Anaesthetist, Dr B

A District Health Board

A Report by the

Health and Disability Commissioner

(Case 05HDC07699)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Dr B	Provider/Anaesthetist
A District Health Board	Provider/District Health Board
Dr C	Anaesthetist
Dr D	Orthopaedic surgeon

Complaint

On 30 May 2005 the Commissioner received a complaint from Mrs A about the services provided by Dr B. The following issues were identified for investigation:

- *The appropriateness of choice of anaesthetic (morphine based) and the method (spinal) it was administered by Dr B to Mrs A at a public hospital on 10 January 2005.*

- *The appropriateness and adequacy of the information provided by Dr B to Mrs A about the proposed anaesthetic.*

An investigation was commenced on 13 September 2005.

The investigation has taken 12 months to complete, owing to unavoidable delays. Information from the parties highlighted systems issues and a conflict of evidence, which required further investigation, expert advice and legal analysis. The investigation was also temporarily suspended to acknowledge a family bereavement suffered by one of the parties.

Information reviewed

Information provided by:

- Mrs A
- Mrs A's general practitioner
- Dr B
- Dr C
- A District Health Board
- ACC

Independent expert advice was obtained from Dr Vaughan Laurenson, anaesthetist.

Information gathered during investigation

Background
Mrs A, aged 76 years, had a history of osteoarthritis in her left knee, arthritis of the spine, problems with her left Achilles tendon, Parkinsonism, angina, hypertension, chronic obstructive pulmonary disorder (COPD), ischaemic heart disease (IHD), and gastro-oesophageal reflux disease (GORD). She also has an allergy to morphine, and wears a MedicAlert bracelet, which states: "Adverse reaction to Codeine, Morphine and Lumuth. Hypertension. NZ56835".

Decision to perform surgery
Mrs A was referred to orthopaedic surgeon Dr D regarding her ongoing knee pain. She decided to have elective surgery to replace her left knee joint. On 19 May 2004, Dr D obtained Mrs A's consent for surgery and any anaesthesia needed for this procedure. Mrs A's morphine allergy was included under the special alerts on the request for admission form completed by Dr D. The surgery was scheduled for 10 January 2005.

Preoperative assessments
Mrs A attended a preoperative assessment at a public hospital on 4 November 2004. She was seen by a house surgeon and anaesthetist Dr C. Dr C told Mrs A that she would be given morphine, which would be injected into her back. Mrs A told Dr C that that could not happen because she was allergic to morphine. Dr C informed Mrs A that "they would have to wait and see what happened when they got down to surgery and mentioned other alternatives". Dr C recorded "morphine causes colic" under the allergies section of the pre-assessment form, as well as "understands risks and accepts all". Dr C also noted that spinal anaesthesia was probably not appropriate in Mrs A's case. Dr C did not explain any alternatives to Mrs A. Mrs A assumed that morphine would not be used. Dr C thought she had recorded Mrs A's wishes regarding morphine in the medical notes but there is no record of this discussion in Mrs A's clinical record.

Prior to the surgery on 10 January 2005, Mrs A was seen by anaesthetist Dr B, while she was on the bed outside the operating theatre. Mrs A had not previously met Dr B. Mrs A said there were four or five other people with Dr B. Dr B informed Mrs A that he was going to inject a small amount of morphine into her spine. Mrs A said that he could not do that because she was allergic to morphine, and indicated her MedicAlert bracelet. Dr B did not look at the bracelet, but stated that it was only a small amount of morphine and that she would be fine. He said that he believed her reaction to morphine was only a side effect, not an allergy. Mrs A said she did not consent to the morphine, and told Dr B: "If you do it, you can take the consequences as I might die."

The DHB advised that the other staff present either do not recall or were not close enough to overhear the conversation.

In his report to ACC, Dr B stated:

> "In my mind intrathecal morphine was the preferred option. The confounding thing was the morphine allergy. Though I had no doubt that it was only a side effect and not an allergy, I was well aware of the fact that [Mrs A] was very anxious due to her past experience and did not want me to use morphine. I proceeded to explain to her that she did not have an allergy and what she described was a side effect. I stressed the need for effective pain relief in the peri-operative period and that intrathecal morphine which consisted of injecting a minute amount of morphine into the spinal fluid was the best option in spite of her fears of morphine allergy.
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> I wholeheartedly believed I had her consent and understanding.
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> Her intra-operative course was uneventful. She developed chest pain typical of angina relieved by GTN spray in the PACU. Though her ECG was normal she was observed in the ICU for a number of hours till we were reassured that she was stable. She had some nausea which was relieved by an anti-emetic. She felt well enough to eat after this. This was followed by more nausea again relieved by anti-emetics. She had excellent post-operative analgesia.
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> [Mrs A] continued to have symptoms of nausea and dizziness for the next several days. It is worth noting that she was put on tramadol for her pain after the effects of intrathecal morphine wore off. This has a high propensity to cause nausea and vomiting. Her dizziness was due to postural hypotension related to her antihypertensive medication and was present long before her operation.
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> **Summary**
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> In summary [Mrs A] was seen in the preoperative clinic where her consent was taken. Her reported 'allergy' to morphine was noted and considered. After careful consideration and review it was my opinion that she was not allergic to morphine but rather had a history of suffering some side effects. Providing optimal care for her required balancing a number of considerations. I clearly believed there were distinct advantages in using intrathecal morphine, given the fact that she had COPD and IHD.
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> Post operatively [Mrs A] did not have colicky abdominal pain which was the stated symptoms of her allergy. She had excellent analgesia. Nausea on the 1st postoperative day onwards is most likely to have been due to tramadol. Dizziness was a pre-existing condition related to anti-hypertensives."

Knee surgery
The operation was successfully performed by Dr D with no complications. The medical notes record that intrathecal morphine was used as part of the anaesthesia.

Postoperatively Mrs A was unwell, with chest pain, bilateral chest wheeze, nausea, vomiting and hypotension. She was admitted to the Intensive Care Unit (ICU).

Mrs A was discharged on 18 January 2005, but returned to the Emergency Department on 26 February 2005. She reported feeling unwell since the operation, with dizziness, and had fallen approximately four times after discharge. During the last of these falls on 25 January she had struck her head and had had neck pain and headaches ever since.

Complaint
Mrs A complained that Dr B gave her morphine prior to the operation on 10 January, even though she was allergic to it, and he was aware of this allergy. She believes the reason she ended up in ICU, and her subsequent dizziness and falls, was due to being given morphine.

ACC
Mrs A's claim to the Accident Compensation Corporation (ACC) Medical Misadventure Unit was declined on 21 October 2005. ACC obtained independent expert advice from Dr Dave Chamley, anaesthetist.

Dr Chamley advised:

> "In my opinion, there is no causal relationship between the administration of intrathecal morphine and her dizziness and falls.
>
> … Her GP records are difficult to read, however I interpret the comment of 26 October 2004 as a consultation re complaints of frequent dizziness."

Dr Chamley went on to state:

> "This case does highlight a system issue at [the public hospital], that is, the lack of documentation of specific anaesthetic consent, as required by the College of Anaesthetists. While not an issue raised by ACC, my understanding of [Mrs A's] complaint is that she was given a drug which she thought she was allergic to, and that inherent in this is that she did not agree to this.
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> The specific College requirement is:
>
> > '**DOCUMENTATION OF CONSENT**
> > The extent of documentation may be dictated by local legislation and practice but it is wise to record significant details of the consent as part of the patient's notes, including reference to the discussion of relevant material risks and the agreement by the patient to undergo the treatment.

