General Practitioner, Dr B

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 13HDC01041)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mr A had a complicated medical history and was taking several medications. On 14 June 2007 he went to a medical practice, now known as the medical centre, due to experiencing shoulder pain and was prescribed diclofenac (trade name Voltaren) by general practitioner (GP) Dr C.

2. On 25 September 2007 Mr A was reviewed by GP Dr D at the medical centre following an episode of faintness. Blood test results showed a significant deterioration in renal function and Dr D thought the diclofenac, prescribed previously, might be causing the deterioration and he documented this in Mr A's clinical notes. Dr D told Mr A to stop taking the medication and advised him not to take it again. A warning was placed on the clinical file stating "Diclofenac sodium – renal failure/retention – avoid."

3. On 12 December 2007 Mr A saw GP Dr B for a check up. Dr B recorded at the time in Mr A's clinical notes "Note renal impairment with addition of Diclofenac".

4. On 10 Month1[1] 2012 Mr A saw Dr B for ongoing ankle pain not relieved by ibuprofen. Dr B prescribed a two week supply of diclofenac 75mg sustained release tablets twice daily. Dr B said that he did not recall that Mr A had previously had a bad reaction to diclofenac and advised that he did not remember any warning coming up on the computer system about Mr A's previous reaction to diclofenac.

5. On 7 Month2 2012 Mr A returned to Dr B with pain in the joints of his right foot. Dr B made a diagnosis of probable gout and advised that he keep taking the diclofenac. On 9 Month2 Mr A returned to see Dr B as Mr A had been unable to pass urine in the last two days. Dr B diagnosed urinary retention and referred him to the public hospital.

6. Mr A was assessed at the public hospital that day and was diagnosed with acute on chronic renal failure. HDC was advised that it became evident that Mr A had had issues with 'Voltaren' and renal impairment in the past and that he had not realised that diclofenac and Voltaren were the same thing.

7. Mr A began showing signs of multi-organ failure and sadly passed away.

Findings

8. By failing to appropriately establish Mr A's medical history either by adequately questioning Mr A or reviewing his clinical notes, take adequate regard of Mr A's NSAID associated risks, particularly cardiovascular risks and interaction with concurrent medication and adequately monitor Mr A's renal function when prescribing diclofenac to him, Dr B did not provide services with reasonable care and skill and therefore breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[2]

[1] The relevant months in 2012 are referred to as Month1 and Month2 to protect privacy.

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

9. Dr B breached Right 6(1)(b) of the Code[3] because the risks of diclofenac use compared with risks or benefits of alternative treatments were not discussed with Mr A at either the 10 Month1 or the 7 Month2 appointments. Without this information Mr A was not in a position to make an informed choice, and give his informed consent to taking the medication. Accordingly, Dr B also breached Right 7(1) of the Code.[4]

10. Adverse comment is made about the medical centre for not ensuring that its computer systems were fully functioning, or that a temporary system was in place for its doctors to follow, while the systems were undergoing changes.

Complaint and investigation

11. The Commissioner received a complaint from Mrs A about the treatment provided to her late husband Mr A by the medical centre. The following issues were identified for investigation:

- *The appropriateness of the care provided to Mr A by Dr B between June 2007 and Month2 2012.*
- *The appropriateness of the care provided to Mr A by the medical centre between August 2010 and Month2 2012.*

12. An investigation was commenced on 24 February 2014.

13. The parties directly involved in the investigation were:

Mrs A	Complainant
Dr B	General practitioner/Provider
The medical centre	Provider

14. Information was also reviewed from:

Dr C	General practitioner
The District Health Board	

Also mentioned in this report:

Dr D	Locum general practitioner

15. Independent expert advice was obtained from General Practitioner (GP) Dr David Maplesden (**Appendix A**).

[3] Right 6(1)(b) of the Code 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."

[4] Right 7(1) of the Code states: "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."

Information gathered during investigation

Background

16. Mr A, aged 80 years at the time of his death, had a complex medical history including ischaemic heart disease,[5] osteoarthritis,[6] hypertension,[7] gout[8] and chronic renal impairment[9] (mild). He was taking a number of medications for these conditions, including frusemide,[10] cilazapril,[11] aspirin, omeprazole,[12] isosorbide mononitrate,[13] metoprolol,[14] simvastatin,[15] perhexilene,[16] diltiazem,[17] paracetamol, GTN spray,[18] Seretide[19] and Duolin[20] inhalers.

Mr A's first prescription for diclofenac

17. On 14 June 2007 Mr A went to see GP Dr C at a medical practice which merged in Month2 2012 with the medical centre. Mr A was experiencing shoulder pain and was prescribed the non-steroidal anti-inflammatory (NSAID) diclofenac sodium (diclofenac). Voltaren is a trade name for diclofenac. Mr A's clinical notes state "for Voltaren prn initially". The written prescription was for 25mg diclofenac three times daily as required. There was a three month repeat on the prescription.

18. Three months later, on 25 September 2007 Dr D, a locum GP, reviewed Mr A following an episode of faintness. Routine blood tests were ordered.

19. On 28 September 2007 Dr D reviewed Mr A again. The blood test results showed a significant deterioration in renal function from previous tests and Dr D thought the diclofenac might be causing the deterioration. He documented in Mr A's clinical notes "[Significant] renal impairment appears to be related to diclofenac". Dr D told Mr A to stop taking the medication and advised him not to take it again. A warning was

[5] Reduced blood supply to the heart.
[6] The most common form of arthritis causing cartilage breakdown in the joints.
[7] High blood pressure.
[8] A common, painful form of arthritis (joint inflammation).
[9] Also known as kidney failure or renal insufficiency, a medical condition in which the kidneys fail to adequately filter waste products from the blood.
[10] Used to treat congestive heart failure and edema. It is a diuretic which means it promotes the production of urine.
[11] An angiotensin-converting enzyme inhibitor (known as an ACE inhibitor) used for the treatment of hypertension and congestive heart failure.
[12] Used to treat conditions caused by excess stomach acid.
[13] A drug that dilates the blood vessels so as to reduce blood pressure.
[14] A beta-blocker that affects the heart and circulation (blood flow through arteries and veins). Metoprolol is used to treat angina (chest pain) and hypertension (high blood pressure). It is also used to treat or prevent heart attack.
[15] A cholesterol-lowering medication that blocks the production of cholesterol.
[16] Used in the treatment of unresponsive or refractory angina.
[17] Used to treat high blood pressure, angina and certain heart rhythm disorders.
[18] Glyceryl trinitrate (GTN) is used for angina. A short-acting preparation (such as a spray or a tablet) is taken to ease angina pain when it happens. In Mr A's case this was prescribed as PRN medication (taken as needed).
[19] Used for the treatment of reversible obstructive airway disease including asthma, and for the treatment of chronic obstructive pulmonary disease (COPD).
[20] Used for prevention as well as treatment of bronchospasm (which is caused by various respiratory conditions).

placed on the electronic clinical file stating "Diclofenac sodium – renal failure/retention – avoid."

20. On 12 December 2007 Mr A saw Dr B at the medical centre for a check up. Dr B recorded at the time in Mr A's clinical notes "Note renal impairment with addition of Diclofenac".

