HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Failure to appropriately manage medication change for prison inmate

Introduction and complaint

1. On 4 December 2023, the Health and Disability Commissioner (HDC) received a complaint from Mr A about the care provided to him by Dr B in a prison under the remit of the Department of Corrections. The complaint raises concerns that Mr A's anticoagulation[1] medication had been changed without an explanation or without Mr A being advised of possible side effects. He subsequently suffered a stroke on or around 13 November 2023. Following this, he experienced diminished eyesight, which hospital staff told him was attributed to the medication change. Mr A has raised this matter to ensure this does not happen to anyone else.

2. Under Rights 4(2),[2] 6(1)(b),[3] and 7(1)[4] of the Code of Health and Disability Services Consumers' Rights (the Code), Dr B had an obligation to provide services that complied with legal, professional, ethical, and other relevant standards. He was also expected to provide information that a reasonable consumer in that consumer's circumstances would expect to receive, including an explanation of the options available, and an assessment of the expected risks, side effects, and benefits of each option.

3. Having reviewed all the information, I find that Dr B breached Right 4(2) for changing Mr A's medication from warfarin to dabigatran without seeking advice from a specialist and/or carrying out research, and for failing to sufficiently document his discussions with Mr A. I also find Dr B in breach of Rights 6(1)(b) and 7(1) of the Code for failing to provide Mr A with sufficient information regarding the change in his prescribed medication, preventing him from making an informed choice, as discussed further in this report.

Recommendations

4. Noting the changes already made by Dr B and that he provided an apology for Mr A in response to the provisional decision, I make no further recommendations for him.

5. Noting that the Department of Corrections complied with the recommendation in the provisional decision regarding the summary of findings from its review of prison patients taking anticoagulants, I recommend that the Department of Corrections provide HDC with a summary of the National Nursing Manager's follow-up audit on the use of anticoagulants in prisons and the findings of the Clinical Director's audit carried out in August 2025 of all

[1] A substance that helps prevent blood clots from forming, also known as a 'blood thinner'.
[2] Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'
[3] Right 6(1) 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) 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.'

Names have been removed (except the Department of Corrections and the clinical advisor on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

patients prescribed warfarin. This information is to be provided to HDC within 12 months of the date of this report.

Background

6. Mr A was taking regular medications (diltiazem and bendroflumethiazide,[5] frusemide,[6] Span K,[7] Vannair inhaler,[8] and warfarin (a blood thinner)) and having monthly blood tests for various medical conditions.[9] One of these conditions was rheumatic heart disease for which Mr A had undergone a mitral valve[10] (artificial mechanical heart valve) replacement in 2003.

7. On 9 April 2022, the clinical records note that Mr A informed health staff at the prison of his decision to change his anticoagulation medication from warfarin to dabigatran (commonly known by the brand name Pradaxa). An appointment was booked for him with the prison medical officer (MO), Dr B.

8. Dr B told HDC that Mr A had mentioned to him 'conversationally on several occasions' during 2021–2022 that he would like to stop the frequent blood tests (these are a requirement for international normalised ratio (INR) testing). Dr B said he had 'explained the significant risk of stroke if he were to stop warfarin or monitoring' and that Mr A appeared to accept this advice. However, this information is not documented in the clinical records.

9. On 21 April 2022, the clinical records reflect that Mr A saw Dr B to discuss his decision to stop taking warfarin and that the plan was to 'consider switching to dabigatran'. Dr B told HDC that he advised Mr A of the 'significant risks' of stopping warfarin and gave him a week to consider his decision. However, this latter information was not included in the clinical records. Dr B advised HDC that these discussions occurred when he saw Mr A briefly in his cell on 22 April 2022; however, again, this is not reflected in the clinical records.

10. On 28 April 2022, Mr A had a further appointment with Dr B, where he agreed to change his medication from warfarin to dabigatran. The clinical records for this appointment noted that Mr A wanted to stop warfarin because he was 'tired of getting his bloods taken'. It was arranged for Mr A to start taking dabigatran three days after he stopped warfarin. The clinical records from the prison's Medtech[11] system reflect that Mr A was advised to report any stomach issues and that the common side effects of the medication were explained to him. Dr B stated in his subsequent response that Mr A was visibly upset at this appointment. However, again, this is not reflected in the clinical notes.

11. Mr A informed HDC that he had received 'no explanation' of why his medication was changed and was not advised of any side effects. He believed the change was made to avoid the need for monthly blood tests; otherwise, he could not identify any logical reason for it.

