] complained, voluntary follow up by Southern Cross may not have occurred.

5.4 Unfortunately, in the letter of 12 June 2018, the opening statement was, in my opinion unfortunate because it implies that the event can be attributed to a 'busy working environment'. This was not a good start when trying to explain factors that may have contributed to the event. In hindsight, with an event of this severity (SAC 2, High) it would have been appropriate to have offered to meet with [Mrs A] to go through the review outcomes with her, provide opportunity for input and discussion and then follow up with a summary letter and any agreed actions. [The private hospital] did acknowledge the impact on [Mrs A's] trust in Southern Cross however this was not acknowledged until 29th June 2018 after a number of exchanges of correspondence.

In summary, as stated, an event of this nature is a surgical 'never event'. In hindsight, [the private hospital] could have been more proactive working in partnership with [Mrs A]. If this had happened earlier, e.g. consistent contact person, early and proactive arrangement to meet, agreed time of contact, she may have been less inclined to complain. It is evident throughout her complaint that [Mrs A] felt abandoned, anxious and that she needed to advocate for herself.

In this event, [the private hospital] failed to follow parts of their own expected standards of open disclosure (which reflect Health and Disability Sector Standards). Whilst this would be considered a **moderate** departure from accepted standards, my preferred recommendation is that opportunities for improvement and learnings across the entire case are reflected upon.

6.0 Any comment I wish to make about [the private hospital's] internal review.

Whilst the focus of this (and most other) reviews is to find the 'root cause' fault/s and correct it, what is overlooked are the actual work patterns of a highly flexible workforce accustomed to variability. For example, whilst the 'huddle' did not occur how often this does happen and with no adverse outcome? The review identifies dual leadership roles as one causative factor however this appears to have been commonplace with no adverse event? Therefore there are patterns in the way staff worked that went 'right' nearly all of the other times. Having company representatives

in theatre is commonplace and their participation evidenced in point 12 of [RN B's] statement yet incidence of adverse events low? Role confusion is evident however unlikely the first occasion where roles blurred. The point is, whilst the focus is on 'doing the right thing' I hope consideration has also been given to why it goes right nearly all of the other time? Consistent with principles of Safety II, these are the things, often less visible, that should also be fostered and which enhances safety. The use of simulation within the review is noted and an opportunity to explore 'work as done' and not only 'work as planned'. Follow up audits and documentation are timely and demonstrate vigilance.

6.1 The internal review identified two key findings; that the sterility checks failed and that the company representative sourced missing equipment without supervision. Incidental findings include inadequate equipment storage and signage. In my opinion an additional key finding is that the patient was already in theatre which placed additional pressure on staff to find the missing instrumentation and start the case. The direct causative factor/issue was that the instrument was not sterile.

Referring to the follow up audits provided in the Chief Executive's response, I note the updated corrective action that all equipment is now sterilised. That is appropriate because this action will likely eliminate rather than minimise the risk of unsterile equipment entering theatre and remove the need for signage which is a far less reliable corrective action. Furthermore this action directly resolves the direct causal factor that the equipment was unsterile.

6.2 Whilst reference has been made to loan equipment, essentially **all** equipment loan and consignment should be sterile for use. The April 2019 review update alludes to this however, consistent with point 2.5 above, suggest this point is clarified by [the private hospital].

What would then need to occur is a process in place to monitor sterility expiry dates of instrumentation put in place, e.g. in another hospital all equipment sterility is maintained within 6 month period, after which items are re-sterilised and/or considered for return to the company, or retired from use.

7.0 Any other matters in this case that I consider warrant comment

7.1 Referring to the OT record, there were other people recorded in theatre. In addition to [RN B] and [RN C] there [were] also [three other people] but who they are and their roles are not defined and their contribution to this event unable to be determined. Therefore, I recommend that if allocation of roles is a key review recommendation to be reinforced then consideration is given to amend the theatre record, operation details section so that key roles are able to be explicitly recorded, e.g. the role of the CRN is not explicit on the OT record.