GP care from 2008-2012

21. Mr A's clinical notes show that his renal function was monitored regularly. His renal function gradually improved with Dr C documenting on 7 March 2008 "Kidney function recovered off voltaren". Mr A continued to be reviewed at the medical centre approximately every three months.

22. There are several entries in the clinical notes during 2010 which state that Mr A's renal function showed no further deterioration. An entry by Dr B on 20 September 2010 recorded "Renal function ok".

23. On 16 May 2012 Mr A went to Dr B complaining of shoulder pain. At this appointment Dr B recorded in the clinical notes "Shoulder painful on and off over last 3 years – Diclofenac caused DU [duodenal ulcer]"[21]. Dr B prescribed Kenacort[22] and paracetamol for the shoulder pain.

Mr A's second prescription for diclofenac

24. On 5 Month1 2012 Mr A's clinical notes record that he had pain in his right foot and left heel and that he was self medicating ibuprofen[23] which seemed to help. The notes record that he should take 400mg of ibuprofen as required.

25. On 10 Month1 Mr A saw Dr B for pain and swelling in his left foot and ankle. Mr A's renal function was noted to be "OK". Dr B prescribed a two week supply of diclofenac 75mg sustained release tablets twice daily (to be taken as required) with Omeprazole for gastrointestinal cover[24] and referred Mr A for an X-ray.

26. Dr B stated that he did not recall at the time that Mr A had "previously suffered renal impairment, possibly due to Diclofenac". Dr B said that he does not recall any warning coming up on the computer when he prescribed diclofenac for Mr A. He also said that if a warning had come up, it is possible he interpreted such a warning for "renal impairment" as being a relative contra-indication (i.e. advising precaution with the use of NSAIDs) rather than an absolute contraindication, and therefore that he may have chosen to "use Diclofenac and monitor for renal deterioration". He further stated: "I do not think that I would have prescribed Diclofenac had I seen the warning."

[21] There is no other reference in the clinical notes to a duodenal ulcer.
[22] Used to treat painful muscles, joints or tendons by injecting directly into the painful site.
[23] A non-steroidal anti-inflammatory drug which can be purchased over the counter.
[24] As diclofenac can cause gastric irritation.

Mr A's third prescription for diclofenac

27. On 7 Month2 Mr A returned to Dr B with pain in the joints of his right foot. Mr A advised Dr B that he had stopped taking the diclofenac.[25] Dr B made a diagnosis of probable gout. He noted in Mr A's clinical notes: "Not taking diclofenac at present. Has been on Allopurinol in past. Renal function reasonable. Restart diclofenac and omeprazole. RFT [renal function tests] 1 month then see me."

28. Although not documented, Dr B advised that, while he knew there were a number of alternative treatments for acute gout, he considered the use of a NSAID such as diclofenac with monitoring of renal function, as the most suitable option in Mr A's case. Furthermore, he advised: "Diclofenac has for many years been the NSAID of choice for many general practitioners in NZ".

29. In addition, Dr B referred to a Best Practice Advocacy Centre (BPAC) publication[26] which recommended NSAID use as first line treatment for acute gout and included diclofenac in its recommended list of drugs.[27]

30. There is no documented evidence that Dr B discussed the prescription of diclofenac with Mr A or noted that diclofenac was often known as Voltaren. Dr B advised HDC that all his prescribing is done generically "I rarely use the name Voltaren and prefer to use the generic name Diclofenac". He advised that it is "possible I did ask [Mr A] during the consultations of [10 Month1 and 7 Month2] if he had previous problems with diclofenac [as opposed to Votaren]. This may have resulted in failure to recognise the potential for an adverse reaction by [Mr A]".

31. Dr B advised HDC that he asked Mr A to return in one month for a blood test to check his renal function. Dr B advised HDC this was to ensure that Mr A's renal function was not affected by the diclofenac. He further advised HDC "I did not expect there to be deterioration given that he was not taking continuous Diclofenac". He also said that following the one month review "Diclofenac dose reduction would likely have occurred".

32. On 9 Month2 Mr A returned to see Dr B as Mr A had been unable to pass urine in the last two days. Dr B noted that Mr A's gout pain had gone. Dr B diagnosed urinary retention and, given Mr A's complicated medical history, Dr B referred Mr A to the public hospital. Mr A's referral letter stated "Gout 2 days ago – started on Diclofenac – unable to pass urine for 2 days. Palpable bladder and enlarged prostate".

33. Later that day Mrs A visited Dr B and advised him that Mr A had previously had problems with Voltaren. Dr B said he reviewed the notes and found the medical warning entered by Dr D in 2007 stating that diclofenac had caused "renal

[25] It is not recorded why he had stopped taking the drug.
[26] *Medical Management of Gout Revisited*, August 2011.
[27] Previous publications from BPAC cited other drugs as being more suitable than diclofenac (see: http://www.bpac.org.nz/BPJ/2006/October/docs/nsaids_pages_18-21.pdf) and since these events, a BPAC publication dated October 2013, 'NSAID – Making Safer Treatment Choices', was circulated to GPs which advised against prescribing diclofenac, particularly for older patients, patients with increased cardiovascular risk, patients with type 2 diabetes, patients with reduced renal function, or patients with a history of renal problems.

impairment". He advised Mrs A that the wording of the warning would be "changed and highlighted 'acute renal failure'".

Admission and treatment at the public hospital

34. At 10.45am, that same day, Mr A was assessed in the Emergency Department (ED) at the public hospital. The medical notes record that he presented with urinary retention and dizziness. By 3pm the following diagnosis had been made:
    1. Acute on chronic renal failure secondary to NSAIDS.
    2. Gout
    3. Hypotension

35. The consultant physician treating Mr A at the public hospital advised HDC that during the initial assessment "it became evident that [Mr A] had issues with 'Voltaren' and acute renal failure in the past. [Mr A] had not realised that Diclofenac and Voltaren were the same thing".

36. Medical staff stopped any potentially nephrotoxic agents which in Mr A's case were diclofenac, cilazapril and frusemide, as these could contribute to renal failure and hypotension. Mr A was admitted to the ward with a plan in place for a renal ultrasound to look for structural renal disease, and to have his urine output monitored. By 5pm, however, Mr A had developed hypotension and bradycardia and vomiting.

37. Mr A continued to deteriorate over the next 1-2 hours and at around 8pm suffered a cardiac arrest. CPR was commenced and Mr A was intubated. CPR was successful leading to a return of spontaneous circulation. Mr A was subsequently transferred to the intensive care unit for further management.

38. On 10 Month2 Mr A continued to deteriorate, he began showing signs of multi-organ failure and his neurological function appeared severely impaired.

39. At 2pm Mr A's family were made aware of the poor prognosis and due to ongoing clinical deterioration despite maximal therapy, it was decided to withdraw ICU level care. All active treatment was discontinued and Mr A died that day at 2.43pm. The cause of death was documented in the hospital notes at the time as "acute on chronic renal failure probably secondary to NSAID with resulting hyperkalaemic[28] cardiac arrest".

Further information provided to this Office

40. Dr B provided this Office with comments from Dr E regarding Dr B's decision to prescribe diclofenac in the circumstances. That commentary was, as is evident from Appendix A, provided to Dr Maplesden for consideration and comment. I have considered and weighed all such advice provided to this Office in making my decision.