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[5] Both used to treat high blood pressure; bendroflumethiazide is a diuretic used to reduce excess fluid retention.
[6] A diuretic used to treat hypertension.
[7] A potassium chloride supplement used to increase the amount of potassium in your body.
[8] A combination of two medicines, budesonide and formoterol, used for asthma and chronic obstructive pulmonary disease.
[9] Chronic obstructive pulmonary disease and asthma, hypertension, atrial fibrillation, a history of hepatitis C, and psoriasis.
[10] A cardiac valve consisting of two triangular flaps that allow only unidirectional blood flow from the left atrium to the left ventricle.
[11] A practice management system used by healthcare professionals to diagnose and treat a patient.

12. In contrast, Dr B told HDC that he explained the common side effects to Mr A 'as far as he was aware of them' and the potential health risks (which included the increased risk of deep vein thrombosis, gastrointestinal bleeding, and stroke) though, as outlined above, this specific information was not recorded in the clinical records. Dr B also advised that a registered nurse (RN) was present at the 22 April 2022 appointment (noting the clinical records document this as 21 April 2022) and the 28 April 2022 appointment, when the risks of stopping warfarin were explained to Mr A, and a witness statement has been provided to this effect.

13. Dr B told HDC that, although he was aware that warfarin was the standard anticoagulant for patients with mechanical valves, he had wanted to respect Mr A's wishes to change his medication because of his insistence. Dr B also stated he considered 'sub optimal anti-coagulation with [dabigatran] would be preferable to no anti-coagulation at all' if Mr A had declined warfarin because of the blood tests.

14. However, HDC was informed by the prison that the Medtech entry on 28 April 2022 reflects that Dr B did not complete the 'prescribing assistant', which is designed to prompt the prescriber to consider any prescribing guidelines or advice, including in some cases the need for specialist authority. The prison also acknowledged that 'there were two clinical criteria of significance related to kidney function (creatinine clearance) and clotting factors (INR)' and that Mr A's blood tests taken on 28 April 2022 indicated that both these criteria were met. The prison advised that it did not know why Dr B decided not to complete the prescribing assistant despite the criteria being met.

15. On 30 April 2022, Mr A began taking dabigatran.

16. On 13 November 2023, Mr A started to experience right eye peripheral (outer part) vision loss, headaches, and confusion and was seen at the prison clinic. Following consultation, Dr B advised that Mr A should be taken to the emergency department (ED) at the nearby public hospital for evaluation for retinal detachment. Mr A was subsequently taken to the ED, where it was noted he also had nausea, was vomiting, and had pain when coughing.

17. On 14 November 2023, Mr A was admitted for close monitoring and neurological assessment.

18. On 15 November 2023, clinical records state that, on assessment, Mr A was diagnosed with a subacute[12] ischemic stroke[13] in the left posterior cerebral artery territory. This was most likely caused by cardio-embolism[14] from his metallic mitral valve and atrial fibrillation and mild chronic obstructive pulmonary disease exacerbation. Mr A reports that he was told by a doctor at the hospital that he should never have been prescribed dabigatran because of his 'mechanical valve' as it was not able to be used with it.[15] Review of the clinical records also noted that dabigatran should be discontinued as it is 'contraindicated in prosthetic mitral valves' and for Mr A to be started on warfarin in two days' time. Mr A's discharge summary outlined the diagnosis as 'left occipital thromboembolic infarct (ischemic stroke) secondary to inadequate anticoagulation for metallic heart valve'.

19. On 20 November 2023, Mr A was seen at the prison clinic with confusion, disorientation, and visual disturbance and had been unable to walk independently to the clinic. Mr A was

[12] Falling between acute and chronic in character.
[13] A common type of stroke caused by the narrowing or blockage of a blood vessel supplying the brain.
[14] A clot formed in the heart.
[15] Noted in the clinical records as 'explained how heart valve and med[ication] changes have led to stroke' (page 18 of Health NZ clinical notes).

subsequently taken by ambulance to the hospital ED and had a CT brain scan already booked for that day. The radiology report of Mr A's CT scan showed no acute intracranial bleed or haemorrhagic transformation of the subacute left posterior cerebral artery territory infarct and chronic left pansinusitis.[16] Mr A was again admitted to hospital under the General Medical team.

20. On 21 November 2023, Mr A was discharged back to the prison with a plan and prescription to restart warfarin that day and to have his bloods taken regularly for around six weeks. The clinical records document that the stroke and visual loss were discussed with Mr A and that his vision may improve in time. He was also referred to the stroke service for support.

21. The prison advised that Mr A recommenced taking warfarin on 24 November 2023.

22. On 30 November 2023, Mr A made a formal complaint to the prison regarding this incident, which was closed on 12 December 2023, as it was being dealt with by HDC.

23. In its response to HDC, the Department of Corrections states that 'In hindsight, it would have been appropriate to complete a Refusal of Health or Dental Services Form[17] to fully capture Mr A understood the risks associated with his decision'.