7.2 On the day of surgery, [Dr D] has clearly documented the conversation with [Mrs A] in the clinical record. In addition the ward charge nurse and clinical duty managers were made aware of the event, yet [Mrs A's] experience was not one of a co-ordinated effort. Given the short length of stay and significant nature of the event it is

disappointing that [Mrs A] gained the impression that nursing staff were unaware of the event.

7.3 It is not clear how Southern Cross intend to share this event with their other hospitals. I expect this will occur, the mechanism for this being via National Infection Prevention and Control committee (NIPCC), the Hospital Safety Quality and Risk Committee (SQR) or other (Credentialing and Scope of Practice Guide supplied). It is important this is clarified to demonstrate the opportunity to learn across the Southern Cross hospitals nationally to examine consistency across review recommendations made, particularly in regard to company representatives and CSU processing and sterilisation of consignment and loan equipment.

7.4 Again referring to the supplied document Credentialing and Scope of Practice Guide supplied (page 12), I note reference to responsibilities of the recommending surgeon when technical experts are invited into theatre, that is

'… the recommended surgeon must provide direct supervision and is responsible for the performance and behaviour of their invitee at all times.'

Company representatives are invited to attend theatre by a medical specialist for technical produc[ts] or clinical support (Guidelines for Medical Representative or Technical Support Person in the Operating Room). Whilst I acknowledge some practical limitation of the surgeon being able to carry out this responsibility, neither is this mentioned in the internal review which has focused solely on the performance of other members of the team.

8.0 Summary and Recommendations for Improvement

As an outcome of this review I have identified **three** areas where a departure from accepted standards has occurred,

1) Two controlled documents reviewed were dated 2011 and would be considered 'old'. Reference to a controlled document that was nine years old would be considered a **minor** departure from accepted standards.
2) Unsterile instruments entering the sterile field would be considered a **severe** departure from accepted standards of practice. However mitigating system errors on that occasion impacted staff performance. Therefore it would not be reasonable to apportion fault in any one person's direction.
3) [The private hospital] failed to follow parts of their own expected standards of open disclosure (which reflect Health and Disability Sector Standards). This would be considered a **moderate** departure from accepted standards.

Recommendations

1) Referring to document **Guidelines for medical representative or technical support person in the operating room (March 2015),** this document does not yet appear to have been reviewed as recommended in the internal review action plan.

2) Referring to document **Instruments on loan guidelines (2011)** I recommend [the private hospital] reviews their documentation around management of owned and consignment stock.

3) The currency date for **Instruments on loan guidelines (2011) and Checking of sterile packaging procedure (2011)** documents are old. I recommend that these documents are reviewed to refresh current practice.

4) [The private hospital] failed to follow aspects of their expected standards of open disclosure (which reflect Health and Disability Sector Standards). Whilst this would be considered a **moderate** departure from accepted standards, a preferred recommendation is that opportunities for improvement and learnings across the entire case are reflected upon.

5) Because allocation of roles is a key review recommendation, I recommend that the theatre record document, operation details section, is amended so that key roles are able to be explicitly recorded, e.g. the role of the CRN is not explicit on the OT record.

Rosalind Jackson
Associate Director of Nursing
Bay of Plenty District Health Board

11 February 2020

References

Hollnagel, E. Wears, R.L. Braithwaite, J. (2015) *From safety-I to safety-II: A white paper*. The Resilient Health Care Net: Published by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.

Agency for Research, Healthcare and Quality (ARHQ). *Never Events, Patient Safety Primer (Updated September 2019)* https://psnet.ahrq.gov/primer/never-events

Health and Disability Service Standards (Core) Standards, NZ8134.1.2.2008 Standard 2.3 (Quality, Risk and Patient Safety framework)."

