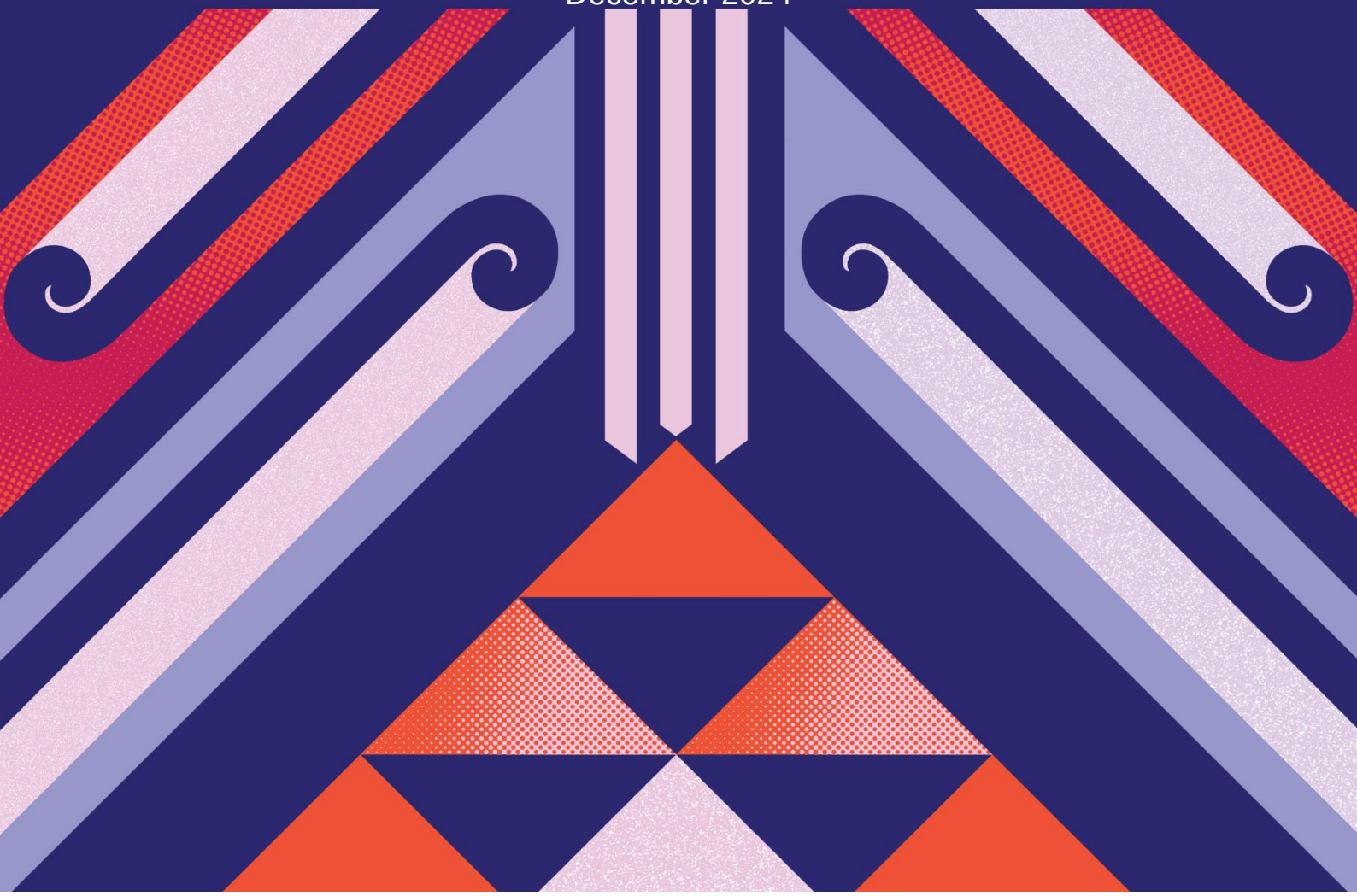
Te Tāhū Hauora
Health Quality & Safety Commission

He pūrongo whakarāpopoto
Te hōtaka whakahaere rongoā ārai poketoto Wāhanga whakamātautau

Summary report
Anticoagulation stewardship programme
Testing phase

December 2024



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Executive summary

The Anticoagulation Stewardship Programme (ACSP) was initiated by Te Tāhū Hauora Health Quality & Safety Commission (Te Tāhū Hauora) to improve the safety and effectiveness of anticoagulant use in Aotearoa New Zealand's healthcare system. This report presents the main findings from testing the ACSP in four hospitals across the country and outlines recommendations for future implementation and sustainability.

Anticoagulants, used to treat conditions such as venous thrombosis and atrial fibrillation, carry significant risks, particularly the risk of bleeding. This programme was developed in response to concerns raised by the National Medication Safety Advisory Group and the Health and Disability Commissioner regarding the management of these medications. The literature review and feedback from healthcare professionals highlighted that a stewardship approach would allow for greater flexibility and applicability within local contexts. Consequently, the ACSP was established, with four hospitals participating in the 6-month project.

Valuable lessons were learned during the testing phase, which provided insights into improving clinical practices, patient education and data monitoring, particularly considering the small number of patients involved and the limited timeframe. Moreover, collaboration with international experts, and the adaptation of global best practices to local contexts, including the incorporation of Te Tiriti o Waitangi principles and consumer perspectives, has been crucial in establishing a holistic and culturally responsive programme. The findings highlight the advantages of further developing the ACSP in Aotearoa to promote safer use of anticoagulants.

The overarching recommendation is to establish a nationwide anticoagulation stewardship programme that supports safer and more effective use of anticoagulants. This report recommends further development and standardisation of clinical tools, educational materials and a national indicator for anticoagulant-related adverse events. It also emphasises the importance of strong governance, leadership, and a unified approach to data collection and reporting, to ensure the programme's success and sustainability.

He whakamihi

Acknowledgements

Ehara taku toa i te toa takitahi, engari he toa takitini

Success is not the work of an individual, but the work of many.

Te Tāhū Hauora acknowledges the significant work and feedback from everyone who has been involved in the development and testing of the Anticoagulation Stewardship Programme | Te hōtaka whakahaere rongoā ārai poketoto, along with those involved in the programme's first phase, the 'Safer use of anticoagulants' project.

In particular, the national team at Te Tāhū Hauora would like to thank:

- the four hospital teams from the Health New Zealand – Te Whatu Ora sites at Taranaki, Hauora a Toi Bay of Plenty, Whanganui and Lakes
- programme clinical lead Dr Paul Harper
- members of the established special interest group and anticoagulation advisory group
- Marion Lake and Russ Aiton, our lived-experience consumers
- the whānau of the late Carla Brosnan, who served as a consumer in the first phase of the project.

He kupu whakataki

Introduction

Purpose

This summary report presents the main findings from testing of the Anticoagulation Stewardship Programme |Te hōtaka whakahaere rongoā ārai poketoto (ACSP) within four hospitals located across Aotearoa New Zealand. It includes recommendations for the implementation and sustainability of the programme nationwide.

Background

Optimising the use of medicines in the health sector has been an important focus for Te Tāhū Hauora | Health Quality & Safety Commission (Te Tāhū Hauora). Anticoagulants are a class of medications that can pose risks to patients, highlighting opportunities to support their safer use.

Anticoagulants are commonly prescribed to treat venous thrombosis, including deep vein thrombosis and pulmonary embolism, and to prevent blood clots in individuals with atrial fibrillation or mechanical heart valves. In Aotearoa New Zealand, several anticoagulant options are available, which can be taken orally or administered subcutaneously. While anticoagulants, like other medications, have known side effects, most notably bleeding, many of these incidents are potentially preventable.