24. After the stroke, Mr A was unable to work because he had partial right vision loss and confusion.

Medical Council of New Zealand's standards

25. The Medical Council of New Zealand's (MCNZ's) standards in relation to managing patient records[18] outline that clinicians must maintain clear and accurate patient records that include the information given to and options discussed with patients, decisions made, and the reasons for them.

In-house clinical advice

26. To assist in my assessment of this complaint, I sought in-house clinical advice from Dr David Maplesden, an experienced and vocationally registered general practitioner (**Appendix A**). Dr Maplesden advised that dabigatran was not a suitable anticoagulant for Mr A and that warfarin is the only anticoagulant recommended and approved for use in a patient with a mechanical mitral valve, such as Mr A. Although Dr Maplesden acknowledges Dr B's thought processes that some anticoagulation must be better than none given Mr A's insistence on changing his anticoagulant medication, Dr B was aware that the use of dabigatran represented a departure from accepted practice. However, Dr Maplesden stated that Dr B may not have been aware it was contraindicated (the risks outweighed the potential benefits) but advised that 'specialist input was required in order to ensure Mr A could make an adequately informed choice'. Dr Maplesden found the following departures from accepted practice:

- **Severe departure** – change from warfarin to dabigatran.

[16] Inflammation of the sinus.
[17] Which documents the patient understands the consequences of not receiving the prescribed treatment for their condition, confirms they decline to receive the treatment offered and in doing so accepts full responsibility for the consequences of their decision.
[18] MCNZ. (2020). *Managing patient records*. Wellington: Medical Council of New Zealand. https://www.mcnz.org.nz/our-standards/current-standards/patient-records

- **Moderate departure** – provision of information around the risks/informed choice.
- **Moderate departure** – failure to seek advice from a specialist/cardiologist on how to manage Mr A's medication change request.
- **Mild to moderate departure** – failure to appropriately document discussions held with Mr A.

Other information

27. In its response to HDC, the Department of Corrections agreed that the appropriate standard of care was not provided to Mr A in relation to the decision to change his prescription from warfarin to dabigatran.

28. Dr B acknowledged that the care provided to Mr A fell below the standard of care he expected and that this has caused distress and harm and impacted on his health and quality of life. Dr B offered his unreserved apology for the role he played in this outcome.

29. Dr B also acknowledged that his documentation of consultations with Mr A fell below accepted standards. Dr B considered that this was due to systemic pressure and a significant increase in workload during a period of COVID-19 cases at the prison at the time. However, Dr B accepted that his clinical documentation should still have been maintained.

Responses to provisional decision

Mr A

30. Mr A was given an opportunity to comment on relevant sections of the provisional decision and said that he would not have agreed to change his medication if not for the nurses finding it hard to do the INR testing for him. Mr A said he had never heard of dabigatran prior to that.

Dr B

31. Dr B was given an opportunity to comment on the provisional decision and provided an apology for Mr A for the failings identified. Dr B stated that he had further reflected extensively on the concerns raised in the provisional decision and has continued to make improvements as outlined in the 'changes made' section of this final report to meet expected professional standards.

Department of Corrections

32. The Department of Corrections was given an opportunity to respond to the provisional decision. In response to a recommendation made in the provisional decision, it provided an update on the findings of its reviews carried out in December 2022 and May 2023 of prison patients taking anticoagulants, including warfarin and dabigatran. The Department of Corrections confirmed that, of 10 patients across the four regions identified, 80% had the required information in relation to their anticoagulant medication recorded in their patient notes (below the 90% expected standard). As a result, changes and improvements were made, as outlined in the 'changes made' section.

33. The Department of Corrections also confirmed that, in August 2025, the Clinical Director completed an audit and reviewed the clinical records of all patients at the time who were prescribed warfarin to ensure appropriate prescribing and INR management.

Decision

Dr B – breach

34. Under Right 4(2) of the Code, Dr B had an obligation to provide services of an appropriate standard that complied with legal, professional, ethical, and other relevant standards.

35. Having reviewed all the information in this case, including that of HDC's in-house clinical advisor, Dr Maplesden, I note that Dr B changed Mr A's medication from warfarin to dabigatran despite dabigatran being a medication that was contraindicated for patients with mechanical heart valves. Although Mr A insisted on the change, I agree with Dr Maplesden that Dr B had a duty to have sought input from a specialist or cardiologist or carried out some research on an appropriate alternative medication for Mr A given his high risk of stroke.

