Private Hospital Owner

Anaesthetist, Dr B

A Report by the

Health and Disability Commissioner

(Case 16HDC00882)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 10 May 2016, Mrs A was admitted to a private hospital to have decompression surgery on her back under general anaesthetic following diagnosis of spinal stenosis.

2. During the surgery, the anaesthetist, Dr B, administered an additional 6mg of morphine (to the prescribed 2.5mg of morphine) into Mrs A's epidural space in error. Dr B said that it was a "slip/lapse" by him in picking up the wrong syringe.

3. A record-keeping system is used by anaesthetists at the private hospital to record, amongst other things, what types of drugs were administered during an operation. Dr B said that the record-keeping system could have alerted him to the error but did not, owing to certain limitations with the system and how he used it during Mrs A's operation.

Findings summary

4. Dr B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code)[1] by failing to administer the correct drugs, by failing to undertake appropriate safety checks to ensure that he was administering the correct drugs, and for storing syringes for two patients in close proximity. Criticism is also made about Dr B not ensuring that the record-keeping system speaker was audible.

5. The owner of the private hospital (the company) did not breach the Code.

Recommendations

6. In light of the remedial steps already taken by Dr B following this incident, no further recommendations are made in relation to him.

7. It is recommended that the company conduct an audit of five record-keeping system records at the private hospital to ensure that drugs scanned into the system can now be linked to the epidural drug record, advise its record-keeping system supplier of the issues regarding the use of the system noted in this report, and provide an update on the implementation of the policy dealing with safe administration of drugs in this context.

Complaint and investigation

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

- *The appropriateness of the care provided to Mrs A by Dr B in May 2016.*

[1] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

- *The appropriateness of the care provided to Mrs A by the owner of the private hospital in May 2016.*

9. The parties directly involved in the investigation were:

Mrs A	Consumer
The owner of the private hospital	Provider
Dr B	Anaesthetist

10. Independent expert advice was obtained from anaesthetist Dr Malcolm Futter (**Appendix A**).

Information gathered during investigation

Background

11. On 10 May 2016, Mrs A was admitted to the private hospital to have decompression surgery on her back under general anaesthetic following diagnosis of spinal stenosis.[2] The anaesthetist was Dr B.[3]

12. During the surgery, Dr B administered an additional 6mg of morphine[4] (to the prescribed 2.5mg of morphine) into Mrs A's epidural space[5] in error. Mrs A awoke from surgery and was advised by Dr B of the error. Mrs A spent the night in the intensive care unit (ICU) as a precaution.

Medication error — how it happened

13. Dr B said that the intended dosing for Mrs A's postoperative epidural pain relief consisted of three separate drugs:

1. Morphine 2.5mg;
2. Fentanyl[6] 30 micrograms; and
3. Ropivacaine[7] 22.5mg.

14. However, instead of administering the mixture of ropivacaine/fentanyl, Dr B administered an additional 6mg of morphine into Mrs A's epidural space. He stated:

> "This occurred when I picked up another 10ml capacity syringe containing 6mg of morphine solution instead of the 10ml syringe containing the 6ml of intended

[2] Narrowing of the spine.
[3] Dr B is an independent contractor at the private hospital. He holds Anaesthesia — General privileges to provide anaesthesia services for patients operated on at the private hospital.
[4] A narcotic pain reliever used to treat moderate to severe pain.
[5] The epidural space is an anatomical space that is the outermost part of the spinal canal. Drugs may be injected through a catheter into the epidural space of the spinal cord. This is different from drugs being administered intravenously, which is where medication is administered directly into a vein.
[6] A synthetic opiate that is a powerful painkiller and tranquilliser.
[7] Local anaesthetic.

ropivacaine/fentanyl mix. The morphine syringes had been prepared for the next patient on the operating list."

15. Dr B said that it was a "slip/lapse by him in picking up the wrong syringe". He identified the following factors that he considers contributed to his error:

a) Preparing the syringes/drugs for subsequent patients before the current patient's operation has been completed.

b) Epidural syringes for two patients were in close proximity on the drug trolley.

c) The other patient's epidural morphine syringe contained 6ml (more than the dose that would be needed) and was the same volume as the intended ropivacaine/fentanyl syringe, which contributed to the misidentification of the correct syringe and increased extent of the overdose.

d) Not identifying the best sequence for administering the epidural drugs and recording their administration in the record-keeping system (discussed further below).

e) Label dispensers for the record-keeping system reducing free space on the workbench of the anaesthesia drug trolley.

f) The record-keeping system keyboard obscured his view of the benchtop on the anaesthesia machine.

