Auckland District Health Board

A Report by the
Health and Disability Commissioner

(Case 18HDC01085)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to an elderly woman by Auckland District Health Board (ADHB) when she was admitted to hospital with rectal bleeding in 2018. The woman was taking dabigatran (a blood-thinning medication) for stroke prevention, and this was withheld during her admission. On day three, the woman was discharged from hospital with no advice about the management of her dabigatran. Three days later the woman had a stroke.

2. The report considers the woman's discharge planning and the management of her dabigatran on discharge from hospital. It highlights the importance of clear decision-making and accurate documentation about medication at discharge, so that clear advice is provided to the consumer and the consumer's GP.

Findings

3. The Commissioner found ADHB in breach of Right 4(1) of the Code. She was critical of ADHB for not ensuring that a clear plan for the woman's ongoing anticoagulant management was formulated and communicated to the woman and her GP on discharge. The Commissioner was also critical of the lack of information or instructions in the discharge summary, which provided insufficient guidance for the woman's GP. The Commissioner considered that systemic issues associated with the discharge summary template, together with the cumulative failings of several clinicians, indicated poor discharge planning processes.

Recommendations

4. The Commissioner recommended that ADHB use an anonymised version of this report as a case study to provide education sessions for nurses and doctors on the importance of communication of discharge plans; provide education to house officers on the discharge summary, with emphasis on the importance of accuracy and the need to seek clarification if there are uncertainties; provide HDC with the outcome of a review of the new eMR programme and the changes to the electronic discharge summary; consider developing a multi-disciplinary approach to anticoagulation management for clinical situations where the management may not be clear; consider sharing the re-designed electronic discharge summary with other DHBs; and provide a formal written apology to the family.

Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided by ADHB to her mother, Mrs A. The following issue was identified for investigation:

- *Whether Auckland District Health Board provided Mrs A with an appropriate standard of care in May and June 2018.*

6. The parties directly involved in the investigation were:

Mrs A	Consumer
Ms B	Complainant/consumer's daughter
ADHB	Provider

7. Further information was received from:

Dr C	Clinical director
Dr D	House officer
Dr E	General practitioner (GP)

8. Independent expert advice was obtained from a general surgeon, Dr Christoffel Snyman (Appendix A), and from HDC's in-house clinical advisor, GP Dr David Maplesden (Appendix B).

Information gathered during investigation

Introduction

9. On 24 May 2018, Mrs A, aged in her eighties, presented to the Emergency Department (ED) of ADHB because of rectal bleeding. Mrs A had a history of atrial fibrillation (AF) [1] and was taking dabigatran [2] (Pradaxa [3]) for stroke prevention. This report concerns the management of Mrs A's dabigatran on her discharge from hospital on 28 May 2018.

GP visit

10. On the morning of 24 May 2018, Mrs A had large bowel motions with large amounts of bleeding, and she presented to her GP, Dr E.[4] Dr E examined Mrs A and noted an external haemorrhoid, but no evident recent bleeding from it.

11. Dr E told HDC:

> "I was concerned about the amount of blood she described, her tachycardia,[5] her age and the fact she was on dabigatran. Dabigatran reduces the ability of blood to clot and there is therefore a risk of prolonged bleeding when the patient has a bleeding source such as a stomach ulcer."

[1] A condition that affects the heart, causing an irregular heartbeat.
[2] Dabigatran is an anticoagulant used for patients at increased risk of blood clots. It is administered orally to reduce the risk of stroke associated with atrial fibrillation in the absence of heart valve disease, and to treat or prevent deep vein thrombosis and pulmonary embolism.
[3] Pradaxa is the brand name for dabigatran.
[4] In-house expert advice was obtained from GP Dr David Maplesden, and no departures were identified in the care provided by Mrs A's GP.
[5] A rapid heartbeat.

12. Dr E consulted the on-call General Surgery registrar at the public hospital, and it was agreed to transfer Mrs A to hospital by ambulance.

Assessment in Emergency Department

13. On arrival in the Emergency Department (ED), Mrs A's regular medication was noted as dabigatran, zopiclone,[6] paracetamol, metoprolol,[7] and furosemide.[8]

14. Mrs A was reviewed by an ED clinician, who found an external haemorrhoid and assessed her as having a diverticular[9] bleed.[10] The plan was to admit Mrs A under the care of the General Surgery service in the Acute Surgical Unit (ASU). A colonoscopy[11] was planned to investigate the cause of the bleeding further.

Admission to Acute Surgical Unit

15. Mrs A was admitted to the ASU at 2.45pm on 24 May 2018. The ASU provides care to acute surgical patients. ADHB told HDC that during the period of 24 May until 28 May 2018, four consultants provided care and oversight on different days. Mrs A was also cared for by a team of four surgical registrars and five house officers in the ASU. ADHB stated that it is standard practice for registrars to report to the ASU consultant on duty about patient care and management plans.

16. ADHB told HDC that on admission to the ASU, the differential diagnoses for Mrs A were diverticular disease in the colon, or bleeding from an ulcer in the stomach because on examination dark old blood was found. ADHB told HDC that these diagnoses can cause low blood counts and may require multiple blood transfusions, an angiography,[12] or surgery. ADHB stated that Mrs A was at a high risk for bleeding, and therefore a gastroscopy[13] and a colonoscopy were arranged as an inpatient. ADHB commented that in most cases, diverticular bleeding is self-limiting and typically stops on its own.

25 May 2018

17. At 9.30am on 25 May 2018, Mrs A was reviewed by consultant Dr C in the ASU. The planned gastroscopy and colonoscopy were documented with a plan to "withhold dabigatran". ADHB told HDC that dabigatran was withheld to prevent further bleeding during the investigations to establish the source of bleeding. Dabigatran was not charted for Mrs A during her admission.

