Northland District Health Board

A Report by the

Health and Disability Commissioner

(Case 12HDC00599)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. On 3 May 2012, Mr A, aged 74 years, was seen at a public hospital by a consultant, Dr B, who instructed that Mr A be given sotalol as prophylaxis against atrial flutter.[1] This was done with the knowledge that Mr A suffered from asthma and chronic obstructive pulmonary disease (COPD).[2]

2. Dr B intended that a trial dose be administered in hospital, but Mr A was discharged and took the first dose of sotalol at home on 4 May 2012.

3. Mr A suffered an acute exacerbation of his asthma and required emergency treatment at the local medical centre.

Findings

4. As a result of communication failures between the prescribing doctor and the nursing and medical teams, services were not provided to Mr A with reasonable care and skill and, accordingly, Northland District Health Board (NDHB) breached Right 4(1)[3] of the Code of Health and Disability Services Consumers' Rights (the Code). In addition, Mr A's continuity of care was inadequate, and NDHB therefore breached Right 4(5)[4] of the Code.

5. Mr A was not informed about the risks, benefits, and need to take a trial dose of sotalol. This was information that a reasonable person in Mr A's circumstances would expect to receive. Provision of this information would have enabled Mr A to be a partner in his own treatment. By not giving Mr A this information, NDHB breached Right 6(1)(b)[5] of the Code.

Complaint and investigation

6. The Health and Disability Commissioner received a complaint from Mrs A about the services her husband, Mr A, received from Northland District Health Board. On 17 May 2013, the Commissioner commenced an investigation. The following issue was identified for investigation:

- *Whether Northland District Health Board provided services of an appropriate standard to Mr A in May 2012.*

[1] Atrial flutter (AFL) is an abnormal heart rhythm that occurs in the atria of the heart.
[2] Chronic obstructive pulmonary disease (chronic obstructive airways disease) is a progressive disease of the airways that makes breathing difficult.
[3] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[4] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."
[5] Right 6(1)(b) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including … an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option …"

7. The parties directly involved in the investigation were:

Mr A	Consumer
Mrs A	Consumer's wife
Dr B	Medical consultant
Dr C	Medical registrar
Northland District Health Board	Provider

8. Independent clinical advice was provided by a general practitioner, Dr David Maplesden (attached as **Appendix A**), and a physician, Dr Kingsley Logan (attached as **Appendix B**).

Information gathered during investigation

Mr A

9. Mr A has a history of asthma and chronic obstructive pulmonary disease. In July 2008 he had a hospital admission for asthma, shortness of breath, and COPD and, in November 2008, a further admission for acute asthma.

10. On 1 May 2012, Mr A was admitted to the local hospital with a three-day history of shortness of breath and a cough, and a reoccurrence of atrial flutter, which had been treated the previous month with cardioversion.[6]

11. On 2 May 2012, Mr A was transferred to the hospital in the main centre for further cardioversion for atrial flutter. Mr A reverted to sinus rhythm after the cardioversion and was admitted to the medical ward overnight.

12. Mr A lives approximately 45 minutes by road from the main centre hospital. On 2 May the clinical records noted that Mrs A had contacted the hospital advising that, as she did not drive, there could be a problem with her husband being transported home on his discharge. A nurse therefore spoke to a social worker regarding the need to arrange transportation for Mr A.

13. In response to my provisional opinion, Mrs A stated that she told the staff that she does drive, but that the trip was too long for her to manage twice in one day.

Review

14. At 9am on 3 May 2012, Mr A was reviewed by a consultant, Dr B. Mr A said that this was the first time he had met Dr B.

15. A medical registrar, Dr C, completed the clinical record for the consultation and noted that Mr A was feeling well and was pain free. The following plan was recorded:

[6] Cardioversion is a medical procedure by which an abnormally fast heart rate (tachycardia) or cardiac arrhythmia is converted to a normal rhythm, using electricity or drugs.