16. Dr B said that all the syringes were labelled correctly, and he discovered the error when the next patient's epidural had two ropivacaine/fentanyl syringes and no morphine syringe.

The record-keeping system

17. The record-keeping system can be used from the preoperative clinic through to the post-anaesthetic care unit (PACU). It is a way of recording vital signs, what types of drugs were administered during an operation, and any complications that may have arisen. In order to use the record-keeping system, each drug that is to be administered is drawn up and labelled with a barcode. Prior to administering each drug, the anaesthetist scans the barcode, which will give both a visual and an audio prompt as to which drug is being administered. These prompts act as additional safety checks prior to administration. All data is automatically recorded in the record-keeping system online record.

18. The company introduced the record-keeping system at the private hospital in May 2016. Dr B told HDC that the company did not provide any training to him on the use of the system. Dr B had been using the system in his work as a specialist anaesthetist at a district health board (DHB) for approximately 15 months prior to its introduction at the private hospital. Dr B told HDC that at the time of its introduction at the DHB, he was provided with comprehensive training by the record-keeping system's manufacturer and distributor.

19. The company told HDC that on 5 May 2016, a memorandum was sent by email to all anaesthesia specialists,[8] advising of the implementation date of the record-keeping system, and the availability of an anaesthetic technician who was trained as a super user. The record-keeping system trainer was available on site for the first three days following the implementation of the system in May 2016. On 14 July 2016, which was after this event, a further email was sent to all anaesthesia specialists[9] offering further training as required. In response to the provisional opinion, Dr B told HDC that the memorandum sent on 5 May 2016 did not provide any documentation about the record-keeping system but offered the assistance of a technician if required. He also noted that he was not working at the private hospital between 6 and 9 March 2016, and the incident occurred on 10 March 2016.

Use of the record-keeping system

20. Dr B told HDC that he was "fully cognisant with [the record-keeping system's] operation and the application of software used to create anaesthesia records".

21. Dr B said that the record-keeping system could have alerted him to the error, but did not because he entered all the data for the epidural needle and catheter insertion by hand after the epidural process, rather than scanning the syringes just prior to injection. By way of explanation, Dr B said that he had used the scanner to record intravenous drugs for general anaesthetics (and had done so for Mrs A), but he did not know how to link a scanned drug to an epidural in the record-keeping system.

22. Dr B further explained that entering data in the record-keeping system and administering drugs are both clean procedures[10] in an operating theatre environment, but placing an epidural catheter[11] is a sterile procedure.[12] It was because placing an epidural catheter is a sterile procedure, and entering data into the record-keeping system is not, that Dr B manually recorded the epidural drugs given after the event (rather than just prior to injection) as part of the process of recording the technique.

23. The company said that at the time of the incident, the record-keeping system recorded a scanned syringe used for an epidural amongst the record of intravenous infusions. The company explained that to avoid this and keep the epidural medication record accurate, many anaesthetists enter epidural data by hand to get it recorded in a separate part of the record (in the way that Dr B did in this case). In response to this incident, the company raised the issue with the record-keeping system, which has now

[8] Including Dr B.
[9] Including Dr B.
[10] A clean procedure (also known as a non-sterile procedure) is a procedure where strategies are used in patient care to reduce the overall number of microorganisms or to prevent or reduce the risk of transmission of microorganisms from one person to another or from one place to another. Clean technique involves meticulous handwashing, maintaining a clean environment by preparing a clean field, using clean gloves and sterile instruments, and preventing direct contamination of materials and supplies. No "sterile to sterile" rules apply (see also footnote 12).
[11] See footnote 5 above.
[12] A sterile procedure is a procedure where strategies are used in patient care to reduce exposure to microorganisms and maintain objects and areas as free from microorganisms as possible. Sterile technique involves meticulous hand washing, use of a sterile field, use of sterile gloves for application of a sterile dressing, and use of sterile instruments. "Sterile to sterile" rules apply and involve avoiding contact between sterile instruments or materials and any non-sterile surface or products.

modified the software to address the issue. The company did not indicate whether the issue of being unable to enter data in the record-keeping system during a sterile procedure has been addressed.