18. Dr C ordered the gastroscopy, and the pre-procedure checklist recorded that Mrs A's last dose of dabigatran was on 24 May 2018.

[6] A medication used to treat difficulty with sleeping.
[7] A medication used to treat chest pain and high blood pressure.
[8] A medication used to treat high blood pressure, heart failure, and oedema (a build-up of fluid in the body).
[9] Small bulging pouches that can form in the lining of the digestive system.
[10] Bleeding caused by injury to the small blood vessels next to the diverticula.
[11] A procedure to examine the lining of the bowel.
[12] An imaging procedure used to examine the arteries of the heart.
[13] A procedure to examine the lining of the upper part of the digestive system.

19. The gastroscopy on 25 May 2018 showed that the oesophagus,[14] stomach, and duodenum[15] were all normal, and there was no evidence of bleeding in either the stomach or duodenum.

26–27 May 2018

20. Between 26 and 27 May 2018, Mrs A's condition remained stable while she awaited a colonoscopy, although on one occasion she passed blood in her bowel motion.

28 May 2018 — colonoscopy and discharge

21. On 28 May 2018, Dr C was the consultant responsible for Mrs A, and a relieving house officer, Dr D, was responsible for discharging Mrs A.

22. On the morning of 28 May 2018, Dr C and the ASU team reviewed Mrs A, who remained stable. The plan was for a colonoscopy at approximately 1pm that day.

23. The colonoscopy showed diverticular disease [16] of the colon, as well as haemorrhoids, and no further intervention was recommended. ADHB stated that no active bleeding was found, and therefore no firm conclusion could be drawn as to whether the bleeding was from diverticular disease or haemorrhoids. ADHB told HDC that it was reassuring that no malignant pathology[17] was found.

24. ADHB said that owing to a normal colonoscopy and no evidence of further bleeding, a plan was made at the afternoon handover meeting to discharge Mrs A if she was well.

25. ADHB stated:

> "We counselled [Mrs A] that the bleeding may occur again in the future but that the exact risk was somewhat unknown and advised, if there were ongoing concerns, that she should see her General Practitioner."

26. ADHB acknowledged that there was no documentation of this discussion with Mrs A.

27. At 3.30pm, House Officer Dr D reviewed Mrs A and documented:

> "Colonoscopy (N) [normal]. Discussed @ handover.
>
> Plan — 1. Home
>
> 2. no F/U [follow-up]."

[14] The oesophagus is a muscular tube that connects the mouth to the stomach.
[15] The first part of the small intestine.
[16] Diverticular disease is the general name for a common condition that causes small bulges (diverticula) or sacs to form in the wall of the large intestine (colon).
[17] Cancerous tumour.

28. At 3.33pm, Dr D prepared the discharge summary and documented:

> "Discharge Medications: metoprolol; candesartan;[18] colecalciferol; furosemide and paracetamol.
>
> Advice to GP: 'no change to regular medications'.
>
> Advice to [Mrs A]: 'Keep well hydrated and ensure you have a diet high in fiber. Try to avoid constipation and straining. If you experience further episodes of bleeding that do not settle, or if you feel unwell, please seek advice from your GP.'"

29. On discharge, a medication prescription was given to Mrs A, which listed all of her regular medication, but did not include dabigatran.

30. Mrs A's daughter stated that her mother asked her nurse for instructions about re-starting dabigatran, and the nurse told her mother that she would clarify this with the medical team and contact her mother the following day. According to Mrs A's daughter, the nurse told Mrs A that if she had not contacted her by the following day, Mrs A should seek advice from her GP.

31. The nurse recollected that she tried to speak to the medical team about Mrs A recommencing her dabigatran, but was unable to contact the medical team before Mrs A was discharged. The nurse recalls having a discussion with another doctor, who advised that usually dabigatran is re-started one week after the bleeding has finished, and that this should be confirmed by Mrs A's medical team. The nurse recalls that she conveyed the doctor's comments to Mrs A and advised her to see her GP if she had not been contacted by the following day. The nurse said that by the end of her shift, she had still not managed to speak to Mrs A's medical team, and she telephoned Mrs A, but there was no reply.

32. Mrs A was discharged from hospital at 4.00pm.

33. Dr D stated that she has no recollection of any details relating to this discharge.

30 May 2018

34. By 30 May 2018, the nurse at ADHB had not telephoned Mrs A with advice about re-starting dabigatran, so Mrs A presented to her GP that day.

35. ADHB said that the nurse intended to telephone Mrs A on 30 May 2018, as agreed, but this did not occur, and the nurse apologises for this omission.

36. Mrs A's GP, Dr E, reviewed Mrs A and advised her to return in two weeks' time for a review, and told her that if her haemoglobin levels were normal, he would re-start her on dabigatran.

[18] A medication used to treat high blood pressure (hypertension) and heart failure.

5 June 2018

37. On 5 June 2018, Mrs A had a stroke and was re-admitted to the public hospital. It had been 12 days since her last dose of dabigatran.

Additional information from ADHB

38. ADHB told HDC that Dr D was responsible for discharging Mrs A, and acknowledged that the discharge summary did not state that dabigatran should be re-started. Regarding the discharge summary advice to the GP, "No change to regular medications", ADHB stated: "In hindsight, we acknowledge the ambiguity this advice has caused around the restarting of [dabigatran]." ADHB accepts that it could have been conveyed more clearly that this advice was intended to include Mrs A's dabigatran. ADHB explained that there was an omission to include dabigatran on Mrs A's medication script because the clinical decision was made to withhold dabigatran during her admission.