"1. Stopped Augmentin
2. Cont. Roxithronycin for another few days
3. Start Sotalol[7] 40mg BD[8] — start one dose now. If tolerating well can continue on maintenance dose
4. Can be discharged home today
5. Continue on Warfarin/lifelong for A. Flut."

16. HDC asked NDHB whether Mr A received information about the fact that sotalol would be prescribed on a trial basis, and whether he had been given information on its risks and side effects, and what to do if side effects presented.

17. Dr B stated that information about sotalol "would have been given by him to Mr A at the bedside during the ward round". Dr B advised that his usual practice is to explain about the medication, why the patient is being prescribed it, any particularly important and relevant side effects, and how long the patient will need to take the medication. Dr B stated that because this is his usual practice, it is not necessarily written in the clinical records. As he was aware of the possible respiratory side effect, it was Dr B's intention that Mr A would have the first dose of sotalol whilst in hospital so that he could be under supervision.

18. Mr A stated that he was given no information at any time about what sotalol is, why he needed it, what the side effects might be, or that it should initially be taken as a trial dose.

19. There is no documentation in the notes as to the potential risks of administering this medication to Mr A, and there are no written instructions to the nursing staff setting out the requirement for a test dose or any necessary observations.

Discharge

20. Mr A was relying on a shuttle to return him home once he had been discharged.

21. NDHB advised that the transportation was organised swiftly because the shuttle was in the main centre earlier than usual that day. NDHB stated that if Mr A had not been transported that day he would have remained in hospital until the following day, as the shuttle travels between the two centres only once a day. NDHB stated that "it is likely the opportunity of getting transport back [home] meant he left before he had the trial dose of Sotalol".

22. The discharge summary prepared at 9.25am by Dr C states: "We start him on Satolol [sic] 40mg BD orally." The plan included instruction for Mr A to "continue satalol [sic] and diltezim [sic]". The discharge medication reconciliation states that sotalol hydrochloride had been "started".

[7] Sotalol is a non-selective beta-adrenergic blocker used primarily in the management of cardiac dysrhythmias because of its class II (β-adrenoceptor blockade) and class III (potassium channel inhibition) antiarrhythmic activity. Medsafe product information lists bronchospasm (eg, bronchial asthma or chronic obstructive airways disease) as a contraindication to use.
[8] Twice daily.

23. At 9.50am a nurse (signature illegible) noted in the clinical records that the shuttle bus was "on way over now. Will pick up [Mr A] and take him home. [Mr A] needs to be at front entrance at 10.30. H/O [house officer] aware will do paper work by 10.30."

24. At 10.15am Mr A was transferred to the discharge lounge and, at 10.40am, he left on the shuttle. The discharge note states: "Script not given to patient by dr. Rang [Mr A's] wife and asked where to fax it. Faxed to [the] Pharmacy." The medication record was completed by the house officer.

25. Mr and Mrs A advised that they were later contacted by the hospital and told that Mr A had not been given a prescription, so it had been faxed through to the pharmacy. Mr A said that the prescription said only to take half a tablet, and there were no other instructions or warnings.

26. NDHB stated: "[I]n our experience it is not unusual for patients to be anxious to return home, particularly when their family is not close by and able to be with them. With the benefit of hindsight we can clearly see that Mr A's discharge should have been delayed for a day to enable the trial to be undertaken." Dr B apologised for the distress experienced by Mr A.

27. Mr A said that no hospital staff member warned him that he should have a trial dose of sotalol before leaving. He said he took the shuttle coincidentally because someone else had been dropped off at the hospital, and neither he, his wife nor hospital staff arranged the shuttle.

Medication reaction

28. On 4 May 2012, Mr A started the prescribed sotalol while alone at home. Mr A had an adverse reaction, which he said was so acute that he had the strength only to push the button on his medical alarm, and could not have made a telephone call. He suffered an acute exacerbation of his asthma and required emergency treatment at the local medical centre.

Responses to provisional opinion

Mr A

29. Mr A agreed with the information in the "facts gathered" section of my provisional opinion. He said that he and his wife do not understand why the doctors sent Mr A home early when they should not have done so.