24. The further issue that Dr B identified was that the speaker in the record-keeping system monitor in theatre had not been switched on, so there was no audible identification of scanned drugs prior to administration. The company said that "typically we would expect the volume setting of systems such as the record-keeping system to be at a level sufficient to alert specialists and staff working … but not sufficient to disrupt the overall conduct of theatre".

Post-error care

25. Following the operation, Mrs A was taken to PACU and, at that time, Dr B realised his error.[13] He said that at that time he still had the next patient on the operating list and under his care. Dr B informed PACU staff of the medication error. Dr B said that no particular issues of concern had been raised by the PACU staff attending to Mrs A.

26. Nursing notes from staff at PACU state that at 5.20pm, a co-ordinator informed the nurse and team leader of the medication error. Prophylactic naloxone[14] 40mg was given per a verbal order from Dr B when PACU nurses reported that Mrs A's breathing had "slowly fallen". It was noted that Mrs A was rousing easily and her vital signs were stable, although she was complaining of nausea. Dr B prescribed two further drugs, ondansetron[15] and droperidol,[16] to be used postoperatively.

27. Dr B arranged for Mrs A to be transferred to ICU for overnight monitoring as a precaution. It was noted that at 6.15pm, Dr B advised Mrs A's family of the medication error and completed an incident report. Mrs A was discharged home on 13 May 2016.

Subsequent events

28. On 24 May 2016, Dr B wrote to Mrs A and apologised. He explained the medication error in detail and the changes he has implemented.

29. On 15 June 2016, the owner of the private hospital wrote to Mrs A to apologise and advise that it had carried out a review of its systems and processes, and outlined its recommendations.

Further information — Dr B

30. Dr B acknowledged from the outset that he was responsible for the error.

31. Dr B said that as a result of this case:

[13] Dr B intended to give, and recorded as having been given, ropivacaine and fentanyl (electronically on the system, in real time); however, when that record was printed (which accompanies the patient to PACU), Dr B corrected the record by hand to reflect that ropivacaine and fentanyl had not been given.
[14] An opioid antagonist (antidote).
[15] A drug used to prevent nausea and vomiting.
[16] A drug used in the treatment of nausea.

a) He now physically separates all pre-prepared drugs for subsequent patients by placing them on a separate surface from the current patient's anaesthesia drugs.

b) He now ensures that single-dose epidural morphine syringes contain only the intended dose.

c) He now knows how to link scanned drugs to the record-keeping system.

d) The record-keeping system's speaker has been made audible, and the speaker volume in other theatres has been checked.

Further information — the owner of the private hospital

32. The company told HDC that it considers it inappropriate to place syringes for different patients on the same drug trolley, and that it is developing a policy to address concerns about this practice (mentioned further below). The company considers that the management of syringes is part of the anaesthetist's practice.

33. The company stated that "[The private hospital] goes to great lengths to ensure a safe, efficient and robust clinical environment is provided to clinicians". It said that no concerns have been raised by the anaesthetists about a lack of space for anaesthesia drugs.

34. The company conducted a Root Cause Analysis following this incident. It was reviewed by the private hospital's Clinical Advisory Committee on 12 July 2016. The findings were:

a) Training had not been provided for the DHB anaesthetists, as the record-keeping system was already in use in DHB theatres.

b) Drugs had been drawn up in advance for the next patient and kept on the anaesthetic machine with the current patient's drugs.

c) The record-keeping system had not been used in the manner in which it was designed to be used.

35. The company advised that it has made the following recommendations and improvements:

a) It has developed a policy to deal with safe administration of drugs in this context. The policy recommends that only one patient's medications be prepared at any one time.

b) It has recommended that the record-keeping system drug scanning facility be used by all anaesthetists before medications are given to patients.

c) The record-keeping system's monitor speaker will be checked each morning to ensure that the volume level is clearly audible. The check is now included on the daily checklist.

d) The record-keeping system's Super Users are available on request to provide further training to anaesthetists.

Responses to the provisional opinion

Mrs A

36. Mrs A was provided with an opportunity to comment on the "information gathered" section of the provisional opinion. She advised that she had no further comment to make.

Dr B

37. Dr B provided responses to the provisional opinion personally and through his legal counsel. Where relevant, parts of his response have been included in the "information gathered" section above or set out below.

38. Dr B reiterated the rehabilitative steps that he took immediately following the incident. He acknowledged his part in the error and submitted that HDC should consider taking a systems-level approach to this incident.