39. ADHB also told HDC that dabigatran could have been re-started at discharge, since it had already been withheld for one week.

Re-starting anticoagulation

40. In response to this complaint, ADHB told HDC that in Mrs A's case, the issue of re-starting anticoagulation is controversial. ADHB stated that Mrs A's risk profile measured by risk prediction tools such as the CHADS-VASC2 score[19] indicated that her risk of stroke was 4.8% per year without blood thinners, and anticoagulation reduced this risk by approximately half. ADHB said that the HAS-BLED scoring tool[20] predicted Mrs A's risk of bleeding if anticoagulation medications were prescribed, and this was 5.8% per year. ADHB explained that risk prediction tools provide a guide to aid the decision-making for initiating anticoagulation, and that because of Mrs A's large bleed, the risk of a heart attack or stroke was increased. ADHB considered that withholding the anticoagulant for a period of two weeks amounted to an overall risk of 0.2%.

41. ADHB told HDC that it has no formal policies or guidelines on the re-starting of anticoagulation in patients with gastrointestinal bleeding. ADHB stated that there is no General Surgery Department policy on the optimal timing of re-starting these medications once they have been stopped. It said that factors taken into consideration include an individual patient's condition and the clinician's practice. ADHB said that the consensus among general surgeons is that anticoagulation medications can be re-commenced when investigations have been completed, bleeding has stopped, and the patient is physiologically normal.

Supervision of house officers

ADHB told HDC that house officers, including relievers, are supervised clinically at all times by registrars, fellows, and consultants, and that house officers are fully qualified practitioners responsible for completing the electronic discharge summaries. ADHB said that electronic discharge summaries are pre-formatted with a template to ensure that all

[19] Used to calculate the risk of stroke for patients with atrial fibrillation.

[20] A risk score to estimate the one-year risk for major bleeding in patients with atrial fibrillation.

the information required is documented. Electronic discharge summaries are not checked routinely by a more senior clinician; however, at times, if they are not accurate or are incomplete, they will be revised at a later date. ADHB stated that house officers are encouraged to check with a more senior clinician if they have questions or need clarification.

Further comment from Dr C

42. Dr C told HDC:

> "It is acknowledged that there should have been more clarity regarding the instructions to [Mrs A] and her GP regarding re-starting [dabigatran] … It would have been our normal practice to have patients restart anticoagulants once the bleeding has stopped and investigations were completed. There was no statement recorded in the medical notes that there should be a departure from this practice in [Mrs A's] case … We apologise to [Mrs A] and her family for the team's lack of clarity in regards to the re-starting of [dabigatran]."

Subsequent events

43. Dr C told HDC that following these events, Mrs A's case was discussed at a monthly surgical audit meeting. It was acknowledged that documentation in the clinical notes needed to be improved and a safety-netting process for advice on anticoagulant medications needed to be instituted to prevent a similar situation from occurring again.

Actions taken

44. ADHB advised HDC that since Mrs A's case, the following actions have been taken:

- It has implemented an electronic medication history form (eMR). The eMR is populated from the community pharmacy dispensing records, and supports an accurate medication history record. The eMR informs the electronic discharge summary and alerts the medical team to admission medication that has been withheld during admission. This provides a prompt to reconcile and review the need to continue any withheld medication.
- The General Surgery service has now included a mandatory section in the electronic discharge summary regarding a patient's anticoagulant status, to ensure that this is discussed and documented at discharge.

Response to provisional opinion

45. Ms B (Mrs A's daughter) and ADHB were given the opportunity to respond to relevant sections of the provisional opinion.

46. Ms B stated: "My brothers and I want to say how much we appreciate the work that has gone into the report."

47. ADHB stated:

> "We appreciate your detailed review of [Mrs A's] case and the recommendations. We will ensure all the relevant points are carried out and that our staff has the opportunity to learn from this event."

Opinion: Auckland District Health Board — breach

Introduction

48. ADHB had a responsibility to ensure that Mrs A was provided with services that complied with the Code of Health and Disability Services Consumers' Rights (the Code), and for having in place adequate systems to ensure that Mrs A was provided with appropriate care.

49. On 24 May 2018, Mrs A was admitted to the public hospital and treated by the General Surgery team in the ASU. A gastroscopy was performed on Friday 25 May, and a colonoscopy was performed on Monday 28 May, both of which were reassuring. My clinical adviser, general surgeon Dr Christoffel Snyman, considers that the treatment and investigation of Mrs A's PR bleeding was timely, appropriate, and commendable. He commented that few hospitals in New Zealand would be able to offer both a gastroscopy and an acute colonoscopy within such a short time frame.

50. At the time of her admission, Mrs A was taking dabigatran to manage her risk of stroke. On 25 May 2018, the treating team withheld Mrs A's dabigatran because she was bleeding on admission. Dr Snyman advised that dabigatran was withheld appropriately prior to the gastroscopy. On 30 May 2018, Mrs A was reviewed by her GP, Dr E, two days after her discharge from ADHB. My in-house clinical advisor, GP Dr David Maplesden, advised that Dr E made an "appropriately considered decision to withhold [Mrs A's] dabigatran until he could be confident her GI bleeding had settled and would not be exacerbated by recommencing the medication".

51. I accept Dr Snyman's and Dr Maplesden's advice. Accordingly, the focus of this report is the DHB's failure to formulate and communicate instructions to Mrs A about recommencing dabigatran when she was discharged from hospital on 28 May 2018.