Northland District Health Board

30. NDHB submitted as follows:

- There were communication and documentation errors. An initial single event, which was the failure to clearly document the need for the trial of sotalol, led to a lack of awareness by staff of the necessity to trial the medication.
- The house surgeon who completed the discharge documentation either assumed the drug had been given, or did not pick up the need for a trial.

- The arranged discharge was done in the best interests of the patient, and there were beds available should discharge not have occurred. The intention was to try to get the patient home, which was done with the best of intentions, rather than being a push to discharge.
- GP care was able to address the matter, and there was no long-term issue for Mr A. The case is at the low end of departures from expected care and, as a single event triggered the scenario, in NDHB's opinion, the Commissioner's findings are unfair.
- NDHB has done a "massive" amount of work on improving documentation standards.

Opinion: Breach — Northland District Health Board

Introduction

31. In my view, this case demonstrates a failure to do the basics well. The notes are insufficiently clear and were not queried by the nursing or medical staff, and important information was not given to the patient.

32. Although NDHB submitted that the intention was to try to get Mr A home, rather than being a push to discharge him, I remain of the view that the discharge planning was rushed, as is shown by the failure to give Mr A his first dose of sotalol and his prescription.

33. As advised by my independent expert advisor, physician Dr Kingsley Logan:

> "The information transcribed on ward round and later translated into the discharge summary is limited and the prescription was not given under guidance/instruction on the ward round. All of these represent missed opportunities and impacted on the unfavourable outcome."

34. Dr Logan noted that not only are discharge documents and prescriptions essential for handover, but they also create the opportunity to inform, clarify, and educate.

Appropriateness of sotalol

35. Sotalol is a non-selective beta-adrenergic blocker used primarily in the management of cardiac dysrhythmias (also known as arrhythmias).[9] The MedSafe product information lists bronchospasm (eg, bronchial asthma or chronic obstructive airways disease) as a contraindication to use. Dr Logan advised me that beta-blockers are not usually prescribed for patients with severe asthma, particularly if this is unstable or the patient is prone to severe exacerbations.

36. However, Dr Logan also advised that sotalol has been shown to be the most effective beta-blocker in promoting sinus rhythm after cardioversion. Dr Logan considered that,

[9] Irregular heartbeat.

as Mr A had been evaluated clinically and with an echocardiogram, it was reasonable to prescribe an antiarrhythmic to prevent further occurrences of atrial fibrillation.

37. Dr Logan noted that the recommended initial dose of oral sotalol in adults is 80mg twice daily. Mr A was prescribed a smaller dose of 40mg twice daily. Dr Logan stated that, "as a rule, Sotalol should be initiated and doses increased in hospital. This predominantly relates to the proarrhythmic effects rather than broncho spasm. Sotalol as with many of the antiarrhythmics are thought to have a significant risk in patients with left ventricular hypertrophy."

38. I accept that it was appropriate to prescribe sotalol for Mr A. However, he should have been administered a test dose in a controlled situation, such as in hospital.

Instructions

39. The notes from the 9am ward round, completed by medical registrar Dr C, state: "Start Sotalol 40mg BD — start one dose now. If tolerating well can continue on maintenance dose." The medication was written up on the medication record by the house officer as a twice daily ("BD") regular prescription rather than as a stat dose (to be given immediately). The clinical notes do not state explicitly that Mr A was required to remain in hospital for a defined period following his initial dose of sotalol, nor are there any instructions to the nursing staff on what observations were to be undertaken or specific symptoms to watch for following the test dose. As submitted by NDHB, the failure to clearly document the need for a trial of sotalol led to a lack of awareness by staff of the necessity to trial the medication. In addition, I have been provided with no evidence that any staff member questioned whether the "one dose [of sotalol]", as referred to in the ward round notes, had been administered.

