AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D21-29961

October 2021

National Anticoagulant Incident Analysis

Published by the Australian Commission on Safety and Quality in Health Care

Level 5, 255 Elizabeth Street, Sydney NSW 2000
Phone: (02) 9126 3600
Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

ISBN: 978-1-922563-13-2

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care.
National Anticoagulant Incident Analysis. Sydney: ACSQHC; 2021.

Disclaimer

The content of this document is published in good faith by the Australian Commission on Safety and Quality in Health Care (the Commission) for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your health care provider on particular healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

Contents

Preface

Data for this report is drawn from incidents that occurred within state and territory health services during the period July 2016 through June 2017. Whilst time has passed since the reporting of these incidents, the lessons remain pertinent for clinical practice today. Safe use and management of anticoagulants continues to be challenging for health services across the country.

The Commission has reviewed four years of hospital acquired complications data from 2017 to 2020 inclusive, which indicate that the management of anticoagulants is improving. For instance, national venous thromboembolism (VTE) and pulmonary embolism rates have both declined during this period. In addition, multiple interventions have been developed and implemented within health services and many preventive strategies operationalised. National and international discussion on VTE, in particular, has also increased clinicians' awareness of both the scale of the issue and its preventability.

Appropriate use of anticoagulant medicines is essential in supporting the downward trend in these clotting events. However, risks remain around their use and management. Whilst interventions have been developed to support detection and mitigation of these risks, health services remain challenged by the complex requirements for managing these medicines and the need for better system integration and useability.

For example, a recent coroner's report has investigated how a patient had inadvertently been administered two anticoagulants, one of which, enoxaparin, is commonly used to prevent VTE. Both anticoagulant medicines were prescribed via an electronic medication management (EMM) system. The coroner's report highlighted the ongoing challenges of interventions to support safer anticoagulant use.

Findings within this Report confirm that duplicate anticoagulant therapy is the most frequently occurring prescribing issue for these types of medicines. Given the frequency with which anticoagulant medicines are prescribed to *prevent* clotting events, it will be important to ensure that information regarding interventions and safe practices for prescribing and administering these medicines are shared and implemented to raise awareness and support ongoing system improvements.

Executive summary

In 2017, the Australian Commission on Safety and Quality in Health Care's (the Commission) Health Services Medication Expert Advisory Group members and other stakeholders raised concerns that incidents involving anticoagulant medicines were rising. Of particular concern, the inappropriate concomitant prescribing (and administration) of heparins and direct oral anticoagulants (DOACs). Anticoagulant medicines not being identified within the DOAC group was anecdotally described as a contributing factor to this problem.

This report describes and quantifies incidents that have involved anticoagulants. Incidents have been captured from healthcare settings (primarily hospitals) in states and territories across Australia.

Data received by the Commission for the period July 2016 to June 2017 was reviewed and classified according to:

- Medicine group (Direct oral anticoagulant {DOAC}, Heparin, Low Molecular Weight Heparin {LMWH}, Vitamin K antagonist and Factor Xa Inhibitor[1])
- The medication management process in which the incident occurred (for example prescribing or administration)
- Incident type.

A total of 3,580 incidents were submitted by states and territories. A random sample of 350 incidents was selected for analysis. Two of these incidents were excluded due to insufficient or irrelevant information. Western Australia (WA) Health provided a comprehensive report on anticoagulants for the reporting period and the Clinical Excellence Commission, provided a summary report for the 2013–2014 period in addition to a data set.

The Therapeutic Goods Administration (TGA) also provided information on anticoagulants at the Commission's request. This data was analysed qualitatively as a separate cohort of incidents. Thirty of the reports were included for this analysis.

For prescribers, duplicate therapy was revealed as the most frequently occurring incident. For nursing staff however, omitted dose followed by incorrect rate of administration were the two most frequent incident types respectively. Following completion of the analysis, the preliminary findings were presented and potential recommendations discussed at meetings 41 (June 2019) and 44 (March 2020) of the Health Services Medication Expert Advisory Group (HSMEAG). In addition, during 2018 and 2019 candidate anticoagulant stewardship strategies were proposed, and HSMEAG state and territory representatives were individually interviewed regarding the current situation relating to:

- the proposed recommendations
- ongoing incidence and nature of incidents involving anticoagulant medicines
- development of resources or implementation of initiatives to support safe prescribing and management of anticoagulant medicines, including stewardship programs
- challenges faced with implementation or uptake of local or national initiatives.

[1] It is acknowledged that Apixaban and Rivaroxaban have a mode of action that corresponds to classification as a Factor Xa inhibitor. However, for the purposes of reporting, these medicines have been classified into the DOAC medicine group.

Feedback from HSMEAG along with state and territory interviews has been incorporated and summarised. The information within **Appendix 2** provides details of various resources and initiatives that have been developed, and are available nationally as well as within the various states and territories. Relevant material collated on anticoagulants during the development of Australia's response to the *WHO Global patient safety challenge: Medication without harm* has also been included. It was considered that these resources were all very useful in supporting local anticoagulant stewardship efforts.

Some of the main themes identified that could assist with mitigation of anticoagulant prescribing risks include:

- implementation of electronic medication management (EMM) systems
- modification of the national standard medication charts to:
    - accommodate an anticoagulant management section, or
    - develop a separate anticoagulant chart
- introduction of an anticoagulant stewardship program
- support and guidance regarding suitable indicators.

Whilst it was noted that EMM was being implemented or in use in many states and territories already, WA and Tasmania expressed the need for a localised solution involving a paper-based chart. WA reported that they developed and have been using their own specialised paper-based medication chart for the prescribing of anticoagulants since 2011. Tasmania advised that they will continue using the National Inpatient Medication Chart (NIMC) for the foreseeable future.