Management of dabigatran on discharge

52. House officer Dr D completed Mrs A's discharge summary on 28 May 2018. The "Advice to GP" indicated "no change to regular medications". The discharge summary did not document that dabigatran was one of Mrs A's regular medications and that it had been stopped on her admission to hospital, and did not include advice or a management plan for her GP regarding if and when to re-start the dabigatran.

53. Mrs A sought clarification from her nurse about recommencing dabigatran. The nurse advised Mrs A that she would consult the medical team and get back to her. The nurse told

Mrs A to contact her GP if she had not heard back by the following day. The nurse did not follow up with Mrs A.

54. Mrs A presented to her GP the following day as instructed. The GP decided to withhold dabigatran for two weeks, and re-start it if Mrs A's haemoglobin remained stable. Regrettably, Mrs A had a stroke before the scheduled follow-up with her GP.

55. Dr Snyman advised that there are no clear guidelines in the literature about when to re-start anticoagulation after a major bleed. He said that it would be reasonable to re-start anticoagulation either on discharge, or at least within seven days of discharge. However, he advised that "the decision to start or withhold anticoagulation was not the error or deviation from care", but rather "the lack of a conscious decision regarding [Mrs A's] dabigatran management on discharge was a departure from the standard of care". He considers that the decision about dabigatran management could have been noted in the discharge summary as well as communicated to Mrs A.

56. Dr C told HDC that his usual practice is to resume a patient's oral anticoagulation once bleeding has stopped and investigations have been completed, and that he gave no instructions in the clinical notes to depart from this practice.

57. ADHB told HDC that on the day of discharge, the ASU doctors gave verbal advice to Mrs A about the risk of bleeding, and to contact her GP if she had ongoing concerns. This discussion was not documented.

58. ADHB advised that dabigatran was omitted from Mrs A's prescription on discharge because she was not given dabigatran during her admission. ADHB acknowledged that the discharge summary did not state that dabigatran should be re-started, but advised that the instruction to the GP for "no change to regular medication" was intended to include the anticoagulation medication. ADHB accepts that the advice caused ambiguity around re-starting dabigatran.

59. I am not persuaded that an intention for Mrs A to resume her dabigatran can be inferred from the phrase "no change to regular medication", or that this indicates conscious discharge planning in respect of the dabigatran. In this respect I agree with Dr Snyman that for Mrs A (or her GP) to infer from that instruction that she was to continue her anticoagulation is "obscure at best", particularly as that medication had been withheld during her admission. There is also no other evidence that the plan for discharge included any consideration of, or instructions for, ongoing anticoagulant management. With reference to Dr C, I do not accept that the absence of an instruction in the clinical notes to depart from his "usual practice" of re-starting anticoagulation is adequate communication of the plan to other clinicians that Mrs A should resume dabigatran. Although Dr D was responsible for completing the discharge summary documentation, she was a junior doctor and reliant on a clear, positive plan for discharge being communicated to her by the more senior clinicians in her team.

60. Accordingly, I conclude that a clear decision about Mrs A's ongoing use of dabigatran should have been made and documented. This would have ensured that relevant hospital staff were aware of the plan and included it in the discharge summary and discussed it with Mrs A at discharge. The completion of an accurate discharge summary containing relevant information is a basic requirement that should have been met. In this case, the discharge summary lacked essential information, including an accurate record of Mrs A's medications, advice to Mrs A about re-starting dabigatran on discharge, and clear advice to her GP.

61. The ambiguity in the plan is further highlighted by the fact that Mrs A asked for clarity about re-starting dabigatran. The nurse's inability to access information regarding the plan, either from the discharge summary, the clinical notes, or by contacting the medical team before Mrs A's discharge, resulted in a lost opportunity to give Mrs A clear instructions at that time.

62. Lastly, the lack of information or instructions in the discharge summary meant that there was insufficient guidance for Mrs A's GP. As noted by Dr Snyman:

> "To have left the decision up to her GP to make was inappropriate and an abrogation of duty of care. If specialists dealing with this particular problem couldn't firm up a clear decision and treatment plan, it would have been unfair to expect the GP to have this conversation and come up with a plan."

Conclusion

63. I am critical of ADHB for not ensuring that a clear plan for Mrs A's ongoing anticoagulant management was formulated and communicated to Mrs A and her GP on discharge. I note Dr Snyman's comment:

> "The overall impression, right or wrong it created with me is one of a highly efficient admission, investigations, results and discharge driven process, and that perhaps the finer nuances of holistic care such as the anticoagulation management fell by the wayside."

64. While individual staff members hold some degree of responsibility for their failings, noting some of the systemic issues associated with the discharge summary template, together with the cumulative failings of several clinicians, I consider that the deficiencies outlined above indicate poor discharge planning processes, for which ADHB is responsible. In my opinion, ADHB failed to provide services to Mrs A with reasonable care and skill, and, accordingly, breached Right 4(1) of the Code.[21]

65. I acknowledge that ADHB has implemented the eMR programme to support the accuracy of medications on admission and discharge, and that the electronic discharge summary includes a section on a patient's anticoagulation status. I consider these changes appropriately directed to the issues of concern.

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

Recommendations

66. I recommend that ADHB undertake the following and report back to HDC within three months of the date of this report:

a) Use an anonymised version of this report as a case study, to encourage reflection and discussion during education sessions for nurses and doctors on the importance of communication of discharge plans.

b) Provide further education to house officers on the discharge summary, with emphasis on the importance of accuracy and the need to seek clarification if there are uncertainties.

c) Review the effectiveness of the new eMR programme and the changes to the electronic discharge summary, and report back to HDC on the outcome of the review.

d) Consider developing a multi-disciplinary approach to anticoagulation management, particularly in the presence of a clinical situation where the management may not be clear.

e) Consider sharing the re-designed electronic discharge summary with other DHBs.