41. Dr B told HDC that he was shocked to find that acute renal failure could have ensued after two days of diclofenac. Dr B advised HDC that in a later telephone discussion the consultant physician expressed the view that the acute renal failure was

[28] High levels of potassium in the blood.

multifactorial and unlikely to be due to four doses of diclofenac on its own. I note that it is not my role to determine the cause of death.

42. Dr B said that he had known and cared for Mr A for many years and that Mr A's "death and the circumstances have been distressing to me. I regret not having chosen an alternative approach to his management".

Computer systems

43. Dr B accepted that Mr A's clinical notes did already contain a warning regarding the use of diclofenac entered from 2007. He stated however that "the medical record system on which Mr A's records are kept should post an alert when there is an attempt to prescribe a medication for which an alert has been entered". As discussed above, Dr B advised that he does not recall a warning coming up on the computer when he prescribed diclofenac.

44. Dr B advised HDC that the merging of the medical practice with the medical centre in Month2 meant that from the beginning of Month1 through Month2 there were "possible computer difficulties", due to the computerised notes being amalgamated. He said this may have impacted access to Mr A's file, although he added "I cannot confirm this". He later advised HDC that during Month1 and Month2 "we experienced considerable frustration and inconvenience with the slow speed of access to the computerised clinical notes, patient notes were split between different files, and new laboratory data was not being received into the notes".

45. The medical centre uses the Medtech 32 database. The medical centre advised that there is an alert system contained in the patient's clinical records under the heading of Medical Warnings and this can show in black, blue or red. The medical centre said this is the alert system used to record no known allergies, or known allergies to drugs or other substances.

46. It further advised that, during Month1 and Month2 the databases were merged when the medical practice and the medical centre merged, resulting in periodic declines in computer performance. It stated however that at the time of the merger, Dr B received orientation and training to ensure his team and patients were safely integrated into their new environment. It advised that Dr B was a competent user of the database.

Changes to practice

47. Dr B advised that these events resulted in significant changes to his medical practice. He advised that when he is prescribing he no longer relies on the "automatic" warnings that are generated by the electronic medical notes software, and that he now actively searches the Medical Warnings folder in the patient's clinical notes.

48. Furthermore he advised that when he is not familiar with a patient's past medical history, he inserts an entry into the patient's notes to record that he has enquired about past adverse drug reactions. He said that when he is considering the potential renal implications of his prescribing, he now requires a recent assessment of renal function of less than 4 weeks and that when adding medications that are potentially renal toxic, he now requires renal function to be checked within 4 weeks of starting the medication. In response to my provisional opinion, Dr B further advised that, "where

clinical concern existed", he would request renal function tests to be undertaken within 1 to 2 weeks.

49. He further advised that he no longer uses diclofenac as his first choice of NSAID and that he uses lower doses of NSAIDs and for shorter periods of time. He advised that had the BPAC publication 'NSAID – Making Safer Treatment Choices' (as referred to previously at Footnote 27), been available at the time of these events then he believed that he would not have prescribed diclofenac to Mr A.

Responses to provisional opinion

50. In response to the provisional opinion the medical centre responded to comments about the potential for errors arising out of the merger process. It submitted that in its view the merger process allowed for "no such errors". However it advised that, in the interests of patient safety, it would undertake an audit of clinical records for Month1 and Month2 to ensure no other critical alerts were missed during this period and report the results of the audit to this Office within 3 months of the date of the final opinion, as per my recommendation (see below).

51. Dr B made several submissions which have been incorporated above as appropriate. In addition he asked that I remove from my report the conclusion that he did not take adequate regard of Mr A's NSAID associated risks and adequately monitor Mr A's renal function when he prescribed diclofenac to him.

52. Dr B considers it to be an erroneous finding that, "despite him not knowing about [Mr A's] prior reaction at the time, it was nevertheless wrong to have prescribed diclofenac", but he added that he "accepts that it would have been 'best practice' to discuss the risks of diclofenac and any alternative treatments with [Mr A]".

53. In addition he submitted that he resists "the unfairness that would result from a reader assuming from [the Commissioner's] findings that his decision to prescribe diclofenac is worthy of the same level of criticism as his failure to appropriately establish [Mr A's] medical history".

54. He submitted that his actions "must" be judged from the perspective that he did not have knowledge about Mr A's prior reaction to diclofenac, and that this is most likely due to the "computer system problems the practice was experiencing at the relevant time."

55. Mrs A made no comment in response to the provisional opinion.

Professional standards

56. In April 2010, the Medical Council of New Zealand issued a document entitled "Good prescribing practice".[29] Its stated aim is to "assist doctors to maintain appropriate prescribing practice", and advises that it may be used as a standard by which a doctor's conduct is measured.

57. The document advises doctors to prescribe medicines or treatment only in instances where they have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are satisfied that the medicines or treatment are in the patient's best interests.

58. The statement advises doctors to take the following precautions to ensure their prescribing is appropriate and responsible:

- *"Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe. Be aware that promotional and other drug information distributed by commercial interests is unlikely to be impartial; independent sources of information (such as bulletins certified by www.isdbweb.org) are preferred where available.*
- *Take an adequate drug history of the patient, including: any previous adverse reactions to medicines; current medical conditions; and concurrent or recent use of medicines (including non-prescription, complementary and alternative medicines).*
- *Consider whether a prescription is warranted given the nature of the patient's complaint and presentation, and whether a non pharmacologic treatment could be as effective and safe.*
- *Ensure that the patient (or other lawful authority) is fully informed and consents to the proposed treatment and that he or she receives appropriate information, in a way they can understand, about the options available; including an assessment of the expected risks, side effects, benefits and costs of each option. Satisfy yourself that the patient understands how to take any medicine prescribed and is able to take it.*
- *Never prescribe indiscriminately, excessively or recklessly.*
- *Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. In such circumstances, it might be useful to discuss the proposed treatment with a senior colleague before completing the prescription."*

[29] Available at www.mcnz.org.nz.

Opinion: Dr B - Breach

Mr A's care prior to 10 Month1

59. During the course of this investigation I obtained clinical advice from GP Dr David Maplesden. Dr Maplesden advised me, after reviewing Mr A's clinical notes, that there is nothing of concern regarding the management of Mr A's care between 2007 to the beginning of Month1 2012.

Prescriptions for diclofenac

60. As noted above, my role does not extend to determining the cause of Mr A's death. I am primarily concerned with the standard of care provided by Dr B to Mr A and whether that care accorded with accepted standards.

61. Under Right 4(1) of the Code, Mr A had the right to have services provided by Dr B with reasonable care and skill. When prescribing medication to a patient, a doctor must ensure they are familiar with the patient's medical history, in order to accurately assess the patient's needs and to satisfy themselves that the medication will be in the patient's best interests. Failing to do so can have serious and potentially fatal consequences for the patient.

62. Dr Maplesden has advised me that Mr A's clinical notes record that he had an absolute contraindication to the use of diclofenac – his previous significant adverse reaction to the drug. The reaction had been well documented in Mr A's clinical notes and an appropriate warning placed on his electronic file by Dr D in 2007.