Globally, millions of people rely on anticoagulant therapies for the prevention and treatment of thromboembolic disease, a need expected to double in the next two to three decades due to an ageing population, rising obesity rates and increasing hospitalisations. However, despite their critical role, anticoagulants are a leading cause of medication-related adverse events, often resulting from inappropriate prescribing and management. As noted by Burnett et al (2022), effective anticoagulation stewardship is essential to address these challenges and improve patient safety.

The issue of harm from anticoagulants was initially raised at the National Medication Safety Advisory Group coordinated by Te Tāhū Hauora in mid-2018. In late 2018, the Health and Disability Commission raised concerns about the frequency of complaints regarding suboptimal management of anticoagulants. In response to these concerns, a literature review was conducted to assess the latest evidence and identify best practice interventions aimed at improving safety in anticoagulant use. A case for change highlighting the opportunity for improving the safer use of anticoagulants in Aotearoa was also developed.

Case for change

The US Institute for Healthcare Improvement classifies 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, an Aotearoa New Zealand study in 2017 identified that anticoagulants and antiplatelet agents accounted for 7.1 percent of medication-related harm in an Aotearoa 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).

International data shows similar rates of adverse events. Studies from the United States of America reported that anticoagulants caused an estimated 10 percent of drug-related adverse outcomes (Burnett and Barnes 2022; Lucado et al 2011) and, in a nationally representative sample of hospitalised Medicare patients, anticoagulants accounted for one-third of identified adverse events (12 of 40 events) (Levinson 2010). The level of concern is so high that the US National Action Plan for Adverse Drug Event Prevention dedicated a whole chapter to anticoagulants (US Department of Health and Human Services 2014).

Data from inpatient settings suggests that anticoagulant-related adverse events most commonly result from medication errors. Two specific international 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). A Canadian study highlighted poor transitions of care as a contributing factor (Holbrook et al 2021).

Warfarin is the drug most associated with errors. However, more recent pharmacovigilance studies from Saudi Arabia and Israel have shown that prescribing errors are a concern with the newer direct-acting oral anticoagulants (Alrowily et al 2021), for which the prevalence of prescribing errors can be as high as 33 percent (Raccah et al 2021).

Other factors that contribute to the errors include challenges that may result from clinicians having to rely on a wide range of anticoagulants with differing pharmacodynamic and pharmacokinetic profiles. These are affected by the acuity and complexity of hospitalised patient populations, unique inpatient dosing, dietary inconsistency, the need to interrupt anticoagulation in preparation for invasive procedures, transitions of care settings and transitions between different anticoagulants. Transitions between wards and hospital discharge pose significant challenges to optimal anticoagulant management due to factors such as changes in care teams, inadequate medication reconciliation, variability in protocols, insufficient patient education, heightened risk of adverse events, and difficulties in coordinating follow-up care.

In Aotearoa, the total number of people on oral anticoagulants has more than doubled over 10 years (Harper et al 2022). Data from various sources was analysed to understand types of adverse events related to anticoagulants (outcome measure) in Aotearoa and to gain a deeper understanding of the extent of the problem. This analysis includes reports from the Health and Disability Commissioner, adverse events reports, data from the Accident Compensation Corporation, and hospital collections data from the National Minimum Dataset (NMDS).

Table 1 provides a summary of the number of events recorded over six years from each of these data sources, highlighting trends and patterns that underscore the significance of the issue at hand.

Table 1: Number of events from four data sources

Data source	Number of events	What they are	Period
Adverse events	28	Severity assessment code 1 and 2 events	Approximately 6 years
Health and Disability Commissioner	12	Health and Disability Commissioner complaints	Approximately 6 years
Accident Compensation Corporation	219	Accepted claims	5 years
National Minimum Dataset	24,000	Admissions with code 'anticoagulants causing adverse effect in therapeutic use' (Y44.2 code)	5 years

Data from the NMDS was analysed to understand anticoagulant-related adverse events. Findings are provided in the 'NMDS data analysis' section.

More information on the Case for Change can be found on the Te Tāhū Hauora website (www.hqsc.govt.nz/resources/resource-library/the-safer-use-of-anticoagulants-case-for-change).

Quality improvement programme

In September 2022, Te Tāhū Hauora initiated a quality improvement programme with several hospitals to enhance the use of anticoagulants, aiming to develop a national package of interventions. The testing teams focused on implementing specific local interventions in various clinical areas. Although these interventions enhanced certain aspects of the process, the need for a whole-of-system focus was acknowledged. This was supported by the literature review, which indicated that a stewardship programme not only provides a holistic approach but also encourages collaboration among various stakeholders, including healthcare providers, pharmacists and patients, to ensure consistent application of best practices.

This approach considered all aspects of anticoagulant management, including prescribing, monitoring, patient education and addressing potential risks, leading to improved safety and outcomes. Considering these early results, and in consultation with stakeholders, Te Tāhū Hauora changed from developing a package of specific interventions to adopting a stewardship approach.

Anticoagulation stewardship programmes

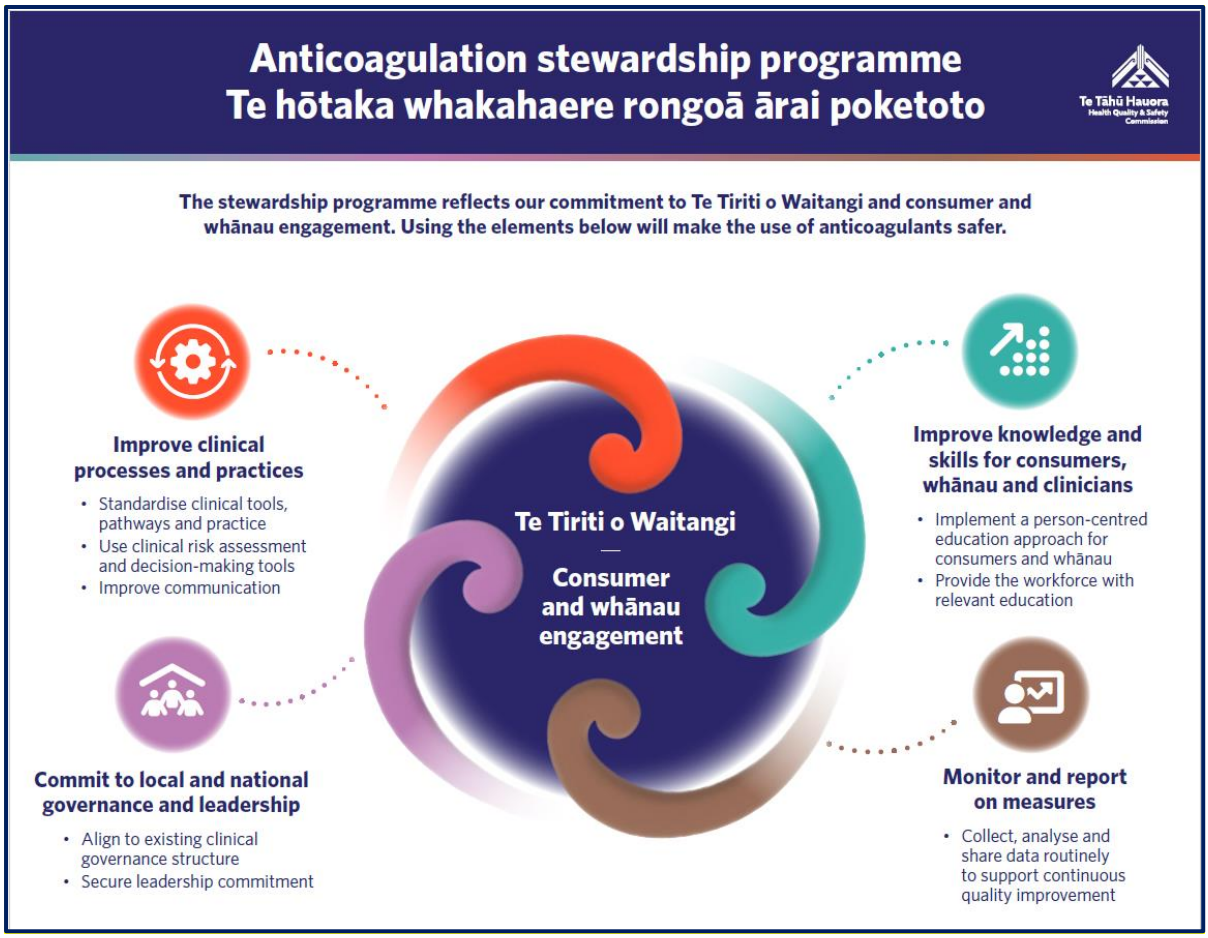
Promising results have been reported by overseas anticoagulation stewardship programmes (Koolian et al 2022; Silvari et al 2024). In 2019, the US Anticoagulation Forum, in partnership with the US Food and Drug Administration, identified and developed seven core elements (intervention areas) of these programmes.

