

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195

Complaint	<p>The Commissioner received the following complaint from the complainant, Mr A, on behalf of his daughter, Miss E (the consumer):</p> <ul style="list-style-type: none">• <i>On 13 September 1999 Miss E underwent surgery at a public hospital. Ms D was the scrub nurse for the operation. Ms C was the circulating theatre nurse for the operation. The instrument and swab count was recorded as complete, but it was later discovered that two surgical swabs had been left inside the wound in Miss E's hip. These swabs caused an infection and another operation was required to remove them.</i>• <i>On 13 September 1999 Dr B operated on Miss E at the public hospital. Dr B left two swabs in the wound in Miss E's hip, which caused an infection and the need for another operation in early October to remove them.</i>• <i>The drain that Dr B inserted into Miss E's hip wound during the operation to remove the swabs was not correctly placed. Miss E required a further operation to remove the drain.</i>• <i>Following removal of the drain, wound stitches came undone and a fourth operation was required to re-suture the wound.</i>
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Investigation Process	<p>The complaint was received on 12 November 1999 and an investigation began on 30 November 1999.</p>
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Information was received from:

Mr A	Complainant / consumer's father
Dr B	Provider / orthopaedic surgeon
Hospital and Health Services	Provider / public hospital

Hospital and Health Services provided information on behalf of the nurses, Ms C and Ms D.

Relevant medical and Accident Compensation Corporation (ACC) records were obtained and reviewed. Advice was obtained from an independent orthopaedic surgeon.

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Information Gathered During Investigation

Twelve-year-old Miss E, consumer, was admitted to the public hospital at 1:30pm on 13 September 1999 for an operation on her cervical spine that was funded by ACC. The operation involved taking a bone graft from Miss E's right hip (posterior iliac crest) to stabilise her cervical spine, which she had injured in a trampoline accident two years earlier.

Orthopaedic surgeon Dr B explained that Miss E had a potentially serious condition of her cervical spine with ongoing symptoms of pain and a risk of more serious injury to her spinal cord. After discussion with the family it was decided to proceed with surgery under an ACC elective surgery contract. (This means that the surgery was not considered necessary within a week and can be carried out at an approved hospital.) Dr B chose the public hospital as necessary equipment and support facilities were available.

Dr B performed the operation, with the assistance of two nurses. Ms D was the scrub nurse and acted as surgical assistant and Ms C was the circulating theatre nurse. The anaesthetic was started at 5:15pm, the operation commenced at 5:50pm and finished at 7:40pm. Because the orthopaedic theatre was being used for a major trauma case Miss E's surgery was performed in a smaller theatre that was usually used for eye surgery.

At the beginning of all surgical procedures, the instruments and equipment to be used are counted by nursing staff. During the operation all swabs and instruments used are counted. At the end of the operation the used swabs and instruments are counted again, to ensure that nothing has been left inside the patient. The public hospital has a form for staff to use during surgical procedures to record the surgical count. As well as the pre-operative count and the count kept as instruments and swabs are used during the surgery, two counts were supposed to be carried out at the end of the operation; one when wound closure began and the other at skin closure.

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Ms C wrote in a statement to the ACC Medical Misadventure Unit that:

“...

The surgical procedures took a lot longer than was expected and required more instrumentation than was at first thought to be necessary.

As a major trauma case was being carried out in the Orthopaedic Theatre we were operating in OT3 which is on the other side of the block and this meant running for any extra equipment that was needed. As a result I was having to leave [Ms D] on her own a good deal of the time which is not very satisfactory and I was very concerned that she could be needing my assistance at any time whilst I was unavailable.

Part way through the surgery [Dr B] needed to change to the other side of the table but when [Ms D] moved she was unable to take her trolley with her due to the position of the image intensifier. This created a lot of unnecessary running around the table to retrieve any equipment needed as she was also acting as surgical assistant. As a result, the surgeon also took equipment when he needed to. I do not know if packs and swabs were also taken by him.

At the completion of both procedures and before closure of the wounds at the graft and donor sites, there was a count of all packs, swabs and any needles [Ms D] had at that time. All packs and swabs were counted individually and kept on her trolley. This count was correct and the surgeon notified. Closure of the neck wound was completed. [Ms D] cleaned and dressed the neck wound. [Dr B] continued with the closure of the donor site. This was then cleaned and dressed by [Ms D] and both dressings were fixed in place. I recall assisting with this part of the procedure. [Ms D] and I removed [equipment] in readiness for the reversal of the patient's position on the Stryker bed. Normally at this point a final skin count would be carried out but I was needed to assist with the reversal procedure and we obviously missed this count.

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[The anaesthetist] reversed the patient's anaesthetic and when he was satisfied with her condition, she was transferred to her own bed. At this point I was required to transfer her to recovery and I needed to commence recovery until the recovery nurse was free to take a hand-over from me. I then returned to theatre where [Ms D] and I completed the paperwork. We were not aware that we had not done this final count of packs, swabs and needles and I can only think that the confusion of the whole process had resulted in us missing this count."

Ms D commented in a statement to the ACC Medical Misadventure Unit that:

*"...
Being the assistant and Scrub Nurse was difficult at times as I had to move around the extra machinery, organise my drills etc. then move back and assist again. When we commenced suturing the cervical wound we did a routine count and all the swabs, packing and instruments were accounted for. Following this I was unaware of any further swabs taken.*

[Dr B] continued suturing the iliac crest wound on his own, it is at this time that I would normally do my second count. I attempted to tidy my trolley, which was in a mess after [Dr B] had been using it himself. I then put a dressing on the top wound. When [Dr B] finished clipping the skin (and he is a very fast surgeon), I dressed the wound, we took off [equipment] and prepared the patient for turning to the supine position.

..."

At the end of the operation the swab count was recorded as being completed and as being correct. Under the heading "*Surgical Count*", circulating nurse Ms C and scrub nurse Ms D signed that the count was made and indicated that the surgeon had been notified.