63. Dr B accepted that Mr A's adverse reaction to diclofenac was recorded on the system. It was submitted that, due to the merging of the medical practice with the medical centre in Month2 2012 and "possible computer difficulties" in the lead up to, and during the merger, that the medical practice experienced at that time, that the warning may not have featured at the time Dr B prescribed Mr A diclofenac in Month1 2012. However, it is clear from Mr A's clinical notes that Dr B was aware of a contraindication when he saw Mr A on 12 December 2007 and again on 16 May 2012, as he noted a precaution against using diclofenac. Nevertheless, from Month1 Dr B failed to refresh his memory by establishing Mr A's history including any previous drug reactions either by adequately questioning Mr A or by reviewing Mr A's clinical notes or his electronic records before prescribing diclofenac.

64. Knowing the medical centre was experiencing possible computer issues at the time, should have resulted in an increased alertness by Dr B to the potential for significant drug interactions or adverse reactions being overlooked.

65. I note Dr B's comment that he prefers to use the generic name diclofenac, and that he may have asked Mr A if he had any previous problems with diclofenac and not mentioned the name Voltaren. However, there is no documented evidence of this.

66. I have previously highlighted the importance of taking a comprehensive history from the patient, reviewing risk factors, and having a discussion with the patient about the

medication before prescribing it.[30] Furthermore, the Medical Council of New Zealand's Standards: "Good prescribing practice", require a doctor to take an adequate drug history of the patient, including any previous adverse reactions to medicines, current medical conditions, and concurrent or recent use of medicines.

67. Even putting aside Mr A's previous adverse reaction, Dr Maplesden has advised me that there were multiple clinical considerations that made the prescribing of diclofenac a relatively high risk prescription for Mr A on 10 Month1 and 7 Month2.

68. Dr Maplesden advised me that Mr A's advanced age, history of chronic renal disease, history of ischaemic heart disease and concurrent use of aspirin, an ACE inhibitor and diuretic, all placed him at an increased risk of NSAID related side effects – particularly cardiac and renal side effects. Dr Maplesden advised me that the prescription of 75mg twice daily of diclofenac was also a relatively high dose given Mr A's age and other side-effect risk factors. Dr Maplesden said that Dr B's response did not indicate to him that Dr B took adequate regard of Mr A's NSAID associated risks, particularly cardiovascular risks and interaction with concurrent medications, when making the decision to advise use of diclofenac.

69. I note that Dr Maplesden advised me that, based on his review of many clinical records over the past years and noting the recent research on this topic,[31] he felt a significant number of his peers may have prescribed Mr A a NSAID (providing there was no documented past history of significant adverse reaction to the medication) even if this did not represent best clinical practice.

70. In Mr A's situation however, Dr Maplesden advised me "I feel the proposed and actual monitoring of [Mr A's] renal function if this drug and dose were to be used was inadequate. I make this comment irrespective of whether [Mr A's] previous adverse reaction to diclofenac had been recognised."

71. In relation to Dr B's concern about the perception of the relative seriousness of this decision to prescribe diclofenac as compared to his failure to appropriately establish Mr A's medical history, I note that I am not suggesting these failures were equal in magnitude.

72. I note that Dr B has now said that he will "check renal function within 4 weeks of starting the medication". In his response to my provisional opinion, Dr B added that he will request renal function tests to be undertaken within 1-2 weeks "where clinical concern existed".

73. Overall, I consider that by failing to appropriately establish Mr A's medical history either by adequately questioning Mr A or reviewing his clinical notes, not taking adequate regard of Mr A's NSAID associated risks, particularly cardiovascular risks and interaction with concurrent medications, and inadequately monitoring Mr A's

[30] See Opinions 10HDC00753 and 12HDC01062 available at www.hdc.org.nz.
[31] *BPAC. Non-steroidal anti-inflammatory drugs (NSAIDs): Making safer treatment choices. BPJ. Issue 55, October 2013*

renal function when prescribing diclofenac to him, Dr B did not provide services with reasonable care and skill and therefore breached Right 4(1) of the Code.

Information provided and informed consent

74. Before prescribing diclofenac, Dr B had a duty to provide Mr A with the information that a reasonable consumer, in the consumer's circumstances, would expect to receive. This includes information about the nature of the proposed medication, and its expected risks and side effects. The giving of such information in these circumstances was important to allow Mr A to make an informed choice and give his informed consent to diclofenac. Although at the time he prescribed the medication Dr B had overlooked Mr A's previous history of adverse reaction to it, Dr B should nonetheless have discussed with Mr A the general contraindications and possible side effects of the medication.

75. There is no documented evidence that the risks of diclofenac use compared with risks or benefits of alternative treatments (even an alternative NSAID with lower cardiovascular risk) were discussed with Mr A when advice was given to use diclofenac at either the 10 Month1 or the 7 Month2 appointments. Dr B said "when patients are elderly and acutely unwell, there is limited ability to weigh up all the options and risks of treatment choices with the patient".

76. However, I remain of the view that the risks and benefits of diclofenac in Mr A's circumstances should have been explained to him. Although I note that according to Dr Maplesden, at this time there was an apparent lack of awareness of cardiovascular risks associated with NSAID (particularly diclofenac) prescribing in primary care, diclofenac was a high risk drug for a patient such as Mr A. Mr A had a right to be informed about the risks and benefits before being prescribed it. In Mr A's circumstances, this was information that was crucial to him. It is possible that had Dr B had this discussion with Mr A, the unsuitability of the medications he was intending to prescribe would have become apparent, either to Dr B or Mr A himself.

77. On that point, Dr B advised that it is possible that he did ask Mr A if he had previous problems with diclofenac, pointing out that the public hospital had noted that Mr A was not aware that Voltaren and diclofenac were the same medication. Dr B commented that:

> "Consultation notes do not always reflect the discussion and advice that takes place with a patient in a typical 10 – 15 minute consultation. As much as we would like to document all matters relating to the consultation, time constraints make it difficult to do so."

78. However, the Medical Council of New Zealand's standards require that doctors must keep clear and accurate patient records that report, among other things, information provided to patients.[32] Baragwanath J stated in his decision in *Patient A v Nelson*–

[32] Medical Council of New Zealand, *Good medical practice*. See also the Medical Council of New Zealand publication "The maintenance and retention of patient records" (August 2008).

Marlborough District Health Board[33] that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter. This Office has previously stated that "this applies to all health professionals who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted."[34]

79. In my view Mr A was not provided with the information that a reasonable consumer in Mr A's circumstances would expect to receive and Dr B breached Right 6(1)(b) of the Code. Without this information Mr A was not in a position to make an informed choice, and give his informed consent to taking the medication. Accordingly, Dr B also breached Right 7(1) of the Code.

Opinion: The medical centre - Adverse comment

80. A doctor's decision to prescribe a particular medication is ultimately a clinical decision which is made using the experience and information available to the doctor at the time.

81. The medical centre had systems and policies in place for the management and documentation of drug reactions, but it is not known whether those systems were functioning adequately between 10 Month1 and 7 Month2. The medical centre has acknowledged that there were computer issues during the merger that may or may not have resulted in any recorded warnings not "popping up" during Mr A's visits to Dr B on 10 Month1 and 7 Month2. I am critical that the medical centre did not ensure that its computer systems were fully functioning or have in place a temporary system for its doctors to follow, while the two medical centres' systems were being merged.

82. Nevertheless, while Dr B could have expected to be able to rely on the Medtech system to advise him of any alerts, he was aware that there may have been issues with the system, had previous knowledge of Mr A's renal history and issues around diclofenac as evidenced from the clinical notes, and he should have checked with Mr A as to whether he was aware of any reactions. In addition, knowing that the medical centre was experiencing possible computer issues at the time, should have resulted in an increased alertness by Dr B to the potential for significant drug interactions or adverse reactions being overlooked.