This supported the effective implementation of anticoagulation stewardship practices across healthcare entities. These core elements have been published in *Advancing Anticoagulation Stewardship: A playbook* (National Quality Forum 2022). Evidence relating to the effect of these programmes has been documented on the Anticoagulation Forum website (acforum.org/web/downloads/ACF_Evidence.pdf).

Te Tāhū Hauora collaborated with the Anticoagulation Forum to adapt the core elements to fit the context of Aotearoa and its local settings. This adaptation emphasised integrating Te Tiriti o Waitangi principles and incorporating consumer lived-experience perspectives (see figure 1). The Aotearoa ACSP includes the following elements:

1. improve clinical processes and practices
2. commit to local and national governance and leadership
3. improve knowledge and skills for consumers, whānau and clinicians
4. monitor and report on measures.

Figure 1: Adapted core elements of anticoagulation stewardship in Aotearoa New Zealand



Ū ki Te Tiriti me te hauora tautika

Commitment to Te Tiriti and health equity

The Te Tāhū Hauora team incorporated Te Tiriti principles and applied an equity lens to various areas of the project by:

- having a Māori co-chair for the anticoagulation advisory group
- using an ethnicity or demographic lens for data collected
- requesting that hospital project teams include Māori representation and consider other demographic representation to reflect their testing populations.

The hospital project teams took part in an in-person workshop around embedding and enacting Te Tiriti. The teams considered how their projects aligned to the five principles endorsed by the 2023 Wai 2575 Hauora report and what actions they could take to improve in each of these areas (Waitangi Tribunal 2023).

Teams integrated these principles into their projects by:

- incorporating te reo Māori and Samoan translations into their project resources
- encouraging whānau to be involved in consultations
- knowing demographics and acknowledging areas of inequity, to provide better services around health literacy, rural communities and socioeconomic deprivation
- starting discussions with patients and whānau with mihi and whakawhanaungatanga, to form connections and build relationships.

Consumer and whānau engagement

Throughout the project, participants referred to and applied the *Code of Expectations for Health Entities' Engagement with Consumers and Whānau* and its principles (Te Tāhū Hauora, 2022). The consumer members were from varied backgrounds and brought their different lived experiences to the project. Feedback from the consumers confirmed the following.

- The project was co-designed with input at all stages.
- The lived experience of consumers and their whānau informed the project, resulting in improvements for all.
- Te Tāhū Hauora and Te Whatu Ora worked in partnership with consumers, whānau and the community.
- The project provided accessible resources and engaged consumers, while it also had areas for improvement.
- The project recognised the need to resource consumer engagement. Planning considered the consumers and their wellbeing as part of their travel to in-person hui. Transparency about lack of resources for consumers was important. An opportunity for better policy for consumer engagement was recognised.

Overall, the Code of Expectations was embedded into the project, the consumer engagement was successful, the consumers felt included and that their contributions were valued.

He whanake rauemi, he wawao mō te ACSP

Development of resources and interventions for the ACSP

Stakeholder groups

Two specific stakeholder groups were established to support the review process, along with the programme working group, including the following.

- A special interest group consisted of haematologists and consumer representatives. Its role was to develop new or review existing clinical tools for testing.
- A multidisciplinary anticoagulation advisory group included consumer and Māori representation. Its role was to review the tools and resources developed and recommended by the special interest group and provide feedback on its appropriate use for testing.

Clinical resources

Several clinical resources were developed following the literature review and collaboration with peers. International guidelines from various societies, colleges and associations were used as source material. Literature relating to specific aspects of anticoagulant management was also reviewed. Established guidelines and protocols used in hospitals around Aotearoa New Zealand were collected to review current practices and establish whether they were aligned with international standards.

The aim was to empower clinicians with the necessary tools to manage anticoagulants effectively and in line with published guidelines and international standards of care.

The two stakeholder groups provided guidance and expertise in developing specific resources (appendix 1) for the following clinical areas:

- assessing the risk of thrombosis
- managing acute bleeding
- safer prescribing
- transition of care between secondary and primary services
- protocols for perioperative management.

The resources and templates included:

- online interactive tools
- checklists for clinicians and patients
- patient information
- training material for clinicians.

Consumer resources

Existing and new resources for patients and their whānau were reviewed by the consumer representatives at a national and hospital level. They were also tested for usefulness as patients were treated with anticoagulants during the testing phase, with the aim of improving the knowledge and awareness of anticoagulants for the patients discharged from hospitals.

Accessibility of resources

A website was developed to create a central repository for all the resources, which is to provide easy access for both clinicians and patients. This website was also part of the testing process.

Data and measurement

During the initial phase of the project, Te Tāhū Hauora engaged with the stakeholders to identify existing national or local anticoagulant-related harm, adverse events measures and indicators, to support the national programme. No specific national measures or indicators were identified. As a result, the team agreed to develop a national measure or indicator. Data from various sources was examined to support the measure and to understand the extent of the problem. Due to the small number of events captured through various sources (as table 1 outlines), data from NMDS was used to develop the measure.

Due to multiple challenges in the way information was captured in clinical notes and in the way it was then coded, it became apparent that it may not be possible to identify the true prevalence of anticoagulant-related adverse events. This has led to the development of an indicator. See appendix 2 and appendix 3 for details of the indicator and its limitations.

He whakamātautau mō te ACSP

Testing of the ACSP

Testing of resources and the process for using them is a critical part of the quality improvement methodology. The purpose of this testing was to develop resources that are useable and fit for purpose in a hospital setting, and that meet the needs of consumers, patients and whānau.

In January 2024, an expression of interest letter was distributed to the interim District Directors of Health New Zealand Te Whatu Ora hospitals seeking their participation in the ACSP testing.

Sites were selected to get a range of settings based on their rurality, type of medication system, geographic location, population and the availability of a haematology service within the hospital. For details of these hospitals, see appendix 4.

Four Te Whatu Ora hospitals located in Taranaki, Hauora a Toi Bay of Plenty, Whanganui and Lakes were selected to participate. Of these, Whanganui, Taranaki and Lakes had been involved in the 2023 ‘safer use of anticoagulants’ collaborative project.

Testing teams were established, and they identified which clinical areas and related resources they would test. Testing was carried out between February and May 2024. A list of resources (see appendix 1) was made available to the teams through the website and Microsoft Teams.

Te Tāhū Hauora supported the four testing teams through regular online meetings and in-person workshops to discuss progress, measurement and testing outcomes.

He kōrero, he kitenge i te whakamātautau

Feedback and findings from testing

Testing limitations

Testing was carried out when the health sector was going through a period of reform. The reforms required the hospitals to focus on the national change, which led to local changes. This was a primary challenge and reduced the availability of clinical staff to fully participate, resulting in a shorter testing duration. Teams were also not able to test interventions related to various clinical topics and ACSP in its entirety.