> In order to defend claims that 'informed consent' information was not given or was inadequate, it is highly recommended that detailed notes of the discussion and all risks considered are kept by the provider.'

This does not appear to have occurred. While the use of a specific anaesthetic consent form does not mean that consent has actually been given, it does encourage the documentation referred to above. While [Dr C] had briefly documented some discussion, as she was not conducting the procedure, and as no decision had been made at that time as to exactly what anaesthetic would be used, it is hard to see how this is adequate. Given that [Dr B] intended to give a drug which he was aware [Mrs A] did not want, then regardless of the validity or otherwise of his views re the allergy, discussion re this should have been documented. There is no contemporaneous record of any discussion between [Dr B] and [Mrs A], or any record of [Mrs A] giving consent to the proposed course of action.

The NZ Medical Council requires consent to comply with the HDC Act. The Code of Rights states:

> 'Where informed consent to a health care procedure is required, it must be in writing if —
> a) The consumer is to participate in any research; or
> b) The procedure is experimental; or
> c) The consumer will be under general anaesthetic; or …'

While this is not explicit that written consent must be given for anaesthesia, and while in this case sedation was used, not general anaesthesia, the clear implication to me is that consent for anaesthesia should be in writing, particularly where there are contentious issues, as the morphine 'allergy' was in this case.

[The public hospital] should be encouraged to consider introducing specific written consent for anaesthesia."

Dr Chamley also commented:

"[Mrs A] appears unhappy that intrathecal morphine was used when she clearly considered she was allergic to it, and that morphine should not be used. The validity, or otherwise, of the allergy is not the point at issue. It is clear from [Dr B's] letter of 8 August, in which he states that [Mrs A] was 'very anxious due to her past experience and did not want me to use morphine', that he understood she did not want him to use Morphine. It is difficult to reconcile this with his later statement 'I wholeheartedly believed I had her consent and understanding'.

It is difficult to understand [Dr B's] decision to use intrathecal morphine in light of [Mrs A's] objections, regardless of whether or not he considered her objections valid. While there may be significant agreement with his avoidance of general

anaesthesia in view of his concern re general anaesthesia, this would by no means be unanimous. The use of intrathecal morphine was however, for post-operative pain relief, and it is difficult to understand why [Dr B] felt that there were only two alternatives. His letter of 8 August completely ignores the use of post-operative epidural analgesia, and the use of sciatic/femoral block, both of which are common techniques to provide analgesia in the post-operative period. I do not consider that there is good evidence that any one particular technique is 'better' than any other, different techniques have different advantages and disadvantages. His statement that 'intrathecal morphine was the preferred option' is merely a statement of his personal opinion and preference.

It is extremely unfortunate that there is no contemporaneous written record of any discussion between [Dr B] and [Mrs A] regarding the use of morphine. I do not disagree with [Dr B's] assessment of the significance of [Mrs A's] allergy to morphine, but consider that it was unwise to use morphine without contemporaneously documenting any discussion with her, and the outcome of such discussions."

Independent advice to Commissioner

The following expert advice was obtained from anaesthetist Dr Vaughan Laurenson:

"Thank you for asking me to provide expert advice on this case. The complaint concerns the standard of care, and in particular, issues related to consent, when [Mrs A] underwent surgery on the 10th of January 2005. I have read and agreed to follow the Health and Disability Commissioner's guidelines for independent advisers.

I qualified as a specialist anaesthetist (FFARACS) in 1981, and I have practised full-time in Christchurch since then. My clinical practice has a significant component of anaesthesia for orthopaedic surgery.

The Commissioner's office has asked me for advice on:

1. In your professional opinion, was the service [Dr B] provided to [Mrs A] appropriate? Please give reasons for your opinion, with reference to the individual staff members involved.

2. If the care provided was not appropriate, please explain why.

3. What standards apply in this case? Were these standards satisfactorily applied by [Dr B]?

If not covered above, please answer the following:

4. Was [Dr B's] decision to use morphine to anaesthetise [Mrs A] appropriate? If not, why not?

5. Were there other anaesthetic options available to [Dr B] apart from morphine? Please explain.

6. Was [Dr B's] discussion with [Mrs A] about anaesthetic prior to surgery appropriate? If not, why not?

7. Please comment on the issue of informed consent regarding the administration of morphine to [Mrs A].

8. Did [Dr B] follow [the District Health Board] policies in administering morphine to [Mrs A]? If not, why not?

If, in considering the information provided, you believe that [Dr B] did not provide an appropriate standard of care, please indicate the severity of the departure from that standard.

To assist you on this last point, I note that some experts approach the question by considering whether the providers' peers would view the conduct with mild, moderate, or severe disapproval.

Are there any aspects of the care provided by [Dr B] that you consider warrant additional comment?

I have reviewed the following documents which were supplied:

1. Letter from [Mrs A's solicitor] on behalf of [Mrs A], dated 26 May 2005, marked 'A' (numbered 1–2).
2. Medical records received from [the District Health Board] on 18 July 2005, marked 'B' (numbered 3–86).
3. Copy of letter sent to [Mrs A's solicitor] by [the District Health Board's solicitors], on 20 July 2005, marked 'C' (numbered 87–88).
4. Letter dated 17 September 2005 from [Mrs A's general practitioner], marked 'D' (numbered 89).
5. Letter dated 3 October 2005 from [Dr B] and enclosures, marked 'E' (numbered 90–95).
6. Letter dated 6 October 2005 from [the District Health Board] and enclosures, marked 'F' (numbered 96–127).
7. Letter dated 11 October 2005 from [Mrs A's solicitor] on behalf of [Mrs A], marked 'G' (numbered 128–129).
8. Letter dated 12 October 2005 from [Dr C], marked 'H' (numbered 130).
9. Email dated 14 October 2005 from [Dr C], marked 'I' (numbered 131).

History

In reviewing the history of the case I will only comment on matters relevant to those I have been asked to report on.

The consent for both surgery and anaesthesia (p61) was obtained by the surgeon, apparently when [Mrs A] was booked for surgery. It is dated 19/5/04 which is approximately seven months before the surgery occurred. The request for admission (p59–60) included morphine allergy under the special alerts.

The next recorded contact [Mrs A] had with the hospital was on 4/11/2004 when she attended for orthopaedic preadmission and an anaesthetic consultation (p53–55). Both [the orthopaedic house surgeon] and anaesthetist, [Dr C] recorded 'morphine causes colic' under allergies. Eleven months later, in an Email (p131) [Dr C] recalled a consultation with someone she thinks was [Mrs A]. She recalled that when she tried to explain that colic was a side effect, rather than an allergy to morphine, [Mrs A] was adamant that she did not want morphine to be given to her. There was apparently a failure to record this in the notes and hence make the information available to [Dr B].

[Dr B], the anaesthetist in this case, first met [Mrs A] in the reception area outside the operating theatre. There are no contemporary records of this consultation, and there is conflicting information in the three relevant reports; [Mrs A] with her lawyer (p1–2) dated 26/5/05, [Dr B's] report to ACC (p91–93) dated 8/8/05, and [Mrs A's] response to the HDC (p128–129) dated 11/10/05.