83. Accordingly, I find that the medical centre is not liable for Dr B's breaches of the Code, but I remain critical that the medical centre did not ensure that an adequate information system was in place at the time.

[33] *Patient A v Nelson–Marlborough District Health Board* (HC BLE CIV-2003-204-14, 15 March 2005).
[34] See for example Opinion 12HDC00413 available at www.hdc.org.nz.

Recommendations

84. I recommend that Dr B:

(a) Provide a written apology to Mrs A for his breaches of the Code. This should be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.
(b) Undergo further training on good prescribing practice, and report to my Office within **six months** of the date of this report on the outcome of the training.

85. I recommend that the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.

86. I recommend that the medical centre conduct an audit of its clinical records for Month1 and Month2, to ensure no other critical alerts were missed during this period and report the results of the audit to my Office within **three months** of the date of this report.

Follow-up actions

- A copy of the final report with details identifying the parties removed, other than the expert who advised on this matter, will be provided to the Medical Council of New Zealand and the Royal New Zealand College of General Practitioners and they will be advised of Dr B's name.

- A copy of the final report with details identifying the parties removed, other than the expert who advised on this matter, will be provided to the Health Quality and Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A - Independent clinical advice – Dr David Maplesden

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

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the care provided to her late husband, [Mr A], by [Dr B]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. [Mrs A] complains that in [Month1] and [Month2] [Dr B] prescribed her husband medication he had previously suffered an adverse reaction to (diclofenac (Voltaren) causing acute kidney injury in 2007) and this led to her husband's death from kidney failure soon after commencing the medication. I have reviewed the information on file: complaint from [Mrs A]; response from [Dr B]; GP notes from [the medical centre]; statement from [the] physician treating [Mr A] at [the public hospital]; [public hospital] clinical notes.

2. [Mr A] had a complex past medical history including ischaemic heart disease (CABG 1995, non STEMI February 2010 – multiple cardiac medications), moderate aortic stenosis but normal left ventricular systolic function, COPD, osteoarthritis, hypertension, gout and chronic renal impairment (mild). At the time of his hospital admission on 9 [Month2] [Mr A] was taking the following medications; frusemide (diuretic), cilazapril (ACE inhibitor), aspirin, diclofenac (short-term), omeprazole (short-term), isosorbide mononitrate, metoprolol, simvastatin, perhexilene, diltiazem, paracetamol, GTN spray (PRN), Seretide and Duolin inhalers.

3. In June 2007 [Mr A] was seen at [the medical centre] and was prescribed diclofenac (Voltaren) for chronic shoulder pain. In September 2007 [Mr A] saw a locum following an episode of faintness and blood tests were ordered. These showed a significant deterioration in renal function from previous tests and this was thought to be most likely due to the diclofenac. [Mr A] had stopped the medication and was advised not to take it again. An alert was placed on the clinical file 28 September 2007: *Diclofenac sodium – renal failure/retention – avoid.* On 11 October 2007 the disease classification *renal impairment was entered.*

4. Renal function was monitored regularly and by June 2008 had returned to normal. Renal function remained within normal limits in blood tests taken on 1 December 2008 and 4 June 2009 but on 18 November 2009 was noted to be mildly impaired (creatinine 111 umol/L (normal range 60-105) and eGFR 59 mL/min (normal range >60 although decreases with age) compared with the two previous results. In February 2010 [Mr A] was admitted to the public hospital with a NSTEMI treated with cloidogrel and clexane with adjustments made to his regular cardiac medications. Renal function in April 2010 had deteriorated a little (creatinine 124 umol/L, eGFR 52 mL/min) but was subsequently stable with results either within the normal range or mildly elevated on subsequent testing until the events in question. On 13 August 2012, creatinine was 115 umol/L and eGFR 53 mL/min.

5. [Dr B] has summarised consultation details between 2007 and [Month1] 2012 and these are consistent with the contemporaneous notes. There is nothing in the notes to generate concern at [Dr B's] management of [Mr A] over this period. No NSAIDs

were prescribed following the events of September 2007 until the consultation referred to below. In fact, on 16 May 2012 [Dr B] had noted *Diclofenac caused DU* [duodenal ulcer] when considering what to treat [Mr A's] complaint of shoulder pain at that time. It is not clear whether this was accurate history (in which case it would remain a precautionary factor regarding subsequent use of NSAIDs) or whether [Dr B] meant to refer to the history of renal impairment.

6. On 5 [Month1] [Mr A] presented to [Dr B] with right forefoot pain consistent with gout. He had been self-medicating with ibuprofen (NSAID available over-the-counter) with some relief. Blood tests were taken (CRP and blood count – normal). I note the tests of 13 Aug 2012 had shown stable mild renal impairment, and uric acid level had been elevated in May 2012. At review on 10 [Month1] [Mr A's] right foot pain had improved but he now had left ankle pain. [Dr B] commenced him on diclofenac 75mg BD with omeprazole cover (28 tablets of each prescribed – unclear if there were repeats) and organised an X-ray (soft tissue swelling only - no acute bony injury). [Dr B] does not recall seeing the medication alert regarding diclofenac, or he feels he may have interpreted it as a disease code (renal impairment) for which precaution in use of NSAIDs is required.

7. On 7 [Month2] [Mr A] presented again with recent onset of pain in his right MTP joint consistent with gout. Notes include *Not taking diclofenac at present. Has been on Allopurinol in past. Renal function reasonable. Restart diclofenac and omeprazole. RFT* [renal function testing] *1 month then see me.* In his response, [Dr B] confirmed his intention to monitor [Mr A's] renal function given he was being prescribed diclofenac. On the morning of 9 [Month2] [Dr B] saw [Mr A] again and diagnosed him to have acute urinary retention probably secondary to prostatic hypertrophy. [Mr A] was referred to [the public hospital].

8. The notes 9 [Month2] record [Mr A's] attendance in ED at 1045hrs with urinary retention and dizziness. A two day history of increased shortness of breath and lower leg oedema was recorded together with recent use of diclofenac. ECG at 1148hrs showed sinus bradycardia but no signs of acute cardiac ischaemia. A catheter was inserted and 2.5L urine drained at 1412hrs. Blood pressure at triage was not recorded. At 1120hrs BP 130/90, P 50. At 1230hrs BP 98/46 and P 45 with bradycardia and hypotension persisting subsequently. Creatinine was markedly elevated at 562 umol/L and potassium 5.0 mmol/L (normal range 3.5 – 4.2). At the time of MO examination at 1350hrs [Mr A] was felt to be fluid overloaded clinically with lab results suggesting acute on chronic renal failure, attributed to NSAID use.