The following further advice was received on 17 June 2020:

"We (HDC) have received a response to your expert advice report by Southern Cross. We have also received the following comment from [Ms E]: 'It was not that 3 instruments were missing from a tray, it was that an entire tray had in fact NOT been ordered or sent and hence the alternative tray I got from the store room had to be opened.'

We would be grateful if you could review the additional information and advise if it causes you to amend the conclusions drawn in your advice in any way. In addition, please provide your advice in the following two scenarios

1) Where [Ms E] was asked to open the package and

2) Where [Ms E] opened the package on her own volition.

In addition to [the private hospital's] reply, attached documentation included,

- Checking and opening of sterile items
- Management of instruments on loan or evaluation
- Policy for medical company representatives and technical support persons in the theatre environment
- Theatre roles and responsibilities
- Intraoperative record
- Network update sterilisation documents
- Hospital layout map

Reflecting on whether this additional information alters the conclusions I reached and advice provided I am mindful that I do not have the original file of documents to refer back to. Therefore, I am relying solely on information contained in my opinion above submitted February 2020.

Following review of the additional evidence provided including feedback from [Ms E] and [a Southern Cross representative], I find that my advice is substantively unchanged. My rationale is as follows.

1.0 We would be grateful if you could review the additional information and advise if it causes you to amend the conclusions drawn in your advice in any way.

[The private hospital] has provided a response to the summary and recommendations for improvements made including changes to their policies and processes. Consideration of this response and material is a matter for HDC.

The matter for my further consideration is centred on the actions of [Ms E] in opening unsterile equipment and the extent to which she did this under instruction or by her own volition.

2.0 In addition, please provide your advice in the following two scenarios

- where [Ms E] was asked to open the package and
- where [Ms E] opened the package on her own volition.

As previously stated above in 3.0, if [Ms E] **was** asked to open the instruments she was working within the Guidelines for medical representative or technical support person in the operating room (March 2015) document that was active at the time.

If, [Ms E] was **not** asked to open the instruments she was still acting in a pressured situation, i.e. the company had provided incomplete loan instruments, the patient was on the table and anaesthetic underway. As the company representative, these factors would have been a strong incentive for [Ms E] to do all she could to help get the case underway and prevent case cancellation or postponement.

Southern Cross explained that [Ms E] was informed by her colleague that the instrument required was in another set and that she obtained this set herself from a storage area significantly outside of the theatre department, and without talking to the SSD or theatre staff. [Ms E] has herself commented that

'It was not that 3 instruments were missing from a tray, it was that an entire tray had in fact NOT been ordered or sent and hence the alternative tray I got from the store room had to be opened.'

Southern Cross accepts that the situation of [Ms E] opening the instruments should not have been able to occur within its theatre, but maintains the view that [Ms E] knew this and acted contrary to Southern Cross's expectations. However they go on to add that they have no hesitation in also accepting that [Ms E] did this with the best of intentions.

'She was the medical representative present who was in a difficult position when her employer had supplied an incomplete instrument set and would have felt the need to rectify that situation as soon as possible. Her actions would also have been informed by her familiarity with Southern Cross having worked at a different Southern Cross hospital for a considerable length of time. She was also well known to staff inside the theatre. This level of familiarity has been identified as a contributing factor.'

Therefore, I find that both Southern Cross and my opinion are substantively consistent in that we agree that [Ms E] acted with the best intentions to rectify the situation and enable the surgery to continue. Both opinions are mindful of mitigating circumstances that impacted on the performance of [Ms E] on that occasion.

Furthermore, whilst attention has been on [Ms E's] actions in obtaining the equipment it is also agreed that [RN B] failed in his responsibility to check instrument sterility before it was placed on the trolley which is a breach against standards expected of the scrub nurse role. However, for reasons already stated in my advice, there were mitigating factors that contributed to this system failure and these have been accepted by Southern Cross. Therefore it is important to accept equally mitigating circumstances that applied to both [RN B] and [Ms E].