67. I also recommend that ADHB provide a written apology to Mrs A's family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

Follow-up actions

68. A copy of this report with details identifying the parties removed, except ADHB and the experts who advised on this case, will be sent to the Health Quality & Safety Commission and the Royal Australasian College of Physicians, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from general surgeon Dr Christoffel Snyman:

"11 February 2019

The Commissioner
Health and Disability Commission
PO Box 1791
Auckland 1140

REF: C18HDC01085

Complaint: [Mrs A]/[the public hospital] (Auckland District Health Board)

I have been asked by the HDC to provide an opinion to the Commissioner on case number **C18HDC01085**. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. My name is Christoffel Gerhardus Snyman. I hold a fellowship in general surgery (FRACS) since 2003. I have trained and worked as a specialist general surgeon in New Zealand. I am a full time consultant general surgeon in a medium sized public hospital. Acute and elective gastro-intestinal conditions are a major part of my practice. I perform acute and elective endoscopies. I do not have a personal or professional conflict in this case.

Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Mrs A] at [the public hospital] was reasonable in the circumstances, and why. In particular, please comment on: The appropriateness of the decision to stop the anticoagulant during [Mrs A's] admission to [the public hospital]; The appropriateness of the decision to not recommence anticoagulant upon [Mrs A's] discharge from [the public hospital]; The adequacy of [Mrs A's] discharge from [the public hospital], including the safety netting advice provided, the discharge summary and instructions provided to her general practitioner; Whether the care provided was consistent with Auckland DHB's policies and protocols; Whether Auckland DHB's policies and protocols are consistent with evidence based best practice; and Any other matters in this case that you consider warrant comment.

Documents provided

Letter of complaint dated 7 June 2018.

Auckland DHB's response dated 23 July 2018.

Clinical records from Auckland DHB from 24 May 2018 to 13 June 2018.

Additional Resource

Little et al. Resumption of anticoagulant therapy after anticoagulant-related gastrointestinal bleeding: A systematic review and meta-analysis. Thrombosis Research 175 (2019) 102–109

Radaelli et al. Management of anticoagulation in patients with acute gastrointestinal bleeding. Digestive and Liver Disease 47 (2015) 621–627

Truman et al. Re-initiation of Dabigatran and Direct Xa Antagonists after a major bleed. American Journal of Medicine 129 (2016) 54–63

Oakland et al. Diagnosis and management of acute lower gastrointestinal bleeding: guidelines from the British Society of Gastroenerology. Gut 2019;0:1–14

UpToDate. Approach to acute lower gastrointestinal bleeding in adults

Strate et al. ACG Clinical Guideline: Management of patients with acute lower gastrointestinal bleeding. American Journal of Gastroenterology March 2016;111(4):459–474

Summary

[Mrs A], aged [in her eighties], was admitted to [the public hospital] on 24 May 2018 following a severe rectal bleed. She has a history of atrial fibrillation and was on Pradaxa for stroke prevention. Her medication was stopped by clinicians on 25 May 2018 and she underwent a gastroscopy and colonoscopy. No obvious cause for the bleeding was found, except for a haemorrhoid. She was kept in hospital over the weekend, and hardly mobilised at all. [Mrs A] was discharged from [the public hospital] on 28 May 2018, but her Pradaxa was not recommenced. A registered nurse (RN) on the ward told [Mrs A] that she would follow up with the treating team as to whether her Pradaxa should be restarted and that she would call her to let her know the following day. However, the RN said that if she forgot to follow up on this, [Mrs A] should see her general practitioner (GP). [Mrs A] presented to her GP on 30 May 2018 and queried whether Pradaxa should be recommenced. Her GP advised for her to return in two weeks and if her haemoglobin levels were normal, he would restart her on Pradaxa. On 5 June 2018, [Mrs A] had a stroke.

Expert advice requested

The appropriateness of the decision to stop the anticoagulant during [Mrs A's] admission to [the public hospital]; *This would be the appropriate and recommended standard of care. No deviation from standards.* I consider the treatment of [Mrs A's] PR bleeding to have been appropriate and commendable. Stopping anticoagulation under those circumstances was the correct action. The investigations to determine a cause for the bleeding were timely and appropriate. It is worth noting that few hospitals in New Zealand would be able to offer both a gastroscopy and acute colonoscopy within such a short time frame.

The appropriateness of the decision to not recommence anticoagulant upon [Mrs A's] discharge from [the public hospital]; *Below standard of care. Severe deviation from standard of care.* In considering the question, I have to be clear that the deviation relates to the lack of a conscious decision regarding [Mrs A's] anticoagulation management on discharge, not whether it was ultimately restarted or withheld. Not restarting [Mrs A's] anticoagulation upon discharge was not necessarily