As a result of the incident analysis and other findings, the following recommendations have been made:

Recommendation 1: Review and implement education programs for clinicians on incident management systems and the importance of data quality

Recommendation 2: Implement medication review as outlined in Action 4.10 of the National Safety and Quality Health Service Medication Safety Standard and enhance local or state/territory resources reflecting on case studies and lessons learned

Recommendation 3: Continue to implement and optimise electronic medication management systems to facilitate the identification and prevention of missed doses, incorrect doses and duplicate therapy orders

Recommendation 4: Commission to partner with Tasmania on a suitable hard-copy solution, including potential modification of the National Inpatient Medication Chart (NIMC).

Incident data analysis

1. Summary of findings

National (state and territory) incident data

- Omitted dose was the most frequently reported incident type (72 incidents out of 348) followed by incorrect dose (24 incidents out of 348) and duplicate therapy (23 incidents out of 348)
- Duplicate therapy was the top prescribing incident reported nationally (22 incidents out of 115) with 13 of the 22 prescribing incidents involving a DOAC with heparin or enoxaparin. Eleven of these incidents involved subsequent administration to the patient
- Rivaroxaban was implicated in half of all incidents involving DOACs (25 incidents out of 50), closely followed by apixaban (23 incidents out of 50). The most common incident involving DOACs was inappropriate concomitant prescribing with another anticoagulant (15 incidents out of 50), typically heparin or enoxaparin
- Data quality in these reports was problematic. Importantly, 'unclear' was assigned to 11 of the 348 incidents analysed. This number represents missed opportunities for meaningful additions to the collective knowledge and understanding of anticoagulant incidents and how problems involving these medicines may be addressed
- 'Near miss'[2] incidents were not clearly articulated in the data limiting opportunities for prospective solutions to be implemented and mitigate known risks
- Heparins were the largest group of medicines implicated in incidents analysed for this report (115 incidents out of 348). Upon review of the information entered, it is clear that medication management processes around use of unfractionated heparin are many and complicated and these are easily confused. Clear and consistent communication is required to accurately prescribe, monitor and administer heparins. Workflows relating to administration and documentation need to be addressed to improve medicines safety.

While potential causative/contributing factors were considered during data analysis, the paucity of information did not allow these results to be included with the degree of confidence required for this report. However, a report provided by WA Health identified the top three causative/contributing factors: not checking properly (ensures application of medication administration 'rights'); poor documentation; and lack of clinical handover. Although these findings are not derived from national data, they provide sound indication of what can be seen at a national level.

TGA adverse event data

Information supplied by the TGA detailed adverse events experienced by patients. This included severe if not fatal bleeding-related outcomes such as sub-arachnoid haemorrhaging, gastro-intestinal haemorrhaging, epistaxis and haematomas. Other outcomes for patients included increased bleeding risks due to high International Normalised Ratios (INR) when on warfarin, heparin-induced thrombocytopenia and pruritic rashes.

[2] For the purposes of this report 'near miss' is aligned with the following definition: incident occurred but did not harm the patient.

Given the limited descriptions and complexity of the cases reported, it was not possible or appropriate to classify this information in the manner applied to state and territory-based data. The TGA reports highlighted the complex nature of care for some patients and the severity of the potential risks involved.

2. Context and background

Anticoagulants are considered high-risk medicines, and are included in the high-risk medicines framework referred to under the acronym 'APINCHS': Heparins and other anticoagulants.

The Commission has received anecdotal cases from hospitals implicating direct acting oral anticoagulants (DOACs) in adverse events, particularly concomitant prescribing of anticoagulants. DOACs include apixiban, dabigitran and rivaroxiban.

While medicines of the same type can sometimes be prescribed together to enhance their effect, in the case of anticoagulants, unintentional and inappropriate prescribing can increase the risk of adverse effects for patients.

Since these data were sourced, most jurisdictions and health care organisations have independently identified, developed and implemented a number of 'stewardship' strategies for safe and appropriate use of anticoagulants, including:

1. Modification of the National Standard Medication Chart (NSMC) or development of a specialised chart
2. Local anticoagulant incident data analysis
3. Electronic medication management (EMM)
4. Education strategies
5. Venous Thromboembolism (VTE) Clinical Care Standard implementation
6. Alerts, notifications and advisories relating to anticoagulants
7. Assessment, indicators and audit of appropriate use.

The aim of this project was to describe and quantify incidents that have involved anticoagulants, nationally. These incidents were captured from healthcare settings (primarily hospitals) in states and territories across Australia. In the first instance, the analysis focuses on concomitant use of anticoagulants, that is, inappropriate therapeutic duplication of anticoagulants involving DOAC and heparin-based medicines.

Preliminary findings from this project were used to provide an evidence-base for formulating proposed targeted interventions in healthcare settings.

3. Scope

This report draws on 2016–17 data and collated reports provided to the Commission by states and territories. In addition, a sub-analysis of adverse event reports provided by the TGA have been included as a qualitative assessment.

Severity Assessment Code (SAC) ratings were not part of the Commission's original data request to states and territories, therefore analyses of SAC ratings have not been included in this report. In addition, incident causation could not be established from a national perspective.

Feedback from states and territories was sought on the preliminary findings and recommendations, and also to confirm existing strategies and resources in place to support safe and appropriate use of anticoagulants.

Data sources

A request was circulated via the Inter-Jurisdictional Committee on 5 October 2017, to provide state and territory de-identified retrospective anticoagulant incident data for the 12-month period from July 2016 to June 2017. This request was also circulated to the TGA at the same time.

Data and information supplied for analysis are summarised in **Table 1**.

Table 1: Summary of data and information provided for analysis

Data and information provided by	Type of data or information provided
NSW	Raw data[3] + Summary anticoagulant incident report, 2013–2014
Vic	Not available
Qld	Raw data[3]
SA	Raw data[3]
WA	Collated report and analysis
Tas	Raw data[3]
NT	Raw data[3]
ACT	Not available
TGA	Adverse event reports
Total number of incidents (raw data[3]) submitted	**3,580**

[3] It is acknowledged that apixaban and rivaroxaban have a mode of action that corresponds to classification as a Factor Xa inhibitor. However, for the purposes of reporting, these medicines have been classified as DOAC medicines.