There is agreement from both parties that a discussion about the use of intrathecal morphine took place. [Dr B] was aware of her reported allergy to morphine. He reviewed her old notes, where he noted she had received omnopon (active ingredient morphine) during a previous anaesthetic, without any apparent problems during a previous admission. He advised her it was safe to administer morphine. [Mrs A] is sure she did not give consent, while [Dr B] believed he had consent. [Dr B] proceeded to do the spinal anaesthetic, which included intrathecal morphine.

[Mrs A] was admitted to the intensive care unit postoperatively, but made a good recovery and was discharged from hospital eight days after her operation. Whether her admission to the intensive care unit, or any other adverse effects were related to the use of intrathecal morphine is outside my instructions to comment on. I note that there is a dispute between [Dr B], and [Mrs A] about the cause of her intensive care admission and subsequent events during her hospital stay.

Comments on the questions asked by the Commissioner.

1. In your professional opinion, was the service [Dr B] provided to [Mrs A] appropriate?

   The choice of anaesthetic technique by [Dr B] was medically appropriate on the basis of preoperative assessment and the information he was provided

with. It was apparently administered with technical skill. The area of dispute is that of consent for morphine. I am unable to be sure of what took place in the reception area outside operating theatre. The immediate preoperative period is a difficult time to be exploring this sort of issue. [Mrs A] had reason to believe that her feelings about the morphine, which had been expressed clearly at preanaesthetic assessment, were recorded in the notes. Regrettably, [Dr B] did not have this information. The result was [Mrs A] received substandard care, in relation to the obtaining of consent for the use of morphine.

2. If the care provided was not appropriate, please explain why. Covered in 1.

3. What standards apply in this case? Were these standards satisfactorily applied by [Dr B]?

   The relevant standard in New Zealand is that published by ANZCA, Recommendations on the Pre-Anaesthesia Consultation, (PS7 obtainable from the ANZCA web site, www.anzca.edu.au). This document makes recommendations about the principles and provides some guidelines to be followed. These were superficially adhered to. An anaesthetic consultation took place in advance of the surgery in which the anaesthetic was outlined. However, [Mrs A] did not agree to part of the plan (administration of intrathecal morphine), a fact which was not recorded in the notes or passed to the anaesthetist doing the case. The assigned anaesthetist ([Dr B]) met the patient for the first time in the reception area of the operating theatre. While this is accepted practice in many hospitals in this country the ANZCA standard would recommend time in theatre scheduling to allow for appropriate time for a private consultation. [Mrs A's] account comments on the lack of privacy, 'there were four or five other people with him'. The pre-anaesthetic assessment service provided to [Mrs A] was in my opinion, substandard. [Dr C] failed to record [Mrs A's] concerns about morphine, and [Dr B] did not meet with the patient before she arrived at operating theatre. I have not been provided with information about the hospital's admission processes which may have impacted on [Dr B's] ability to provide an appropriate service before [Mrs A] arrived at operating theatre.

4. Was [Dr B's] decision to use morphine to anaesthetise [Mrs A] appropriate? If not, why not?

and

5. Were there other anaesthetic options available to [Dr B] apart from morphine? Please explain.

   While spinal anaesthesia with intrathecal morphine was obviously the expected anaesthetic for knee replacement surgery in this hospital, there are other alternatives. The anaesthetist's choice of technique when faced with an

individual patient will vary depending on the anaesthetist's perception of the patient's other medical problems and the personal preference of both the patient and anaesthetist. For the anaesthetist doing an anaesthetic for total knee replacement surgery, the requirements are that the patient's leg is pain-free and relaxed, which can be achieved with either regional anaesthesia or general anaesthesia. There is also a need to plan and initiate postoperative pain relief, because knee replacement surgery is particularly painful.

[Dr B] chose to use spinal anaesthesia with intrathecal morphine, because [Mrs A] had pre-existing heart and respiratory disease; conditions which tend to be aggravated by general anaesthesia. She also had gastro-oesophageal reflux which meant she would need a deeper general anaesthetic to allow endotracheal intubation rather than a simpler lighter laryngeal mask anaesthetic. The intrathecal morphine was used because this has been shown to provide good postoperative analgesia with a low incidence of side effects. Apart from the issue of consent this represented a good choice of anaesthesia for [Mrs A].

A standard spinal anaesthetic without intrathecal morphine would have provided adequate intraoperative conditions, but [Mrs A] would be likely to need large doses of opioid drugs, which in her case would be pethidine, to achieve moderate comfort. Such doses are highly likely to cause nausea and vomiting in someone with [Mrs A's] history. A general anaesthetic would face the same problems. Another alternative would be to place an epidural catheter and run an epidural infusion postoperatively. While this would provide good pain relief there are other side-effects associated with epidurals, and these would need to be discussed with [Mrs A] before commencing. I am also unsure whether [the public hospital] has the nursing processes in place to manage epidural catheters postoperatively. Another alternative, is to do a general anaesthetic and use femoral and sciatic nerve blocks to provide post-operative analgesia. Again, this would need to be discussed with [Mrs A] before starting.

6. Was [Dr B's] discussion with [Mrs A] about anaesthetic prior to surgery appropriate? If not, why not?

   [Dr B's] discussion with [Mrs A] about the anaesthetic prior to surgery, was not only appropriate, it was essential. If the issues had been appropriately addressed and documented at the pre-anaesthetic consultation it should not have been necessary. Had the issues been addressed [Dr B's] consultation could have been confined to introducing himself and simply confirming the anaesthesia plan. Unfortunately, that was not the case, and both the patient and the anaesthetist were faced with trying to have a meaningful discussion at a stressful time. This in part explains why the two parties have very different perceptions of the conversation.

7. Please comment on the issue of informed consent regarding the administration of morphine to [Mrs A].

and

8. Did [Dr B] follow [the District Health Board] policies in administering morphine to [Mrs A]? If not, why not?

   [The District Health Board] enclosures (p98–127) contain three policy documents. An informed consent policy and an informed consent procedure, both dated January 2004 were current at the time of the episode. An Alerts, Allergies and Medical warnings procedure, dated November 2004, may not have been introduced at the time of the pre-assessment consultation.

   The informed consent policy is a subsection of the informed consent procedure, which is a more detailed document. In my opinion there are several breaches of procedure in this case.

   The first issue is the length of time the consent was obtained before the operation. While section 4 (p106) 'How long is consent valid?' clearly states that there are no limits placed on the length of time over which a consent remains valid. Appendix 3 section 5 (p117) 'Validation of consent by the patient' requires that the patient who gives consent some time before the procedure takes place, should validate the consent close to the time of the procedure. In my opinion, this provision should apply in this case, as it was seven months before the surgery occurred. There is no record of this having been done. The document also states in section 1 (p103) that 'informed consent is never implicit'. Just because she came to pre-assessment clinic does not mean she gave consent.

   Consent in anaesthesia. Appendix three section 3 (p116) requires the use of a separate consent form for the administration of anaesthetics. There is no evidence of this happening. The behaviour of the anaesthetists involved would suggest that there was no attempt or intention to obtain a separate anaesthesia consent. This behaviour makes me wonder if this policy document has actually been implemented by management.