I maintain that irrespective of what instruments were missing and where they were located from a key finding is that the patient was already in theatre and anaesthetised when the instruments were found to be incomplete which placed additional pressure on staff to find replacement instrumentation and continue the case. This increased the risk of error occurring which, on this occasion, led to the direct causative factor/issue — that the instrument was not sterile.

Rosalind Jackson
Associate Director of Nursing
Bay of Plenty District Health Board

17 June 2020"

Appendix B: SCHL Policies

Checking of Sterile Packaging Procedure (KB 4367) (2011)

125. The Checking of Sterile Packaging Procedure states:

> "Before opening, check packs for:
>
> 1. Integrity of outer wraps
> 2. Integrity of seals
> 3. Correct labelling
> 4. Correct colour change of the external chemical indicators
> 5. Use by date on the package on commercially prepared items
>
> When opening, check packs for:
>
> 1. Ease of opening
> 2. Correct packaging techniques e.g. filters, fasteners and lids
> 3. Correct contents
> 4. Correct layout of contents
> 5. Condition of contents e.g. cleanliness, alignment and function
> 6. Correct colour change of the chemical integrator
>
> When completed:
>
> - Confirm checking in the patient's perioperative record
> - Attach batch labels to patient perioperative record
>
> If any breach is found, the item is considered unsterile and is not to be used."

Guidelines for medical representative or technical support person in the operating theatre (KB 16178) (2015) (Medical Representative Guideline)

The Medical Representative Guideline states:

> "Attendance in theatre of a Medical Representative/technical support person has been requested by the Medical Specialist or a Southern Cross Team Member for Technical Product or Clinical support, therefore, consent from the patient is not required, as the visitor is regarded as, and included as part of the Perioperative team.
>
> …
>
> Medical Representative/technical support personnel Must
>
> …
>
> - Follow the directions given by theatre CRN or designee [of the private hospital staff]
>
> …

Medical Representative/technical support personnel Must NOT

…

- Participate in any clinical activity unless authorised to do so
- Open any instrumentation or implant or use any [of the private hospital] equipment, unless requested to do so by [the private hospital] staff
- Give information they are unsure about

…"

Instruments on Loan Guidelines (KB 4374) (Loan Guidelines)

The Loan Guidelines state that collectively hospitals and suppliers need to develop standardised procedures to allow adequate time for SSD to carry out effective decontamination prior to and after use. Manufacturers and suppliers must provide adequate documentation, training, and education on the care and handling of equipment, and systems must be in place to track instruments through the facility.

Under the heading "Management of instruments during loan period", the Loan Guidelines state that on receipt into the facility, the instruments are to be checked against an instrument checklist, and the lender is to be contacted if any discrepancies are noted. The equipment then undergoes full cleaning, decontamination, and sterilisation by SSD staff.

Following use, all instruments on loan are subjected to the full cleaning process, rechecked, sterilised, and returned to the original source or per instructions. Any faults, breakages, or missing items must be recorded, and incidents reported via the Incident Summary System. The lender is to be advised by telephone so that replacements can be organised.

Open Disclosure: Fully Informing Patients and Patient Right to Know Guidelines (2016) (Open Disclosure Guidelines)

The Open Disclosure Guidelines detail the process to be taken following an adverse event. This includes acknowledgment of the incident, an explanation of what happened, how and why it happened, and the consequences for the consumer, including arrangements for continuity of care.

The "Process of open disclosure" includes:

"• The patient must be fully informed of incidents, accidents or events

…

- The patient is seen and spoken with by the Admitting Doctor, usually the Surgeon, and this is followed up with the arrangement for or offer for further meetings.

…

- The patient is requested to confirm their understanding of the situation, including what the risks might be and what actions to take for monitoring and follow-up care. Record instructions for the patient on the Discharge Form.

…

- … a verbal and sincere apology … within 24 hours of the incident even having occurred …"