Protocol for analysis

A protocol for analysis of these data was designed. The protocol aligns closely with methodology described in the collated anticoagulant incident report provided by the Department of Health, Western Australia (WA Health) with minor modification to ensure its suitability nationally. See **Appendix 1** for further information on the Anticoagulant Incident Review Protocol.

Incident data (raw data) were collated for analysis. Given the large number of incidents provided by states and territories and the potential time requirements for review of all of these, a subset of 350 records were instead randomly selected for review.[4] Analyses presented in this report are based on this subset of 350 records. Two of the 350 records were excluded because they contained insufficient information or were apparently unrelated to the topic.

Reports and information provided by the TGA, WA Health and the Clinical Excellence Commission (Anticoagulant incident summary report, 2013–2014) have been analysed in parallel with the raw data.

Medicines included in this review were classified as described below in **Table 2**.

Table 2: Description of medicine classes included in this anticoagulant incident analysis

Medicine class	Medicines within this class (trade name)[5]
Direct Oral Anticoagulant (DOAC)	Apixaban (Eliquis)
	Dabigatran (Pradaxa)
	Rivaroxaban (Xarelto)
Heparins	Heparin [Unfractionated heparin]
	Heparinised saline
Low Molecular Weight Heparins (LMWH)	Enoxaparin (Clexane)
	Danaparoid (Orgaran)
	Dalteparin (Fragmin)
	Nadroparin (Fraxiparine)
Vitamin K antagonists	Warfarin (Coumadin and Marevan)
Factor Xa Inhibitor[6]	Fondaparinux (Arixtra)

[4] Ong M, Magrabi F, Coiera E. Automated categorization of clinical incident reports using statistical text classification. Qual Saf Health Care 19 (2010) 1–7.

[5] Note that not all states and territories searched for the same medicines in their incident management systems.

[6] It is acknowledged that apixaban and rivaroxaban have a mode of action that corresponds to classification as a Factor Xa inhibitor. However, for the purposes of reporting, these medicines have been classified as DOAC medicines.

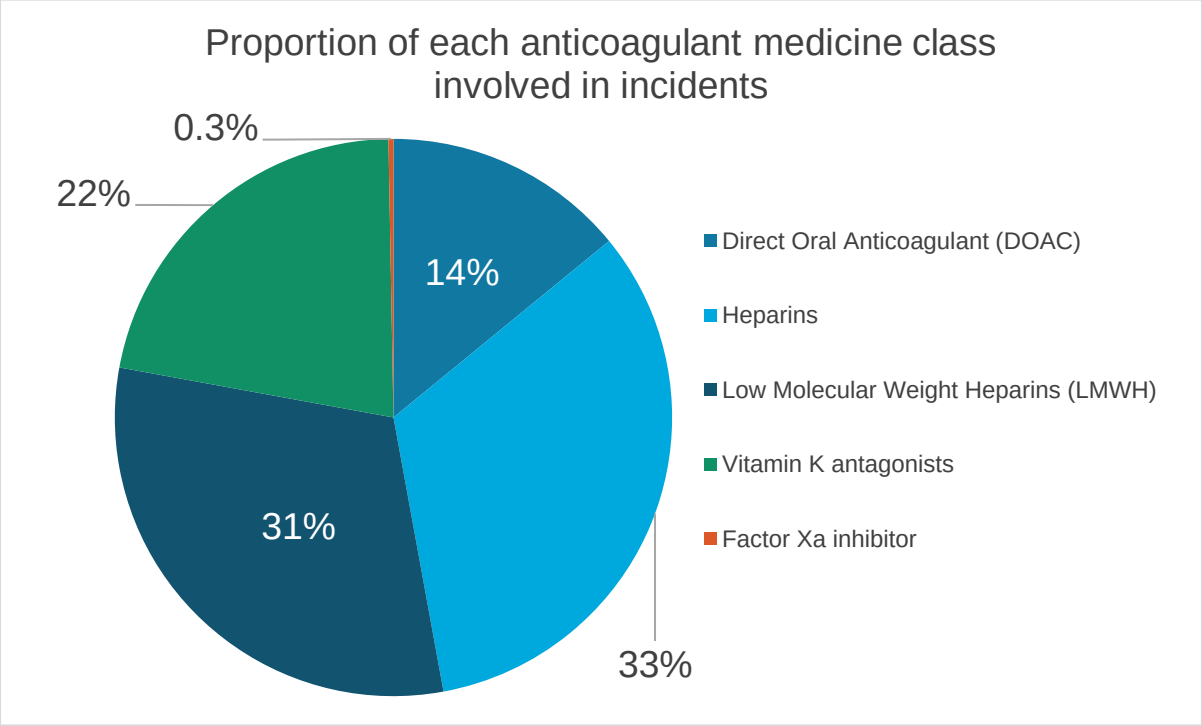
4. Results

National (state and territory) incident data

Anticoagulant medicine classes implicated

Across the five different anticoagulant medicine classes, the classes most commonly implicated were the heparins and low molecular weight heparin which accounted for just under two thirds of all incidents analysed, see **Figure 1** below.

Figure 1: Describes the proportion of each anticoagulant medicine class involved across all incidents analysed



Of the 348 incidents analysed, 115 involved a heparin (heparin unfractionated or heparinised saline), and 106 incidents involved low molecular weight heparins (LMWH). These proportions closely aligned with WA Health findings.

Heparins

Both heparinised saline and heparin (unfractionated) were included within the heparin group for this analysis, despite differences in their clinical application. Thirteen incidents involved heparinised saline. Use of heparin (unfractionated) for anticoagulation, and the complex prescribing, administration and monitoring processes to ensure this medicine is managed safely, create a number of potential medication safety risks. There were 74 administration-related incidents with the leading type of incident being incorrect rate of administration (15 incidents) and 29 incidents involving prescribing processes. Incident types were fairly evenly distributed across the prescribing responsibilities. The most common prescribing incident-type involving heparins was incomplete prescription (six incidents).