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Dr B stated that post-operatively there was slight inflammation around the wound on Miss E's hip, but said this was not unusual as haematoma and bruising often occur following surgery of this type. Post-operatively Miss E had a slight rash, but no problems with the wounds were noted. Miss E was discharged home with antibiotics on 17 September 1999.

When Dr B saw Miss E again, two weeks after the operation, there was some reddening and a slight discharge from her hip wound, but this was settling on the antibiotics she had been prescribed.

On 6 October 1999 Miss E was readmitted to the public hospital because she had been having ongoing problems with the bone graft wound site in her hip. Miss E had been in pain and the wound was discharging fluid. The wound was infected so she was given antibiotics.

A x-ray was taken on 7 October and showed that two gauze swabs had been left in Miss E's right hip wound during the operation on 13 September.

In her response to ACC Ms D identified four critical issues that she considered were influential in the final swab count being omitted:

- She was working in a dual role as a surgical assistant and scrub nurse. In hindsight the operation was more complex than had been anticipated and she stated that a surgical assistant would have been helpful.
- The orthopaedic theatre was occupied with a major trauma case so a different theatre had to be used which was some distance from the instruments they needed.
- The complexity of this surgery meant that extra instruments were required which had not been anticipated, so Ms C had to leave the theatre several times to fetch them.

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Ms D had to change sides of the table with Dr B and consequently lost control of her trolley. The trolley could not be shifted to the same side of the bed as the image intensifier and leads and air hoses prevented her from moving it. She stated that once Dr B moved to the iliac crest wound and she was dressing the cervical wound she was unaware of what he was using from the trolley. Had she not been acting in a dual role she would have known exactly what was being used.

Hospital and Health Services subsequently conducted a review to determine how and why swabs had been left inside Miss E's hip wound. The review memorandum dated 5 November 1999 stated:

"Following interviews with the nurses and surgeon involved in this case we conclude that the systems and processes currently in place should ensure a good outcome.

The nurses involved in this incident were experienced and competent theatre nurses. However, in this case human error resulted in the final (skin) count of the surgical count apparently being omitted.

The incomplete documentation on the intra-operative record supported the nurses' interpretation of events that the final skin count had been omitted.

We would like to reinforce to all theatre staff the importance of following the established procedures to reduce to an absolute minimum the opportunity for error to occur. ...

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Key points to emerge ... included the following:

- *There is a clear process for ensuring the surgical count details are correct. This includes a pre-operative count, a count at the commencement of wound closure, and a third and final count at skin closure. These counts are undertaken by the scrub and circulating nurse and are documented under 'surgical count details' on the intra-operative record. There is also a section on the front of this record where it is documented whether the count is routine/no count required; whether the count is correct/incorrect and if an incident form has been completed and the surgeon notified – both the scrub and circulating nurses sign this section.*
- *There is a theatre policy that deals with the procedures surrounding the instrument and swab count. This is available in the theatre policy manual and is addressed with staff during their orientation to the service. ...*
- *From the interview with the two nurses it would seem that the final skin count was not completed, although documentation on the intra-operative record indicated it had occurred.*

Conclusions

The systems in place to ensure swab counts are accurate and patient safety is maintained appear adequate. However, in this situation human error resulted in the final skin count apparently not being undertaken.

Although various circumstances made some aspects of this case more difficult we do not believe that any of these factors impacted significantly on the apparent failure to complete the final skin count.”

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Hospital and Health Services identified the circumstances that made aspects of this case more difficult as including:

- The surgery was performed in the eye theatre rather than the orthopaedic theatre, as there was a major trauma in the orthopaedic theatre. This meant the circulating nurse had to leave several times to fetch additional equipment;
- The scrub nurse doubled as the surgeon's assistant. She therefore had dual roles and at one point was on the opposite side of the bed to her trolley;
- There were two wound sites involved in the operation; and
- Both nurses were working overtime.

Hospital and Health Services' memorandum made several recommendations to address the problems identified:

- A discussion by the theatre management team about the timing and number of surgical counts required when two surgical sites are involved.
- Discussion between the orthopaedic surgeons and the theatre manager of guidelines needed when managing ACC orthopaedic cases, particularly in regard to surgeons needing an assistant and the timing of these cases.
- An audit of intra-operative documentation.
- Revision of the instrument and swab count policy.
- Concerning the nurses involved:

"Although the nurses involved in this incident were experienced and competent theatre nurses, and human error does occur, the serious nature of the apparent omission to complete the final skin count and the incomplete accompanying documentation, will be further reinforced during an interview with the theatre manager. Although the theatre manager has confidence in the competence of these staff members, future incidences of this nature would result in disciplinary action."

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Miss E had another operation on 7 October 1999 to remove the retained swabs from her right hip. Dr B performed this operation. During the surgery a Redivac drain was inserted into the wound to drain any fluid that had accumulated.

The next day nursing staff tried to remove the drain but were unable to do so as it was stuck. Attempts to remove the drain were very painful even after Miss E had been sedated, so it was decided to put her under a general anaesthetic to reopen the wound and remove the drain.

After discussion with Dr B, another surgeon operated on Miss E later that day. The operation note recorded "*the redivac was found to be caught deep in the vicryl sutures*".

Dr B advised that the drain appeared to have become tangled on itself which prevented it from being removed without considerable pain. He said that this is an occasional complication when wound drains are used. In his experience the fact that the drain had become tangled did not necessarily appear to be a consequence of incorrect placement of the drain. As the drain is flexible it can become twisted or knotted on itself during the removal process. He said that in spite of taking care to avoid this, this problem does occasionally still occur.

Following removal of the drain Miss E remained in hospital. There were ongoing problems as the wound in her hip would not heal, and it reopened on several occasions.

