



Te Tāhū Hauora
Health Quality & Safety
Commission

The safer use of anticoagulants | Te hōtaka whakahaere rongoā ārai poketoto

Case for change

December 2023



Contents

Acknowledgements.....	2
Purpose	3
Background.....	3
Problem analysis.....	3
Project start up.....	4
Benefits	6
Next steps	7
Project timeline	7
References	8

Acknowledgements

Te Tāhū Hauora Health Quality & Safety Commission (Te Tāhū Hauora) thanks the consumers on the project for sharing their lived experience with the use of anticoagulants. They brought great knowledge, expertise and insight and guided the team in key decisions on the safer use of anticoagulants.

We acknowledge the Anticoagulation Forum from the USA in the development of this guidance.¹

This document was developed through a collaborative with Te Tāhū Hauora and the following hospitals:

- Te Whatu Ora – Health New Zealand Counties Manukau
- Te Whatu Ora – Health New Zealand Waikato
- Te Whatu Ora – Health New Zealand Lakes
- Te Whatu Ora – Health New Zealand Taranaki
- Te Whatu Ora – Health New Zealand Te Pae Hauora o Ruahine o Tararua MidCentral
- Te Whatu Ora – Health New Zealand Whanganui
- Te Whatu Ora – Health New Zealand Waitaha Canterbury
- Te Whatu Ora – Health New Zealand Nelson Marlborough

We thank the hospital project teams and sponsors who contributed to localising systems and practice improvements for the safer use of anticoagulants within geographically diverse settings. Their support and feedback before and during the first stage of this project was invaluable.

Te Tāhū Hauora also thanks the project leadership and expert advisory group, who provided clinical oversight, guidance and feedback from the planning and implementation to the development of the project work.

¹ National Quality Forum. 2022. *Advancing Anticoagulation Stewardship: A Playbook*. Washington, DC: National Quality Forum. URL: [acforum-excellence.org/Resource-Center/resource_files/1977-2022-08-24-063128.pdf](https://www.aforum-excellence.org/Resource-Center/resource_files/1977-2022-08-24-063128.pdf)

Purpose

The purpose of this document is to provide information on current issues with the use of anticoagulants in hospital care and a proposed intervention to address them. It provides background information on the problems identified within the sector, the complexities of taking these medications and a proposed solution to reduce the occurrence of adverse events and promote the safer use of anticoagulants.

Background

Te Tāhū Hauora Health Quality & Safety Commission (Te Tāhū Hauora) works with others within strong partnerships and relationships (involving) to gather and share intelligence (informing), to raise awareness and encourage thought and knowledge sharing (influencing) and to support change to improve the health and disability system (improving).

Te Tāhū Hauora partners with the sector to develop and implement quality improvement initiatives. Strategic priorities include improving consumer² and whānau experiences of care, enabling the workforce as improvers, strengthening systems for quality services, leading health quality intelligence and guiding improvement to prevent early mortality.

Optimising the use of medicines in the sector has been one area of focus for Te Tāhū Hauora. Medicine optimisation is a person-centred approach to improving the safe and appropriate use of medicines, including minimising the risks associated with anticoagulants.

Problem analysis

An anticoagulant is a medication that is used to prevent blood clots from forming or getting larger. They are given to people at a high risk of getting clots to reduce their chances of developing serious conditions such as strokes and heart attacks. Several anticoagulants are used in Aotearoa New Zealand; some are administered orally, and others are provided subcutaneously and intravenously. The total number of people on oral anticoagulants in Aotearoa New Zealand has more than doubled over 10 years (Harper et al 2022).

Anticoagulants carry a risk of potential side effects and complications. All anticoagulants are associated with bleeding, and a proportion of events are unavoidable. They are associated with significant preventable patient harm, and 10 percent of reported adverse medication events involve anticoagulants (Burnett and Barnes 2022).