an error in itself. There are no clear guidelines on when to restart anticoagulation after a major bleed. There are a multitude of factors to take into consideration prior to making a decision to restart anticoagulation. These are, but not limited to: The type of anticoagulation and its reversal agent in the event of further bleeding, The reasons for anticoagulation in the first place, The cause of the bleeding, The balance between the risk of thrombo-embolic events and the risk of further bleeding. There are to the best of my knowledge and following a literature search no definitive guidelines or studies that can clarify this for us. Almost all the studies are retrospective with recommendations and suggestions largely based on expert opinions. In the absence of a clear cause for bleeding and given the self-limiting nature of the event, it would have been considered reasonable to restart anticoagulation upon discharge or at least within 7 days of discharge. Ultimately, the decision to start or withhold anticoagulation was not the error or deviation from care. I conclude that the options were not discussed with [Mrs A] and thereby denied her the opportunity to make an informed choice in the matter. To have left the decision up to her GP to make was inappropriate and an abrogation of duty of care. If specialists dealing with this particular problem couldn't firm up a clear decision and treatment plan, it would have been unfair to expect the GP to have this conversation and come up with a plan. If there was uncertainty around the restart of the anticoagulation, then it should have been discussed with appropriate medical specialties, or, in a multi-disciplinary setting prior to discharge. The decision could then have been noted in the discharge summary as well as communicated to [Mrs A]. [The public hospital's] reply mentions the CHADS-VASC2 and HAS-BLED scoring tools. These are helpful to get an idea of the risk/benefit profile for initiating anticoagulation. They have not been validated for use after you've had a major bleed and are considered to be of doubtful help in this setting. I therefore conclude that the apparent lack of a decision to restart or withhold anticoagulation is the error, not whether it was ultimately restarted or stopped.

The adequacy of [Mrs A's] discharge from [the public hospital], including the safety netting advice provided, the discharge summary and instructions provided to her general practitioner; *Below standard of care. Severe deviation from standard of care.* The discharge summary is sparse and to the point. It contains reasonable information on investigations performed and their results. However, there is no mention of stopping the anticoagulation as part of her treatment and there is no mention of future management plans for anticoagulation. There is a clear list of discharge medications and no mention of her anticoagulation. The advice to the GP is 'No change to regular medications.' I consider the intent behind this sentence to imply that [Mrs A] was to continue her anticoagulation to be obscure at best. I find the lack of specific information regarding her anticoagulation management to fall severely below the standard of care. The advice to [Mrs A] is to seek advice from her GP if there is further bleeding. The advice in general is adequate but does not mention anticoagulation management. [The public hospital's] reply stated that [Mrs A] was counselled regarding the risk of bleeding and the uncertainty surrounding this. They may very well have counselled her, but this is not documented and the fact that [Mrs A] herself asked for clarification around her anticoagulation from the nurse upon discharge would indicate that the counselling did not take place, or was done poorly.

For these reasons I conclude that the discharge process fell severely below the standard of care. [The public hospital] states that the eMR program will support the accuracy of medications on admission and discharge. Provided it performs as stated in the reply, this would hope to eliminate this type of error. It would also be worth educating staff on the importance and worth of the accuracy of the discharge summary.

Whether the care provided was consistent with Auckland DHB's policies and protocols; *No policies or protocols provided for review* As stated above, no clear guidelines/protocols/policies currently exist for us to build on. I would recommend that the teams who deal with gastro-intestinal bleeding be encouraged to familiarise themselves with current literature, sparse as it is, and be encouraged to consider a multi-disciplinary approach to anticoagulation management in cases where the management may not be clear.

Whether Auckland DHB's policies and protocols are consistent with evidence based best practice; and *See above* **Any other matters in this case that you consider warrant comment.** I think it is worth reflecting that there was an opportunity prior to discharge to clarify the question around [Mrs A's] anticoagulation management. This opportunity presented itself in [Mrs A's] question to the nurse, and again in the nurse's question to one of the registrars. Although neither of them was at fault for their behaviour, we have to wonder about the opportunity lost at that moment. As per the nurse's advice, [Mrs A] presented to her GP two days after discharge when she did not hear from the hospital. The decision made by the GP to withhold anticoagulation for another 2 weeks and then to restart it, provided the haemoglobin remains stable, was reasonable. I would not have expected the GP to specifically ring the Hospital to clarify this decision. In reviewing this case and reading through the surgical admission and progress notes, I couldn't help but notice that it seemed quite sparse. The nursing template seemed to be filled in diligently every day. The surgical admission and continuation notes in contrast seemed to be very sparse, even for a surgical admission. Several entries are noted to be not clearly notated with legible identifiers, or scrawled writing that I could not read. On the admission proforma large sections are left blank even though some clearly states 'for every patient on admission'. I appreciate the ease of a proforma, but it does lose its function and purpose if not used as intended. In contrast, some of the other documentation, such as the endoscopy booking form, is filled out very well. The overall impression, right or wrong, it created with me is one of a highly efficient admission, investigations, results and discharge driven process, and that perhaps the finer nuances of holistic care such as the anticoagulation management fell by the wayside."

The following further clinical advice was received from Dr Snyman:

"I have reviewed the reply from ADHB. I have reviewed the attachments. I have reviewed these with my original report. My opinion remains unchanged from my report. It is worth mentioning that the new redesigned discharge summary to reflect anti-coagulation medication, could have prevented this had it been in use at the time.

The future use of this design will hopefully and likely prevent a similar situation. It would be worth encouraging ADHB to promote this to other DHBs. [The] reply refers to appendixes 1, 2 and 3. They were sent to me electronically as a bulk document and therefore I am not sure which document is which appendix. However the single paper, presumed appendix 3, under the heading 'Electronic Discharge Summary' gives excellent advice on the purpose and format of a discharge summary. If this advice is followed by the discharge author and combined with the mandatory discharge field as modified for anticoagulation medication, then it ought to clarify and prevent a similar situation in future. Is this e-mail sufficient or would you like a more formal report?

Thank you

Gerrie Snyman
General Surgeon"

Appendix B: In-house clinical advice to the Commissioner

The following advice was received from in-house clinical advisor GP Dr David Maplesden.