The owner of the private hospital

39. The Chief Operating Officer provided the following response to the provisional opinion:

> "I am comfortable with your provisional opinion, proposed course of action and recommendations. As part of our own investigation into this matter we have finalised the policy [to deal with safe administration of drugs], taken this through our Medical Advisory Committees at each of our [facilities], and communicated same to all anaesthetists practicing across our [facilities]."

Opinion: Dr B — Breach

Safe administration of medication — Breach

40. The sequence of events leading to the error in this case is not in dispute. Dr B acknowledged his error and made immediate changes to his practice to prevent a recurrence. I note that Dr B took immediate and appropriate action following his error.

Medication administration error

41. During surgery, Dr B administered an additional 6mg of morphine into Mrs A's epidural space instead of the intended ropivacaine/fentanyl mix. He stated:

> "This occurred when I picked up another 10ml capacity syringe containing 6mg of morphine solution instead of the 10ml syringe containing the 6ml of intended ropivacaine/fentanyl mix. The morphine syringes had been prepared for the next patient on the operating list."

42. Dr B also acknowledged that picking up the wrong syringe was a "slip/lapse" by him.

43. As part of this investigation, I obtained independent expert advice from anaesthetist Dr Malcolm Futter. Dr Futter advised that, overall, the care provided by Dr B was

good, and Dr Futter considered the medication administration error to be a minor departure from accepted standards.

44. Dr B was aware that the record-keeping system would not alert him to any error relating to the epidural medication because, for the reasons he has provided, he did not scan the drugs prior to administering them. Despite this, it is apparent that he did not undertake any alternative safety check to verify that he was administering the correct drugs before doing so. This is suboptimal. In my view, the safe administration of drugs in anaesthesia cannot be compromised, as failing to do so, particularly in relation to the epidural space, can have potentially life-threatening consequences for the patient.

Storage of syringes

45. Dr B told HDC that one aspect that contributed to him making the medication error was that he had prepared the epidural syringes for two patients in advance of the surgery, and they were in close proximity on the drug trolley.

46. Dr Futter advised that it is not unusual to have syringes on the trolley that may not be intended for use on the current patient but, if there are, they need to be quite separate. I acknowledge Dr Futter's advice that this practice is not unusual.

47. In my view, it is inherently risky to place epidural syringes for two patients in close proximity on the drug trolley. If syringes for two patients need to be prepared in advance, the syringes need to be sufficiently separate to ensure that they cannot get mixed up. It is clear that Dr B's own system for ensuring that the two patients' syringes did not get mixed up was inadequate and unsafe.

Conclusion

48. I have noted above that, in my opinion, Dr B took immediate and appropriate action following his error. I also acknowledge that Dr Futter considers the medication error to be a minor departure from accepted standards, and that Dr B's storage of syringes was not an unusual practice. However, in my view, by failing to administer the correct drugs, by failing to undertake appropriate safety checks to ensure that he was administering the correct drugs, and for storing syringes for two patients in close proximity, Dr B did not provide services to Mrs A with reasonable care and skill. Accordingly, Dr B breached Right 4(1) of the Code.

Use of the record-keeping system — Adverse comment

49. Dr B said that the record-keeping system could have alerted him to the error but did not because he entered all the data for the epidural needle and catheter insertion by hand after the epidural process, rather than scanning the syringes just prior to injection. Dr B explained that entering data in the record-keeping system and administering drugs are both clean procedures in an operating theatre environment, but placing an epidural catheter is a sterile procedure. Because it is a sterile procedure, he records the drugs initially given after the event as part of the process of recording the technique.

50. Dr Futter advised that Dr B's use of the record-keeping system was not "atypical", and that his manual entry of dosing into the record-keeping system rather than scanning the syringe barcodes is not uncommon, and cannot be regarded as

inappropriate. I accept Dr Futter's advice that Dr B's use of the record-keeping system was not unusual. I am therefore not critical of Dr B's practice in this respect. However, in my view, there is a flaw in the record-keeping system if there is no way to enter data into the system during a sterile procedure. This flaw needs to be addressed.

51. Dr B told HDC that he was provided with comprehensive training by the DHB on the record-keeping system, and that he was fully cognisant with its operation. However, he has acknowledged that he did not know how to link a scanned drug to an epidural.