The Institute for Healthcare Improvement classes anticoagulants as one of four groups of medicines (along with opioids, insulins and sedatives) that can cause harm to patients, even when used as intended. Using a global trigger tool methodology, a New Zealand study in

² A *consumer* is a person who has accessed or is currently using a health or disability service or is likely to do so in the future. For the purposes of this document, a consumer can also be a client, patient or resident. It is the person who uses/receives health and disability services, or their representative. *Consumer engagement* is when consumers/patients, families/whānau, their representatives and health professionals work in active partnership at various levels across the health care system – direct care, organisational design and governance and policy-making – to improve health and health care. It is a process whereby consumers of health and disability services are encouraged and empowered to actively participate in decisions about the treatment, services and care they need and receive. It is most successful when consumers and clinicians demonstrate mutual respect and active listening and have confidence to participate in full and frank conversation. Systems that support consumer engagement actively seek input from consumers and staff at all levels of an organisation.

2017 identified that anticoagulants/antiplatelet agents accounted for 7.1 percent of medication-related harm in an Aotearoa New Zealand hospital inpatient cohort (warfarin 1.8 percent, enoxaparin 1.6 percent, aspirin 3.7 percent) and were associated with the most common cause of serious harm (Robb et al 2017).

Two specific studies have captured some of the potential causes of harm. A US study in 2011 reported that 48 percent of adverse events were due to prescription errors and 70 percent of all events were preventable (Piazza et al 2011), and a Canadian study highlighted poor transitions of care as a contributing factor (Holbrook et al 2021).

Other factors identified include poor management of high-risk periods and failing to assess risk.

Project start up

The issue of harm from anticoagulants was raised at the National Medication Safety Advisory Group coordinated by Te Tāhū Hauora. The Health and Disability Commissioner also raised concerns relating to the frequency of complaints regarding suboptimal management of anticoagulants.

A comprehensive literature review identified systems, processes or practices relevant to the safe use of anticoagulants, focusing on evidence since 2015 in a public hospital setting where there had been a change in or adjustment of anticoagulant. This included reversal of anticoagulation, treatment planning, procedure or surgery postponement and discharge.

Evidence included surprisingly few high-quality studies given the long history of anticoagulation-related harm.

The following three areas were supported by evidence.

Expanding the role of pharmacists: Of the 11 studies retrieved that described pharmacist interventions to reduce anticoagulant harm, four described patient education or counselling, four evaluated pharmacist prescribing or oversight of anticoagulation use, two assessed routine pharmacist review of direct-acting oral anticoagulant prescriptions and one described routinely including pharmacists on ward rounds.

Anticoagulation stewardship programmes (ACSPs): ACSPs have been evaluated in several locations. They usually consist of a multicomponent approach involving leadership, guidelines, protocols, anticoagulation services such as pharmacist screening or expert consultation, medication review/reconciliation, education, patient counselling, data collection and analysis and are based on principles imported from antimicrobial stewardship programmes.³

Improved use of electronic health records and clinical decision support systems: The impact of pharmacists and multidisciplinary stewardship teams would likely be enhanced by systematic implementation of electronic systems that allow daily reports, clinical-rule-based

³ An *antimicrobial* is an agent that destroys or slows the growth of microorganisms, including parasites, fungi, viruses and bacteria. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics. *Antimicrobial stewardship* involves actions that promote the responsible use of antimicrobials (including antibiotics) to improve patient/resident outcomes, which in turn reduce antimicrobial resistance and the spread of infections caused by multidrug-resistant organisms.

alerts to pharmacists and other health care team members and automated audit and evaluation of progress to facilitate ongoing quality improvement.

Te Tāhū Hauora facilitated workshops with relevant stakeholders to explore and understand the issue of harm from anticoagulants. When we combined the feedback and the data exploration, we concurred that there was evidence to support quality improvement work in the hospital setting, provided it included discharge. The proposed area of focus was when there is a change or adjustment to anticoagulants in a hospital setting.