Core elements of ACSP

1. Commit to local and national governance and leadership

The feedback raised included the following.

- Running quality improvement projects with organisational support is challenging in the current environment with limited resources and conflicting priorities.
- Several hospitals do not have haematology departments. If ACSP is to be implemented nationwide, regional support may need to be considered.

The testing teams benefited from having sponsors in leadership who were able to support their work. General agreement was that:

- oversight, leadership and governance would be essential to successful implementation
- nationwide recognition or mandate for this work would improve governance and create better leadership buy-in
- for sustainability, the ACSP should not sit with individual members of staff, and strengthening the system would lead to better implementation and outcomes.

2. Improve knowledge and skills for consumers, whānau and clinicians

Resources developed to improve consumer understanding of anticoagulants were welcomed and well received. Resources were tested with both consumers and staff, and their feedback included the following.

- Resources could be made available on how life changes or resumes once a person is on anticoagulants. For instance, how it might affect sports and hobbies, how a patient can manage their own risk levels, and an explanation given on why.
- Teams also found that a range of communication methods may need to be considered. Some patients still preferred printed resources while others preferred theirs digitally.
- It was identified that education or counselling provided to patients during their stay in hospital may not be retained for very long. Patients requested post-discharge follow up.

- It could be helpful to make the resources more visual and use graphics that reflect local communities.
- Availability of education resources for clinicians varied across hospitals, with some having access to online training modules and others not having consistent training programmes. Often, these resources were not kept up to date and required project leads to review them regularly.
- Staff orientation was not available consistently across the testing teams. Often, the pharmacists in the project team led education on the wards. Several participants appreciated the educational resources on the testing website.
- Have consistent resources nationwide and more education on anticoagulants at a tertiary level.
- Medical staff, particularly doctors in hospitals and general practitioners, had gaps in clinical knowledge around warfarin because its use has decreased.

3. Clinical processes and practices

The short duration of testing, along with resource constraints within each hospital, prevented the teams from testing interventions for all clinical topics and areas of the ACSP.

- Teams started testing one clinical topic and then moved on to others. Most of the teams tested transition of care interventions and some tested interventions related to safer prescribing and venous thromboembolism (VTE) risk assessment.
- Hospitals vary in which tool they use to assess a patient's risk of VTE. Few hospitals have their own tool. However, teams compared their assessment tool with the one provided through the ACSP. Feedback from a few of the teams indicated that risk assessments are not done consistently across the country. They also identified that different specialties may use different processes for the same type of assessment.
- The discharge checklist was tested in multiple hospitals. House officers found this a helpful resource. One suggestion was to combine the multiple checklists into one that can be used from admission to discharge.

4. Monitor and report on measures

Data and reporting were explored by the teams using:

- a local adverse event (reportable events) reporting system, such as Datix, to learn about and measure anticoagulant-related adverse events. They recognised that:
  - these events are potentially under-reported, and the way of capturing event information is inconsistent
  - data extraction and analysis were other important challenges, with some teams using their own Excel spreadsheets to capture data manually
- qualitative methods, such as surveys or questionnaires, to understand and capture the process-related measures, such as patient feedback on education of anticoagulants at discharge.

Findings from testing a national indicator point to the following challenges.

- **Reproducibility:** While the indicator provided a good indication of the prevalence of adverse events at a national level, the methodology could not be replicated at the hospital level due to lack of access to community dispensing data. The teams

identified that the NZ ePrescription Service system may be used to access the dispensing data, however, the feasibility of this needs to be explored further.

- **Preventable and non-preventable adverse events:** Side effects of using anticoagulants are well known. However, it was not possible to differentiate between an event that was a side effect, and an event caused by error. A chart review may be the only method available to identify the true cause of the event.
- **Multiple data sources**: Many teams used Datix as an easier data source to gather information related to anticoagulant-related issues in supporting their improvement work. Multiple data sources led to a non-standardised approach to measuring adverse events.

The ability of a hospital to extract, analyse and report the data depends on the capacity and capability of the local data team. The testing phase highlighted significant variation in this activity across the country.

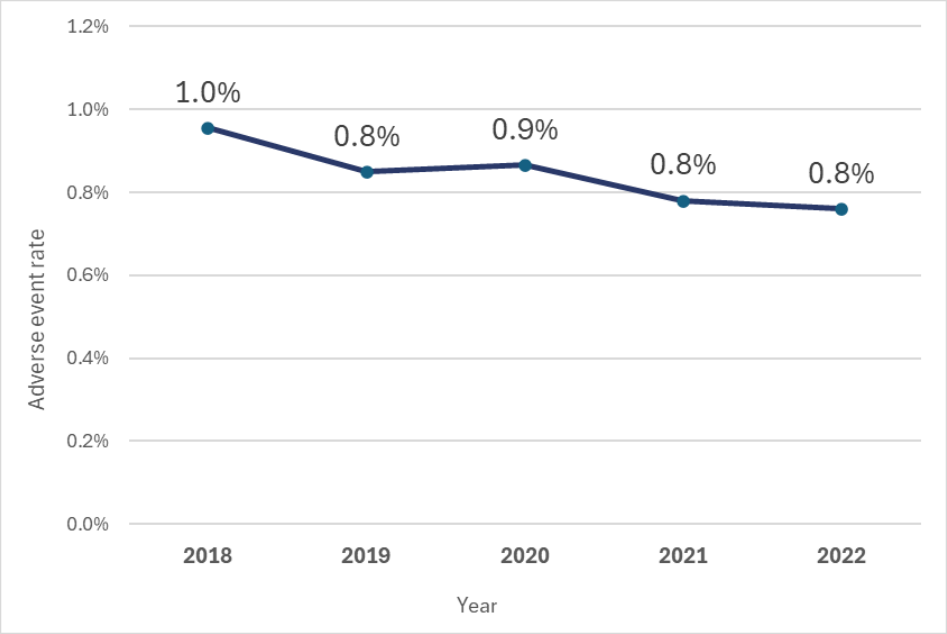
While reproducibility of the indicator was challenging, feedback highlighted opportunities for teams to use systems like Pyxis to identify patients on anticoagulants during their hospital stay. This approach would allow teams to use this data as the denominator for the indicator rather than relying on the proposed denominator.

NMDS data analysis

Using the methodology developed for the indicator (appendix 2), data was analysed to learn more about anticoagulant-related adverse events in the participating hospitals.

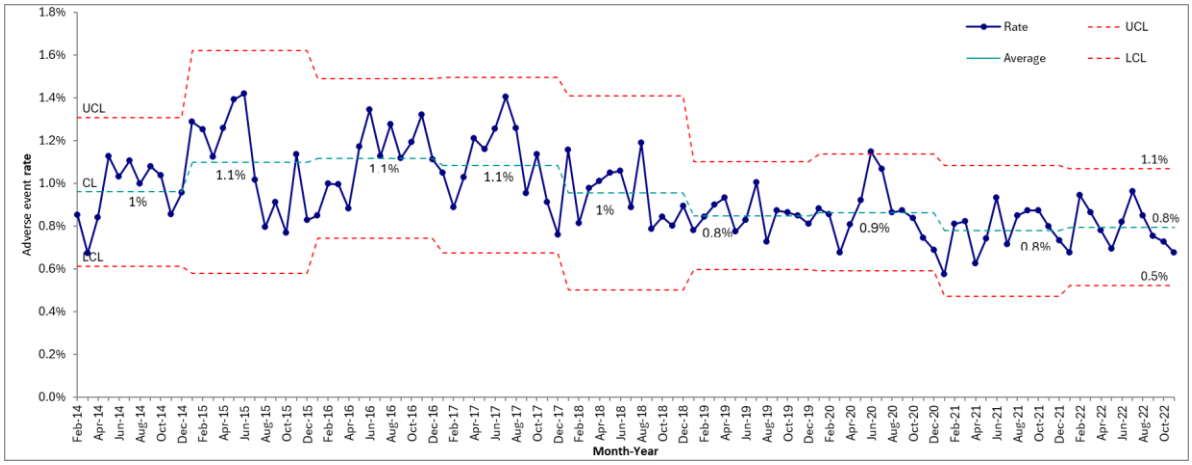
Figure 2 shows that, overall, the rate of anticoagulant-related adverse events per 100 discharges across Aotearoa New Zealand has reduced from 2018 to 2022. Figure 3 provides further support for this trend, with a statistical process control chart that breaks down events by month. Potential factors that may be causing this change are explained below.