   Section 2 (p100) makes reference to 'respects the rights of patients to refuse treatment'. This did not occur. [Mrs A] had clearly refused treatment, namely intrathecal morphine, at preadmission and should not have had to engage in the same process of refusal again. By her failure to document this refusal [Dr C] failed in her standard of care.

In summary, several system problems have contributed to failure to recognise refusal to agree to a treatment. The history of the case suggests that although policy and procedures were in place, they had not been fully implemented.

With regards to the Alerts, Allergies and Medical Warnings procedure, it is notable that on a number of occasions, [Mrs A's] reaction was recorded as an allergy. In fact, by definition it should have been an adverse reaction as there was no suggestion that there was any abnormal hypersensitivity. However, as it is possible the procedure had not been implemented this does not represent a failure of care.

Summary

[Mrs A's] care has failed to meet the expected standards of the code with regard to consent or refusal of consent to intrathecal morphine. It is my opinion that system deficiencies, failure by [Dr C] to document refusal, and a flawed consultation by [Dr B], all contributed to this failure.

The failure of the individuals and the hospital systems are a moderate level of severity individually, but collectively they have produced a major failure in the delivery of the expected standard of care, by failing to accept [Mrs A's] right to refuse part of the care offered, especially since it was not essential and there were alternatives available."

Responses to Provisional Opinion

Responses to my provisional opinion were received from the District Health Board, Dr B and Dr C. Further expert advice was sought from Dr Vaughan Laurenson.

The District Health Board
The District Health Board accepted the findings and recommendations made in my provisional opinion and has taken steps to improve its informed consent processes.

Dr B
Dr B accepted that it would have been prudent to obtain written consent from Mrs A prior to her anaesthetic, as her other co-morbidities meant she was at risk for adverse effects, and that he should have documented the consent discussion. Dr B confirmed that he has changed his practice to ensure this is done.

Dr B did not, however, accept that the information he provided to Mrs A was inadequate. Dr B advised me that he "did a good job of giving her information such that she understood that she was not allergic to morphine". Dr B explained that he gives the information that, in his experience, most patients want to receive then tailors the rest of the consultation to addressing the issues that matter most to the patient concerned. He did not explain the difference between an allergy and a side effect because he was not asked to do so.

Dr B noted that many patients believe they have allergies when they are in fact experiencing the side effects of the treatment, such as nausea with morphine and diarrhoea with antibiotics. Dr B stated that "if we were to accept [the objection] at face value, we would be doing our patients a disservice because they would be denied the use of valuable drugs". In his view, "there is a need for balance between explaining the mechanism behind allergies and other adverse reactions and the strategies we might use in each case which may not be of interest to every patient and giving usual information with time for patients' chosen issues to be discussed".

Dr B agreed that it was unfortunate that he had to carry out these discussions with Mrs A in the reception area just before entering the operating room, and stated:

> "In hindsight, I had two options when faced with [Mrs A's] concern about morphine:
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> - accept it at face value and give her an anaesthetic which was less safe. Numerous doctors had accepted (Mrs A's] 'allergy' without question over the years. It would have been practicing poor medicine if I did.
>
> - refer her back to the clinic. This may have resulted in her operation being postponed by several weeks.
>
> [Mrs A] would have been ill served by both these options. But I respect this might have made her feel more empowered."

Dr B considered the alternatives to spinal anaesthesia that were discussed by the expert advisors for ACC and Dr Laurenson, and explained that he recommended a spinal anaesthetic, rather than a general anaesthetic, because of Mrs A's co-morbidities. Dr B explained that he could not have offered a sciatic and femoral nerve catheter technique because he had not done this procedure before. He could not offer an epidural infusion as the hospital "did not have the nursing facility to provide round the clock monitoring and management of the block" and that "in [Mrs A's] case it would have been unsafe as under dosing or overdosing could have precipitated a heart attack". Dr B stated that these techniques have a higher failure rate "compared to the near 100% success rate with intrathecal anaesthesia" and require back-up resources and monitoring that are not available at the public hospital.

Dr B noted the other regional techniques described but explained that he does not use them and that pethidine PCA is contraindicated in Mrs A's age group.

Dr B said that he explained to Mrs A that he "would use only a minute dose [of morphine] and even if she developed a colic it was possible to reverse it with an antidote (naloxone) without undoing the benefits. In fact that was the rationale for recommending intrathecal morphine as the technique of choice, given her multiple co-morbidities and fear of morphine."

Dr B does not accept that he provided treatment without Mrs A's informed consent and stated: "It was my belief at the time that she was satisfied with my explanation and accepted my recommendation." Dr B explained that, in order to perform the procedure, Mrs A was required to sit on the operating table in a bent- over position, and that it would have been impossible to administer the anaesthetic without the full co-operation of Mrs A. Dr B maintained that Mrs A was very helpful in following instructions and did not appear to be undergoing the procedure against her wish.

Dr B said:

> "I did not dismiss [Mrs A's] concerns about morphine nor did I accept it, I addressed it. Numerous doctors before me had accepted it at face value. I could have done the same but it would have been substandard practice. I looked for the evidence from her notes, found it and then proceeded to give her information about why in my opinion it was safe to use it, and, as I have stated many times, I thought she accepted the explanation."

Dr B denied that he was testing out a theory that Mrs A was not allergic to morphine and noted that an allergy test had already been done twice before in 1990.

Dr B suggested that Mrs A's recollection was not accurate, and raised the following issues:

- Mrs A was given a generous dose of midazolam for intra-operative sedation. Midazolam causes powerful sedation and amnesia. Her complaint was made months after the event. Both of these factors could have affected her recollection of events.

- Mrs A claims that Dr C advised her that she would be given intrathecal morphine. Dr C denies this.

- Dr B denies that Mrs A said she would die if he used morphine and that he could take the consequences. Had she done so, Dr B would have been very concerned that she still felt anxious and would have talked through the issues, including possible postponement of the surgery.

- In the recovery room Mrs A described her chest pain as the same as she experiences at home and it was explained to her that this was the reason for observing her in ICU, but she later attributes her chest pain to the morphine.

In summary, Dr B stated:

> "[Mrs A] has multiple co-morbidities which put her at risk of developing a stroke, heart attack, pulmonary complications or even death. She had a successful operation without any of these dreaded complications. The ICU admission and symptoms she attributes to morphine were from pre-existing causes and, more importantly, she did not manifest any signs or symptoms of an allergy. I had no doubt I had her consent for the procedure. I have never acted against the wishes of my patients. I have some satisfaction in managing a difficult case well."

Dr C
Dr C explained that when she saw Mrs A for her preoperative assessment at the public hospital there was no specific form for anaesthetic consent and, because of a lack of resources, patients almost never saw the anaesthetist who would be performing the procedure on the day. As a compromise, the discussions at preoperative assessments were broad and tried to cover a range of possibilities. This can be hard for the average patient to digest.

Dr C recalls having a very prolonged discussion with Mrs A, who was very concerned about "her perceived allergy to morphine". Dr C attempted to persuade Mrs A that her symptoms did not suggest an allergy. Dr C confirmed that she had agreed to note Mrs A's concerns and is sorry that she did not do so.

Dr C said she explained to Mrs A that anaesthesia without morphine was possible but that this would be explained to her more fully by the anaesthetist when Mrs A went to theatre.