9. [Mr A] was treated with IV fluids and any potentially nephrotoxic agents were stopped (in his case diclofenac, cilazapril and frusemide). ECG taken at around 1700hrs showed changes suggestive of hyperkalaemia and serum potassium was noted to have increased to 6.4 mmol/L. This was treated but [Mr A] remained hypotensive and bradycardic and there was involvement of the ICU team. [Mr A] suffered a cardiac arrest about 2000hrs and cardiac output was eventually restored after approximately 40 minutes (paced rhythm). [Mr A] was admitted to ICU and treated with vasopressors and inotropic support, mechanical ventilation and insertion of a temporary pacing wire. [Mr A] continued to deteriorate and following a family

meeting on 10 [Month2] active treatment was withdrawn with [Mr A] dying shortly afterwards. Cause of death was attributed to *acute on chronic renal failure probably secondary to NSAID with resulting hyperkalaemic cardiac arrest*. The formal death certificate records cause of death as *Hypoxic Brain Injury And MOF* [multi-organ failure] *Secondary Cardiac Arrest Hours, Acute And Chronic Renal Failure, Ischaemic Heart Disease Hours, Chronic Renal Failure, Aortic Stenosis, Advanced Age.*

10. Additional comments from [Dr B] in his response include:

(i) In [Month2] [Dr B's] practice was amalgamating with a larger practice and this led to a period of difficulty accessing computerised notes. This may have influenced [Dr B's] access to [Mr A's] drug alert although this cannot be confirmed.

(ii) [Dr B] considered other management options for [Mr A's] acute gout but considered that *use of a NSAID such as Diclofenac with monitoring of renal function* [was] *the most suitable option…the use of Colchicine was relatively contraindicated with his level renal function and he had suffered GI upset when previously used in 2010. I chose not to use Prednisone as high doses would be required and I believed fluid retention might jeopardise his finely balanced cardiac status.*

11. Relevant extracts from the Medsafe Voltaren datasheet[35]:

(i) *Voltaren SR should only be prescribed when the benefits are considered to outweigh the potential risks. After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used…*

The recommended initial daily dose is 100 to 150 mg, in 1 or 2 divided doses. In milder cases, as well as for long-term therapy, 75 to 100 mg daily is usually sufficient… No adjustment of the starting dose is required for elderly patients… Voltaren is contraindicated in patients with renal failure… No specific studies have been carried out in patients with renal impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering Voltaren to patients with mild to moderate renal impairment… Treatment with Voltaren SR is generally not recommended in patients with established cardiovascular disease or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension or significant risk factors for cardiovascular disease should be treated with Voltaren SR only after careful consideration and only at doses ≤100 mg daily if treated for more than 4 weeks…

(ii) Contraindications include known hypersensitivity to the active substance or to any of the excipients, active gastric or intestinal ulcer, bleeding or perforation, renal failure and severe cardiac failure. Patients with previous myocardial infarction (within the last 6 to 12 months) should not use diclofenac.

[35] Available at http://www.medsafe.govt.nz/profs/datasheet/v/voltarensrtab.pdf

(iii) Under Warnings and Precautions: *Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events including myocardial infarction and stroke, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk factors may also be at greater risk… Treatment with Voltaren is generally not recommended in patients with established cardiovascular disease (e.g. congestive heart failure, established ischaemic heart disease or peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking) should be treated with Voltaren only after careful consideration and only at doses ≤100 mg daily when treatment continues for more than 4 weeks… Prescribers should inform the individual patient of the possible increased risk when prescribing diclofenac for patients at high risk of cardiovascular events. Physicians and patients should remain alert for such events, even in the absence of previous cardiovascular symptoms. Patients should be informed about the signs and/or symptoms of cardiovascular toxicity and the steps to take should they occur… Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.*

(iv) *Caution is advised in patients with risk factors for gastrointestinal events who may be at greater risk of developing serious gastrointestinal events, e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events.* Prophylactic use of PPIs (such as omeprazole) if use of diclofenac was required in patients at increased risk of developing GI side effects.

(v) *As fluid retention and oedema have been reported in association with NSAID therapy, including diclofenac, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with substantial extracellular volume depletion from any cause… Monitoring of renal function is recommended as a precautionary measure when using Voltaren in such cases. Discontinuation of therapy is usually followed by recovery to the pre-treatment state.*

(vi) Cardiac failure, myocardial infarction, palpitations and chest pain are listed as uncommon side effects (≥1/1,000, <1/100); while renal failure acute, haematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis are listed as very rare side effects (<1/10,000).

12. Additional background information on precautions with NSAID use[36]:

[36] From: *BPAC. Non-steroidal anti-inflammatory drugs (NSAIDs): Making safer treatment choices. BPJ. Issue 55, October 2013* (this publication is sent to most NZ GPs and the article cited summarised recommendations contained in previous articles over the preceding few years). Available at: http://www.bpac.org.nz/BPJ/2013/October/nsaids.aspx

(i) *Non-steroidal anti-inflammatory drugs (NSAIDs) are the most frequently prescribed medicines for analgesia in primary care, after paracetamol. However, NSAID use can be associated with a range of serious adverse effects including: cardiovascular events, gastrointestinal complications, renal failure and hypersensitivity reactions. Even if the risk of an individual patient experiencing an NSAID-related adverse event is relatively low, the frequent use of NSAIDs within the community means that the potential for NSAID-related adverse events to occur is a concern. NSAID use therefore requires careful consideration of individual patient risk factors. To maximise patient safety it is recommended that clinicians consider the following points before prescribing an NSAID:*

- *Prescribe all NSAIDs with caution, in all patient groups, even over short periods of time*
- *Prescribe the lowest effective NSAID dose, for the shortest possible time, and review the need for continued use at each consultation*
- *Older patients, patients with increased cardiovascular risk, patients with type 2 diabetes, and patients with reduced renal function or a history of renal problems are at increased risk of NSAID-related complications and should be advised about adverse effects and regularly monitored when taking NSAIDs*
- *Naproxen (up to 1000 mg per day) or ibuprofen (up to 1200 mg per day) are the recommended first-line choices for adults based on our current knowledge of NSAIDs and cardiovascular risk; ibuprofen is the most appropriate NSAID for children*
- *Avoid prescribing long-acting formulations of NSAIDs, where possible, as these are associated with an increased risk of gastrointestinal adverse effects*

(ii) *If it is decided that NSAID treatment is appropriate, having weighed the risks versus benefits of treatment, ensure the patient's history is known before an NSAID is prescribed. In particular:*

- *Ensure the patient is aware which over-the-counter (OTC) products contain NSAIDs and that they know that they should not take any other NSAID-containing products while they are being treated with an NSAID*
- *Determine if the patient has any co-morbidities that may increase the risk of NSAID treatment, e.g. cardiovascular disease, CKD, diabetes, hypertension or duodenal ulcer*
- *Query if the patient is taking any medicines that may interact with NSAIDs, e.g. angiotensin converting enzyme (ACE) inhibitors, angiotensin-II receptor blockers (ARBs), diuretics, clopidogrel, warfarin, dabigatran or aspirin*
- *Discuss any history of NSAID-related adverse effects with the patient. Their preference may affect the dosing regimen. Some patients may prefer to tolerate adverse effects if a higher dose is likely to result in improved symptom control, while other patients may take the opposite view.*

(iii) *All non-selective NSAIDs and COX-2 inhibitors are associated with increased cardiovascular risk - except naproxen up to 1000 mg per day or ibuprofen up to 1200 mg per day. This increased risk begins within the first week of treatment and translates to an additional three major vascular events per 1000 patients, per year.*