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It was not clear why Miss E's hip wound continued to break down, but Dr B identified some possible factors. Wound infection prevents healing, and results in wound dehiscence, but there were no signs of infection in Miss E's case. Dr B stated that the wound required re-suturing three times following the operation to remove the drain and that the wound was breaking down in the presence of well-secured sutures. Nursing staff noted that the dressing over the wound, which was supposed to have been left untouched, sometimes looked like it had been opened. This suggested excess friction on the wound might have caused the sutures to become undone or loosened. Miss E's medical notes recorded staff members' concerns that she was '*fiddling*' with the stitches.

Due to the continuing problems with Miss E's wound re-opening it was decided to re-suture the wound under general anaesthetic. This operation was performed on 13 October 1999. Dr B did not perform this surgery. The operation note recorded the history leading up to the operation as follows:

"A 13 year old girl who had stuck drain removed from the right iliac crest on the 8th October. She made good progress until the 11th when one side of the wound dehisced. It was resutured under local. That same night a further part of the wound dehisced despite re-suturing and steristrips and was re-sutured under local by one of the house surgeons. She made satisfactory progress until today. She had a fall last night and part of the wound became dehisced again. It was therefore decided to perform formal debridement and re-suturing in theatre."

Miss E was discharged from hospital on 15 October. The discharge letter summarised Miss E's hospital stay. It stated that retained swabs from previous surgery were surgically removed, as was the Redivac wound drain that had been inadvertently sutured in. The wound had required re-suturing three times, once under general anaesthetic, and Miss E had been treated with intravenous antibiotics for a group B strep infection.

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Miss E was admitted to the public hospital again on 16 October 1999, as the wound on her hip had come apart once more. The wound was steristripped and she was given oral antibiotics and observed. Miss E was discharged on 22 October.

ACC accepted Miss E's claim for medical misadventure on 12 March 2000. The claim was accepted on the basis of medical error, due to the failure by Ms C and Ms D to observe the standard of care and skill reasonably to be expected in the circumstances, in that the final swab count was not completed. Had this count been completed, the two swabs would not have inadvertently been left in place causing the ongoing morbidity that resulted in Miss E having to undergo further procedures under general anaesthesia.

**Response to
Provisional
Opinion**

Hospital and Health Services and Dr B responded to my provisional opinion as follows:

Hospital and Health Services

"I would like to make the following comments:

1. *Please find enclosed the comments of [Dr B].*
2. *Hospital and Health Services fully agrees with [Dr B's] comments.*
3. *I would like to draw your attention to the internal report by [three people]: 'Although various circumstances made some aspects of this case more difficult we do not believe that any of these factors impacted significantly on the apparent failure to complete the final skin count.'*

The implications of your provisional opinion would be far reaching for all hospitals, eg elective surgery after 5pm and use of theatres."

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Dr B

"I would first like to offer my sincere regrets to [Miss E] and her family for the unfortunate set of events surrounding her surgery. I would certainly not hesitate to apologise for any of the events for which I am found responsible. Certainly an unfortunate and rare chain of events occurred. There are a number of points I would like to comment on.

[Miss E] had a potentially serious condition of her cervical spine following previous trauma which resulted in ongoing symptoms of pain and an ongoing risk of more serious injury to her spinal cord. After discussions with [Miss E] and her mother outlining the risks and benefits of surgery to stabilise her spine it was decided to proceed with a posterior cervical fusion under the ACC elective surgical contract. Any surgery not considered necessary within a week falls into this category and can be carried out at an approved hospital. I elected to perform the procedure at [the public hospital] because the necessary equipment and support facilities were available there. I am pleased that the eventual outcome of the operation was successful as pointed out in [the advisor's] report stating:

'The primary point of the surgery to stabilise her cervical spine appears to have been entirely satisfactory and a good outcome is expected ... the risk of a catastrophic failure of the cervical spine has been corrected.'

I draw attention to this point merely to emphasise that the basic aim of the procedure was successful, not however to minimise the complications that occurred.

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I would like to endorse [the advisor's] statement that the surgeon is reassured by a correct swab count. I would add that the surgeon is absolutely dependent on a correct swab count as there is no other way to determine (other than routine x-rays of all surgical sites) whether all swabs have been retrieved. Unfortunately swabs packed into wounds during surgery can be impossible to see or feel during surgery. This point however appears to have been acknowledged in your conclusions.

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**Response to
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[The advisor] states that there 'were several circumstances that set the scene for human error'. He believes that one circumstance was the starting time for surgery of 5.00pm and the fact that the nurses involved had done a full days shift. I submit, however, that starting complex cases at 5.00pm is not an unusual situation. Indeed, many of the most complex surgical cases are performed outside of 'normal' hours. Many of these are major trauma cases and it is most unusual for the swab counts to be incorrect in these cases. It is a simple reality in hospitals that surgery, whether elective, semi-elective or acute, frequently commences outside the 'ideal' 8 hour day. Whilst clearly this can, in the extreme, be accompanied by human fatigue, I deny that this was the reality in this case. To conclude that it was a breach of rights simply because there was a mere theoretical possibility of personnel tiredness is, with respect, onerous in the extreme. The limits of the 'ideal' 8 hour day do not inherently impose fatigue. I am aware of no evidence related to the facts of this case which suggest that fatigue was a factor in, nor that I could have been considered to have been on notice that it was a factor. With respect, I submit that without some evidence that I should have been on notice that fatigue may have been material to the clinical risks of this case, it is unreasonable to conclude that, of itself such a theoretical consideration could indicate a breach of rights. Furthermore, the resource implications for the sector of such a conclusion would be massive insofar as its influence on access to surgical care is concerned. Finally on this point, if it is concluded that the ideal 8 hour day is to be imposed as a standard, this is a systems issue for which hospitals should be responsible, not individual practitioners. Indeed, the sector would need to be notified of this revised standard.