Low Molecular Weight Heparins (LMWH)

LMWH were the second largest group of medicines involved in this incident analysis. Enoxaparin was implicated in the vast majority of these (101 out of 107 incidents). Administration was the leading medication management process involved with the most common incident type being omission of a dose.

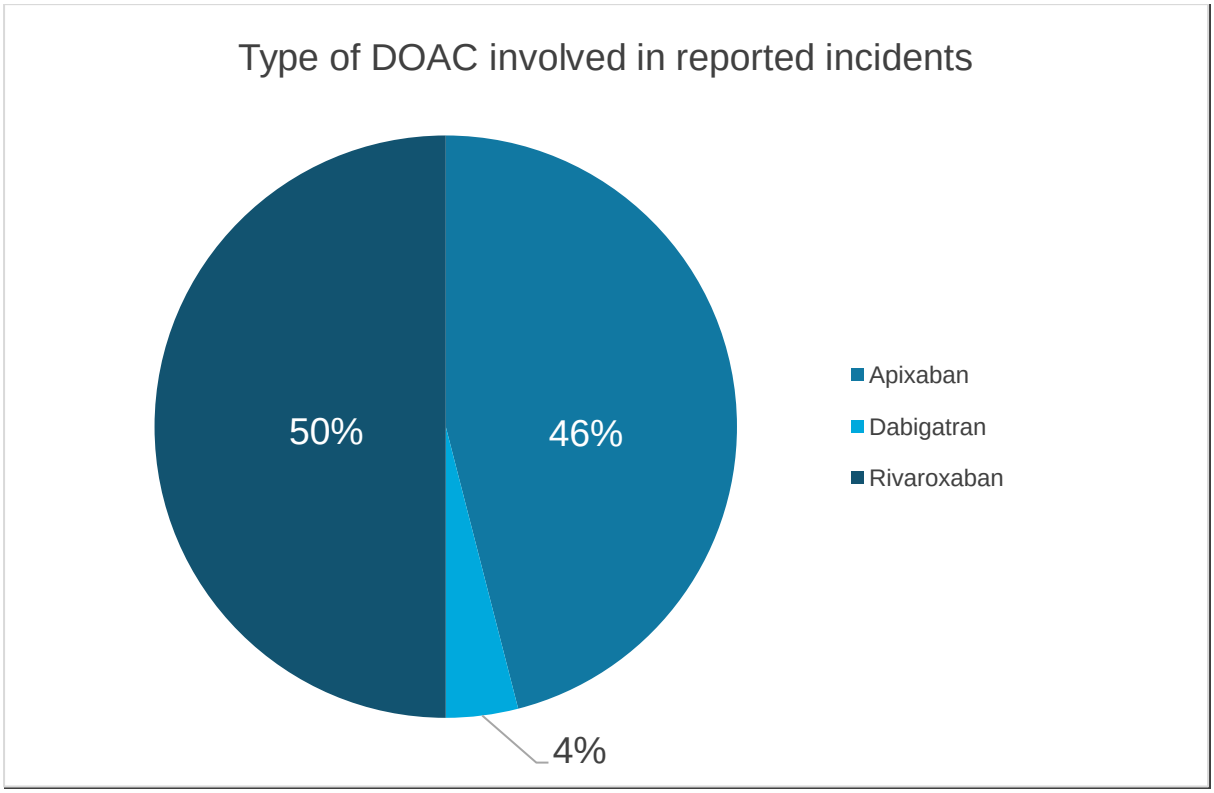
Warfarin

Warfarin was involved in 76 incidents (22%) of all incidents reviewed, the third most common anticoagulant to be involved. In over half of these cases, the incident was implicated in the administration of the medicine (36 out of 76 incidents) and just under half involved prescribing (31 incidents). Omitted dose (24 incidents), documentation error – no dose (10 incidents) and medication not prescribed (nine incidents) were the top three incident types reported.

DOACs

DOACs were involved in 50 incidents (14%) of all incidents reviewed. Of this group, rivaroxaban and apixaban were by far the most commonly implicated medicines (25 incidents and 23 incidents respectively). In comparison with the other anticoagulant medicine classes, the prescribing process was most commonly involved. The most frequent incident type identified was duplicate therapy.

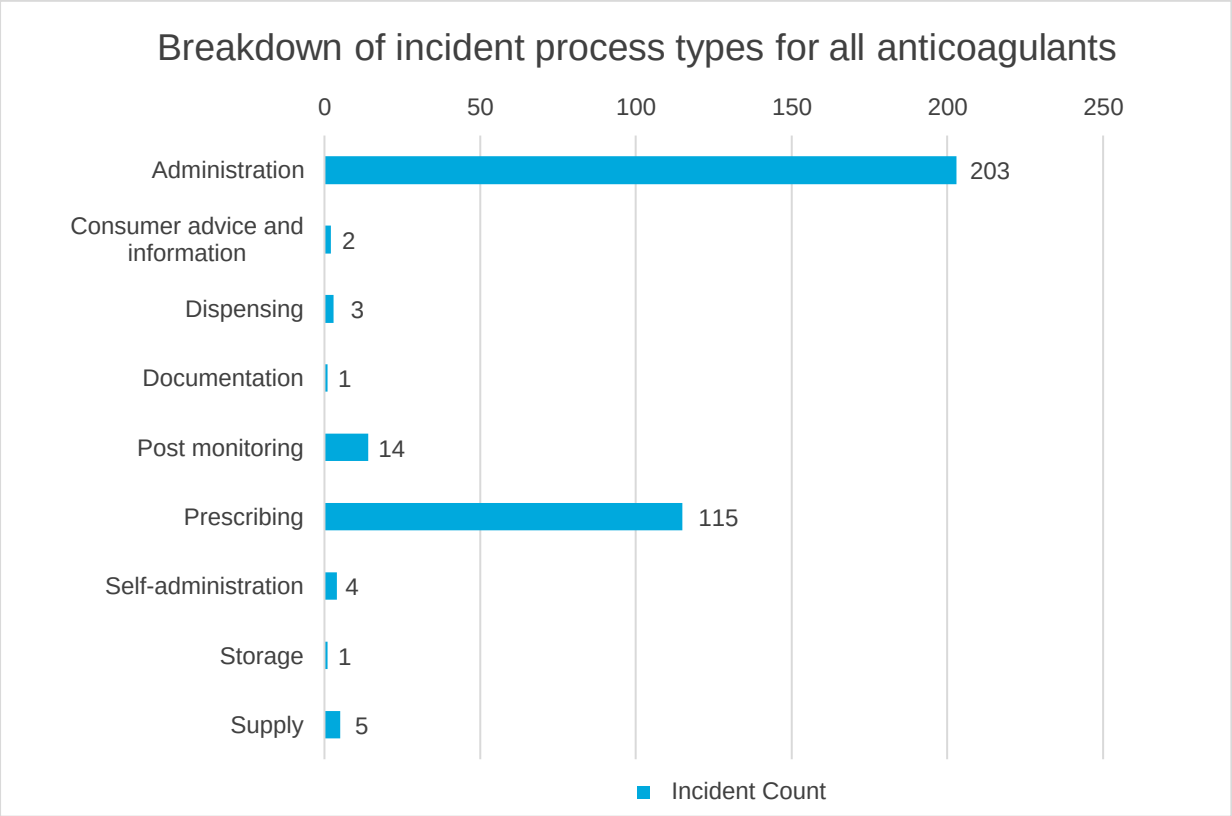
Figure 2: Describes the proportion of each DOAC medicine implicated across all incidents analysed