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms B] about the care provided to her mother, [Mrs A], by [Dr E] and Auckland DHB. 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. I have reviewed the information on file: complaint from [Ms B]; response from Auckland DHB and clinical notes [public hospital]; response from [Dr E] and [GP notes].

2. [Ms B] states her recently widowed mother ([in her eighties]) was living independently and still driving prior to being admitted to [the public hospital] on 24 May 2018 following a leger rectal bleed. She had history of atrial fibrillation and was taking dabigatran (Pradaxa) for stroke prevention. The dabigatran was stopped while [Mrs A's] bleeding was investigated (no confirmed cause found) and [Mrs A] was discharged on 28 May 2018. Prior to discharge [Mrs A] asked for advice on whether or not she was to restart the dabigatran. A nurse stated she would ask the doctors for advice but if she forgot [Mrs A] would need to see her GP. [Mrs A] did not hear back from the nurse and went to her GP ([Dr E]) on 30 May 2018. She was instructed to stay off the dabigatran and get blood tests done in two weeks' time. If the results were normal, she could restart the dabigatran. Sadly, [Mrs A] suffered a stroke on 5 June 2018 and was readmitted to [the public hospital]. [Ms B] is concerned regarding the management of her mother's dabigatran and the role this played in her stroke.

3. The DHB response includes the following points:

(i) [Mrs A] was admitted on 24 May 2018 with *large volume rectal bleeding.* The source was considered to be most likely haemorrhoids or diverticulosis, or possible upper GI loss (suspected when altered blood was passed). [Mrs A's] dabigatran was stopped and she was investigated with gastroscopy (25 May 2018) and colonoscopy (28 May 2018). While she was noted to have both haemorrhoids and diverticulosis no active source of bleeding was confirmed, and the bleeding settled during the admission without the need for transfusion (haemoglobin 124 g/L on admission with drop to 115 g/L on 25 May 2018 and 118 g/L prior to discharge).

(ii) The response notes [Mrs A] was receiving dabigatran to reduce her risk of stroke secondary to her co-morbidity of atrial fibrillation. Dabigatran reduces this risk but does not remove the risk. Dabigatran is associated with an increased risk of haemorrhage and the decision whether or not to initiate or continue the medication is based on the relative risk of stroke versus haemorrhage using validated scoring tools, in conjunction with the patient making an informed choice. Prior to discharge [Mrs A] was thought to be stable from the haemorrhage perspective and was advised to see her GP for follow-up. *We counselled her that the bleeding may occur again in the future but that the exact risk was somewhat unknown.*

(iii) The response notes that guidelines regarding timing of re-initiation of dabigatran following a haemorrhage are varied but *in recent years, our clinical practice has been erring towards restarting anticoagulation earlier [than previous practice of up to four weeks], within 1–2 weeks in most cases, depending entirely on clinical circumstances. In [Mrs A's] case, we felt that anticoagulation could have been restarted at discharge since it had already been withheld for one week.* The response notes the discharge summary states [Mrs A] could resume all her regular medications, but dabigatran was not included in the list of regular medications because it had been stopped while in hospital. It is acknowledged this advice could prove ambiguous to the recipient of the discharge summary and methods of better clarifying discharge anti-coagulation instructions are being investigated.

(iv) The nurse referred to by the complainant notes she attempted to speak to the medical team regarding [Mrs A's] dabigatran on the day of her discharge but was unsuccessful. She tried to contact [Mrs A] later that day but was unsuccessful and apologises for not contacting [Mrs A] the following day. However, she had instructed [Mrs A] to see her GP for advice and [Mrs A] heeded this advice.

4. [Public hospital] notes are consistent with the response. The discharge summary is probably the most relevant document with respect to the complaint as this was the information received by [Dr E]. This document includes [Mrs A's] history of PR blood loss (*bright red blood, black and loose stool*) and gives a primary diagnosis of haemorrhoids and *bleeding likely secondary to this* (which I do not think accurately reflects the true clinical situation given the degree and nature of the bleeding and the absence of an actively bleeding haemorrhoid noted on assessment). Results of the endoscopies were attached. The section 'Discharge Medications' includes metoprolol, candesartan, cholecalciferol, frusemide and paracetamol but did not include dabigatran (in fact the drug is not mentioned at all in the discharge summary — no comment on cessation or recommencement). The section 'Advice to GP' is *No change to regular medications.* The section 'Advice to Patient' is *Keep well hydrated and ensure you have a diet high in fibre. Try to avoid constipation and straining. If you experience further episodes of bleeding that do not settle, or if you feel unwell, please seek advice from your GP.* There is no reference in the clinical notes to assessment of bleeding risk (HAS-BLED[1] score) or stroke risk (CHA_2DS_2-VASc score[2]) using the validated scoring tools and I could find no reference to discussion of, or plan for, recommencement of dabigatran following results of investigations.

5. [Dr E] includes the following points in his response:

(i) [Mrs A] had been commenced on dabigatran in January 2016 following diagnosis of atrial fibrillation. At that stage her CHA_2DS_2-VASc score was 4 and HAS-BLED score 2.

[1] https://www.mdcalc.com/has-bled-score-major-bleeding-risk
[2] https://www.mdcalc.com/cha2ds2-vasc-score-atrial-fibrillation-stroke-risk

(ii) On 24 May 2018 [Mrs A] presented with a history of passing large amounts of altered blood PR. She was noted have an elevated pulse rate compared with usual. An external haemorrhoid was noted on examination with no recent bleeding evident from this. [Dr E] was concerned at the degree of bleeding and the fact [Mrs A] was on an anticoagulant, and arranged urgent surgical review at [the public hospital] (ambulance transfer).