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The facts of this case as they relate to the above considerations are as follows. The nurses involved were both senior nurses with many years experience. It is usual for theatre charge nurses at our hospital to work a 'normal' day shift then remain on call for that evening, often until the following morning. In my view a 5.00pm start for a procedure expected to take approximately 2 hours is not unreasonable. I do not believe I should cancel/postpone the case because of the 50 minutes required to start the procedure. In fact, refusing to proceed with surgery once the anaesthetic process had commenced could be seen as a more serious breach of the 'duty of care' than others mooted.

Furthermore, the anxieties of patients and their families prior to surgery need to be considered. If on arriving in theatre I add up the issues raised ie. surgery starting at 5.50pm, operating in a different theatre (albeit the same in everything but number) and the presence of two senior nurses and decide not to continue with surgery because of supposed unreasonable risks, I am contributing further to the pre operative anxieties that inevitably surround any surgery.

In conclusion I do not believe that there was sufficient reason to not proceed with [Miss E's] operation.

A number of points have been raised in the nurses' report (amended by [Hospital and Health Services]) which require comment in light of my submissions above.

[Ms C] wrote:

'the surgical procedure took a lot longer than was expected and required more instrumentation than was at first thought to be necessary.'

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The surgery did not take longer than expected (reinforced by [the advisor's] comment:

'the surgery was very satisfactorily completed in good time').

The surgery did not require very much in the way of additional instrumentation. It is very common, if not routine, for further equipment or instruments to be required during orthopaedic cases. Certainly a theatre nurse would expect, at some stage during the procedure, to be required to fetch some equipment.

A number of other comments I believe are irrelevant or inaccurate. Performing the procedure in a theatre other than the orthopaedic theatre did not contribute to the error. Both nurses were used to working in all the theatres (they routinely do so on call), and indeed [Ms C] is not primarily designated to an orthopaedic theatre. It is a hospital policy that theatre nurses rotate through a number of specialities in theatre so they gain appropriate experience (particularly for after hours and acute work).

The theatre the procedure was carried out in was entirely satisfactory. There are no fundamental differences between theatres or unfamiliarities which would or should alert me to not performing the procedure in the theatre in which it was carried out.

The statements that I needed to change to the other side of the table and [Ms D] was unable to take her trolley because of the position of the image intensifier are also irrelevant. The procedure routinely involves changing positions during surgery and the surgeon taking equipment 'when he needed to' is also to be expected.

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The question of a surgical assistant also arises. In my view an extra assistant was not essential and is supported by [the advisor's] comment that 'a medical surgical assistant is by no means necessary'.

[The advisor] states:

'there are several circumstances that set the scene for human error.'

I would contend that any surgical procedure is a potential scene for human error. At all times, systems and individuals working within those systems take due care to minimise those potential risks. None of the events or circumstances mentioned above could have been predicted by me to have been an unreasonable risk and in particular did not indicate an increased risk of an incorrect swab count. The swab count is a fundamental part of any surgical procedure and should be a top priority before the procedure ends.

Indeed [Hospital and Health Services] in the review memorandum dated 5 November 1999 stated:

'although various circumstances made some aspects of this case more difficult we do not believe that any of these factors impacted significantly on the apparent failure to complete the final skin count.'

I certainly could not have foreseen a swab-count error occurring during any of the circumstances surrounding this operation.

None of the factors mentioned should have resulted in the swab count being overlooked. [The advisor] mentioned a review of the policy regarding starting complex procedures at 5.00pm, mentioned an 'unfamiliar' theatre which was not the case and even added that a medical surgical assistant was by no means necessary. These are hardly sufficient grounds to claim I did not act with reasonable care and skill.

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I would also like to take issue on the concept that this was a complex surgical case. In terms of spinal operations this case rates as a relatively simple procedure; it does not require exposure of the spinal cord itself, can be reasonably expected to take less than two hours and does not require any unusual or sophisticated equipment. The bone graft obtained from the pelvis (a routine orthopaedic procedure) is placed on the back of the spine between the two unstable vertebrae and held with a simple wiring technique.

The final issue I would like to comment on is the question of the redivac drain caught deep in the wound requiring further anaesthetic for removal.

I would firstly point out that I do not normally use a redivac drain in a bone graft donor site. It was used in [Miss E's] care because of the retained swabs and resultant infection because of the need to drain the wound to help eradicate the infection.

If it was not for the retained swabs a drain would not have been required.

[The advisor] states:

'that a drain being caught by deep sutures is a mistake easily made should really be detected at wound closure.'

You state that had I 'checked the drain before closing the wound, [Miss E] would not have had to undergo another surgical procedure'.

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I would contend that a deep drain can not be checked for certain whether it is caught by deep sutures unless it is actually pulled out of the wound (thus defeating the purpose of the drain in the first place). An understanding of how the deep drain is placed and the wound then sutured over the drain explains how it is not possible to actually see sutures in or around the drain. A gentle pull on the drain may suggest whether or not it is caught but it is impossible to tell for certain. I always check drains as far as I can to minimise the likelihood of entrapment and there is no evidence to suggest I did not in this case. It is a 'fact of surgical life' that despite appropriate care and checking, it is still possible for a drain to become entrapped in a wound. I submit that drain entrapment is more typical of a mishap than an error. I would recommend further surgeons opinions on the possibility of a drain being caught despite adequate checking if any doubt remains.

[The advisor] states:

'that a drain looping into a knot must be uncommon and probably less than 1%.'

He does not give a figure for drains being caught deep in a wound by a suture. To my knowledge, such a figure is unknown and I would be most interested in any literature or objective evidence as to the incidence. I am not aware of any. I know of a number of occasions where drains have required either pain relief, medication or general anaesthetics to remove them. In [Miss E's] case, considering her age, anxiety (alluded to in your report) and the ordeal she had already been through, a general anaesthetic to remove the drain was considered appropriate.