52. Dr B told HDC that the speaker on the record-keeping system monitor in theatre had not been switched on, so there was no audible identification of the scanned drugs. Dr Futter advised: "[I]t is not uncommon for the volume control of the audio alert component of [the record-keeping system] to be turned down. Sometimes this is because of complaints by other staff of the distraction to them of having information irrelevant to the tasks they are undertaking being broadcast in theatre." He concluded that "the absence of the audio alert in this instance cannot be regarded as particularly unusual". I acknowledge Dr Futter's advice but consider that Dr B should have ensured that the equipment he was using was set up properly and functioning well. In particular, Dr B should have ensured that the record-keeping system speaker was audible.

Opinion: Owner of the private hospital — other comment

Introduction

53. The private hospital is owned and operated by a company. Dr B is an independent contractor at the private hospital. He holds general privileges to provide anaesthesia services for patients operated on at the private hospital.

Medication error

54. In my view, Dr B's drug administration error was a result of an individual clinical error and individual decision-making. The company does not condone storing syringes for two patients on the drug trolley at the same time. As a result of this incident, the company has drafted a policy dealing with safe administration of drugs in this context. The policy recommends that only one patient's medications be prepared at one time. I am not critical of the company in this regard, and consider that the remedial steps taken are appropriate.

The record-keeping system

55. The company introduced the record-keeping system at the private hospital in May 2016. Dr B told HDC that the company did not provide any training to him on the use of the record-keeping system. In contrast, the company provided two emails to HDC (showing Dr B as a recipient to both emails), one of which was sent prior to this incident, where support or training was offered. While I accept that the company offered support with the use of the record-keeping system, I consider that it would have been prudent for the company to have followed up with Dr B, and not to have

assumed his (and other anaesthetists') skill level with the use of the record-keeping system.

56. The company did not ensure that the record-keeping system speaker was being turned on in the operating rooms. Dr Futter advised:

> "[I]t is not uncommon for the volume control of the audio alert component of the record-keeping system to be turned down. Sometimes this is because of complaints by other staff of the distraction to them of having information irrelevant to the tasks they are undertaking being broadcasted in theatre."

57. Dr Futter concluded that "the absence of the audio alert in this instance cannot be regarded as particularly unusual". I note that the company has now included a check of the record-keeping system monitor speaker on their daily checklist, and I consider this to be appropriate.

Recommendations

58. In response to this incident, Dr B apologised in writing to Mrs A, reviewed his practice in relation to injectable drug safety, and undertook further self-learning on the record-keeping system. Accordingly, I do not intend to make any further recommendations in relation to Dr B.

59. I recommend that the company:

a) Conduct an audit of five of the record-keeping system records at the private hospital to ensure that drugs scanned into the record-keeping system can now be linked to the epidural drug record, and report back to HDC with the results of its audit within two months of the date of this report.

b) Advise its supplier of the record-keeping system of the issues regarding the use of the record-keeping system noted in this report, including investigating whether the record-keeping system can be modified to allow data to be entered during sterile procedures, and report back to HDC within two months of the date of this report.

c) Provide an update on the implementation of the policy dealing with safe administration of drugs in this context at the private hospital, within two months of the date of this report.

Follow-up actions

60. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and the DHB, and they will be advised of Dr B's name.

61. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Australian and New Zealand College of Anaesthetists, and the Health Quality and Safety Commission, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent expert advice to the Commissioner

The following expert advice was obtained from anaesthetist Dr Malcolm Futter:

"The following report has been prepared after reading and agreeing to the HDC's 'Guidelines for Independent Advisors'.

Since 1983 I have practised as a specialist anaesthetist, principally at Auckland, Starship and Wellington Hospitals and have had occasion to use [the same record-keeping system]. In addition to acting as an advisor to the Health and Disability Commissioner's office I advise the Accident Compensation Corporation. Other non clinical activities have included New Zealand hospital accreditation and audit, work on behalf of the Australian and New Zealand College of Anaesthetists and the Ministry of Health.

Paragraphs 1–8 below follow the numbering used in the 'scope of advice' requested in the letter from the HDC dated 29th August 2016.

Based on copies of hospital notes, other documents and correspondence provided the following are responses to questions posed regarding the anaesthesia care provided to [Mrs A] by [Dr B] on 10th May 2016 at [the private hospital].