Figure 2: Rate of anticoagulant-related adverse events per 100 discharges, 2018–22



Source: NMDS

Figure 3: Statistical process control chart of anticoagulant-related adverse events per 100 discharges, 2014–22



Source: NMDS

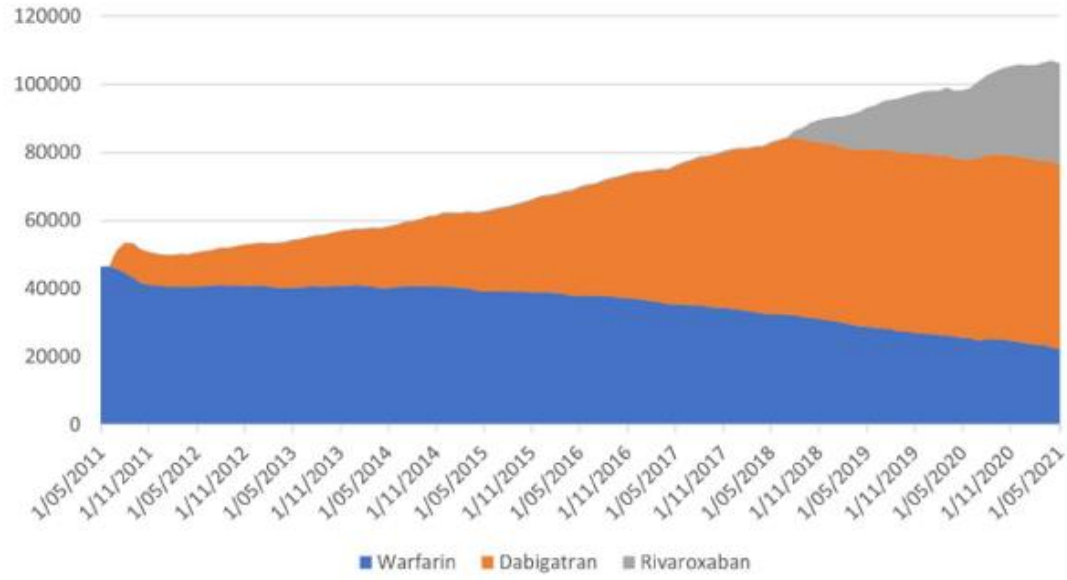
Potential factors contributing to the reduction in anticoagulant-related adverse events

It is challenging to establish the cause of the reduction in anticoagulant-related adverse events observed in the NMDS data without proper statistical testing. However, the following two potential reasons have emerged in the literature and during the discussion with stakeholders. No other nationwide practice change has been identified that may have caused this reduction.

1. Reduction in warfarin use

A recent article (Harper et al 2022) provides one possible explanation for this reduction in adverse events. Warfarin can cause more harm, compared with other anticoagulants. It follows that a reduction in the use of warfarin could, in turn, reduce the adverse event rates. Data shows that the use of warfarin has indeed reduced while the use of other anticoagulants has increased (figure 4). Overall, the use of anticoagulants has increased; however, it is only since 2018 that rivaroxaban has been used more.

Figure 4: Anticoagulant use in Aotearoa New Zealand, 2011–21



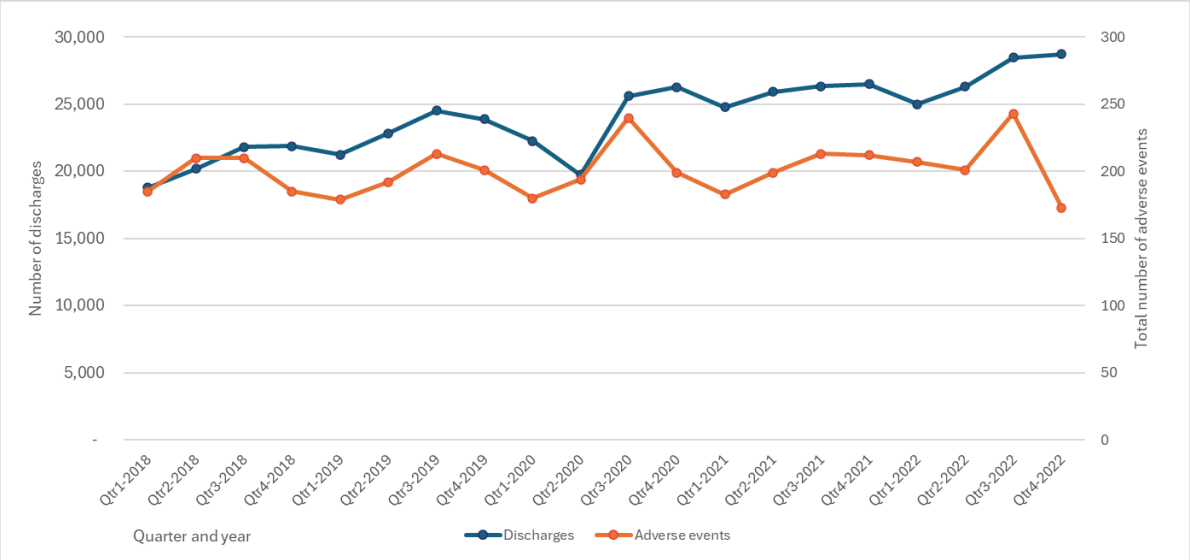
2. More patients on anticoagulants

NMDS data indicates that the denominator used to calculate the rate of adverse events has increased, meaning more patients are being discharged where anticoagulants were dispensed within 90 days of their hospital admission (Figure 5). This rise in the denominator, coupled with a steady number of adverse events (numerator), may have contributed to a lower rate.

Anticoagulant-related adverse events are still a significant problem and need to be a focus

With the arrival of new anticoagulants, such as direct-acting oral anticoagulants, it was assumed the rate of adverse events would fall significantly because these drugs were marketed as being safer than warfarin. While a reduction has occurred, from 1.0 percent to 0.8 percent in the anticoagulant-related adverse event rate, significant opportunities still exist with improving anticoagulant management for both warfarin and other anticoagulants (e.g., direct-acting oral anticoagulants).