I feel that each event in [Miss E's] case must be considered in isolation rather than as an accumulation of unfortunate events which in their totality may appear to suggest a breach of rights. I fully acknowledge that [Miss E] suffered an unfortunate series of adverse events, all of which can be attributed to the original failed swab count."

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Independent Advice to Commissioner

The following advice was obtained from an independent orthopaedic surgeon:

“...

CASE SUMMARY

[Miss E] was admitted to the [public hospital] at 13.30 [1:30pm] on 13-9-99. The admission diagnosis was instability of the 2nd and 3rd cervical vertebra due to an injury in a trampoline accident some two years previously.

The anaesthetic for her surgery started at 17.15 [5:15pm] and the surgery at 17.50 [5:50pm] and ended at 19.40 [7:40pm].

The surgery was a posterior cervical fusion using a bone graft from the right posterior iliac crest of the pelvis. The neck was stabilised with skull traction during the procedure which followed a standard technique.

The patient was in Intensive Care overnight and returned to her ward the following morning.

The Discharge Summary dated 8-10-99 reports an uneventful recovery apart from a rash thought to be due to morphine. A good summary of her hospital stay is contained in the document information on leaving hospital signed by the nurse and the patient.

Study of the ward treatment and progress notes shows normal progress from a complex spinal operation.

There was some concern at a possible chest infection on the third post-operative day and it was thought some of the analgesic medication might have been causing nausea.

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Independent Advice to Commissioner continued

It appears [Miss E] was a little apprehensive on discharge on 17-9-99 but managing well after appropriate instruction from an occupational therapist and a physiotherapist.

She was readmitted late in the evening of 6-10-99 with pain and discharge from the right hip wound where the bone graft had been obtained.

This was found to be infected and intravenous antibiotics commenced. The following morning x-ray suggested retained swabs in the wound and surgery under general anaesthetic was undertaken later that day. Two retained gauze swabs were found in the wound which was washed out and drained and the patient returned to her ward at 20.30 [8:30pm].

The drain could not be removed the following morning and in the evening of 8-10-99 she had a further anaesthetic to remove the drain which had been caught by deep sutures in the wound.

Over the following days the Treatment and Progress Notes record difficulty with controlling the patient's pain and some apprehension at impending discharge home. There was difficulty with healing of the hip wound, some sutures broke and [Miss E] had a fall, further delaying wound healing.

The notes record concern that there might have been interference with the wound sutures and also at the psychological status of the patient and a possible depressive illness.

Her wound required re-suturing under another general anaesthetic on 13-10-99.

The Treatment and Progress Notes continue with problems about wound healing and the patient interfering with her wound.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

**Independent
Advice to
Commissioner
*continued***

[Miss E's] condition slowly improved. It appears she received psychological help and was discharged home on 22-10-99 making good progress.

COMMENT

[Miss E] underwent a complex procedure on her cervical spine. Obtaining a bone graft from the iliac crest involves packing away muscles and to get the exact shape of bone graft required involves a fairly deep wound. The patient's height and weight are not recorded but this can be quite an exacting procedure and it is standard practice to pack the muscles away with the gauze swabs and retractors.

Two swabs were overlooked and retained in the hip wound which subsequently became infected and management of this required readmission on two occasions and three further general anaesthetics.

The complications of the wound infection caused the patient considerable psychological stress and these problems are extensively categorised in the Case Notes.

The primary point of her surgery to stabilise her cervical spine appears to have been entirely satisfactory and a good outcome is expected with a stable cervical spine, and the risk of a catastrophic failure of the cervical spine has been corrected.

There has been human error in that the two missing swabs were not detected at the standard swab count. The responsibility to ensure that nothing is left in the wound is primarily the surgeon's but he was reassured by a correct count and the error went unrecognised until the wound infection set in and x-rays showed the problem causing this.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

**Independent
Advice to
Commissioner
*continued***

I would draw attention to the Memorandum [dated 5 November 1999]. It appears there were several circumstances that set the scene for human error. In my opinion, a policy that allows surgery of this complexity to start at 5.00 in the evening needs reviewing. The nurses involved had presumably done a full shift's work and stayed on overtime working in an unfamiliar theatre. It is certainly helpful for a surgeon to have a medical assistant, particular if two wounds are involved so that the nurses can concentrate on their own roles. However, the surgery was very satisfactorily completed in good time and a medical surgical assistant is by no means necessary. It may, of course, not be possible if there was another complex case going on in the theatre suite.

To answer the specific points you raise:

- *I consider [Dr B] and [Hospital and Health Services] exercised reasonable care and skill in providing services to [Miss E].*
- *A human error occurred at her surgery when two swabs were undetected in the bone graft donor site and subsequently caused infection. To overcome this three further operations were required and the patient's progress was complicated, not only by the infection but by delayed wound healing.*
- *In my opinion, [Hospital and Health Services] had a satisfactory instrument and swab count policy in accordance with national standards. The revised policy of 30-11-99 amplifies the necessity for each wound to have a separate swab count. In my opinion, these revisions are entirely adequate and responsible.*

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Independent Advice to Commissioner continued

- *The difficulty in retrieving the Redivac drain appears to have been due to it being caught by deep sutures. These would be placed to try and eliminate dead space for further infection to form. This is a mistake easily made deep in a wound and should really be detected at wound closure if there is concern that one of the stitches might have gone round or through one of the holes in the drain. The flexible drain can loop into a knot but complications of this nature in the use of a drain must be uncommon and probably less than 1%.*

Once it is established the drain is stuck, it is usually necessary to reopen the wound and a general anaesthetic would be required for this.

- *With regard to the breakdown of the wound on [Miss E's] hip; one can only surmise from study of the Case Notes that this was in part due to her slipping injuring the wound, in part due to continuing infection which only slowly responded to antibiotics and it does appear there may have been deliberate interference with the wound, possibly related to the patient's anxiety at being discharged home before she felt fully able to manage. From the Ward Treatment and Progress Notes this situation seems to have been competently and sensitively managed with a satisfactory final outcome.*

..."