36. I note that the Department of Corrections also advised that Dr B did not complete the prescribing assistant tool, which may have helped him realise the significance of Mr A's clinical criteria from his blood tests regarding his kidney function and clotting factors. In my view, this was also a missed opportunity to have made different decisions in relation to seeking specialist advice. Given that Mr A subsequently suffered a stroke, which he states has left him with permanent loss of vision in his right eye, I am extremely critical that Dr B changed his medication to dabigatran despite the lack of consultation and research when doing this.

37. I note that Dr B also failed to sufficiently record his discussions with Mr A around the risks, and it was only with evidence of the RN who had been present that those discussions were able to be substantiated. I note that this went against MCNZ standards for managing patient records, and I agree with Dr Maplesden that failing to document these discussions was a mild to moderate departure, and I am further critical of this.

38. Accordingly, I find Dr B in breach of Right 4(2) of the Code.

39. Under Rights 6(1)(b) and 7(1) of the Code, Dr B had an obligation to provide Mr A with an explanation of the options available, including an assessment of the expected risks, for him to make an informed choice on his request to change his anticoagulant medication.

40. Although Mr A may have insisted on the change to his medication, he was reliant on receiving appropriate clinical advice and information to make an informed decision on this.

41. As Dr B did not seek specialist advice or carry out research as outlined above, Mr A did not receive sufficient information on the appropriate medication for him given dabigatran was contraindicated, and I am critical of this.

42. Accordingly, I find Dr B in breach of Right 6(1)(b) of the Code.

43. It follows that, because Mr A was unable to make an informed choice before taking the contraindicated medication, I therefore also find Dr B in breach of Right 7(1) of the Code.

Department of Corrections

44. Given these were individual decisions and actions by Dr B and that MCNZ and the Department of Corrections had appropriate measures and policies in place, including around the recording of discussions with patients, I make no finding in relation to the Department of Corrections.

Changes made

Department of Corrections

45. The Department of Corrections told HDC that it planned to use an anonymised version of Mr A's complaint as a discussion topic during the MO monthly peer review session, which would remind staff to make use of the refusal form in appropriate circumstances. It also confirmed that an audit had been conducted in May 2023 of the use of warfarin, a copy of which has been provided to HDC. Following changes made in 2025 of a new medical manager and clinical director, a review of the current prescribing and documentation was to be carried out that included a review of all patients at the prison on anticoagulants, including warfarin and dabigatran, to triangulate the appropriateness of treatment. A meeting was also arranged with Dr B to discuss the case and provide support that may be required.

46. In response to the provisional decision, the Department of Corrections outlined further improvements and changes made as a result of audits into whether patients prescribed warfarin had all the required information recorded in their patient notes. These changes are as follows:

- The patient's target INR is recorded in the 'recommend' field.
- The patient has received education about warfarin in the previous 12 months.
- Warfarin or INR management education is to be explored for nurses.
- Patients are to be checked as to whether they should still be on warfarin or whether oral novel anticoagulation medicine would be more appropriate.
- INR management is to be explored as an internal nurse-led service.
- Māori patients prescribed warfarin in its care will receive renal function testing at least annually to ensure appropriate monitoring and treatment (noting that anticoagulant therapy can adversely affect renal function and that Māori experience higher rates of renal disease than non-Māori).
- Patients receiving rongoā medicine (traditional Māori healing) initially have an increased INR monitoring regimen (to ensure there are no interactions between rongoā medicine and warfarin).

Dr B

47. Dr B advised HDC that he has substantially reflected on and learned from this case and has since made a conscious effort to carry out changes to his practice as follows:

- When changing long-term medication, he allows the patient a longer period to consider their decision and tries to involve the hospital consultant to help the patient make an informed decision.
- He recognises the importance of obtaining specialist input when a patient refuses guideline-mandated therapy in a high-risk context and has adopted a much lower threshold for seeking cardiology or haematology advice in such situations.
- He has taken steps to ensure that, even during periods of high pressure, documentation of high-risk clinical decisions is robust and contemporaneous, and he now uses structured documentation templates for informed refusal.

- He has undertaken targeted educational courses[19] and changed his practice.

Follow-up actions

48. A copy of the sections of this report that relate to Dr B will be sent to MCNZ.

49. A copy of this report with details identifying the parties removed, except the Department of Corrections and HDC's in-house clinical advisor, Dr David Maplesden, will be sent to the Chief Executive of the Department of Corrections, and placed on the HDC website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner

[19] Including the General Practice Education Programme, communication training, and a review of *Good Medical Practice* and the Best Practice Advocacy Centre New Zealand anticoagulation guidelines and documentation standards.