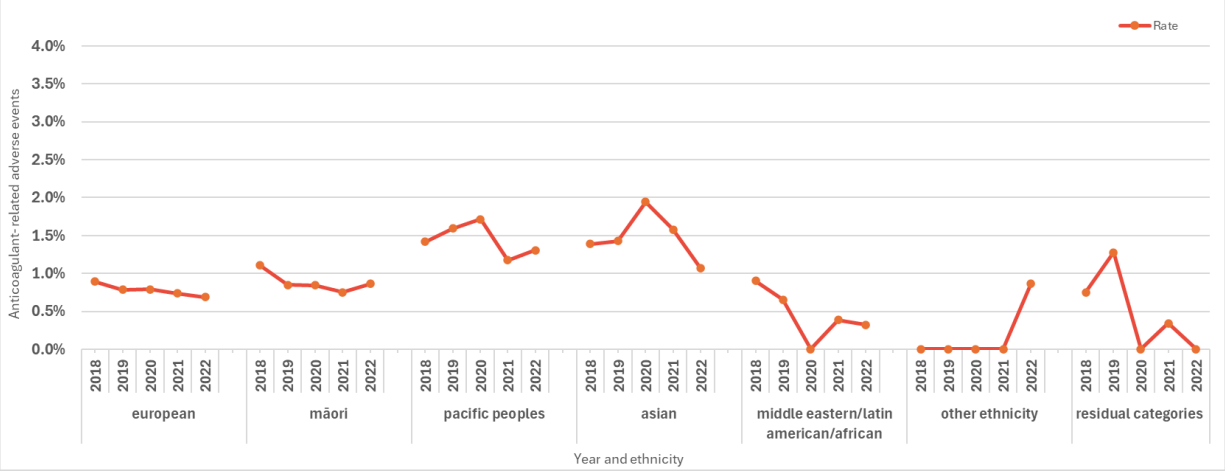
Figure 5: Discharges where anticoagulant was dispensed within 90 days of hospital admission and total anticoagulant-related adverse events, 2018–22



Analysis by ethnicity

Adverse event rates over five years (2018–22) were used to understand the variation related to ethnic groups. Figure 6 shows the changes in adverse event rates for each ethnic group over this time. Prioritised ethnicity (allocation of people to a single ethnic group in an order of priority, even if they identified with more than one ethnicity) was used to complete this analysis. Overall, the Pacific and Asian ethnic groups have a higher rate of adverse events compared with other groups.

Figure 6: Rate of anticoagulant-related adverse events by ethnic group (prioritised ethnicity), 2018–22

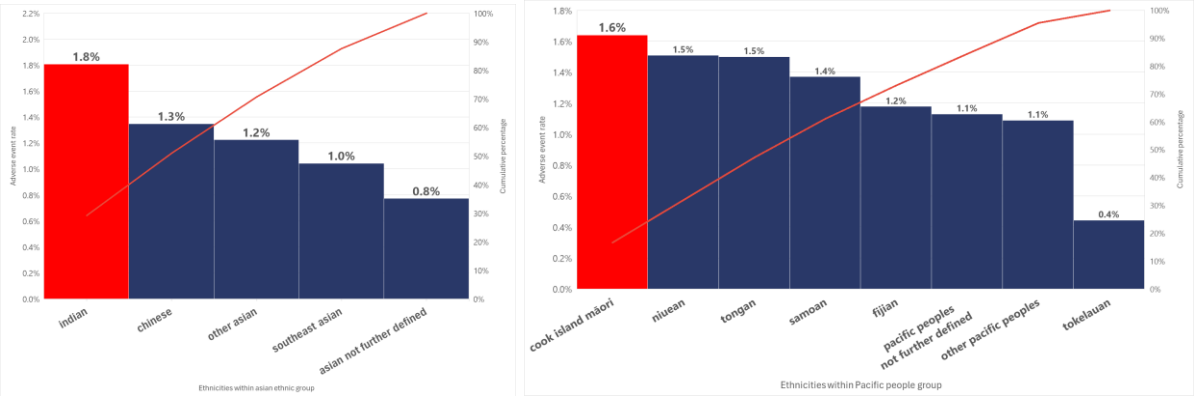


Source: NMDS

Figure 7 presents a Pareto chart, which provides insight into the specific ethnicities influencing the higher rates within the broad Pacific and Asian groups. It shows that Indian and Cook Island Māori populations have the highest rates. Within the Asian population, Indians had a rate of 1.8 percent followed by Chinese at 1.3 percent. Among the Pacific

peoples, Cook Island Māori had a rate of 1.6 percent, followed by Niueans and Tongans, each at 1.5 percent, and Samoans at 1.4 percent.

Figure 7: Rate of anticoagulant-related adverse events by subgroups of prioritised ethnicity, 2018–22

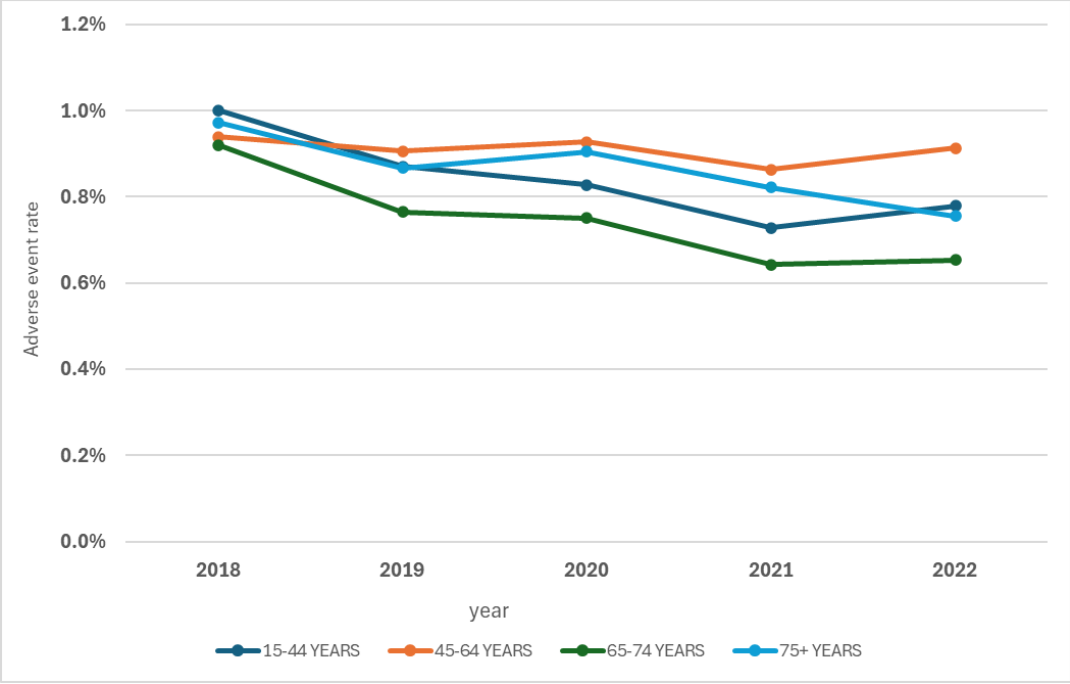


Source: NMDS

Analysis by age

The 2018–22 data was used to examine the rates for different age groups. Figure 8 shows that rates of adverse events have reduced more among those aged 75-plus years, compared with younger age groups.

Figure 8: Rate of anticoagulant-related adverse events by age group, 2018–22



Source: NMDS

Ngā hua o te whakamātautau

Outcomes of testing

Four project teams completed testing of various clinical components of the ACSP.

The testing phase resulted in the following outcomes.

- Teams undertook a standardised approach to anticoagulation management.
- The number of patients who received counselling related to anticoagulants increased. Most patients tested also retained knowledge of their education 14 days after hospital discharge.
- The discharge process improved through using the discharge checklist and patient education.
- Education sessions increased awareness of anticoagulation management in hospitals.
- A national indicator of the prevalence of adverse events was created.
- Anticoagulation stewardship programme materials were tested and refined.
- Appendix 5 contains eight real-life patient stories from ACSP testing, highlighting significant learnings about the importance of thorough patient education, accurate documentation and consistent follow up to ensure proper anticoagulant use and patient safety.

He kupu whakatepe

Conclusion

Given the small number of patients involved in the project and its limited timeframe, it was unlikely that the testing phase would be able to show improvement in practice. However, it did identify valuable lessons, and its findings point to the benefits of continuing to develop an ACSP in Aotearoa New Zealand to support the safer use of anticoagulants.

The ACSP has demonstrated the potential to enhance anticoagulant safety in hospitals across Aotearoa. The testing phase, despite challenges such as limited resources and a short timeframe, generated valuable insights into improving clinical practices, patient education and data monitoring. The collaboration with international experts and adaptation of global best practices to local contexts, including the integration of Te Tiriti o Waitangi principles and consumer perspectives, have been crucial in shaping a holistic and culturally responsive programme.