While investigating various data sets, it was clear that there is no national measure or indicator to measure the harm related to anticoagulants. So, to support the identified issues, we explored various data sources. This included qualitative and quantitative analysis of the information available. Findings from various data sources were as follows.

Adverse events: In a 6-year period (2016–2021), 26 adverse events with a severity assessment code of one or two were reported from hospitals. Severity includes death or permanent major or temporary severe loss of function, eg, medication or treatment plan error resulting in major harm.

Health and Disability Commissioner: From 2014 to 2022, the commissioner investigated 12 complaints related to anticoagulants; reports, including findings and recommendations are available from the Health and Disability Commissioner website: www.hdc.org.nz.

The National Minimum Dataset (hospital events) data dictionary⁴ is a national collection of discharge information, including clinical information, for inpatients and day patients from public and private hospitals. Unit record data is collected and stored. All records must have a valid national health index number. Public hospitals have submitted data electronically in an agreed format since 1993. It is used for policy formation, performance monitoring, research, review and funding. It provides statistical information, reports and analyses about trends in the delivery of hospital inpatient and day patient health services, both nationally and by provider.

Adverse effects related to anticoagulants are captured in hospital using *International Classification of Diseases and Related Health Problems 10th Revision* codes Y44.2 and Y44.3. Exploring these codes in conjunction with specific bleeding and clotting codes gives a clear picture of true adverse events.

Anticoagulation quality improvement project

Te Tāhū Hauora initiated a collaborative (Institute for Healthcare Improvement 2004) to improve the safer use of anticoagulants in September 2022. The aim of the project was to develop a national package of interventions to implement across Aotearoa New Zealand to encourage the safer use of anticoagulants. Seven district hospital teams participated in the collaborative.

As the project progressed, the project team started to critically review the goal and ask questions to ensure that the planned project was beneficial at a system level. The literature review identified ACSPs as a key intervention that has been shown to make a difference. They have been developed and tested overseas, and results are promising (Burnett and

⁴ Manatū Hauora Ministry of Health. 2021. National Minimum Dataset (Hospital Events) data dictionary. URL: www.health.govt.nz/publication/national-minimum-dataset-hospital-events-data-dictionary.

Barnes 2022). On reviewing the information gathered as part of the collaborative and consulting with stakeholders, Te Tāhū Hauora pivoted from developing a specific intervention package towards a stewardship approach.

Stewardship is an approach centred around continuous improvement and promotes a whole-of-system change. This approach was based on antimicrobial stewardship (Mendelson et al 2020) and aims to promote safe, high-quality patient care by improving the systematic management of anticoagulants within and across health care settings.

Building on the local projects undertaken during the initial collaborative, Te Tāhū Hauora is committed to developing an ACSP for Aotearoa New Zealand based on the model developed in the USA (Burnett and Barnes 2022). The project team identified that all elements of the programme need to be applicable to the Aotearoa New Zealand context and local settings. Ensuring that the ACSP places a strong emphasis on integrating Te Tiriti o Waitangi principles, addressing inequities and incorporating consumer lived-experience perspectives is a priority.

Four core elements are proposed to guide the approach to stewardship.

- **Improve knowledge and skills for consumers, whānau and clinicians:** Implement a person-centred education approach for consumers, whānau and staff.
- **Monitor and report on measures:** Collect, analyse and share data routinely to support continuous quality improvement.
- **Commit to local and national governance and leadership:** Secure leadership commitment and align with existing clinical governance structure.
- **Improve clinical processes and practices:** Use clinical risk assessment and decision-making tools and standardise clinical tools, pathways and practice.

When implemented with all the core elements, ACSPs have the potential to improve the whole system (Koolian et al 2022).

Benefits

Some of the benefits of this approach include:

- reduced occurrence of adverse events
- improved data collection, measurement, analysis and reporting
- an overarching programme for Aotearoa New Zealand
- potential for standardisation of pathways and tools
- clinical and economic benefits
- readily available materials and resources
- effective anticoagulation-related care transitions
- a sustainable approach
- alignment with international best practice
- improved consumer involvement, including decision-making and care interventions
- improved health literacy at all levels
- education for clinical staff.