Appendix A: In-house clinical advice to the Commissioner

The following in-house advice was obtained from Dr David Maplesden:

'CLINICAL ADVICE – MEDICAL+ Addenda (FINAL)

CONSUMER : Mr [A]

PROVIDER : Department of Corrections; Dr [B]

FILE NUMBER : C23HDC03299

DATE : 6 August 2025; **Addendum 16 September 2025 (s13)**
Final comments 23 March 2026 (s14)

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1. My name is David Maplesden. I am a graduate of Auckland University Medical School and I am a vocationally registered general practitioner holding a current APC. My qualifications are MB ChB 1983, Dip Obs 1984, Certif Hyperbaric Med 1995, FRNZCGP (Dist) 2003. Thank you for the request that I provide clinical advice in relation to the complaint from Mr [A] about the care provided to him by staff of the [...] Prison health unit. In preparing the advice on this case, to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following information:

- Complaint from Mr [A]
- Response from Department of Corrections (DoC) incorporating a statement from Dr [B]
- Clinical notes [from the] Prison Health Unit (PHU)
- Clinical notes [from the] hospital

3. Background: Mr [A] (B: 1956) was an inmate of [the prison] at the time of the events in question. His medical history included chronic obstructive pulmonary disease (smoking related), St Judes mitral valve replacement 2003 for rheumatic heart disease, subacute bacterial endocarditis 2019, atrial fibrillation, hypertension, hyperlipidaemia and treated hepatitis C. Regular medications prior to May 2022 were diltiazem, bendroflumethazide, frusemide, Span K, Vannair inhaler and warfarin. On 30 April 2022 Mr [A] commenced dabigatran as an alternative anticoagulant to warfarin. On 14 November 2023 (some 18 months after the change) Mr [A] was admitted to hospital after developing sudden partial right vision loss (right homonymous hemianopia) associated with a brief episode of confusion and speech disturbance. CT scan showed a subacute ischaemic stroke in the left posterior cerebral artery territory which, according to hospital notes, *was most likely due to cardioembolism from his metallic mitral valve and atrial fibrillation*. There is reference in the notes and discharge summary to *inadequate anticoagulation of metallic heart valve*. Mr [A] was recommenced on warfarin once the risk of haemorrhagic transformation of his infarct was reduced, and he has been left with a permanent vision defect. Mr [A] complains about the management of his medication which he believes resulted in his stroke. I have been asked to *provide advice on the management of the consumer's medication change from warfarin to Pradaxa (dabigatran) and whether there should have been specialist involvement or other monitoring arranged*.

4. The American Heart Association states that patients with mechanical heart valves such as Mr [A] require lifelong anticoagulation, regardless of the presence of atrial fibrillation[20]. Without antithrombotic therapy, the rate of thromboembolism in patients with mechanical heart valves is approximately 4.4 per 100 patient-years; with antiplatelet therapy, it is 2.2 per 100 patient-years; and with warfarin, it is reduced to 1 per 100 patient-years. The risk is even higher in patients with mitral (as opposed to aortic) mechanical valves and in those with concomitant atrial fibrillation, as both are independent risk factors for stroke and both relevant to Mr [A]. The presence of atrial fibrillation increases the risk of stroke by 3- to 4-fold after adjustment for other vascular risk factors, and patients with valvular heart disease such as mitral stenosis and atrial fibrillation are at the highest risk for embolic events and must be anticoagulated. Aspirin and other antiplatelet agents are inadequate for stroke prevention in this population; warfarin is the standard of care, with a target INR typically between 2.5 and 3.5 for mechanical mitral valves. Even with optimal anticoagulation, a residual annual stroke risk of ~1% remains. The cited guidelines (which represent accepted practice in New Zealand) state *For patients with a mechanical valve prosthesis, anticoagulation with the direct thrombin inhibitor, dabigatran, is contraindicated* and *For patients with a mechanical valve prosthesis, the use of anti-Xa direct oral anticoagulants* (such as rivaroxaban and apixaban) *has not been assessed and is not recommended*.

5. While there is some more recent preliminary research that might support the use of anti-Xa direct oral anticoagulants (DOACs) in patients with bioprosthetic valve replacement, they are not approved in New Zealand or internationally for this indication and warfarin remains the only approved anticoagulant in patients with prosthetic heart valves.[21] The major clinical trial comparing warfarin with dabigatran in patients with mechanical heart valves was terminated early after enrolling only 252 patients due to significantly more thromboembolic and bleeding events with dabigatran. The incidence of strokes (5% vs 0) and major bleeding (4% vs 2%) were significantly higher with dabigatran[22] and the use of dabigatran as an anticoagulant for patients with prosthetic heart valve remains contraindicated with this contraindication listed in NZ Formulary.[23] Dabigatran and available anti-Xa DOACs are not uncommonly prescribed in primary care as thromboprophylaxis in patients with atrial fibrillation and for treatment of deep vein thrombosis and I would expect all prescribers to be aware that these drugs are not indicated for patients with prosthetic heart valves. On discussing this case (anonymised) with a group of my peers, all were aware of this contraindication. However, if Mr [A] was requiring thromboprophylaxis for atrial fibrillation alone (ie he did not have a history of valve replacement), accepted practice would be to use dabigatran or an anti-Xa DOAC depending on Mr [A]'s calculated risk of a thrombotic event versus risk of bleeding[24].