Significant outcomes from the testing include increased patient knowledge retention, the standardisation of anticoagulation management practices, and the development of a national indicator for monitoring adverse events. However, testing also highlighted areas for further development, such as the need for consistent VTE risk assessment tools, simplified clinical checklists, and a unified information technology system for comprehensive data tracking.

The findings emphasise the importance of establishing a nationwide anticoagulation stewardship programme to support ongoing safety improvements. The programme should continue to develop and disseminate standardised resources, enhance education for

healthcare professionals and patients, and refine measurement systems to better capture and analyse adverse events. By building on the lessons learned and continuing to engage with stakeholders, Aotearoa can establish a robust framework for the safer use of anticoagulants, ultimately improving patient outcomes and reducing medication-related harm.

Ngā whakatau

Recommendations

The literature review, clinical input, development of resources and testing strongly indicate that an anticoagulation stewardship programme is the most appropriate way to improve safer use of anticoagulants.

The ideal long-term plan would be to implement an ACSP across all hospitals in Aotearoa New Zealand. This would be envisaged as a centralised resource offering access to all the elements required to improve anticoagulant safety. To achieve this, the following ongoing developments would be required.

1. Improve clinical processes and practices

a. Continue to develop a set of national peer-reviewed recommended resources for both public and private hospitals, which can be adapted to suit local communities and populations. Make these materials available through a central platform, such as a website or an app.
b. Conduct further testing with the aim of:
    - developing a standardised VTE risk assessment process
    - developing anticoagulant perioperative management tools
    - developing guidance for safe prescribing.
c. Continue to develop a checklist for the initiating treatment and discharge process.

2. Improve knowledge and skills for consumers, whānau and clinicians

a. Develop standardised anticoagulation education resources for medical, nursing and pharmacy students.
b. Develop and test more consumer resources, including patient videos and written materials.
c. Make consumer resources available in different languages.

3. Measurement system

- Develop the adverse event indicator further, by broadening the criteria to include codes that capture a wider range of issues and errors related to anticoagulants that are not currently included in the methodology.

a. Hospital teams should apply the relevant criteria outlined in the methodology, to analyse data and generate reports and then share them regularly with their

relevant governance group. This process will help sustain the programme and identify additional opportunities for improvement.

- Investigate the availability of dispensing data through systems like the New Zealand ePrescription Service to support the indicator. The proposed indicator (appendix 2) excludes patients who started anticoagulants in hospital because data related to dispensing of anticoagulants during hospital admission is not readily available through the NMDS dataset. If hospital teams have access to data on patients who are administered anticoagulants during their hospital stay, they can use this data as part of the denominator. In cases where the data to support the denominator is not available, the dispensing criteria can be excluded, and hospitals can use the current methodology to determine the total number (numerator) of anticoagulant-related adverse events in their hospital.

b. Provide training for clinicians on best practices for documenting clinical information in the patient notes, to enhance coding quality.
c. Identify and monitor specific process measures, such as risk assessment to ensure each stage of the process meets the desired performance goals.

4. Commit to local and national governance and leadership

a. The ACSP should be incorporated into the existing national governance structure. For example, the National Quality Forum (a multi-agency group), had updates from this project and could continue to be informed on future progress.
b. Maintain a nationwide leadership or advisory group to oversee the ACSP approach. This could involve continuing to support and further develop the current Te Tāhū Hauora anticoagulation special interest group.
c. Identify champions to drive the ACSP in hospitals.

He whakamihi

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Āpitihanga 1: Ngā rauemi mā ngā tīma mō te whakamātautau

Appendix 1: List of resources provided to teams for testing

Type of resources	Tools and resources
General resources	• **Public-facing website** with consumer resources, including two consumer videos • **Case for change** outlining the reasoning behind the project • **Implementation/testing checklist** to help teams to meet project deliverables • **Team make-up guide** to outline the members needed to make up a successful team • **Requirements and expectations of hospital testing teams** to outline what to test, how to carry out testing, how to report back • **One-page diagram** to give a visual overview of the elements of the Anticoagulation Stewardship Programme • **Literature review**
Quality improvement resources	• **Project charter template** • **Sample driver diagram** • **Data collection template** • **Institute for Healthcare Improvement toolkit** to provide quality improvement templates and resources • **UK National Health Service sustainability model** and instructions, to allow teams to review the sustainability of their projects • **Plan-do-study-act (PDSA) templates** for teams to structure their testing
Core elements – Commit to local and national governance and leadership, improve knowledge and skills, and monitor and report on measures	• **Checklists** for teams to review their own hospital for each of these elements • **Explanation and summary guide** for each of the elements
Core element: Improve clinical processes and practices	**Improve clinical process and practices summary guide**

1. Risk assessment	• **National risk assessment tool:** Risk assessment for venous thromboembolism • **Risk assessment patient checklist** • **Risk assessment patient information**
2. Safer prescribing	**Counties Manukau resources** • Checklist for educator • Warfarin pre-education patient assessment tool • Warfarin education programme • Warfarin patient education flipchart • Warfarin patient information • Warfarin post-education evaluation tool **Patient education resource flipcharts** • Starting an anticoagulant • Starting dabigatran • Starting rivaroxaban • Clinician education **Prescriber checklists for starting patients on anticoagulants:** rivaroxaban and dabigatran
3. Transitions of care	**Discharge checklists** for patients and clinicians

Sources of guidelines for clinical resources

- American Society of Haematology
- British Society for Haematology
- American College of Chest Physicians
- American Academy of Orthopaedic Surgeons
- American Society of Regional Anaesthesia and Pain Medicine
- European Society of Regional Anaesthesia and Pain Therapy
- Thrombosis and Haemostasis society of Australia and New Zealand
- Consensus Guidelines for Warfarin Therapy (Australasia)

Āpitihanga 2: Te tukanga rongoā ārai poketoto- ngā tūtohu kōaro

Appendix 2: Methodology of anticoagulant-related adverse event indicators

Indicator 1:	**Percentage of harm related to anticoagulant within patients where anticoagulant was dispensed within 90 days of admission**
Numerator	Total number of discharges where *anticoagulant was dispensed within 90 days before the hospital admission, and an *anticoagulant-related adverse event (ICD code Y442 or Y443 with material bleeding or material clotting codes) was reported and dated during their hospital stay (onset flag 1)
Denominator	Total number of discharges from hospital(s) where anticoagulant was dispensed within 90 days before the hospital admission
Data source	Pharmaceutical Collection, National Minimum Dataset
Exclusions	1. Transfers (admission source = 'AT') 2. Private hospitals 3. Age younger than 15 years 4. Discharges with Y442 or Y443, where date assigned to the adverse event is before the admission start date 5. Where both clotting and bleeding codes are used in the same event, please use the harm type that appears in the sequence/order first. For example, if there is an event under Y442, where codes for both bleeding and clotting are captured, then we will use the adverse-event type codes that appeared first in the sequence/order
Appendix List of *anticoagulants and doses	Type of anticoagulants  Anticoags chemicals updated 1
Appendix List of codes for material bleeding and clotting	Material bleeding diagnosis codes: D500, D62, D683,H356, H431, I601, I607, I608, I609, I610, I611, I613, I614, I615, I616, I618, I619, I620, I621, I629, J942, K250, K254, K260, K264, K270, K274, K286, K290, K2951, K2961, K2971, K2981, K625, K661, K920, K921, K922, M2501, M2503, M2505, M2506, M2507, M2508, N029, N920, N921, N938, N939, N950, O720, O721, O722, O902, O904, R040, R041, R042, RO48, R233, R31, S0633, S064, S065, S066, S271, S2731, S3701, T810, D689, K550, K551, K558, K559 Material clotting diagnosis codes: H342, I210, I211, I212, I213, I214, I219, I221, I229, I260, I269, I630, I632, I633, I634, I635, I636, I638, I639, I740, I741, I742, I743, I745, I748, I800, I801, I802, I803, I808, I809, I81, I822, I828, N280, O882, I64, I671, I676, I678

Reporting	1. Numerator and denominator by year (2014 to 2023) 2. Numerator and denominator by quarter (2014 to 2023) 3. Numerator and denominator by quarter (2014 to 2023) for each district and facility 4. Breakdown by (2014 to 2022) year and age (grouping by 10 years: <10, 10 to 19, 20 to 29 … >100) 5. Breakdown by gender (Male, Female and Unknown) 6. Ethnicity breakdown (European, Māori, Pacific peoples, Asian, Middle Eastern/Latin American/African, Other ethnicity, Not elsewhere included) 7. AC meds used analysis (for both numerator and denominator) General notes: • data over time (quarterly) for all analysis • keep these categories separate while running data to avoid duplication: ○ Y442 ○ Y443 and group where both Y442 and Y443 are assigned.