Medication management processes

There were ten medication management processes included in the Anticoagulant Incident Review Protocol (refer **Appendix 1**). The majority of incidents related to administration of a medicine (203 out of 348 incidents) and prescribing a medicine (115 out of 348 incidents). Post monitoring was related to 14 incidents, with 10 of these related to heparin monitoring specifically. Comparative numbers for the top 10 management processes involved are displayed in **Figure 3**.

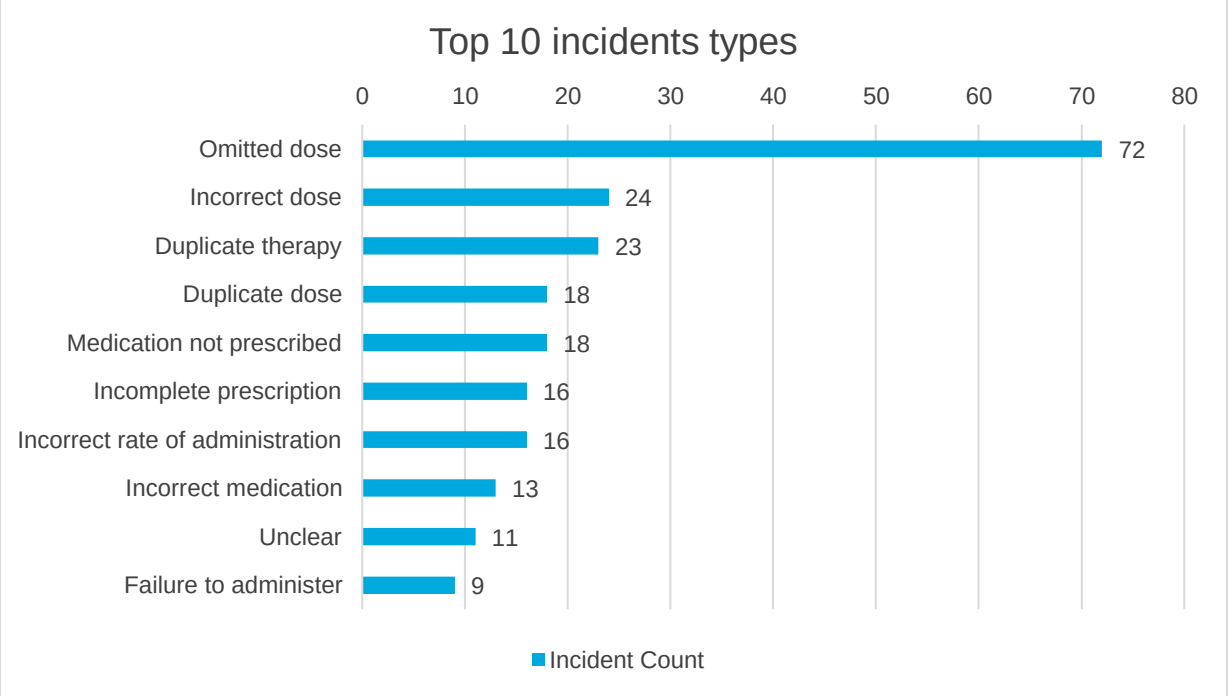
Figure 3: The top 10 medication management processes implicated across all incidents analysed



Anticoagulant incident types

Figure 4 shows the top 10 incident types across all anticoagulants. The top three incident types nationally were omitted dose (72 incidents) followed by incorrect dose (24 incidents) and duplicate therapy (23 incidents).