Discharge

40. Mr A was transferred to the discharge lounge at 10.15am without having been given the trial dose of sotalol. NDHB stated that it is likely that the opportunity of obtaining transportation home meant that Mr A left before he had the trial dose. In response to my provisional opinion, NDHB stated that the house surgeon who completed the discharge documentation either assumed the drug had been given, or did not pick up the need for a trial.

41. NDHB also emphasised that there was no "push" to discharge Mr A, and beds were available. Instead, the intention was to try to get Mr A home on the limited transport available. However, Mr A's first dose of sotalol had not been administered, and he was not given his prescription when discharged. Irrespective of the reason for discharging Mr A, I agree with Dr Logan's comment that "early discharge should not impact on patients going home with completed discharge documentation and prescription. Whilst being essential for handover of care these also create the opportunity to inform, clarify and educate."

Conclusions

42. In my view, poor communication led to this situation. Mr A was not advised of the importance of trialling the sotalol in hospital and the reasons for this, and he was not informed of the risks of taking the medication, which meant that he was not in a

position to express concern when he was discharged before the trial took place. Mr A was not aware of the potential for an adverse reaction. This information would have enabled Mr A to be a partner in his own treatment. There was poor communication to the nursing staff regarding the intended plan to trial the medication, no instructions were given as to observations that were to be undertaken and the period of observation, and no instructions were given as to when it would be safe to discharge Mr A. Furthermore, sotalol was prescribed as a regular medication rather than a stat trial dose, and the discharging doctor either failed to notice, or did not question, the instruction in Mr A's records.

43. There was a further opportunity to identify the missed trial when the prescription for sotalol was written and faxed to the pharmacy, but no information was provided about risks or the need for supervision when starting sotalol.

44. NDHB has a responsibility to ensure that its staff provide services of an appropriate standard. I find that services were not provided to Mr A with reasonable care and skill and, accordingly, NDHB breached Right 4(1) of the Code. Furthermore, Mr A's continuity of care was inadequate, and therefore NDHB breached Right 4(5) of the Code.

45. I have accepted Mr A's account that he was not informed about the risks and benefits of sotalol, and the need to take a trial dose. This was information that a reasonable person in Mr A's circumstances would expect to receive. By not giving Mr A that information, NDHB breached Right 6(1)(b) of the Code.

Recommendations

46. I recommend that NDHB apologise to Mr A. The apology is to be sent to HDC for forwarding by **9 October 2013**.

47. I recommend that NDHB undertake the following:

    1. Use an anonymised version of this case for the wider education of medical and nursing staff.
    2. Arrange for staff to undergo training on the use and contraindications of beta-blockers, in particular for patients with asthma.
    3. Arrange for staff to undergo training on record-keeping and communication.
    4. Conduct a review to assess the effectiveness of the aforementioned training.

48. NDHB is to comply with these recommendations and report back to this Office by **20 December 2013.**

Follow-up action

49. • A copy of this report with details identifying the parties removed, aside from the experts involved in this case and NDHB, will be placed on the Commissioner's website, www.hdc.org.nz, for educational purposes.

Names have been removed (except Northland DHB and the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix A — General practitioner advice to the Commissioner

The following clinical advice was obtained from GP Dr David Maplesden:

"1. Thank you for providing this file for review. I have read all the information available including: complaint from [Mrs A]; response from Northland DHB; clinical notes from [the main centre hospital and the local hospital]. [Mr A] was prescribed sotalol by staff at [the local hospital] on 3 May 2012 as prophylaxis against atrial flutter. This was done with the knowledge he suffered from asthma and COPD. An in-hospital test dose was intended but did not eventuate and [Mr A] was discharged and took the first dose at home on 4 May 2012. He suffered an acute exacerbation of his asthma (a known side effect of the medication) and required emergency treatment at the local medical centre. The risks of the medication trial were evidently not discussed with [Mr A].