Further expert advice — Dr Vaughan Laurenson
Dr Laurensen considered the responses from Drs B and C and did not wish to alter his advice. He noted, however, that both doctors expressed negative views on gaining informed consent while adhering to the public hospital's policies and procedures.

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:

Clause 1
Consumers have Rights and Providers have Duties

(3) Every provider must take action to —

…

(b) enable consumers to exercise their rights.

Right 4
Rights to Services of an Appropriate Standard

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

Right 6
Right to be Fully Informed

(2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

Right 7
Right to Make an Informed Choice and Give Informed Consent

(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise

…

(7) Every consumer has the right to refuse services and to withdraw consent to services.

Relevant standards

The Medical Council statement on 'Information and Consent' (April 2002):

> "Trust is a vital element in the patient–doctor relationship and for trust to exist, patients and doctors must believe that the other party is honest and willing to provide all necessary information that may influence the treatment or advice. The doctor needs to inform the patient about the potential risks and benefits of the proposed treatment and let the patient know that his or her welfare is the paramount concern.
>
> …
>
> In general, separate written consent is required for research, experimental procedures, general or regional anaesthesia, blood transfusion or any procedure with a significant risk of adverse effects."

The Australian and New Zealand College of Anaesthetists 'Guidelines on Consent for Anaesthesia or Sedation' (2005):

> **"DOCUMENTATION OF CONSENT**
>
> The extent of documentation may be dictated by local legislation and practice but it is wise to record significant details of the consent as part of the patient's notes, including reference to the discussion of relevant material risks and the agreement by the patient to undergo the treatment.
>
> In order to defend claims that 'informed consent' information was not given or was inadequate, it is highly recommended that detailed notes of the discussion and all risks considered are kept by the provider."

The Australian and New Zealand College of Anaesthetists 'Recommendations on the Pre-Anaesthesia Consultation' (2003):

> "**2. General Principles**
>
> …
>
> 2.2 A pre-anaesthesia consultation must be performed by the anaesthetist who is to administer the anaesthetic even if an assessment has already been performed previously by some other person.
>
> …
>
> 2.4 The consultation must take place at an appropriate time prior to anaesthesia and surgery in order to allow for adequate consideration of all factors. This is especially important to be as early as possible where there

is significant co-morbidity, major surgery is planned and/or there are specific anaesthesia concerns.

2.5 The difficulties inherent in adequately assessing patients admitted on the day of surgery must be recognised. Ideally such patients should be assessed prior to admission. Otherwise admission time, list planning and session times must accommodate the extra time required for pre-anaesthesia consultations.

…

2.7 Pre-anaesthesia consultation facilities must include appropriate equipment and space to allow for a consultation and clinical examination in privacy

…

3. Guidelines

…

3.2 An appropriate medical assessment of the patient including medical history (which may be assisted by a questionnaire and/or review of available patient notes), clinical examination, review of any medications, the results of any relevant investigations and arrangement for any further investigatory or therapeutic measures which are considered necessary. This medical assessment may lead to delay, postponement or even cancellation of the planned anaesthesia.

…

3.4 A discussion with the patient (or guardian) of those details of the anaesthetic management which are of significance to the patient. This would normally include the anaesthetic procedure, pain management, potential complications and risks, an opportunity for questions and provision of educational material. This material may be in the form of written pamphlets, video recordings or audiotapes.

3.5 Obtaining of informed consent for anaesthesia and related procedures. This should include consent regarding the type of anaesthesia, any invasive procedures, pain management and other medication plan and, where appropriate, informed financial consent.

…

3.6 A written summary of the consultation which should become part of the medical record of the patient.

The DHB 'Informed Consent Procedure' policy document (March 2004):

"2. Scope

[The District Health Board] shall implement processes that ensure that:

- Patients competent to consent to a proposed healthcare treatment or procedure shall be given sufficient information to enable them to arrive at a voluntary decision as to whether or not to agree to that treatment or procedure.

…

Informed consent is a process, not a single event. It involves the patient making an informed choice between the healthcare options available, including the option of refusing the service.

[The District Health Board] respects the rights of patients to refuse treatment or to withdraw their consent to treatment.

2. When is Informed Consent required?

- Responsibility for ensuring valid consent has been obtained lies with the person responsible for the procedure or the course of treatment. This responsibility may be delegated provided the person to whom it is delegated has sufficient knowledge of the patient's condition and proposed treatment. The person with delegated responsibility must be aware of their limitations and must inform the patient of who will be carrying out the treatment.

4. How Long is Consent Valid?

- There are no limits placed on the length of time over which a consent remains valid.

- The need to obtain new consent arises when there is a change to some relevant circumstance, eg. new information about complications of the proposed treatment; a significant change in the patient's condition; a change in the patient's wishes.

6.2 The Process of Obtaining Informed Consent

- The process of obtaining informed consent involves the following steps. The person(s) responsible for obtaining informed consent shall:

- Establish a friendly and supportive environment which encourages open, honest and full communication; and

- Give sufficient information to allow the patient to make an informed choice; and
- Answer questions; and
- Obtain the patient's (or their legally authorised representative's verbal consent and document this in the patient's clinical record; and/or
- Obtain the patient's (or their legally authorised representative's) written consent using an approved [the DHB] Consent Form.
- The process of obtaining informed consent may occur during one or more appointments with the patient.
- To facilitate this process, the relevant health professional(s) shall:
- Make every effort to ensure the privacy of discussions of diagnosis and treatment options with the patient …

6.3 Documentation of Informed Consent

- Documentation of informed consent, whether verbal or written, shall be recorded in the patient's clinical record and shall include the following:
- What information was provided to the patient, when, by whom and who else was present.
- Important questions asked by the patient and the answers given.
- Specific wishes of the patient.
- Who gave the consent, ie whether it was the patient or the person acting on his/her behalf.

Where the patient has declined to give their informed consent, this shall be documented in the clinical record.

Appendix 3:

6. [THE DHB] REQUIREMENTS FOR CONSENT FORMS

…

3. Identification of the Treatment, Procedure, etc

…

- Use a separate consent form for the administration of anaesthetics.

5. Validation of Consent by the Patient

- A patient who gives consent some time before the procedure takes place, should validate the consent close to the time of the procedure.

The DHB Alerts Allergies and Medical Warning Procedure (November 2004):

3. Definitions

…

Allergy: A state of abnormal and individual hypersensitivity to foreign substances by the immune system. This is induced by exposure to an allergen (antigen or foreign substance), which can result in harmful reactions upon subsequent exposures.

The most common allergic reactions may include hay fever (allergic rhinitis), asthma, allergic eyes (allergic conjunctivitis), allergic eczema, hives (uticaria). Anaphylaxis is included in this category.

…

Adverse reaction: An undesirable and injurious reaction caused, or thought to be caused by a medicine, therapeutic procedure or agent."

Opinion: Breach — The District Health Board

The concept of informed consent is central to most medical procedures. It is a fundamental requirement that such consent be appropriately obtained prior to treatment. Informed consent is a process that is embodied in three essential elements under the Code — effective communication (Right 5), disclosure of adequate information (Right 6) and, subject to certain exceptions, a voluntary decision by a competent consumer (Right 7).