Figure 4: Top 10 incident types across all anticoagulant incidents

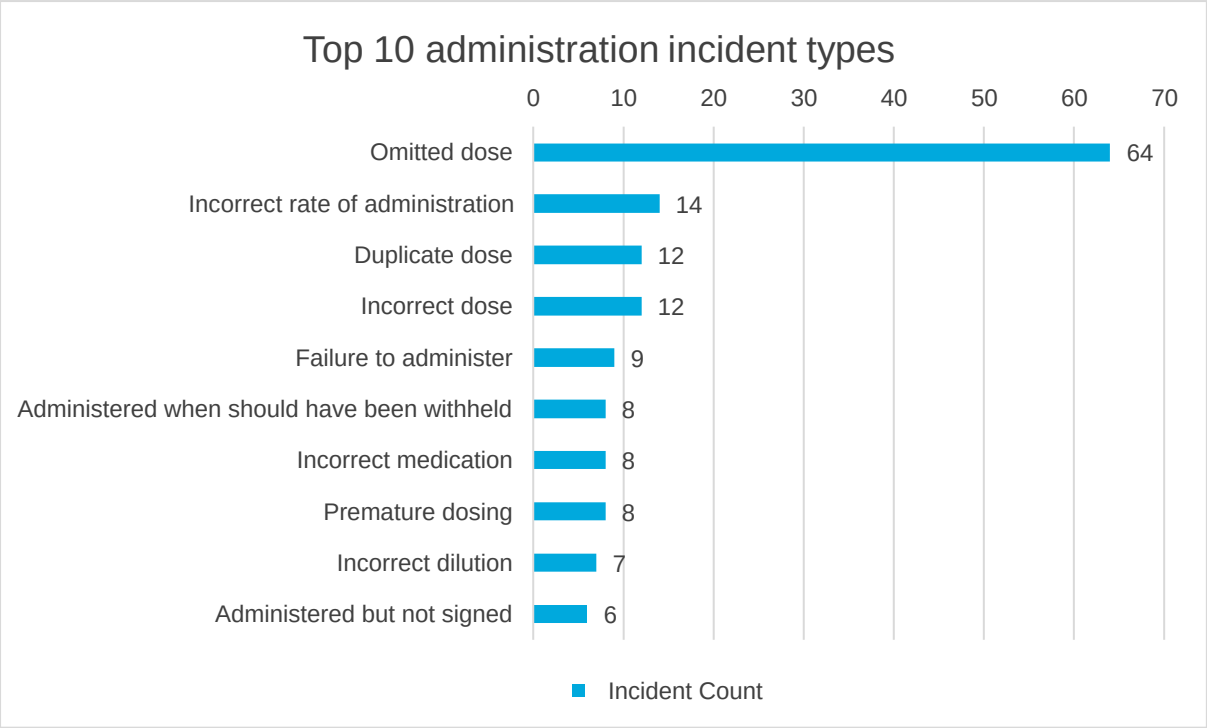


Eleven incidents were assigned ’unclear’ as there was insufficient information to classify them into an appropriate ‘incident type’ category.

Administration of medicines

There were a total 203 incidents associated with the administration process. Omitted doses accounted for almost one third of all administration-related incidents (65 incidents). Incorrect rate of administration was the second most frequently implicated incident type (14 incidents), all of which related to heparin. Duplicate dose and incorrect dose were tied as the third most frequent incident type (12 incidents each). See **Figure 5**.

Figure 5: Top 10 administration incident types across all anticoagulant medicines analysed



Prescribing of medicines

There were 115 prescribing incidents in this analysis.

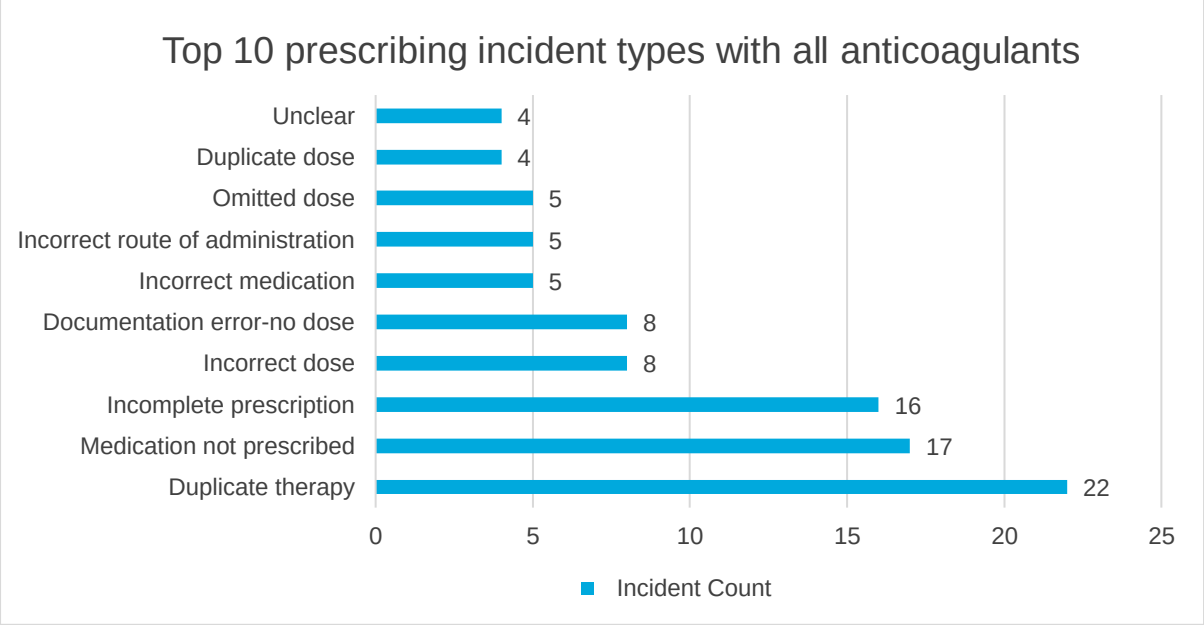
Figure 6 shows the top 10 prescribing incident types across all anticoagulants. Twenty-two of these were related to duplicate therapy, whereby two anticoagulants had been inappropriately prescribed for each patient. All anticoagulant medicine classes are represented in this cohort, except the Factor Xa Inhibitor group (which contains only fondaparinux). Medication not prescribed occurred in 17 of the 116 incidents. The third most frequent incident type, related to incomplete prescription or medicine order documented in the patient record (16 incidents).

Of duplicate therapies prescribed, 10 incidents involved duplicate VTE prophylaxis therapy orders, seven of which were DOACs prescribed with heparin or enoxaparin. Seven incidents involved treatment doses. Five of these involved the combination of enoxaparin and rivaroxaban. There was one incident that was a duplication of heparin – one order for treatment, the other for prophylaxis. There were four incidents for which a determination of VTE prophylaxis or treatment could not be made due to insufficient detail in the incident description.