2. [Mr A] has a history of asthma and COPD. He had stopped smoking about 2009. Hospital records indicate admissions in July 2008 for *asthma, SOB, CORD* and in November 2008 for *acute asthma.* [Mr A's] admission medications included inhaled Flixotide, Ventolin and Duolin. Admission documentation refers to diagnoses of asthma and COPD, and the GP referral letter dated 1 May 2012 included a diagnosis of COPD but did not specifically mention asthma. It is not clear from the information on file whether [Mr A] had spirometry proven reversible airways disease, or the severity of his respiratory disease. However, I conclude that [Mr A's] providers should have been aware of his diagnoses of COPD and asthma at the time Sotalol was prescribed on 3 May 2012.

3. There were sound clinical indications for the use of Sotalol as a means of reducing the risk of recurrence of atrial flutter in a patient who had recently had restoration of sinus rhythm following cardioversion for recurrent atrial flutter.

4. Clinical notes for 3 May 2012 (just prior to [Mr A's] discharge from [the local hospital]) include assessment findings of *feeling well, pain free, SOB, cough, sputum…HR 70…Ch clear.* Management notes refer to changing his antibiotic and *start sotalol 40mg BD — start one dose now, if tolerating well can continue on maintenance dose…can be discharged home today.* The medication was charted but not administered prior to [Mr A's] discharge. It is not clear what information he was given regarding possible side effects (predominantly an exacerbation of asthma) and what to do if such side effects occurred. The complaint notes the medication was picked up on 4 May 2012 and [Mr A] took sotalol as prescribed, experiencing significant breathing difficulties within a short time of taking the first dose. He required emergency attention at his local medical centre.

5. Sotalol is a non-selective beta-adrenergic blocker used primarily in the management of cardiac dysrhythmias because of its class II (β-adrenoceptor blockade) and class III (potassium channel inhibition) antiarrhythmic activity. Medsafe product information[10] lists *Bronchospasm (e.g. bronchial asthma or*

[10] Available at http://medsafe.govt.nz/profs/Datasheet/s/Sotaloltab.pdf

chronic obstructive airway disease) as a contraindication to use. A 1998 study[11] testing the portion of sotalol (which is a mixture of two 'mirror image' molecules) with some cardioselective properties concluded *despite theoretical considerations, it cannot be assumed that (+)-sotalol is safe in patients with asthma.* It seems therefore that sotalol may not be safe to use in patients with bronchospasm, unlike some other beta-blockers which have different (cardioselective) properties (see below).

6. There have been recent studies on the use of cardioselective beta-blockers in the treatment of COPD and asthma. One such study regarding use of the medications in COPD[12] concluded, *We have shown that β blockers (predominantly cardioselective) may confer reductions in mortality, exacerbations, and hospital admissions in patients with COPD, in addition to the benefits attributable to addressing cardiovascular risk. These additive benefits were seen across a spectrum of inhaled stepwise therapy, including inhaled corticosteroids, long acting β agonists, and long acting antimuscarinics, and did not result in any worsening of pulmonary function in our study cohort. Our study supports the use of β blockers in COPD patients.*

7. A 2007 local review article on beta-blocker use in asthmatics and COPD patients[13] concluded *current evidence indicates that cardioselective beta-blockers are not contraindicated in patients with airways disease, and they may be especially useful in patients with COPD due to their increased risk of cardio-vascular mortality. Overly cautious clinicians may be denying important benefits to a group of patients with significant co-morbidity. However, it is still appropriate to apply certain provisos, which are themselves not evidence-based, to minimise the risk of adverse reactions. It is logical not to use beta-blockers in patients with severe asthma, particularly if it is unstable or the patient is prone to severe exacerbations. Moreover, during an exacerbation, beta-blockers should probably be temporarily withheld at a time when beta-blockade may be naturally increased due to the effects of pro-inflammatory cytokines. It would also be prudent to offer a test dose and/or to titrate the dose of beta-blocker at the commencement of treatment to ensure tolerability* [my emphasis]. *Finally, the key to successful treatment should also include patient education of the benefits and risks of beta-blocker use and also to maintain optimal control of their air-way disease.*

Key points from the meta-analyses examined were:

• *Beta-blockers reduce mortality in patients with cardiovascular disease, of which there is a high prevalence in patients with COPD.*

[11] Devereux G et al. Adverse effects of a single dose of (+)-sotalol in patients with mild stable asthma. Br J Clin Pharmacol. 1998 July; 46(1): 79–82.