Effective communication is a key component of the informed consent process. Right 5(2) provides that every consumer has the right to an environment that enables open, honest and effective communication. As an employer, the District Health Board (the DHB) is required to ensure that systems and policies are in place that allow its employees to meet their obligations under the Code.

The ANZCA guidelines recognise that effective communication can only occur in an appropriate environment. The guidelines state that a pre-anaesthesia consultation must be performed by the anaesthetist who is to administer the anaesthesia, even if an assessment has already been performed by someone else, and the "consultation must take place at an appropriate time prior to the anaesthesia and surgery to allow for adequate consideration of all factors". An early consultation is especially important where there is significant co-morbidity, major surgery is planned, or there are specific anaesthesia concerns. The guidelines recognise the difficulty in adequately assessing patients who are admitted on the day of surgery, and suggest that ideally such patients should be assessed prior to admission; otherwise extra time should be set aside for appropriate pre-anaesthetic consultations.

The DHB policy on informed consent states that responsibility for ensuring that valid consent has been obtained lies with the person responsible for the procedure or the course of treatment, unless it is appropriately delegated. The person responsible for obtaining informed consent is required to establish a friendly and supportive environment that encourages open, honest and full communication. However, there is no guidance in relation to the appropriate timing and privacy of these discussions. The DHB policies at the time required a separate consent form for anaesthesia, but there is no evidence that either Dr C or Dr B used such a form as part of consent discussions with Mrs A. The DHB has confirmed that prior to December 2005 only verbal consent was obtained, but that separate written consent is now obtained.

Dr C performed a pre-anaesthetic assessment of Mrs A in November 2004, two months before her operation. However, no decision was made as to the appropriate anaesthesia to be used. While she noted Mrs A's reported morphine allergy, and that spinal anaesthesia may not be appropriate, Dr C did not specifically record that Mrs A refused morphine. Dr C told Mrs A that alternatives would be discussed by the anaesthetist at the time of the surgery. Dr C's comments suggest that it was commonplace for further consent discussions to occur at the time of surgery. I am

satisfied that Mrs A did not give her informed consent for anaesthesia during the assessment with Dr C.

Dr B spoke to Mrs A for the first time outside the operating theatre on the day of surgery, and told her he would be using a small amount of morphine as part of the anaesthesia for her operation. Mrs A said that four or five other people were present during the discussion that took place. The DHB advise that the other people present cannot recall, or did not overhear, the conversation.

Dr Laurenson noted that while meeting the patient for the first time in the reception area of the operating theatre is accepted practice in many hospitals in New Zealand, the ANZCA guidelines recommend that theatre scheduling has appropriate time set aside for private consultations. He also commented on the lack of privacy during Dr B's discussion with Mrs A. Dr Laurenson advised that the pre-anaesthetic assessment service provided to Mrs A was substandard, and noted that the hospital's admission processes may have impacted on Dr B's ability to provide an appropriate service.

In *J v Director of Proceedings*[1] Judge Doogue considered the situation where a patient had consented to major surgery in the corridor outside theatre and noted that the stress of the pending operation may have reduced the patient's ability to absorb and process what she was being told. The judge commented, in relation to the undesirability of attempting to obtain consent outside the operating theatre:[2]

> "… [I]t may be that the circumstances in which she is now being asked to consent are not conducive to making a sensible decision. It may be that because of the circumstances she cannot bring the required concentration to bear that is needed to make a reasoned decision. It may be not enough time is available. It might be that she does not have the chance to first discuss matters with family members. She may sense pressure to make a decision when she is not ready to."

In the reception area immediately prior to the operation was not the appropriate time or place for a detailed discussion about consent for anaesthesia. Dr B and Mrs A were discussing her concerns about morphine in a pressured environment with insufficient time to adequately explore other options. The presence of other people may also have meant that Mrs A felt unable to communicate freely with Dr B.

The conduct of the doctors involved in Mrs A's care suggests that it was common practice at the public hospital for outstanding consent issues to be resolved immediately prior to entering the operating theatre. I accept that in many cases a patient will receive adequate information and give informed consent at a pre-anaesthetic assessment, and that the operative anaesthetist will simply need to confirm

[1] *J v Director of Proceedings* (District Court Auckland, CIV 004/004/1682, 6 February 2005).
[2] Ibid, para 86.

consent immediately prior to the procedure. However, consistent with the ANZCA guidelines, there must be a system in place to cater for cases where specific anaesthesia concerns, such as an allergy alert, are raised. This should prompt a follow-up assessment with the anaesthetist who will be performing the procedure so that those concerns can be addressed. Ideally this should occur before the day of surgery, but if that is not practicable, adequate time should be allocated on the day of the procedure, well before entry to theatre.

Under clause 1(3)(b), providers must take action to "enable consumers to exercise their rights". In not providing adequate systems and time for anaesthetists to carry out consent discussions in an environment that enabled effective communication, adequate information disclosure, and informed choice of anaesthesia by patients, the District Health Board breached clause 1 of the Code.

Opinion: Breach — Dr B

Sufficient information
Under Right 6(2) of the Code, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

When Mrs A first met with Dr B outside the operating theatre, she had concerns about the possibility that morphine would be used as part of her anaesthesia. She had not, at that point, given her informed consent for the use of morphine. The test, for the purposes of Right 6(2), is whether Mrs A received enough information during the following discussion to enable her to make an informed choice.

I have received conflicting information from Mrs A and Dr B about the information that was provided to Mrs A preoperatively, and there is no contemporaneous record of the discussion in Mrs A's medical notes.

Mrs A recalls that she told Dr B she had an allergy to morphine, which was stated on her MedicAlert bracelet, and therefore she could not have it. She says that when Dr B attempted to persuade Mrs A to proceed with using morphine, she told Dr B "it would be on his head" if she died.

In response to my provisional opinion, Dr C confirmed that Mrs A had raised similar concerns at the preoperative assessment and that this had prompted a detailed discussion about Mrs A's reaction to morphine. Dr C said she explained to Mrs A that anaesthesia without morphine was possible but that this would be explained to her more fully by the anaesthetist when Mrs A went to theatre.

Dr B wrote in his report to ACC in August 2005 that he had reviewed Mrs A's medical records prior to the operation, noted her history of "allergy" to morphine

going back to 1987, and was aware that she wore a MedicAlert bracelet stating her allergy to morphine and codeine. Dr B advised that the kind of reaction to morphine that Mrs A described in her patient information questionnaire was colic pain, which had been noted in her records by a number of doctors, including Dr D and Dr C.

Dr B observed that Mrs A had been given omnopon (82% morphine and 12% codeine) during two operations in 1990, despite her "allergy" being noted, and that no ill effects were documented. Due to Mrs A's other medical conditions (such as COPD and IHD), intrathecal morphine had distinct advantages, and in his view it was the preferred option of anaesthesia for Mrs A. In response to my provisional opinion, Dr B explained that many patients believe they are allergic to medications when they are actually experiencing side effects. Dr B stated that "numerous doctors had accepted [Mrs A's] 'allergy' without question over the years. It would have been practicing poor medicine if I did."

Dr B explained that he gives the information that, in his experience, most patients want to receive, then tailors the rest of the consultation to addressing the issues that matter most to the patient concerned. Dr B confirmed that he did not explain the difference between an allergy and a side effect to Mrs A because he was not asked to do so.