6. PHU clinical notes for Mr [A] include long term classifications of *atrial fibrillation* and *anticoagulation* (both recorded 29 August 2017), and *replacement of mitral valve – St Jude*

[20] Otto C, Nishimura R, Bonow R et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association joint committee on clinical practice guidelines. Circulation, 143, E72-227. https://www.ahajournals.org/doi/10.1161/CIR.0000000000000923 Accessed 5 August 2025

[21] Mack C, Lau C, Girardi L. There is still no alternative to warfarin for mechanical valves: It remains the most effective anticoagulant. J Thoracic Cardiovasc Surg. 2025;170(2): 489 – 494 https://www.jtcvs.org/article/S0022-5223(24)00610-X/fulltext Accessed 6 August 2025

[22] Eikelboom J, Connolly S, Brueckmann M et al. Dabigatran versus warfarin in patients with mechanical heart valves. N Engl J Med. 2013; 369:1206-1214 https://www.nejm.org/doi/full/10.1056/NEJMoa1300615 Accessed 6 August 2025

[23] https://nzf.org.nz/nzf_1504 Accessed 6 August 2025

[24] BPAC. A progressive approach to managing atrial fibrillation. 2024. https://bpac.org.nz/2024/af.aspx Accessed 5 August 2025

prosthesis MVR recorded 27 June 2008. There is a medical warning dated 31 December 2020 *On warfarin – Target INR 2.5-3.5 (prosthetic valve)*. There is an addition to the atrial fibrillation classification *On Pradaxa since April 2022*. On review of notes from January 2022 onwards it appears Mr [A] had a stable INR and was having INR tests performed every 3-4 weeks. INR was subtherapeutic in March and April 2022 without any adjustment to the warfarin dosage. I am unable to comment further on Mr [A]'s long-term INR management while on warfarin and it is not the subject of this advice.

7. On 9 April 2022 Mr [A] attended the PHU for review of his most recent INR result (1.7) and warfarin instructions. Notes include *Booked for MO as patient wanting to enquire about coming off Marevan* (warfarin) *and trialling dabigatran*. It is not clear how Mr [A] became aware of dabigatran. I note Mr [A] implies in his complaint that the option to change from warfarin to dabigatran came from Dr [B] as HPU staff did not want to have to manage the blood tests required for warfarin monitoring. He states he was not informed of why the change was being made or of any risks associated with the change.

8. On 11 April 2022 Mr [A] tested positive for Covid. An appointment was booked for MO review and advice provided (per GP) to remain on 6mg warfarin and repeat INR in three weeks. Mr [A] was closely monitored with respect to his Covid symptoms and Paxlovid was prescribed on 12 April 2022. Mr [A] recovered from the Covid infection and on 20 April 2022 Dr [B] prescribed a repeat of all Mr [A]'s regular medications including warfarin. Mr [A] was released from isolation on 22 April 2022.

9. On 21 April 2022 Dr [B] has recorded *Wants to stop warfarin. PLAN consider switching to Dabigatran*. On 28 April 2022 Dr [B] has recorded:
On warfarin for AF. He would like to stop it. GFR >90
PLAN – start Pradaxa 3 days after stopping warfarin.
A prescription was provided for dabigatran 150mg bd (3-month supply). INR on 28 April 2022 was 2.0.

10. Dr [B] states in his response *On 21/04/2023* [sic] *I saw him in the clinic, and he was clear that he wanted to stop his warfarin and switch to Pradaxa. I discussed the pros and cons and gave him a week to reconsider his decision. When I saw him on 22/04/2022 he was adamant that he wanted to change his medication. The decision to prescribe Pradaxa in place of warfarin was made as Mr [A] wanted to stop taking warfarin due to the frequent blood tests (for INR) that Mr [A] needed to have while he was taking warfarin. Although warfarin is the drug of choice for anticoagulation in patients with a mechanical valve, I was compelled to respect the Mr [A] wishes. I therefore decided that sub optimal anti-coagulation with Pradaxa would be preferable to no anti coagulation at all. Mr [A] was informed that warfarin was the drug of choice for anticoagulation for him. He was informed that switching to Pradaxa would increase the risks of clots/strokes and bleeding... Usually, I would have like to give him more time to reconsider his decision and to involve specialist opinion. However, as Mr [A] wanted to stop warfarin immediately, I felt this was next best choice. I provided safety netting advice provide at the time of change of medication was to report immediately if any signs of* [thromboembolic disease or GI irritation].