Dr B and Hospital and Health Services responded to my provisional opinion and disagreed with the advisor's conclusions. The advisor reviewed the responses and commented as follows:

"Thank you for asking me to review additional information on this case.

I have studied the Commissioner's provisional opinion very carefully and if I may say so, this draws together a complex case fairly and accurately and reaches just and justifiable conclusions.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

**Independent
Advice to
Commissioner
*continued***

I would like to comment on the reply of the Chief Medical Advisor to [Hospital and Health Services] to the Commissioner dated 2/5/01. With regard to Paragraph 4, I stand by my opinion that a policy that allows elective surgery of this complexity to start at 5.00 in the evening needs reviewing.

This applies to elective non-urgent surgery, not to urgent surgery or elective surgery with a fresh team.

I have sought further informal opinions on this matter from my hospital colleagues. The Director of Anaesthesia and the Theatre Manager would not accept such a booking.

I asked a Neurosurgeon, and Orthopaedic Spinal Surgeon and a General Orthopaedist and all agreed they would not have started such an operation at that time.

I should point out that to my knowledge in this case, it has not yet been established who was responsible for booking elective surgery at 5.00pm on a Monday evening and what were the reasons for this. What were the pressures on the Surgical and Nursing staff to proceed with this operation?

With regard to Paragraph 3 of this letter, this statement is at variance with the evidence of the two nurses involved and who were obliged to work under rather less than ideal circumstances, as documented.

I would also like to comment briefly on some points in [Dr B's] letter dated 30/4/01.

His remarks that the surgeon is absolutely dependent on a correct swab count is reasonable. However, it is incumbent on the surgeon putting swabs in inaccessible places or deep in a wound, to keep track of them and a useful practice is to draw the scrub nurse's attention to such a situation and make a specific point of drawing her attention to the swab being retrieved.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Independent Advice to Commissioner continued

[Dr B] defends the decision to go with surgery at 5.00pm and it is indeed true that a lot of complex surgery is carried out after hours but these are urgent cases which does not apply here. I might add there is a trend where possible in surgery, to try and carry out all but the most urgent cases during normal working hours or at least to ensure there is a fresh team available for after hours work.

[Dr B], I think to some extent, minimises the complexity of the surgery he undertook, particularly with regard to the staff whose statements are available. The patient was prone on the operating table, I understand, and was transferred from a Stryker turning bed. This makes for difficult anaesthesia. A scrub nurse was expected to act as assistant and the circulating nurse had a lot to do finding instruments, as they were not in the orthopaedic theatre. It is noted that the patient was transferred to Intensive Care for overnight observation.

The question of the Redivac drain arises. My statement that a drain looping on itself being less than 1%, was intended to convey that this is a rare event and under the threshold that ACC regards a Medical Misadventure. Catching a drain with sutures is a common event which is hopefully detected before wound closure. As pointed out, it is not often easy to detect this, sometimes pulling on the drain will free it from the stitch but others, as in this case, a further operation and anaesthetic was required. Catching a drain with a stitch is not uncommon, it is nevertheless a mistake.

As has been pointed out, the problems in this case did originate from the retained swabs but I believe, as has been done, the circumstances which led up to that event must be carefully considered.”

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

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.*

Other Relevant Standards **INSTRUMENT AND SWAB COUNT Hospital and Health Services**

OBJECTIVE: To safeguard against failure to remove swabs, instruments, needles, surgical equipment etc, from the patient's wound.

STANDARDS:

1. When is a count required?

- A full count is required for all operations opening through a hollow viscera, peritoneum or cavity such as herniorrhaphy.
- A count of swabs, needles and blades is required for all other open wound operations.

2. The count is undeniably correct and visible before the operation commences.

- The count sheet is a legal document and therefore all recordings must be legible and in ink. Any crossed out errors need to be initialled.
- [This] must be done and checked by TWO PERSONS: ...
- The count is documented on the Swab Count Sheet as soon as it is done and then transferred to the Count Board in Theatre.
- ...
- Strict discipline should be observed by all medical, nursing and paramedical personnel regarding the count.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

- Other Relevant Standards *continued***
3. **The recognised type of equipment is counted.**
...
- ALL SWABS, INSTRUMENTS, NEEDLES, TAPES, SLINGS, HYPODERMIC NEEDLES ETC MUST ALWAYS BE COUNTED AND CHECKED BY TWO PERSONS.
4. **The final count of equipment is the same as the commencement – count prior to surgery plus additional equipment counted during surgery.**
...
- Any discrepancy is informed to the surgeon immediately.
...
5. **The count process and timing prevents unnecessary delay or reopening of a wound.**
The count must be done as per standard 1.
- Before operation commences.
- During operation if any extras added.
- At the closure of hollow viscera (swabs, packs and needles).
- At the commencement of closure of a wound or cavity.
...
7. **The count sheet is a legal and legible document indicating the count process and personnel concerned.**
- The count sheet is completed after the final count.
- Any discrepancy and notification to surgeon is added if satisfactory outcome not achieved.
- The sheet is signed by the scrub nurse and circulating nurse.
- The sheet is secured into the patient's notes.
-

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion: **Right 4(1)****No Breach****Orthopaedic
Surgeon, Dr B**

In my opinion the orthopaedic surgeon, Dr B, exercised reasonable care and skill in providing surgical services to the consumer, Miss E, and did not breach Right 4(1) of the Code in relation to the following matters:

Swabs

Two swabs were left in Miss E's hip wound during the surgery that Dr B performed on 13 September 1999. However, the theatre nurses were responsible for completing the count of swabs and instruments used during surgery. My advisor's opinion is that although primary responsibility for ensuring that nothing is left in the wound rests with the surgeon, in this case Dr B was reassured by a correct count. In my opinion it was reasonable for Dr B to rely on the nurses' advice that the swab count had been completed and was correct.