Both Dr Laurenson and Dr Chamley advised that there are other alternatives for effective anaesthesia for knee surgery, including postoperative epidural infusion and femoral and sciatic nerve blocks, although Dr Laurenson noted that the public hospital may not have the nursing facilities available for epidural infusions, and that sciatic nerve blocks would have involved general anaesthesia (which may not have been appropriate given Mrs A's other medical conditions). In response to my provisional opinion, Dr B maintained that these alternatives to spinal anaesthesia were not possible owing to Mrs A's other health concerns, her age, the limited resources at the public hospital, and his lack of familiarity with the procedures. There is no evidence to suggest that Dr B discussed these alternatives to spinal anaesthesia with Mrs A.

Dr B accepts that Mrs A raised her concerns about morphine but advised that he "did a good job of giving [Mrs A] information such that she understood that she was not allergic to morphine". Dr B said that he told Mrs A that she had been given morphine safely in the past, that he would be injecting only a small amount into her spine and that, even if she developed colic, it was possible to reverse it with an antidote (naloxone) without undoing the benefits.

Dr B denies that at the end of their conversation Mrs A made any comments about fearing serious complications. Had she done so, Dr B would have been very concerned that she still felt anxious, and would have talked through the issues, including possible postponement of the surgery. Dr B advised me that administration of the spinal anaesthesia requires the patient to sit up in an awkward position, and that Mrs A willingly co-operated with this. Dr B said that she "did not appear to be undergoing a procedure against her wish".

In hindsight, Dr B believes he had only two options when faced with Mrs A's concern: accept it at face value and give her an anaesthetic that was less safe, or refer her back to the clinic, which would have delayed her operation by several weeks.

I do not agree that he had only these two options. I accept the advice of Dr Laurenson that, when faced with Mrs A's concerns about morphine, Dr B should have explained the alternative anaesthetic options, together with his assessment of the relative risks and benefits, so that Mrs A could decide for herself how to proceed.

Dr B appears to have been distracted by his wish to correct Mrs A's belief that she was allergic to morphine. Whether her symptoms indicated an allergy or not, the fact that Mrs A raised significant concerns about the use of morphine, and that similar concerns had been noted in the past, should have prompted a detailed discussion about safe alternatives. If necessary, this may have required postponement of the surgery, but this is an option that should also have been discussed for Mrs A to consider.

Right 6 of the Code recognises that the information a patient might need is not confined to the risks of the treatment option being recommended by the provider. A patient is entitled to information about all relevant treatment options, including those that the provider does not personally offer,[3] because knowledge of alternatives can be as significant as knowledge of risks. Information about alternative treatments, including the option of non-treatment, enables the patient to compare the risks and benefits of those options with those of the recommended treatment.[4]

In my view, Dr B did not discharge his duty to properly inform Mrs A. He was not helped by the unsatisfactory pre-anaesthetic assessment process at the public hospital. However, he failed to provide Mrs A with sufficient information about her condition, alternative anaesthetic options, and her right to refuse treatment. In these circumstances Dr B breached Right 6(2) of the Code.

Consent

Under Right 7(1) of the Code, services cannot be provided to a consumer unless the consumer makes an informed choice and gives informed consent. A consumer cannot give valid consent unless he or she has first received and considered the relevant information and made an informed choice. The Medical Practitioners Disciplinary Tribunal in *Director of Proceedings v Frizelle* stated:[5]

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[3] See Opinion 01HDC00755, 9 May 2003 (failure to provide morbidly obese patient with adequate information about other surgical options for weight reduction, including gastric bypass surgery not offered by that provider).

[4] J. Manning, *Information Disclosure and Informed Consent under the Code of Rights*, [2004] Medical Law Review 181.

[5] Decision No. 219/02/94D, 3 December 1992.

> "The Tribunal stresses that a doctor's duty to inform and obtain informed consent from a patient when required is as fundamental as the doctor's duty to provide treatment in accordance with appropriate professional standards … The doctor should comply with their duty to inform and obtain informed consent because of their respect for the dignity and independence of the patient, not because they feel bound to protect themselves."

The DHB policy on informed consent correctly states that responsibility for ensuring valid consent has been obtained lies with the person responsible for the procedure, and that a patient who gives consent some time before the procedure takes place should "validate" the consent close to the time of the procedure. The policy also states that the DHB respects the rights of patients to refuse treatment or to withdraw their consent to treatment.

Right 7(7) affirms that every consumer has the right to refuse services and to withdraw consent to services. As stated in my Gisborne Hospital inquiry report:[6]

> "The right to refuse consent to a medical procedure is a fundamental recognition of patient autonomy, and is well established in ethics, the common law, and New Zealand statute law. Section 11 of the New Zealand Bill of Rights Act 1990 states that 'everyone has the right to refuse to undergo any medical treatment'.
>
> It is no answer for [the anaesthetist] to say that he was motivated by his patient's long-term safety — in the event of further anaesthetic procedures — in seeking to discover if she was truly allergic to fentanyl. Informed consent is at the heart of patients' rights, and includes the right to withdraw consent for a health care procedure."

Dr D initially obtained Mrs A's consent for knee surgery and anaesthesia related to the procedure on 19 May 2004, seven months prior to the operation. Mrs A's morphine allergy was included under the special alerts on the request for admission form completed by Dr D. This indicated Mrs A's general consent to undergo anaesthesia but, consistent with the DHB policy on informed consent, Mrs A's consent needed to be confirmed by the person responsible for administering the anaesthetic, or an appropriate delegate, closer to the time. Dr Laurenson advised that it was necessary to validate Mrs A's consent in this case, because her original consent to the surgery (in May 2004) was seven months prior to the operation itself.

Mrs A saw Dr C on 4 November 2004 for a pre-anaesthetic assessment, and again raised her concerns about morphine. Dr C did not document the discussion in Mrs A's clinical notes, but did note on the assessment form that morphine causes Mrs A colic, and that spinal anaesthesia was probably not appropriate.

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[6] Gisborne Hospital 1999–2000: A Report by the Health and Disability Commissioner, March 2001.

Dr B, as the operative anaesthetist, needed to ensure that Mrs A had given her informed consent to the proposed anaesthesia when he met her on 10 January 2005. A key element of this responsibility was to check that consent had been given as part of the pre-anaesthetic assessment and, if not, to ensure that consent was obtained before the procedure went ahead.

As I have noted above, there are conflicting accounts of whether Mrs A gave her consent for the administration of morphine on 10 January 2005. Mrs A believes she clearly expressed her belief to Dr B that she was allergic to morphine, and did not consent to the use of it in her anaesthesia. Dr C has confirmed that at the preoperative assessment Mrs A was very concerned about her reaction to morphine, and was told to raise her concerns prior to surgery. In my provisional opinion, I made a finding that, on the balance of probabilities, Mrs A withheld her consent to the use of morphine.

Dr B has acknowledged that Mrs A was anxious because of her past experiences, and that she did not want him to use morphine. However, Dr B believes he convinced Mrs A of the benefits of using intrathecal morphine, and obtained her "wholehearted" consent. In response to my provisional opinion, Dr B noted that he required Mrs A's physical co-operation to proceed with the anaesthesia. He denies that Mrs A said it would be his responsibility if she died during the procedure, and states that it would not have been possible to administer the anaesthesia without Mrs A's physical co-operation. The medical notes confirm that Dr B proceeded to administer morphine as part of Mrs A's anaesthesia.