11. On 28 April 2022 provider AXOW has recorded: *Seen by MO. Patient requested for alternative to warfarin as he is tired of getting his bloods taken for INR. To start on Pradaxa 3 days after stopping warfarin FRI/SAT/SUN and to start taking Pradaxa on Monday. Also advised to report any stomach issues while on Pradaxa. MO also explained to Jo the common side effects of the medication*. Subsequent notes refer to Dr [B] authorising dabigatran to be commenced on 30 April 2022. From then until 13 November 2023 notes refer to Mr [A] being regularly reviewed in

relation to his various chronic medical conditions but there is no reference over that period to presentation of symptoms suggestive of thromboembolic disease that might have prompted review of the appropriateness of Mr [A]'s anticoagulant therapy.

12. Comments

(i) From a purely clinical perspective, dabigatran was not a suitable anticoagulant for Mr [A] and as discussed previously warfarin is the only anticoagulant recommended and approved for use in a patient with a mechanical mitral valve and dabigatran is contraindicated in that situation. If the change from warfarin to dabigatran was proactively initiated by Dr [B] this would represent a severe departure from accepted practice noting Mr [A]'s high risk of stroke and the medical literature recording risk of harm from use of dabigatran as an alternative to warfarin in the clinical scenario presented. As noted previously, if Mr [A] did not have a valve replacement/valve relate atrial fibrillation, use of dabigatran as an alternative to warfarin as thromboprophylaxis was consistent with accepted practice and very reasonable advice. In the scenario that Dr [B] was not aware of Mr [A]'s valve history and based subsequent discussion and treatment choices on the assumption he was taking warfarin in relation to AF only, criticism would relate primarily to the failure to confirm Mr [A]'s medical history (at least moderate criticism) rather than the treatment provided.

(ii) If Mr [A] specifically requested dabigatran as an alternative to warfarin, I believe accepted practice would be to frankly discuss Mr [A]'s high risk of stroke with a mechanical mitral valve and atrial fibrillation, that warfarin is the only medication with a robust evidence base for reducing the risk of stroke and is therefore the only drug recommended in his situation, and that dabigatran is contraindicated for use in patients with mechanical heart valves. If Dr [B] was aware of the trial outcomes of dabigatran in patients with mechanical heart valves, this might have been a further point for discussion. Such discussion should be clearly documented.

(iii) If Mr [A] was adamant that he would stop taking warfarin following being provided with information as discussed above, I believe accepted practice would be to frankly discuss the risks of such a decision including quantification of risk of stroke as much as possible. Given the gravity of such a decision, any such discussion should be clearly documented.

(iv) If Mr [A] persisted with an adequately informed choice that he would no longer take warfarin, Dr [B] was placed with an ethical dilemma: whether to facilitate an alternative non-evidence based anticoagulant against current guidance in the hope this might provide more stroke prevention than no thromboprophylaxis at all, or to let Mr [A] remain at high risk of stroke. I discussed this case (anonymously) with a group of my peers, and they were unanimous in their view that this was a treatment dilemma but that the most appropriate step was to seek the opinion of a cardiologist who might have current knowledge of any preferred alternatives to warfarin. They were also unanimous in their view that it was vital any discussion regarding Mr [A]'s decision to stop warfarin was adequately documented because of the significant risk to him associated with non-use of warfarin.

(v) I believe there was adequate time for Dr [B] to consider how he might manage Mr [A]'s request, and this included adequate time to seek verbal advice from a cardiologist. While I cannot predict what advice might have been offered by a cardiologist, there appears to be some evolving evidence that anti-Xa DOACs might possibly have a role in thromboprophylaxis in patients with mechanical valves in the future while dabigatran does not. I believe the failure by Dr [B] to seek specialist advice on how to manage Mr [A]'s medication change request would be met with mild to moderate disapproval by my peers.

(vi) The extent of any informed consent discussion undertaken with Mr [A] by Dr [B] in relation to the decision to replace warfarin with dabigatran is not evident in the contemporaneous clinical documentation but has been elaborated on to some extent by Dr [B] in his response. I believe the standard of clinical documentation in this regard departs moderately from accepted practice noting again the serious nature of the treatment change being discussed. The response notes that 'pros and cons' of the requested treatment change were discussed. If such discussion included the points noted in 12 (ii) and (iii), I regard such discussion as adequate. However, I note Mr [A]'s comment that there was no such discussion and, in that scenario (no frank discussion of the risks referred to in sections 12 (ii) and (iii)), the failure to enable Mr [A] to make an informed choice regarding his treatment change request represents at least a moderate departure from accepted practice.