Incident descriptions highlighted the need for all clinicians to review all existing orders on the patients' medication chart(s) prior to and following any anticoagulant orders being written or ceased. The descriptions also serve as a reminder of the challenges related to ensuring VTE prophylaxis and/or treatment is well managed perioperatively.[7]

In 14 of the 16 prescribing incidents described, inappropriate concomitant therapy had been administered before the error had been detected. This highlights the need for nursing staff administering medicines to carefully check the complete list of prescribed medicines as part of their medication review, prior to each administration.

Figure 6: Top 10 prescribing incident types across all incidents



Comparisons with collated reports

Both WA Health and the Clinical Excellence Commission (CEC) in NSW provided a collated report of their findings from state-wide analyses.

Table 3 below provides a summary of key national anticoagulant incident analysis results compared with findings from WA and NSW.

[7] Clinical Excellence Commission. *Guidelines on perioperative management of anticoagulant and antiplatelet agents*. Sydney: CEC; 2018.

Table 3: Summary of national anticoagulant incidents results compared with WA Health and NSW Health[8]

WA Health	National	NSW[9]
List of the anticoagulant medicines or classes implicated in anticoagulant incidents, from most frequent (top) to least (bottom)		
Enoxaparin (a LMWH)	Heparins (includes unfractionated heparin and heparinised saline)	Warfarin
Heparin (Unfractionated heparin)	Low molecular weight heparin (LMWH)	Unfractionated heparin
Warfarin	Warfarin	Low molecular weight heparin
DOAC	DOAC	NOAC (=DOAC)
Heparinised saline	Fondaparinux	–
Top three incident types, listed from most frequent (top)		
Omitted dose	Omitted dose	Omitted dose
Incorrect dose	Incorrect dose	Incorrect dose
Incomplete prescription	Duplicate therapy	Duplicate therapy
Top three administration incident types, listed from most frequent (top)		
Omitted dose	Omitted dose	Not available
Incomplete prescription	Incorrect rate of administration	Not available
Premature dosing	Duplicate dose	Not available
Top three prescribing incident types, listed from most frequent (top)		
Omitted dose	Duplicate therapy	Not available
Incorrect dose	Medicine not prescribed	Not available
Contraindication due to a medical condition	Incomplete prescription	Not available

[8] 2013–2014 data. Incidents classified according to impact on patient rather than the stage of the medication management cycle.

Anticoagulant medicine classes

Using the comparisons within **Table 3** above, heparin and LMWH are the anticoagulant medicine classes most frequently implicated in reported incidents for WA and national results. Heparin and LMWH were also implicated in the top three for NSW, with warfarin the most commonly implicated in contrast with national results.

A number of additional findings in the WA Health analysis report closely align with those found in the national incident review some of which are noted below for particular medicines or classes:

Heparin

- Bolus and rate requirements commonly reported as a point of confusion
- Timing of blood sample taken for analysis and how this relates to ongoing monitoring
- Dilution of heparin (unfractionated) is error-prone
- Heparin locks and the need to use heparinised saline as opposed to unfractionated heparin is not well understood by staff.

Warfarin

- There is a knowledge gap regarding the existence of two brands and that these are not interchangeable
- There is a need to ensure INR, dose and prescribers signature have been documented for safe administration. Forgetting to document a dose for administration is a common error for prescribers.

DOACs

- Clinicians are unfamiliar with these medicines and do not recognise (or check for other anticoagulant medicines)
- Clinicians appear to be unfamiliar with policies for after-hours access to (these) medicines.

Types of incidents

Across all three collated reports, dose omitted and incorrect dose were the two most frequently reported incident types. Duplicate therapy was the third most frequent incident type reported by NSW and nationally, while the WA incident analysis report cited incomplete prescription as the third most frequently reported incident type.

Duplicate therapy did not feature amongst the top three incident types, which may reflect the different arrangements in place for managing anticoagulant medicines in WA.

5. Limitations

Data quality

Data analysed for this report was of consistently poor quality. The main issues surrounding these data, its interpretation and comparison are outlined below:

- Data provided did not necessarily focus on the outcome for the patient
- Inadequate information and vague statements in the incident description, made it unclear what had transpired, for instance:

  When checking chart, noticed XX dose given at XX after the XX dose was given

  s/c clexane was given at 12:00 by day staff from incorrect order, then order was recharted in correct order yet different dose, same was given yet team did not indicate for this to commence the following

- A lack of (or application of) consistent terms and definition within the data. This made the analysis process more difficult. For example, the term 'dispensing' was used to describe the process of *administering* a medicine
- Data supplied did not have a scale for clinicians to attribute potential causative factors for the incident. In the majority of cases, the incident description was insufficient to allow determination of a potential cause
- Classifications listed in **Appendix 1 Table B** made it difficult to label 'near miss' incidents. Analysis of 'near miss' incidents and their potential to recur is valuable in prevention efforts. The data provided did not reveal how these benefits, if any, were realised
- Multiple incidents were reported in a single incident entry. For example, multiple missed doses of a medicine were recorded in one incident report
- Classifications in the appendices did not accurately describe some of the specific administration issues, notably: heparin locks; central venous catheters; and multi-lumen catheters
- The most frequently entered incident nationally was 'omitted dose.' Omitted dose on its own is significant. However, it was not possible to determine if any of the incidents were related, and consequently, if patients missed being administered multiple (consecutive) doses
- A number of incidents were assigned a classification of 'unclear'. These data represent missed opportunities for additional meaningful knowledge and understanding of how these incidents unfolded and subsequent learning opportunities
- Each state and territory having different terms or taxonomies and definitions made it difficult to bring these data into alignment.

Other limitations

All incidents were taken as written. There was no clinical review included for each incident. There may be cases where duplicate therapy was considered clinically appropriate. For example, enoxaparin and warfarin prescribed together according to an evidence-based protocol until adequate anticoagulation with warfarin is achieved.

It was noted that the WA Health report provided information on causative factors for incidents. Data provided from states and territories did not include this information and analysis did not allow for causative factors to be attributed and included in this report with the degree of certainty required.