NSAID use has also been found to approximately double the risk of hospital admission due to heart failure and increase systolic blood pressure by an average of 2 – 3 mmHg…A large study found that there was a relative increase in cardiovascular risk, mainly attributed to coronary events, of approximately 33% in patients using high-dose diclofenac (> 150 mg), COX-2 inhibitors and high-dose ibuprofen. Importantly, the trial found that there was no statistical difference in this risk between patient groups with low or high predicted five-year cardiovascular risk. The significance of this study to primary care in New Zealand is that an increased cardiovascular risk has been an under-recognised concern in many patients taking non-selective NSAIDs…Short-term and long-term use of NSAIDs is associated with increased cardiovascular risk. Advise patients who have had a previous cardiovascular event that even one or two doses of ibuprofen or diclofenac may increase their risk of a recurrent event. A study of over 83 000 patients with prior myocardial infarction found that NSAID use increased the risk of recurrent myocardial infarction or death by 1.45 times during the first seven days of treatment and this risk persisted throughout the course of treatment. The greatest risk was associated with diclofenac which increased the risk of myocardial infarction and/or death by 3.26 times at day one to seven of treatment. A recent international study has shown that despite increasing awareness of the cardiovascular risks associated with NSAID use, particularly Voltaren, there is still a high rate of prescribing of these medications in patients at increased cardiovascular risk in primary care[37].

(iii) *In New Zealand over 40% of all renal adverse reactions reported to the Centre for Adverse Reactions Monitoring (CARM)* [related to NSAID or COX II inhibitor use] *were associated with diclofenac. The risk of AKI* [acute kidney injury] *in patients taking NSAIDs and other potentially nephrotoxic medicines is greatest at the start of treatment, therefore even short courses of NSAIDs should be avoided, if possible, in patients at increased risk. All people with CKD should avoid NSAIDs where possible. CKD* [chronic kidney disease] *is a risk factor for AKI and one-quarter to one-third of all people aged over 64 years have CKD…Patients who have had a previous acute decline in renal function should have their notes flagged and be identified as at risk of NSAID-related AKI.*

(iv) *NSAID nephrotoxicity can be exacerbated by ACE inhibitors or ARBs as these medicines impair the regulation of blood flow leaving the kidney. Renal function can be compromised even further if a patient is also taking a diuretic. The combined potential effect of these three medicines has been referred to as the "triple whammy". This can result in hyponatremia or hyperkalemia, AKI and cardiac failure. The risk of this occurring is greatest in the first 30 days of use. This combination of medicines should be prescribed with caution, particularly in people with CKD or diabetes. If patients develop an acute illness it may be appropriate to discontinue or reduce the dose of these medicines. In patients with reduced renal function who are taking NSAIDs, or in patients at increased risk of renal toxicity, serum creatinine and*

[37] Orr C et al., New data, new problem; assessing the prevalence of NSAID prescribing in primary care in those with a background of ischaemic heart disease (IHD) or risk factors for IHD [abstract]. EULAR Annual European Congress of Rheumatology; 12-15 June 2013; Madrid, Spain. Abstract nr. OP0203-PC. Available at: http://www.eurekalert.org/pub_releases/2013-06/elar-hpo061013.php

potassium should be measured after one to two weeks of treatment and then monitored regularly.

13. NZ Medical Council recommendations on prescribing[38] include:
(i) *You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests.*

(ii) *Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe.*

(iii) *Take an adequate drug history of the patient, including: any previous adverse reactions to medicines; current medical conditions; and concurrent or recent use of medicines (including non-prescription, complementary and alternative medicines)*

(iv) *Ensure that the patient (or other lawful authority) is fully informed and consents to the proposed treatment and that he or she receives appropriate information, in a way they can understand, about the options available; including an assessment of the expected risks, side effects, benefits and costs of each option.*

14. Medication errors are common in the provision of healthcare, and the sequelae of such errors varies from no harm to catastrophic. Up to 30% of unplanned admissions for elderly patients may be due to adverse drug events, including prescribing errors[39]. Prescribing errors are not uncommon in primary care. A 2009 prospective study in the UK[40] documented errors in prescriptions from 28 general practitioners as they occurred over a 3-day period in 12 community pharmacies. From a total of 3,948 prescriptions, 491 (12.4%) contained one or more errors. From a total of 8,686 drug items, 546 (6.2%) contained one or more errors. Of the errors the majority were minor (398, 72.9%), a smaller number (135, 24.7%) were major nuisance errors, and there were 13 (2.4%) potentially serious errors. The most common errors related to drug directions and dosage. While medication errors are common and almost part of 'accepted practice', they cannot deemed to be acceptable or expected practice and therefore such errors must represent a departure from expected standards – the degree of departure dependent on the circumstances of the error as much as the outcome.

15. Comments
(i) [Mr A] had an absolute contraindication to use of diclofenac – that was a previous severe reaction to the drug (acute kidney injury) from which he had recovered. The reaction had been well documented and an appropriate alert placed on the patient file. There may or may not have been mitigating circumstances leading to the alert not featuring at the time [Dr B] prescribed [Mr A] diclofenac in [Month1] (computer issues). However, it is clear [Dr B] did not establish [Mr A's] history of drug reaction

[38] From: NZMC statement *Good Prescribing Practice. 2010* Available at: http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf
[39] Chan M, Nicklason F, Vial JH. Adverse drug events as a cause of hospital admission in the elderly. Intern Med J. 2001;31(4):199.
[40] Sayers YM et al. Prescribing errors in general practice: A prospective study Eur J Gen Pr 2009;15

(either by questioning the patient or ensuring the PMS adverse drug reactions had been viewed, or both) before prescribing diclofenac.

(ii) There were multiple additional factors relevant to prescribing of diclofenac for this patient: his advanced age; history of chronic renal disease; history of ischaemic heart disease (particularly if, as [Dr B] stated, he had *finely balanced cardiac status*); possible history of duodenal ulcer and concurrent aspirin use (although a PPI was prescribed concurrently); concurrent use of an ACE inhibitor and diuretic (the so called 'triple whammy' (see 12(iv)). All of these factors placed [Mr A] at increased risk of NSAID related side effects – particularly cardiac and renal side effects.

(iii) Diclofenac was prescribed at a relatively high dose of 150mg daily given [Mr A's] age and other side-effect risk factors.

(iv) There is no evidence the risks of NSAID compared with risks or benefits of alternative treatments (even an alternative NSAID with lower cardiovascular risk) were discussed with [Mr A] when advice was given to use diclofenac. [Dr B's] response does not indicate to me he took adequate regard of [Mr A's] NSAID associated risks, particularly cardiovascular risks and interaction with concurrent medications, when making the decision to advise use of diclofenac.

(v) Mitigating factors taken into account include: the medication was intended only for short-term intermittent use (sufficient for two weeks supply prescribed); there was an intention to monitor renal function even if this was outside the recommended timing (see 12(iv)); at an international level, there is an apparent lack of awareness of cardiovascular risks associated with NSAID (particularly diclofenac) prescribing in primary care; PPI was prescribed concurrently to reduce the risk of GI side effects.

(vi) The contribution diclofenac prescribing made to [Mr A's] demise is unclear, but a significant contribution cannot be excluded. He had a history of ischaemic heart disease and was over 80 years old. The two day history of lower leg oedema and shortness of breath prior to admission suggests an exacerbation of heart failure which may have been related to diclofenac use or an unrelated cardiac event. There is a likelihood diclofenac caused an acute kidney injury (similar to but more marked than the events of 2007), but [Mr A's] persistent hypotension may have contributed to pre-renal failure and his acute urinary retention might also have contributed to a degree of renal damage.