(iii) At follow-up on 30 May 2018 two days after [Mrs A's] discharge from [the public hospital], [Dr E] noted the normal endoscopies but also history from [Mrs A] that she had had two further significant PR bleeds while in [hospital], and her haemoglobin had dropped around 10g/L during the admission (based on admission bloods noted in 3(i)) but in fact her most recent community haemoglobin in June 2017 was 138 g/L raising the possibility the bleeds were of more significant volume than realised in hospital. He notes also that the history of altered blood loss was not consistent with a haemorrhoidal source, and that endoscopy is not 100% sensitive at detecting lesions and a small bowel source for the bleeding (although relatively rare) had not been excluded. [Dr E] also noted the absence of any reference to instruction regarding recommencement of dabigatran in the discharge summary and absence of dabigatran from the list of discharge medications. [Mrs A] confirmed she had not been given any instructions regarding her dabigatran despite enquiring while she was in [hospital].

(iii) [Dr E] then recalculated [Mrs A's] CHA_2DS_2-VASc score (calculated as 6 — compared with [the public hospital] (retrospective) calculation of 4) and HAS-BLED score (calculated as 2 compared with [the public hospital] (retrospective) calculation of 3). However, he considered [Mrs A's] potential bleeding risk in the near future was potentially under-represented by the HAS-BLED score given the severity of her haemorrhage may have been under-estimated and a source of bleeding had not been confidently identified/treated. He has clearly outlined the rationale for his management decision — that being that the estimated risk of stroke over the next two weeks would be around 1:300, while the risk of a bleed (potentially catastrophic) was difficult to define because it had been only a few days since the last haemorrhage and the precise cause of bleeding was unclear. His plan was to retest [Mrs A's] haemoglobin in two weeks and if there was no sign of ongoing overt or occult bleeding, the dabigatran could be restarted.

(iv) [Dr E] discussed the risks of stroke and haemorrhage in broad terms with [Mrs A] and the plan was agreed. In particular, it was emphasised she should go back on the dabigatran in the long-term but there was a relatively small risk of stroke for the period of cessation envisaged until the risks of haemorrhage recurrence could be more confidently assessed. [Dr E] states he also sought advice from a senior colleague who agreed with the management plan. [Dr E] was concerned when he received notification of [Mrs A's] stroke only a few days later.

6. GP notes are of adequate quality and are consistent with the response. The various risk scores are recorded together with discussion around the pros and cons of re-

starting dabigatran, consultation with a colleague, and intention to restart the dabigatran once it was confirmed [Mrs A's] bleeding had settled.

7. On 5 June 2018 [Mrs A] developed dysphasia and mild right-sided weakness and was re-admitted to [hospital]. It had been 12 days since her last dose of dabigatran. MO notes dated 13 June 2018 prior to [Mrs A's] transfer to interim community care that day list the diagnosis as *left MCA infarct — cardioembolic secondary to dabigatran being w/held.* Dabigatran was recommenced prior to discharge.

8. There is a lack of evidence-based consensus regarding optimum time to recommence anticoagulants following a GI bleed. A 2017 literature review article[3] concluded: *Anticoagulation therapy resumption is recommended, with resumption being considered between 7 and 14 days following GI bleed (GIB) regardless of the therapy chosen. Data for warfarin management after GIB should be applied with caution to direct oral anticoagulants* (DOACs — including dabigatran) *because of the quicker onset and experimental nature of reversal agents. Apixaban may be a preferred option when restarting a DOAC therapy.*

9. I think [Dr E] made an appropriately considered decision to withhold [Mrs A's] dabigatran until he could be confident her GI bleeding had settled and would not be exacerbated by recommencing the medication. He took the time to calculate her risks of stroke and bleeding but was somewhat handicapped by the uncertainties surrounding the degree and nature (source) of her bleeding. He was faced with the dilemma of possibly precipitating another major, potentially catastrophic bleed if the dabigatran was recommenced too early, balanced against the small but significant risk of stroke the longer [Mrs A] remained off her medication. With the benefit of hindsight, it appears that even had [Dr E] taken a less conservative approach and advised recommencement of dabigatran after two weeks' cessation (which would have been within the time frame recommended in the cited literature review), this would not have prevented [Mrs A's] stroke. It cannot be stated with certainty that restarting the medication prior to hospital discharge would necessarily have prevented a stroke. I do not believe the [public hospital's] discharge summary was helpful in aiding [Dr E's] decision with no specific reference to in-hospital or discharge anticoagulant management, and the clinical scenario presented (large volume PR bleeding, altered blood at times and mixed with stool) not being particularly supportive of the stated diagnosis of haemorrhoidal bleeding. [Dr E] was conscientious in using validated scoring tools in his decision-making process and in seeking collegial advice. However, I acknowledge the devastating effect on [Mrs A] of her stroke and effect on her previous independence. I recommend [Dr E] review the cited literature review as an adjunct to future decision-making regarding DOAC in patients following a GI bleed.

[3] Kido K et Scalese M. Management of Oral Anticoagulation Therapy After Gastrointestinal Bleeding: Whether to, When to, and How to Restart an Anticoagulation Therapy. Ann Pharmacother. 2017 Nov;51(11):1000–1007.

10. I think the quality of [Mrs A's] discharge summary from [the public hospital] was disappointing in regard to addressing the anticoagulation issue and in accurately representing the likely source of her bleeding. It seems reasonable that her dabigatran was stopped while in hospital, but given her hospital clinicians could most accurately consider the likely source of her bleeding and risk of recurrence, it would seem most appropriate that they give explicit advice to the GP on the optimum timing of recommencing dabigatran."