[12] Short P et al. Effect of β blockers in treatment of chronic obstructive pulmonary disease: a retrospective cohort study. BMJ 2011; 342:d2549.

[13] Sutherland T et Taylor D. Beta-blockers in asthma and chronic obstructive pulmonary disease — shouldn't be used or underused? NZFP. 2007:34(1):35–37.

• In reversible airways disease, a single dose reduces FEV_1 but response to beta-2 agonist is pre-served. Continuous treatment with higher doses of cardioselective beta-blockers appears not to have a detrimental effect on FEV_1 or respiratory symptoms.

• In COPD, the use of cardioselective beta-blockers is unlikely to have a significant effect on FEV_1, respiratory symptoms or response to beta-2 agonists, even in severe airway obstruction.

• Treatment can be initiated at low doses and titrated upwards if there are no clinically adverse reactions.

8. The key recommendations from this study, and on which my subsequent comments are largely based, were:

• Cardioselective beta-blockers may be used in patients with COPD or asthma that is mild–moderate and well-controlled.

• Patients should be optimally medicated with inhaled corticosteroids with or without long-acting beta agonist medication as appropriate, prior to starting beta-blockers.

• Beta-blockers should not be used in patients who have a history of brittle asthma or severe exacerbations.

• There are no definitive data on the benefits of withholding beta-blockers during an exacerbation but it seems prudent to do so.

• In high-risk individuals, after an initial test dose, the dose of beta-blockers should be titrated slowly upwards to ensure tolerability.

• Patients should be educated about potential side-effects, particularly during an exacerbation.

9. Comments

(i) [Mr A] had asthma and COPD. He had required two hospital admissions for asthma in 2008 indicating at least moderate disease.

(ii) While sotalol is indicated for rhythm control in supraventricular tachyarrythmias, there are other options including amiodarone, flecainide, propafenone and calcium channel blockers ([Mr A] had been prescribed the calcium channel blocker diltiazem). Although all of these medications have significant side effect profiles, none are contraindicated in the presence of known asthma/COPD.

(iii) The use of sotalol (a non-selective beta blocker) as a second line agent for rhythm control in [Mr A] ahead of other options, given his history of at least moderate asthma and COPD, may not have been a clinically sound decision. A cardiologist or general physician would be best placed to make definitive comment on this issue.

(iv) While it was apparently intended [Mr A] would receive his first dose of beta-blocker in hospital, this did not happen indicating a breakdown in communication between medical and nursing staff. The clinical notes did not state explicitly that [Mr A] must remain in hospital for a defined period following his test dose of sotalol, nor any instructions to nursing staff on observations to be undertaken or specific symptoms to be watched for following the test dose.

(v) There is nothing in the clinical notes, or in [Mr A's] complaint, to indicate he was explained the potential risks to him of the non-cardioselective beta blocker trial or indeed that it was a trial, what symptoms to watch for, or what to do if the symptoms occurred.

(vi) Taking all of these factors into account, including the potential severity of reactions to non-cardioselective beta-blockers in asthmatic patients (see previous HDC decision 04/19938[14]), I feel the management of [Mr A] by Northland DHB may have been at least a moderate departure from expected standards.

(vii) I recommend HDC gain expert advice from a general physician regarding the following issues:

a. Was it reasonable for sotalol to be prescribed ahead of other anti-arrhythmics given [Mr A's] current and past medical history?

b. If it was reasonable for sotalol to be prescribed, how important was it that a test dose be given while [Mr A] was in hospital?

c. Please comment on the clarity of instructions given regarding the intended test dose of medication (including any formal observation of the patient following the test dose).

d. Please comment on the apparent lack of information given to the patient regarding the risks and benefits of a trial of sotalol in his particular clinical situation."