(vii) Taking the preceding discussion into account, there are two predominant factors influencing my review of this case: [Mr A] was prescribed a drug which had previously caused him a significant adverse reaction – that reaction having been well documented in the notes; [Mr A] was prescribed a drug for which, apart from the previous reaction, there were multiple clinical considerations that made it a relatively high risk prescription and there is no evidence risk, benefits and alternative treatments were discussed with the patient. I conclude that the prescribing of diclofenac 150mg daily to [Mr A] under these circumstances was a severe departure from expected standards. Had there been no recorded history or previous adverse drug reaction, the departure would have been moderate."

Dr Maplesden was asked to provide further clinical advice in relation to this case.

"I have reviewed the response from [Dr B] and independent opinion from [Dr E]. I make the following points:

1. The issue of whether or to what degree the prescribing of diclofenac to [Mr A] contributed to his death was covered in my original advice and I agree absolutely that it is not possible to determine the answer to this, and I agree [Mr A's] acute renal failure was most likely multi-factorial in nature despite comments made by hospital clinicians at the time (and this was stated in my original advice). When providing advice in cases such as this I am aware the outcome is rarely foreseeable and therefore try to minimise the influence of outcome on my assessment of management (ie I try and minimise hindsight bias). I acknowledge that severity of outcome is likely to influence whether a complaint is made in the first place and it is quite possible had [Mr A] experienced a temporary disturbance in renal function following use of diclofenac in [2012] similar to that experienced in 2007, a complaint may not have eventuated. However, had a complaint been made in this circumstance I believe the main issues influencing my original advice would have been unchanged: was it appropriate to prescribed diclofenac to a patient who had experienced a previous significant adverse reaction (which was documented); was it appropriate to prescribe diclofenac to a patient with the co-morbidities suffered by [Mr A] and, if so, was it prescribed at an appropriate dose and with appropriate monitoring; was [Mr A] aware of the potential risks versus benefits of the use of diclofenac in his clinical situation.

2. Comment is made that I quoted extensively from a BPAC article published a few months after the events in question. I believe the cited reference summarised information that had been previously discussed in BPAC publications since at least 2004 including reference to naproxen having less potential for adverse cardiovascular events than diclofenac and COX-II medications, and particular caution required with 'triple whammy' prescribing[41]. While the Medsafe data sheet cited in my original advice may also have post-dated the events in question (current update October 2014 and I am unable to determine the date of previous publication), it does not differ substantially from accessible older manufacturer advice dating from 2011[42]. However, I would like to emphasise the results of the international review on use of diclofenac cited in my original advice which showed that despite increasing awareness of the cardiovascular risks associated with NSAID use, particularly Voltaren, there is still a high rate of prescribing of these medications in patients at increased cardiovascular risk in primary care[43].

3. I acknowledge the management of [Mr A's] gout represented somewhat of a therapeutic dilemma. I note he had an acute attack of gout treated with high dose

[41] See: http://www.bpac.org.nz/BPJ/2006/October/docs/nsaids_pages_18-21.pdf and http://www.bpac.org.nz/resources/campaign/nsaids/nsaids_poem.asp?page=4
[42] See: https://www.pharma.us.novartis.com/product/pi/pdf/voltaren_xr.pdf
[43] Orr C et al., New data, new problem; assessing the prevalence of NSAID prescribing in primary care in those with a background of ischaemic heart disease (IHD) or risk factors for IHD [abstract]. EULAR Annual European Congress of Rheumatology; 12-15 June 2013; Madrid, Spain. Abstract nr. OP0203-PC. Available at: http://www.eurekalert.org/pub_releases/2013-06/elar-hpo061013.php

steroids in April 2010 and he responded well to this treatment without apparent adverse effect. It is unclear to what degree his gastric intolerance of colchicine was dose related – a low dose being used as an alternative to NSAID for prophylaxis if allopurinol is initiated once an acute attack of gout has resolved. However, it is not uncommon for patients to present with co-morbidities requiring careful 'juggling' of medication and sometimes cautious use of a drug with known potential risks for that patient is required, usually with close monitoring and informed consent from the patient. While there has been considerable retrospective analysis of the risks and benefits of the therapeutic options available to [Mr A] for management of his gout, I remain unconvinced that the prescribing of 150mg per day of diclofenac was the most appropriate option in the clinical context described and that sufficient consideration was given to more reasonable alternatives, and I feel the proposed and actual monitoring of [Mr A's] renal function if this drug and dose were to be used was inadequate. I make this comment irrespective of whether [Mr A's] previous adverse reaction to diclofenac had been recognised. However, based on my review of many clinical records over the past few years and noting the research cited above, I feel a significant number of my peers may have prescribed [Mr A] a NSAID in the situation described (providing he did not have a documented past history of significant adverse reaction to the medication) even if this does not represent best clinical practice.

4. I agree with [Dr E's] comments regarding the medication alert functionality in Medtech and I think most GPs using this system are aware of these limitations. However, I think this should result in increased alertness of practitioners to the potential for significant interactions or adverse reactions being overlooked, and as noted in the Medical Council recommendations cited in my original advice[44] every prescriber has a responsibility to determine the patient's medication history and suitability of the medication for that patient when prescribing. This may involve asking the patient specifically whether or not they have any medication allergies when prescribing a new medication, or at least accessing the PMS medication alert module (which in this case did record [Mr A's] previous adverse reaction to diclofenac and advised avoidance of that drug). It appears likely there were some information access issues at the time of the events in question and this is a significant mitigating factor. [Dr B] is unable to recall whether the medication alert information was available to him at the time of his consultations with [Mr A] and it may not have been. Furthermore, [Mr A] was already self-medicating with an over-the counter NSAID (ibuprofen) without apparent adverse effects and may not have realised, if asked about adverse reaction to diclofenac (there is some uncertainty whether [Dr B] did ask about previous reactions but he states he would have used the generic name), that diclofenac and Voltaren were the same drug.

5. Taking into account the discussion above related to the responses reviewed I make the following conclusions:

[44] From: NZMC statement *Good Prescribing Practice. 2010* Available at: http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf

(i) It is not possible to determine whether, or to what degree, the prescribing of diclofenac adversely influenced the outcome of [Mr A's] final illness. This was acknowledged in my original advice.

(ii) I remain of the view that to prescribe diclofenac to a patient with the knowledge that the patient had a previous significant reaction to that drug, and had additional co-morbidities meaning particular caution was required with the use of the drug, was a severe departure from expected practice.

(iii) If [Dr B] failed to establish [Mr A] had had a previous significant adverse reaction to diclofenac because the PMS medication alert system was not functioning properly, and direct questioning of [Mr A] did not elucidate a concerning response, I would be mildly to moderately critical of the prescribing of 150mg diclofenac daily and the intended monitoring regime in the clinical context described.

(iv) If [Dr B] failed to establish [Mr A] had had a previous significant adverse reaction to diclofenac because the PMS medication alert system was not functioning properly but then failed to determine by any other method such as direct questioning whether or not [Mr A] had a previous reaction to diclofenac, I would be moderately critical of his management.

(v) [Dr B] has made appropriate changes to his clinical practice since receipt of the complaint."