Given that only limited data is available to support the development of an ACSP, the collaborative agreed to use the National Minimum Dataset to create measures/indicators. As no national indicator exists, significant effort and collaboration was undertaken with clinicians and health quality intelligence to define anticoagulation-related harm and develop an appropriate indicator.

Implementation of this programme will contribute towards achieving the criteria set out in section 3 of the Ngā paerewa Health and disability services standard.⁵ Specifically, the planned how-to guide will help organisations meet the requirements of section 3.4 of the standard.

Next steps

Te Tāhū Hauora will continue to provide the leadership in terms of project management, quality improvement and stakeholder engagement. Two interim groups have been set up to support the development of and provide direction on the ACSP.

- A special interest group that includes haematologists and a consumer.
- An anticoagulation advisory group that includes different clinical professions and a consumer.

The ACSP will be implemented in two phases. In phase one, the draft ACSP package will be tested with a few hospitals to ensure it meets the needs of local hospitals. Lessons learned from phase one will be used to refine the final package. In phase two, the final ACSP will be developed and made available to the sector to implement.

Project timeline

Phase 1, July–September 2023 (complete)

- Transition to stewardship approach for the programme
- Consider testing approach
- Confirm clinical leadership

Phase 2, October–December 2023 (nearly complete)

- Continue to develop ACPS package
- Develop testing approach
- Establish groups (special interest group, anticoagulation advisory group)

Phase 3, January–April 2024

- Finalise ACPS package
- Establish test sites
- Begin testing phase February

⁵ Standards New Zealand Te Mana Tautikanga o Aotearoa. 2021. NZS 8134:2021: Ngā paerewa Health and disability services standard. URL: www.standards.govt.nz/shop/nzs-81342021.

- Launch website content with consumer videos

Phase 4, May–June 2024

- Complete testing phase
- Receive and review documents and feedback from test sites
- Revise ACPS package

Phase 5, July–December 2024

- Publish and launch ACPS package

Local and national governance and leadership will be essential for the success and sustainability of the programme. Once the programme is developed and ready for implementation, the ACSP will require a framework to support the sustainability. We will be seeking collaboration with other agencies on how this will look in the future.

For further information and details related to this programme, please email us on:

anticoagproject@hqsc.govt.nz

References

Burnett AE, Barnes GD. 2022. A call to action for anticoagulation stewardship. *Research and Practice in Thrombosis and Haemostasis* 6(5): e12757.

Harper PA, Chang A, Stephens M. 2022. The changing use of anticoagulants in New Zealand. *The New Zealand Medical Journal* 135(1554): 35–5.

Holbrook A, Benipal H, Paterson JM, et al. 2021. Adverse event rates associated with oral anticoagulant treatment early versus later after hospital discharge in older adults: a retrospective population-based cohort study. *Canadian Medical Association Open Access Journal* 9(2): E364–75.

Institute for Healthcare Improvement. 2004. The breakthrough series: IHI's collaborative model for achieving breakthrough improvement. *Diabetes Spectrum* 17(2): 97–101.

Koolian M, Wiseman D, Mantzani H, et al. 2022. Anticoagulation stewardship: Descriptive analysis of a novel approach to appropriate anticoagulant prescription. *Research and Practice in Thrombosis and Haemostasis* 6(6): e12758.

Mendelson M, Morris AM, Thursky K, et al. 2020. How to start an antimicrobial stewardship programme in a hospital. *Clinical Microbiology and Infection* 26(4): 447–53.

Piazza G, Nguyen TN, Cios D, et al. 2011. Anticoagulation-associated adverse drug events. *The American Journal of Medicine* 124(12): 1136–42.

Robb G, Loe E, Maharaj A, et al. 2017. Medication-related patient harm in New Zealand hospitals. *The New Zealand Medical Journal* 130(1460): 21–32.