Further clinical advice from Dr Maplesden

"1. I have reviewed the expert advice received from physician Dr K Logan. Dr Logan appears to regard the prescribing of a trial of sotalol for [Mr A] as being clinically reasonable (see section 8(iii) of my original advice dated 23 July 2012), but that a combination of systemic errors leading to his discharge before trialling the medication in hospital was a moderate departure from expected standards. The systemic errors appear to include:

(i) poor communication to the patient regarding the intention of trialling the medication (Sotalol) in hospital, the reason(s) for this and the potential risks of the medication. [Mr A] was therefore unable to express concern when he was discharged without the trial having taken place.

[14] Available at http://www.hdc.org.nz/decisions--case-notes/commissioner%27s-decisions/2006/04hdc19938.

(ii) poor communication (oral and written) to nursing staff regarding the intended plan to trial the medication, what observations were to be undertaken over what period, and when was [Mr A] safe to discharge.

(iii) the prescribing of Sotalol as a regular medication rather than a stat trial dose.

(iv) poor communication between nursing staff regarding [Mr A's] transport and discharge arrangements relative to the intended medication trial.

(v) a lost opportunity to identify the missed trial when a prescription for Sotalol was written and faxed to the pharmacy.

2. I think it is reasonable to address this departure from expected standards by means of an educational approach — specifically using this case (anonymised and with [Mr A's] consent) for education of medical and nursing staff regarding appropriate management of in-hospital medication 'trials'. Such education should include emphasis on the basic issues of patient information and consent, and adequate clinical documentation.

3. I think it is reasonable for [Mr A] to expect a formal written apology from the DHB (if this has not already occurred) for any distress suffered by himself and his family as a consequence of the deficiencies in care leading to him taking a test dose of sotalol in the community rather than in hospital as intended."

Appendix B — Independent physician advice to the Commissioner

The following clinical advice was obtained from physician Dr Kingsley Logan, FRACP:

"Dr Maplesden has addressed the issue of diagnosis of asthma/COPD diagnosis. The description we have suggests that [Mr A] developed significant bronchospasm following the first dose of Sotalol. This would have been easily identified if the drug had been given whilst in hospital.

It is not clear from the notes whether he had spirometry or reversible airways disease. Similarly the severity of his respiratory disease has not been documented. He was however regarded as having COPD/Asthma on a background of smoking.

Beta-blockers are not usually prescribed in patients with severe asthma particularly if this is unstable or the patient is prone to severe exacerbations.

[Mr A] was symptomatic but it appears that these symptoms were associated with his rapid heart rate and it was reasonable therefore to prescribe a drug that could maintain sinus rhythm following successful cardioversion.

Selective beta1 blockers have a 20-fold greater affinity for beta1 adrenergic receptors than beta2 adrenergic receptors and, therefore, are less likely to induce bronchoconstriction.

A retrospective study evaluated 8390 patients with asthma or COPD who were prescribed a beta blocker (either selective beta1 or nonselective beta1/beta2) or an alternative cardiovascular agent for a wide variety of indications. Patients taking beta blockers had the same hospitalisation rate and clinic visit rate for symptoms related to their asthma or COPD as patients prescribed an alternative cardiovascular agent. There were no differences when patients taking selective beta1 blockers were compared to patients taking non selective beta1/beta2 blockers.

The major issue however is that of all the beta blockers, Sotalol has been shown to be most effective in promoting sinus rhythm after cardioversion and is not given therefore as other beta blockers for simple rate control.

Was it reasonable for Sotalol to be prescribed ahead of other anti-arrhythmics given [Mr A's] current and past medical history?
Sotalol can promote maintenance of sinus rhythm after cardioversion in patients with AF. Whilst it is less effective than amiodarone [Mr A] had failed conversion on Amiodarone and there was little to indicate that Amiodarone would have been effective as prophylaxis. The potential for harm for many of the other anti-arrhythmics is also significant and includes Amiodarone Flecainide and Sotalol.