1. *Was it appropriate for [Dr B] to place syringes for different patients on the same drug trolley?*
   It has not been unusual to have syringes on the trolley that may not be intended for use with a current patient. The most common instance has been when syringes of 'emergency' drugs have been prepared and, if unused, remained on the trolley for the duration of the operating list. With increasing awareness of the potential for cross contamination this practice is probably now less common but so long as there is strict asepsis in preparation of such syringes of drugs and they are 'quarantined' in such a way as to avoid any significant risk of cross contamination such practice cannot be considered 'inappropriate'. The other instance when syringes not intended for a current patient are on the trolley is when an attempt is being made to be 'efficient' and reduce the time required between cases by preparing drugs and equipment in advance. Once again, such preparations must observe complete asepsis and/or possible cross contamination and as much for those reasons as to avoid 'syringe swaps' the syringes need to be kept quite separate from those currently in use. That being said there are many operating theatres where the space available is limited and drug syringes are on the same locker albeit in a different drug tray.

2. *Given [Dr B's] comment that there was limited space on the anaesthesia drug trolley and the anaesthesia machine, was administration of the drugs in that setting appropriate?*
   As noted above a relative lack of work space is not uncommon. As intraoperative care has become more complex more equipment and drugs are used or are required to be readily at hand (e.g. [record-keeping system] keyboards and syringe labels). Operating theatres and preparation/storage facilities tend not to keep pace with the demand for more space. To avoid

the administration of drugs in all such circumstances would be impractical and should not be regarded as 'inappropriate'.

3. *Was it appropriate for [Dr B] to have intended to give, and recorded as having given, ropivacaine and fentanyl and subsequently annotating the anaesthetic record to reflect that they were not given?*
   At the time of recording the administration epidural ropivacaine and fentanyl and when the recording was printed [Dr B] believed he had given the ropivacaine and fentanyl (the [record-keeping system] allows recording in real time onto an electronic database which is then used to produce a printed paper copy of an anaesthetic record which accompanies the patient when they transfer from the operating room to PACU). Thus when he had discovered his error the most straight forward way of 'correcting' the record was to annotate it as he did. It may have been possible to retrieve the electronic record from the database, make the corrections directly, added explanatory comment and then reprint it. However it appears [Dr B] was in the operating theatre with the next patient when the error was discovered and attempting to suspend the recording of their anaesthetic to edit [Mrs A's] record may not have been easy. Given that there was no attempt to misrepresent or hide information the anaesthetic record with corrections/annotations is not 'inappropriate'. In fact the 'annotation' was incomplete in that the drugs may have been 'struck through' on one page of the anaesthetic record but remain shown as having been given on the page with the timed physiological data. As an aside, it is not stated anywhere in the information provided to me whether there has subsequently been any correction made to the electronic record of [Mrs A's] anaesthesia record — this is probably held on the [record-keeping system's] server.

4. *Did [Dr B] respond appropriately to [Mrs A's] symptoms?*
   The symptoms noted by [Mrs A] in her letter of June 9th are nausea and dizziness.

   Unfortunately nausea is a relatively common side effect of epidural morphine and is not always dose related despite what [Dr B] implies in his letter of July 14th to [a staff member] in the HDC's office. Thus in someone with a history of nausea in association with two less potent opioids (codeine and tramadol) its occurrence on this occasion might have been anticipated, regardless of whether a 'normal' dose of epidural morphine or an accidentally larger one was given. Indeed [Dr B] appears to have considered this both during the consent process and when he gave intraoperative dexamethasone (an anti nauseant shown to be effective for epidural morphine related symptoms) and prescribed two further drugs for use post operatively (ondansetron and droperidol). In addition [the medical practitioner] who [Dr B] transferred immediate post-operative care to when [Mrs A] went to ICU, prescribed transdermal hyoscine (Scopaderm). The use of four drugs to treat nausea would normally be regarded as appropriate, the use of further medicines (eg cyclizine) increasing the

likelihood of side effects such as dizziness. It is not possible to determine the cause of [Mrs A's] dizziness. It may have been due to the morphine or the droperidol she received, post-operatively (recordings demonstrate it was not due to hypotension). I am unable to comment on how [Mrs A] and her family perceived [Dr B's] approaches to them however from her letter [Mrs A] does appear to have been inappropriately informed (e.g. by 'two different medical people') of the risks of the situation she was in and thus [Dr B's] response may have seemed insufficient.