(vii) I am aware that the recollections of Mr [A] differ significantly from those of Dr [B] in relation to the circumstances surrounding the change in medication. The clinical notes are of limited assistance in this regard. Nowhere in the notes relating to request for or discussion of cessation of warfarin is there reference to Mr [A] having a mechanical mitral valve although there is reference to atrial fibrillation. Given the discrepancies in recollection, I believe it would be of some assistance to request a clinical notes audit printout for the consultation notes (three) referred to in sections 7, 9 and 11 which I can then review. I note that even had Mr [A] remained on warfarin, a risk of stroke remained although somewhat less than that without the drug.

13. **Addendum 13 September 2025**

I have been asked an additional question: *whether it was reasonable for the MO to determine that the risks associated with no anticoagulant were higher than the risks of prescribing dabigatran*.

I remain of the view that any decision with respect to using a non-warfarin anticoagulant in Mr [A]'s case required input from a cardiologist or at least some research into suitable alternatives. Had the MO researched the issue, and as discussed in the body of this report (s5), the medical literature makes it quite clear that dabigatran is not a suitable alternative to warfarin in Mr [A]'s case although it is possible evolving evidence might support the use anti-Xa DOACs in the future (dabigatran is not in this class of drugs). I believe it is common knowledge that anticoagulants other than vitamin K antagonists (warfarin) are not currently indicated for thromboprophylaxis in patients such as Mr [A] with a mechanical mitral valve and if there was to be a departure from this accepted practice, it needed to be a well-informed departure rather than an assumption that 'some anticoagulation must be better than none'. While from a physiological perspective it was probably reasonable to assume that dabigatran would have some impact in terms of reducing the risk of a thromboembolic event (positive effect) this effect is not easily quantified and needed to be balanced against the negative effect (risk of haemorrhage) as per the discussion in s5. While I understand MO's clinical reasoning up to a point, I believe the gravity of the clinical decision being made required cardiology input or at least further self-directed research into the options available to Mr [A].

14. Final addendum 23 March 2026

I have reviewed a further response from Dr [B] together with witness statements (prison RNs and phlebotomist) and comments from Mr [A]. The information appears to clarify some points:

(i) The decision to consider any alteration in Mr [A]'s anticoagulation regime was made in response to Mr [A]'s frequently voiced aversion to the INR monitoring (blood tests) required for warfarin (supported by witness statements). It was not a proactive decision made by Dr [B].

(ii) Mr [A] has denied requesting his prescription be changed to dabigatran. A statement made by one of the prison RNs suggests the RN may have informed Mr [A] of the availability of anticoagulants that did not require monitoring and to discuss this with the MO. The suggestion was made in response to Mr [A]'s concerns about his blood testing regime. It seems possible therefore that Mr [A] was aware of alternatives to warfarin (applicable in some situations) and may have requested consideration of an alternative without specifically requesting or being aware of dabigatran by name.

(iii) On two occasions (22 and 28 April 2022) Dr [B] discussed with Mr [A] the potential risks (as far as he was aware of them) of stopping warfarin and replacing it with an alternative anticoagulant. These conversations were witnessed by an RN who supports Dr [B]'s recollection. Mr [A] agreed to change from warfarin to dabigatran and the changes were implemented by Dr [B]. I am not sure it is possible to state that adequately informed consent was obtained given Dr [B]'s limited knowledge of use of dabigatran in patients with prosthetic heart valves. However, I acknowledge it appears Mr [A] was indicating he would refuse ongoing warfarin treatment and/or blood tests and Dr [B] was placed in a difficult ethical situation.

(iv) I accept Dr [B] was aware of Mr [A]'s indication for warfarin (mechanical mitral valve) and that warfarin was the only approved anticoagulant for use in this situation. He was aware the use of dabigatran represented a departure from accepted practice although may not have been aware it was contraindicated (risks outweighing potential benefits) and I would not expect my peers to be aware of the relevant research findings (see s5) unless these were directly sought. I can understand Dr [B]'s thought processes as he has described that, under the circumstances, some anticoagulation must be better than none'. However, I remain of the view that the potential sequelae of this decision were such that specialist input was required in order to ensure Mr [A] could make an adequately informed choice, and the failure by Dr [B] to seek such advice was a moderate departure from accepted practice ie. It was not sufficient for Dr [B] to assume the benefits of dabigatran would outweigh the risks in Mr [A]'s situation. I remain of the view that when discussing such a critical decision it is vital that there is some documentation of the issues discussed and Dr [B]'s documentation was mildly to moderately deficient in this regard.

(v) The quality improvement and remedial actions undertaken by Dr [B] since this complaint, as outlined in his response, appear appropriate and I have no additional recommendations.