It is unfortunate that Dr B was required to carry out these discussions with Mrs A in the reception area immediately prior to entering theatre. This was not the appropriate time or place for detailed consent discussions to occur. "Patients facing imminent surgical intervention are vulnerable and often fearful, and the health professional involved needs to be aware of this."[7] I accept that it is difficult for even a routine consent discussion to occur in this type of environment. In circumstances where a consumer has raised significant concerns, providers should be particularly careful not to rush or pressure a consumer to make a decision.

In the absence of corroborative evidence, I am unable to establish, as a matter of fact, whether Mrs A expressly withheld her consent to the administration of morphine. What has been established, however, is that the alternatives to anaesthetic involving morphine were not explained to Mrs A. In circumstances where she lacked sufficient information to make an informed choice, Mrs A was unable to give valid consent. In these circumstances, Dr B breached Right 7(1) of the Code.

[7] See Opinion 98HDC15056, 3 August 2003 (failure to provide a pre-anaesthetic patient with sufficient time and information to enable her to make an informed choice and give informed consent to treatment).

Records

It is a fundamental requirement that medical professionals keep accurate records. This is particularly important in relation to any discussions relating to consent.

The relevant Medical Council guidelines state that separate written consent is generally required for regional anaesthesia. The ANZCA standards state that in order to defend claims that "informed consent" information was not given or was inadequate, it is highly recommended that detailed notes of the discussion and all risks considered are kept by the provider.

In addition, the DHB policies specifically state that the information given to the patient is to be recorded, as well as the name of the person who provided the information, and who was present at the time the information was given. Any important questions that the patient asks, and the answers, are to be noted, as are the patient's wishes. A patient's refusal to give consent must also be recorded.

Dr Laurenson commented that there are no contemporaneous records of Dr B's consultation with Mrs A, and the recollections of Dr B and Mrs A about what was discussed, conflict. Dr Laurenson also noted that there was no separate anaesthesic consent form in this case. There is no such form in Mrs A's medical records, although according to the DHB policies a form should have been completed. Indeed, Dr Laurenson noted that "the behaviour [of] the anaesthetists involved would suggest that there was no attempt or intention to obtain separate anaesthesia consent. This behaviour makes me wonder if this policy document has actually been implemented by management."

Dr Chamley noted that, prior to Dr B's conversation with Mrs A outside theatre on 10 January 2005, no decision had been made at that stage regarding the anaesthesia that would be used. Dr Chamley indicated that further documentation (in addition to Dr C's) should have been recorded regarding the discussion about consent. This was particularly the case since Dr C was not performing the procedure, and no decision as to the exact nature of the anaesthesia to be used had been made at the assessment clinic. Dr Chamley also stated that where there are issues of a contentious nature, such as the issue of the morphine allergy, consent for anaesthesia should be recorded in writing: "Given that [Dr B] intended to give a drug which he was aware that [Mrs A] did not want, then regardless of the validity or otherwise of his views re the allergy, discussion re this should have been documented." There was no written record of the information Dr B gave to Mrs A, the decision to use morphine, or her consent.

It is often stated by medical defence lawyers: "If it isn't documented, it didn't happen." Baragwanath J made comments to similar effect in his decision in *Patient A*

v Nelson-Marlborough District Health Board.[8] Justice Baragwanath noted that it is through the medical record that doctors have the power to produce definitive proof of a particular matter (in that case, that a patient had been specifically informed of a particular risk). Doctors whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted.

At the very least it would have been prudent for Dr B to have recorded his conversation with Mrs A, in order to confirm what had been discussed. Dr B acknowledged, in his response to my provisional opinion, that his discussion with Mrs A should have been documented and that, given her significant co-morbidities, he should have obtained her written consent. In my opinion, Dr B's failure to record any details of his discussion with Mrs A, her wishes regarding morphine, or her refusal to be given morphine, amounts to a breach of Right 4(2) of the Code.

Other comments

Preoperative assessment by Dr C
Dr C was responsible for Mrs A's preoperative anaesthetic assessment on 4 November 2004.

Dr Laurenson commented that at this assessment Mrs A was adamant that she did not want to be given morphine. Dr C recalled writing Mrs A's wishes in the records. However, the only notes by Dr C in the records are that "morphine causes colic" under the allergies section of the pre-assessment form, as well as "understands risks and accepts all". Dr C also recorded that spinal anaesthesia would probably not be appropriate.

Mrs A recalled that Dr C did not discuss any alternative anaesthesia with her, and told her that she would have to wait until she got down to surgery, when other options would be discussed. Therefore, at that stage there was no decision regarding the specific anaesthesia to be used.

I note Dr Laurenson's comments that Dr C failed to document Mrs A's wishes regarding morphine at this preoperative assessment, and that this information was not available to Dr B. Dr C also should have explained the options available to Mrs A, so she had time to think about them.

[8] *Patient A v Nelson-Marlborough District Health Board* (HC BLE CIV-2003-204-14, 15 March 2005).

In response to my provisional opinion, Dr C advised that she had a prolonged discussion with Mrs A about "her perceived allergy to morphine". While Dr C attempted to persuade Mrs A that she did not have an allergy, she did reassure Mrs A that there were alternatives available without morphine, and these would be explained to her on the day of surgery. Dr C acknowledges that she undertook to note Mrs A's concerns on the preoperative assessment form and apologises for that oversight.

Postoperative symptoms
Mrs A was concerned that the morphine caused her postoperative symptoms, including nausea and dizziness, which resulted in several falls.

It is not my role to decide whether the morphine caused Mrs A's postoperative symptoms. The focus of my investigation is whether the standard of care provided was appropriate, not the outcome. It is important to bear in mind that there can be a breach of the accepted standards of care without an adverse outcome. Conversely, there can be an undesirable outcome from treatment, even if the care provided was appropriate.

While I am unable to comment on this aspect of Mrs A's complaint, I note Dr Chamley's advice to ACC that Mrs A had a history of occasional dizziness over a long time prior to her surgery, which had been documented by her general practitioner. In addition, Dr Chamley observed that Mrs A takes medication with known side effects — Accupril for her hypertension, which can cause dizziness and orthostatic hypertension (Mrs A's instances of dizziness on the ward on 12 and 14 January 2005 were both attributed to Accupril) — and Madopar for her Parkinson's disease, which can also cause orthostatic hyptension.

Dr Chamley advised that, in his opinion, the single dose of morphine did not cause Mrs A's dizziness and falls. He stated that there is no reported evidence in the literature of such an association.

Actions taken

As a result of the findings in my provisional opinion, the District Health Board has confirmed that it has taken steps to improve its informed consent processes.

Dr B has reviewed his practice to ensure that consent discussions are fully documented and written consent is obtained in situations where there is a significant risk of adverse effects on the consumer.

Recommendations

I recommend that Dr B apologise to Mrs A.

I recommend that the District Health Board:

- Apologise to Mrs A
- Update Mrs A and her family on the steps that have been taken to improve its informed consent processes.

Follow-up actions

- A copy of my final report will be sent to the Medical Council of New Zealand and the Australian and New Zealand College of Anaesthetists.

- A copy of my final report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.