5. *Was it appropriate for [Dr B] to enter the details for the epidural needle and catheter insertion by hand rather than scanning the syringe barcodes into the [record-keeping system] prior to injection?*
   From the information supplied it is unclear how the epidural drugs were given and thus the following comments are based on my own previous experience. It is likely that towards the end of the surgery the surgeon threaded a catheter into the epidural space under 'direct vision' and aseptically handed it to [Dr B] so that he could administer the drugs from syringes the outsides of which were not sterile. The timing of the drug administration and the description of it being a 'single shot' technique would fit with this. If that is the case then [Dr B] did not enter details by hand but used the 'drop down' menus in the [record-keeping system's] program to indicate a single lumbar epidural dose of ropivacaine, fentanyl and morphine was inserted at 14.59h on 10th May by the surgeon. The [record-keeping system] program automatically shows the name of the inserting anaesthetist as the person who has signed into the program. It is not uncommon for details of drugs used in regional anaesthesia to be entered into the record using the same method as [Dr B] (e.g. when the anaesthetist is gowned and draped with a sterile syringe of drugs which does not carry a bar code and is remote from the bar scanning hand piece). Furthermore he noted in his letter to [Mrs A] that at the time he did not know how to 'import' scanned drug data into the regional anaesthesia record. Even if he had known it would still require 'manual' entry of dosing since scanning only identifies the drug not the dose that is given. Because this method of data entry is not uncommon it cannot be regarded as inappropriate.

6. *Comment on the adequacy of the safety systems in place at the time of events, namely, use of the [record-keeping system] record-keeping system and whether it was adequately utilised.*
   For a variety of reasons [the record-keeping system] is rarely used to its full capacity, e.g.:

   - The use of pre-filled barcoded syringes is very limited because of their cost.
   - Scanning of syringes immediately pre administration is not always undertaken because of the delays in administration that can ensue (e.g. in emergent situations) and/or the physical challenge of scanning and injecting at a remote site.

- Event data is also commonly entered non concurrently and may be derived from a personalised drop down menu rather than being constructed as procedures are carried out on a particular patient.
- 'Human factors'.

Thus [the record-keeping system] often does not provide the degree of safety that is theoretically possible.

From the documentation it is not possible to know exactly how the system was utilised by [Dr B], however his description of what occurred and the recordings suggest his utilisation of the system was not atypical.

7. *Should the audio alert speaker in [the theatre] for the [record-keeping system] system have been switched on?*
   Even when switched on it is not uncommon for the volume control of the audio alert component of [record-keeping system] to be turned down. Sometimes this is because of complaints by other staff of the distraction to them of having information irrelevant to the tasks they are undertaking being broadcast in theatre (to 'command attention' in an environment where there is other conversation and tools being used the volume level has to be relatively loud). Thus the absence of the audio alert in this instance cannot be regarded as particularly unusual.

8. *What was the adequacy of [Dr B's] overall care of [Mrs A]?*
   Overall the care provided by [Dr B] was good and with the exception of his error in giving a second dose of epidural morphine instead of ropivacaine/fentanyl there was no departure from accepted standards. Contrary to what [Mrs A] may have been informed by others the dose of morphine she received was only slightly above the normal dose range for epidural morphine (30–100mcg.kg) and she was at little risk of any life threatening side effects particularly since the 'overdosage' was recognised early and appropriate measures taken. After any neuraxial administration of opiates it is routine to carefully observe patients for signs of respiratory depression for about 18 hours — in this case the decision to admit to the ICU was particularly careful. [Dr B's] response to his drug administration error was exemplary and his use of the [record-keeping system] system did not represent a significant departure from the practice of many of his peers. It is unfortunate that [Mrs A] felt he appeared 'unconcerned' and that his appropriate attempts to avoid or treat nausea were unsuccessful.

   With regard to the drug administration error — although the epidural drugs had been placed in a separate tray to ensure nothing could be administered that was neurolytic it was still inappropriate to mistakenly give a larger than intended dose of epidural morphine. Notwithstanding [Dr B's] effective, timely response it is my opinion that his error represented a departure (albeit a minor one) from the normal standard of care.

   Whilst it would be desirable to encourage better organisation of space in anaesthetists' working environment and the optimal use of [the record-

> keeping system] it should be noted that in the Auckland region, where [the record-keeping system] has been used for many years, the same challenges still exist.

If there is any further advice or comment required please do not hesitate to contact me.

Yours sincerely,

Dr Malcolm Futter
19th September 2016"