[Mr A] had been carefully evaluated clinically and on echo. This had shown Echo mild concentric LVH, mild diastolic dysfunction preserved LV systolic function. The Left Atrium was mildly dilated and having had two episodes within a matter of days it was reasonable to prescribe an anti-arrhythmic to prevent further recurrences.

If it was reasonable for Sotalol to be prescribed, how important was it that a test dose was given while [Mr A] was in hospital?
The recommended initial dose of oral sotalol in adults [is] 80mg twice daily, he was prescribed a smaller dose 40mg twice daily. As a rule, Sotalol should be initiated and doses increased in hospital. This predominately relates to the pro-arrhythmic effects rather than bronchospasm. Sotalol as with many of the anti-arrythmics are thought to have a significant risk in patients with left ventricular hypertrophy.

Comment on the clarity of instructions given regarding the intended dose of medication and formal observation of the patient following the test dose.
The notes from the 9am ward round denote specific instructions 'start Sotalol now and if tolerating well can continue on maintenance dose.'

The drug was then written up as a BD prescription that is twice daily rather than a stat dose ie, to be given immediately.

The instructions seemed to have been circumvented by transport arrangements although nursing note suggest at 9.50am that the shuttle bus was contacted that time. Finally the script was not given at discharge and faxed later to the external dispensary.

Comment on the lack of information given to the patient regarding the risks and benefits of a trial of Sotalol in his particular situation.
The information transcribed on ward round and later translated into the discharge summary is limited and the prescription was not given under guidance/instruction on the ward round. All of these represent missed opportunities and impacted on the unfavourable outcome.

The accent on reduced length of stay and early discharge should not impact on patients going home with completed discharge documentation and prescription. Whilst being essential for handover of care these also create the opportunity to inform, clarify and educate.

The departure of standard of care has been addressed by Dr Maplesden and indicates systemic issues of discharge seemingly dictated by transport arrangements rather than specific medical instruction.

Nonetheless the standard of patient information, clarity of instructions regarding the intended dose of medication and formal observation of the patient following the test dose were lacking.

Trial of therapy
The NZ heart foundation guidelines in atrial fibrillation promote combinations of drugs including Beta-blockers as providing effective rate control but also emphasise the limited indication that Sotalol has in promoting sinus rhythm.

As with many drugs the potential side effects has to be considered. Nonselective beta1/beta2 blockers can cause bronchoconstriction in susceptible individuals but rapid atrial arrhythmias also have deleterious effects as manifested in this particular case.

Beta blockers are modestly effective in maintaining sinus rhythm and can be tried first in selected patients, such as those without structural heart disease who are concerned about pro-arrhythmia. Compared to other agents, Amiodarone is associated with the greatest likelihood of maintaining sinus rhythm, but also with the highest risk of long-term complications. Quinidine, procainamide, and disopyramide are no longer recommended for patients with AF.

There were a number of drugs used in an attempt to control the situation as were there anaesthetic agents and electrical conversion all of which are prone to have side effects. Whilst all these risks would not have been fully detailed the drugs were all given under supervision whilst in hospital. The dose of Sotalol should be individualised on the basis of therapeutic response and tolerance and as a rule, Sotalol should be initiated and doses increased in a hospital setting."

Additional advice from Dr Logan

"[…] Whilst the order [for sotalol] was poorly documented the compounding factor was that it wasn't followed [through] by the nursing staff.

The fact the patient left prematurely without adequate documentation or explanation seems to have been dictated by transport rather than clinical direction.

The potential side effect[s] of Sotalol relate more often to rhythm disturbance which was not a factor in this case. The bronchospasm would have been easily identified and treated if the drug had been given whilst in hospital.

There is no indication in the notes that the doctors involved were aware that the patient was discharged without having had the initial dose as prescribed.

There is a combination of systemic errors which impacted and in this situation I would regard as a moderate departure from an acceptable standard of care."