Āpitihanga 3: Te tūtohu kōaro rongoā ārai poketoto me ōna whāititanga

Appendix 3: Anticoagulant-related adverse event indicator and its limitations

Indicator: Rate of anticoagulant-related adverse events per 100 discharges.

Numerator: Total number of discharges where anticoagulant was dispensed within 90 days before the hospital admission, and an anticoagulant-related adverse event (ICD-10 code Y442 or Y443 with material bleeding or material clotting codes) was reported and dated during their hospital stay (onset flag 1).

Denominator: Total number of discharges from hospital(s) where anticoagulant was dispensed within 90 days before the hospital admission.

Limitations: The indicator is a good reflection of the anticoagulant-related adverse events. The team acknowledges there are limitations and advises the understanding of these limitations. In summary, the limitations that could result in the under-reporting of anticoagulant-related adverse events include the following.

1. The indicator does not capture all anticoagulant-related adverse events. It does not include medication-related issues, such as overdosing, due to inconsistent approaches to capturing and coding data.
2. Patients who started anticoagulants in hospital are excluded because data related to dispensing of anticoagulants in hospital is not readily available.
3. If anticoagulants are not dispensed within 90 days of a patient's admission, then that patient is excluded from the indicator.
4. Not all bleeding and clotting events captured under external code Y443 are adverse events and so they are excluded. Specific diagnosis codes were identified that represent material bleeding or material clotting.
5. This indicator only includes onset flag one (adverse event occurred during hospital stay). It does not include codes that reflect patients coming to hospital with material bleeding or clotting (onset flag 2).

See appendix 2 for details of what the indicator excluded and included.

Āpitihanga 4: Ngā wāhi whakamātautau

Appendix 4: Details of hospital testing sites

Hospital testing district	Information
Hauora a Toi Bay of Plenty	As part of testing, Hauora a Toi Bay of Plenty included Tauranga Hospital. The hospital serves a large Māori population across a diverse geographical area. They use paper-based medical records and have a regional quality and governance group. Data collection comes from Datix, adverse events reporting, coding data related to medications and complications, and Health Round Table reporting and data sets.
Te Whatu Ora Lakes	Te Whatu Ora Lakes services were based out of the Rotorua Hospital. This secondary hospital encompasses a large rural area with inequity and access concerns. The hospital has paper-based charts and notes, and access to data sources including ePharmacy and Datix.
Whanganui	Whanganui Hospital serves a population that identifies as Māori that is larger than the New Zealand average and the proportion of those aged over 65 years is also higher than average. The population is scattered over a relatively large service area. Health literacy among the Māori population is low, and a small but growing Pacific community has similar needs to the Māori population. The Whanganui team uses Pyxis dispensing but uses the national medication chart paper prescribing and administration system. They have access to C Gov for reportable events.
Taranaki	Taranaki is made up of two main hospitals within the Taranaki region – Taranaki Base and Hāwera. Testing of the Anticoagulation Stewardship Programme was carried out at Base Hospital. Taranaki uses electronic prescribing (MedChart) on all inpatient wards. There is internal reporting of obvious incidents related to anticoagulants within Datix, but the data set is small and there has been debate on what qualifies as 'harm' – if events are from known side effects or preventable incidents. Most reporting incidents are related to prescribing or administration (human error).

Āpitihanga 5: Tā ngā kiritaki kōrero

Appendix 5: Consumer stories from testing

Patient A: An existing patient on dabigatran was questioned by the pharmacist during medication history taking. It was discovered that the patient was taking all their medications altogether in the morning. The patient was provided with education and a leaflet, emphasising the importance of taking dabigatran twice daily, with at least 6 hours between doses. The patient had been unaware of the correct dosing schedule and was motivated to follow the new instructions.

- Key learning: Anticoagulant knowledge should be confirmed for all patients, regardless of how long they have been on an anticoagulant.

Patient B: This patient initially began dabigatran treatment before ACSP testing and without pharmacist involvement. When the patient returned to the hospital, it was discovered they had stopped taking dabigatran. The patient was unaware that dabigatran was a long-term medication or that they had repeat prescriptions available at the pharmacy (which was not their regular pharmacy). The patient had taken dabigatran for the first month, ran out, and assumed it was a short-term medication. Dabigatran was restarted, and proper education was provided.

- Key learning: The duration of anticoagulant therapy needs to be clearly explained to the patient and documented in the transfer of care process.

Patient C: A patient started rivaroxaban for deep vein thrombosis. Patient and son received anticoagulant education before discharge by a pharmacist. They were informed that the dose was 15mg orally twice a day for 3 weeks, followed by 20mg daily, with a review by the medical team at 3 months. However, during a follow-up call shortly after the 3-week mark, it was discovered that the patient had been taking 20mg twice daily. The patient immediately realised the error when questioned by the doctor.

- Key learning**:** Follow-up calls are helpful to ensure patients are taking their medication correctly.

Patients D and E: Two patients had their anticoagulant decreased after a risk–benefit analysis. For the first patient (D), the reason for the dose reduction was included in the main body of the Transfer of Care. Whereas, for the second patient (E), the explanation was documented next to the anticoagulant in the Discharge Medication List. Both patients were readmitted to ED. Patient D had their anticoagulant dose increased, while patient E continued on the reduced dose with the documented reason throughout their admission.

- Key learning: A reason for selecting a lower dose (if this is decided) after a risk–benefit analysis should be included next to the anticoagulant in the medication list.

Patient F: Patient started on a new anticoagulant by doctor who followed the 'ABCs of Anticoagulants' (resource developed by the local hospital team). This provided a great example of the ABC checklist working without pharmacist involvement.

Patient G: A patient had been identified by pharmacist/doctor as benefiting from a medication card at discharge. The patient's partner was so appreciative that she cried when receiving the card.

- Key learning: Medication cards can be very valuable for patients and their whānau because they clarify what medications they are taking, when they should be taken, and their purposes. Doctors and pharmacists should identify which patients would benefit from these at discharge.

Patient H: A patient aged in their fifties was provided with anticoagulant education before discharge by the pharmacist. The pharmacist identified that the patient was not concentrating. The doctor re-educated the patient after realising they did not have an understanding of their anticoagulant before discharge. When the patient was called as part of this quality improvement project, the patient still lacked understanding.

- Key learning: Many patients will not take the information in initially. Healthcare teams need to assess the patient's understanding at each contact and look for ways of engaging the patient.

Patient I: Patient I is reflective of multiple patients. When rung as part of the quality improvement project, they knew they were on a blood thinner but did not understand that this meant they were at increased risk of bleeding.

- Key learning: The educator needs to check understanding regularly and consider the choice of words used to educate the patient.