Wound breakdown

Miss E's hip wound re-opened on several occasions after the operations on 7 and 8 October 1999. My advisor stated that the wound breakdown was probably due to a number of factors. These included Miss E slipping and injuring herself, a continuing infection that responded only slowly to antibiotics, and some apparently deliberate interference with the wound, possibly because she was to be discharged home before she felt able to manage. My advisor explained that the situation appeared to have been competently and sensitively managed, with a satisfactory final outcome. In my opinion, the fact that Miss E's hip wound reopened on several occasions was not due to a lack of reasonable care and skill on Dr B's part.

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion: **Right 4(1)**

Breach

**Orthopaedic
Surgeon, Dr B**

Decision to commence surgery

In my opinion, the orthopaedic surgeon, Dr B, did not act with reasonable care and skill when he decided to proceed with the consumer, Miss E's, surgery on 13 September 1999.

Several factors set the scene for the human error that evening. These include the fact that complex orthopaedic surgery was not being performed in the orthopaedic operating theatre, as it was being used for an emergency. As a result one of the nurses had to leave several times to fetch extra equipment that was required. The scrub nurse was also acting as the surgeon's assistant. There were two wound sites involved in the operation, which further complicated the procedure. Furthermore, the surgery did not commence until 5:50pm, finished at 7:40pm, and both nurses were working overtime.

In Dr B's response to my provisional opinion he disagreed with this conclusion for several reasons and concluded that he could not have been expected to foresee an incorrect swab count as the result of any one of these circumstances. Dr B cited the following reasons in support of his view:

- It is not unusual for complex surgery to commence after 5:00pm.
- Fatigue was not a factor.
- There would be significant resource implications of restricting elective surgery to an eight hour day.
- Starting this particular surgery was not unreasonable at 5:00pm.
- The surgery itself was not complex.
- The nurses were senior and experienced.
- Postponing surgery at 5:00pm would have unnecessarily added to Miss E's stress.
- The theatre used was acceptable.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion:
Breach
Orthopaedic
Surgeon, Dr B
continued

My advisor reviewed Dr B's submission and maintained his advice that commencing Miss E's surgery under these circumstances was not acceptable practice.

I do not consider it is satisfactory to allow complex spinal surgery to take place in the presence of so many complicating factors, as this increases the likelihood of errors or omissions. In less than optimal conditions such as these, it is preferable to postpone complex elective surgical procedures, such as that performed on Miss E.

I note that Miss E was not admitted to hospital until 1:30pm on the day of her surgery, and I therefore do not accept Dr B's submission that it would have been unnecessarily stressful for Miss E and her family to have postponed her surgery at 5:00pm. It must have been known well in advance of 5:00pm that the surgery would be after hours and therefore there was sufficient time to plan and explain a postponement.

In response to my provisional opinion Dr B submitted that each event in Miss E's case should be considered in isolation rather than as an accumulation of unfortunate events which in their totality constitute a breach of Miss E's rights. He attributed all unfortunate events back to the incorrect swab count. In my opinion it is necessary to consider all the factors that contributed to the incorrect swab count, and not to consider events in isolation.

In my opinion Dr B did not provide services with reasonable care and skill by deciding to begin Miss E's operation in the presence of so many complicating circumstances. He should have postponed Miss E's surgery until a time when the necessary resources were readily available. Dr B therefore breached Right 4(1) of the Code.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion:**Breach****Orthopaedic
Surgeon, Dr B
*continued****Redivac wound drain*

In my opinion Dr B did not exercise reasonable care and skill when placing the Redivac drain into the wound in Miss E's right hip on 7 October 1999. Dr B stated that the drain appeared to have become tangled in on itself, which was an occasional complication when wound drains were used. However, the operation note stated that the Redivac drain was caught in the deep sutures. My advisor stated that the drain appeared to have been caught by deep sutures, that this was a mistake easily made deep in a wound, but that it should have been detected when the wound was closed.

Dr B submitted in response to my provisional opinion that drain entrapment of this nature can still occur in spite of appropriate care and checks. My advisor acknowledged that it may not be easy to detect, and is not uncommon, but it is, nevertheless, a mistake.

I accept that putting Miss E under a general anaesthetic to re-open the wound and remove the drain was a reasonable course of action. However, had Dr B checked the drain before closing the wound, Miss E would not have had to undergo another surgical procedure and general anaesthetic.

In my opinion Dr B should have checked to see if the wound drain had been correctly placed and could be removed before he completed the 7 October surgery. In failing to do so, Dr B did not provide services with reasonable care and skill and breached Right 4(1) of the Code.

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion: **Rights 4(1) and 4(2)**

Breach

Nurses, Ms D and Ms C The consumer, Miss E, had the right to receive services with reasonable care and skill, in compliance with relevant standards.

The scrub nurse, Ms D, and the circulating theatre nurse, Ms C, the two nurses involved in Miss E's surgery on 13 September 1999, acknowledge that they did not complete the final swab and instrument count during Miss E's surgery on 13 September 1999. Accordingly, they did not comply with all the requirements of Hospital and Health Services' Instrument and Swab Count Policy, which required a final count of all swabs and instruments used during a surgical procedure to take place at skin closure.

Under the heading “*Surgical Count*” on the swab count form Ms C and Ms D signed indicating that the surgeon was notified that the count had been completed correctly, despite the fact that that count was not carried out. In my opinion, this is unacceptable practice.

Both nurses should have been aware during the operation that the circumstances surrounding Miss E's surgery were less than ideal. They both subsequently identified those circumstances.

Both nurses were working overtime and the surgery occurred after hours. It was complex surgery involving two wound sites. Ms D was working both as a surgical assistant and a scrub nurse. The orthopaedic theatre was being used for a trauma case so Miss E's surgery had to be done in another theatre and the operation required some additional equipment, which had not been anticipated before surgery. They were some distance from the orthopaedic theatre so that Ms C was absent while fetching necessary equipment and was not available to assist Ms D. At one point Ms D had to change places with Dr B and lost control of her trolley. When Dr B moved to the iliac crest wound and she was dressing the cervical wound, Ms D did not know what Dr B was using from her trolley.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

**Opinion:
Breach
Nurses, Ms D
and Ms C
*continued***

It should have been obvious to both nurses during the surgery that the circumstances impeded their abilities to provide effective support and to effectively monitor equipment used during the operation. The nurses had sufficient knowledge and experience to realise that their reduced ability to monitor the operation could result in serious consequences for Miss E. Therefore it became even more important that the surgical count procedure was rigorously complied with. I recognise that the additional complicating factors were outside the nurses' control, but this does not absolve them of their responsibilities for undertaking the swab count correctly and completely.

If Ms C and Ms D had completed the final swab count, they would have noticed that two swabs had not been accounted for. This omission caused Miss E ongoing problems and distress, including further hospital admissions and surgical procedures.

Ms C and Ms D did not complete the final swab count at skin closure, and did not complete the intra-operative record accurately. In my opinion they did not provide services with reasonable care and skill, or services in compliance with relevant standards, and breached Rights 4(1) and 4(2) of the Code.

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion:	Right 4(1)
Breach	
Hospital and Health Services	In my opinion Hospital and Health Services did not take reasonable actions to prevent the human error which resulted in the final swab count not being completed by the nurses assisting with the consumer, Miss E's, surgery on 13 September 1999.

I accept that, as noted by my advisor, the swab and instrument count procedure that Hospital and Health Services had in place at the time of Miss E's surgery was satisfactory and in accordance with national standards.

However, several factors set the scene for the human error that evening. These include the fact that complex orthopaedic surgery was not being performed in the orthopaedic operating theatre, as it was being used for an emergency. As a result one of the nurses therefore had to leave several times to fetch extra equipment that was required. The scrub nurse was also acting as the surgeon's assistant. There were two wound sites involved in the operation, which further complicated the procedure. Furthermore, the surgery itself began after hours, and both nurses were working overtime.

Hospital and Health Services has submitted that although these circumstances made some aspects of the case more difficult, they did not impact significantly on the failure to complete the count. I disagree, for the reasons set out above.

I consider that it is unsatisfactory to allow complex spinal surgery to take place in the presence of so many complicating factors, as this increases the likelihood of errors or omissions. In suboptimal conditions, it is preferable to postpone complex elective surgical procedures such as that performed on Miss E.

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

**Opinion:
Breach
Hospital and
Health Services
*continued***

Although the omissions were human errors, which Ms C and Ms D must take responsibility for, I recognise that these adverse circumstances had a significant influence on the situation. My advisor described them as setting the scene for the omission. This was an accident waiting to happen, and it was well within Hospital and Health Services' control to take steps to prevent this situation from developing in the first place.

In my opinion by allowing this situation to develop, Hospital and Health Services breached its duty of organisational care and skill, and therefore breached Right 4(1) of the Code.

Hospital and Health Services responded to my provisional opinion and pointed out that the implications of this would be far reaching for all hospitals with regards to use of theatres and elective surgery after 5:00pm. I agree. My advisor pointed out that although it may be acceptable to perform urgent surgery or elective surgery with a fresh team at this late hour of the day, it is not acceptable to allow elective surgery of this complexity to start at 5:00pm under these circumstances.

I have noted that Miss E was not admitted to hospital until 1:30pm on the day of her surgery. It must have been known well before 5:00pm that her surgery would be after hours and therefore there was sufficient time to plan and explain a postponement.

I note Ms C's response to my provisional opinion:

*"I would like to say that both [Ms D] and I wanted to apologise to [Miss E] and her parents when we wrote our report of events and included this in the initial report. We were told to remove this wish and are still being told the time is not yet appropriate to do this. I personally feel it should have been done a long time ago.
..."*

Continued on next page

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Opinion: In my opinion it was not acceptable for Hospital and Health Services to delay apologies to Miss E in this way. Miss E had suffered a distressing series of adverse events, and the cause of the initial problem (retained swabs) was quickly established. Ms C and Ms D should not have been prevented from apologising.

Actions I recommend that the orthopaedic surgeon, Dr B, take the following actions:

- Apologise in writing to Miss E and her parents. This apology is to be sent to the Commissioner and will be forwarded to the consumer's family.
- Review his practice in light of this report.

I recommend that Hospital and Health Services take the following actions:

- Apologise in writing to Miss E and her parents. This apology is to be sent to the Commissioner and will be forwarded to the consumer's family.
- Review the circumstances identified as setting the scene for the human error that occurred in this case, and make the necessary changes in order to minimise the risk of recurrence.
- Review the circumstances in which elective surgery is carried out, to ensure that adequate resources are available to provide an acceptable standard of care.
- Ensure that all theatre nursing staff are familiar with the Instrument and Swab Count Policy.

I recommend that nurses Ms C and Ms D take the following actions:

- Apologise in writing to Miss E and her parents. These apologies are to be sent to the Commissioner and will be forwarded to the consumer's family.
 - Review their practice in light of this report.
-

Orthopaedic Surgeon, Dr B / Nurse, Ms C / Nurse, Ms D / Hospital and Health Services

Opinion – Case 99HDC12195, continued

Other Actions Copies of this opinion are to be sent to the Nursing Council of New Zealand, the Medical Council of New Zealand, the Ministry of Health and ACC.

Copies of this report, with personal identifying features removed, will be sent to the Chief Executive Officer of each District Health Board, and the Royal Australian College of Surgeons, for educational purposes.

Other Comment I am concerned that ACC elective surgery was performed under less than optimal conditions, and will draw this to ACC's attention.