Results are not adjusted according to the frequency with which that anticoagulant class is implicated (prescribed or administered).

Therapeutic Goods Administration (TGA) reports

Approximately 30 of the 120 reports provided by the TGA were reviewed for this analysis. Adverse events experienced by patients included severe, if not fatal, bleeding-related outcomes. Examples include sub-arachnoid haemorrhaging, gastro-intestinal haemorrhaging, epistaxis and haematomas. Other outcomes for patients included increased International Normalised Ratios (INR), heparin-induced thrombocytopenia and pruritic rashes.

Given the limited descriptions within the adverse event reports, it was not possible or appropriate in many cases to assign a specific medication management process (e.g. prescribing, administration, dispensing). Some of the events did document that the patient was on multiple blood thinning agents with a variety of modes of action and that these were ‘suspected’ agents in contributing to the outcome.

6. Post analysis feedback from states and territories

The initial findings from the analysis were presented and discussed during July and August 2019 with HSMEAG. Representatives were contacted subsequently and interviewed from the following five states and territories:

- New South Wales
- Victoria
- Queensland
- Tasmania
- Northern Territory.

Unfortunately, representatives from the remaining states and territories were unavailable for interview during this period. Some representatives advised that they had previously provided feedback at earlier meetings or related activities – for instance during separate discussions relating to the VTE Prevention Clinical Care Standard. The interview questions and summary of responses is included at **Appendix 3**.

Themes raised during these interviews, which could assist with mitigation of anticoagulant prescribing risks into the future, included:

- Modification of the national standard medication charts to:
    - accommodate an anticoagulant management section, or
    - develop a separate anticoagulant medication chart
- Introduction of an anticoagulant 'stewardship' program
- Support and guidance regarding suitable indicators.

These findings were presented and discussed at the March 2020 meeting of HSMEAG, where members were asked to respond to a series of questions about implementation of the Commission resources released since 2017:

- *VTE Prevention Clinical Care Standard* (published 2018)
- Hospital Acquired Complications – Medication Complications (published 2018)
- Introduction of medication review (Action 4.10) into the NSQHS Standards (Implementation commenced in 2019)
- High-risk medicines online course – module on anticoagulants (made available nationally in 2018/19 via www.hrmeducation.health.gov.au/)

The questions asked in relation to these resources were:

1. How have these resources been implemented to date?
2. What barriers to their implementation have been identified?
3. What indicators are being captured and reviewed as part of these implementations?
4. How is this data being used and are there any tangible improvements being realised regarding the incidence of inappropriate concomitant prescribing of anticoagulants?
5. What successes have been experienced from more localised interventions?

It was noted that:

- There is an extensive array of resources available to clinicians, however, operationalising these resources continues to be a challenge
- The themes presented were generally supported
- Most states and territories indicated state-wide or local strategies and initiatives were currently in use or being implemented – including EMM systems.

Both WA and Tasmania advised that they are likely to remain using hard copy medication charts for the foreseeable future. In response to the WA incident analysis report, a revision of the existing local WA anticoagulant chart was pursued.

7. Recommendations

Recommendation 1

Review and implement education programs for clinicians on incident management systems and the importance of data quality

In general, incident data provided for this analysis was of poor quality. Information documented was often inconsistent, incomplete or inaccurate, (for example administration of a medicine was referred to as 'dispensing' a medicine). Clinician education is required to ensure incident entries are complete, accurate and provide the information necessary to enhance or develop policy or implement practice change that supports safe medicine use.

Recommendation 2

Implement medication review as outlined in Action 4.10 of the National Safety and Quality Health Service Medication Safety Standard and enhance local or state/territory resources reflecting on case studies and lessons learned

Duplicate therapy was the top prescribing incident identified from the national data analysis, with administration of these medicines occurring in all but two cases. The National Safety and Quality Health Service (NSQHS) Medication Safety Standard includes medication review as a specific action (Action 4.10). Medication review is considered a multidisciplinary responsibility. To ensure safe and appropriate use of medicines, clinicians who prescribe, administer or dispense medicines for patients are required to undertake a medication review within their scope of practice.

In 2019, the CEC in NSW published *A Guide to Medication Reviews for NSW Health Services*. Documents such as these have provided a sound foundation for implementation. Lessons learned from these incident data present an opportunity to enhance messaging by using practical, de-identified examples, highlighting the most common errors as well as drawing on information available in published literature around anticoagulant error.[9,10,11, 12]

---

[9] Jovanovska T, Fitzsimons K, Ferguson C, Koay A. Types and causes of anticoagulant-related medication incidents across hospitals in Western Australia. JPPR 2019,49(6);523–537. https://onlinelibrary.wiley.com/doi/abs/10.1002/jppr.1576

[10] Institute for Safe Medication Practices (ISMP). Advisory. Oral Anticoagulants: A Review of Common Errors and Risk Reduction Strategies. 2016.

[11] Westbrook JI et al. Associations between double-checking and medication administration errors: a direct observational study of paediatric inpatients. BMJ Qual Safety. 2020;0:1–11. https://qualitysafety.bmj.com/content/early/2020/08/17/bmjqs-2020-011473

[12] Daniel JW, Kramer J, Burgess LH. Assessment of oral anticoagulant adverse drug events before and after implementation of a real-time clinical surveillance tool. J Patient Saf. 2021 17(4); e350–e354. https://pubmed.ncbi.nlm.nih.gov/31045622/

Recommendation 3

Continue to implement and optimise electronic medication management systems to facilitate the identification and prevention of missed doses, incorrect doses and duplicate therapy orders

The top three incident types identified through this review can all be minimised through the use of electronic medication management (EMM) systems. These systems not only provide support through data entry, alerts and reminders, but medication administration reports from these systems could be used to provide accurate and timely information about omitted doses in particular. This information can also be used to support quality improvement and practice change.

Recommendation 4

Commission to partner with Tasmania on a suitable paper-based solution, including potential modification of the National Inpatient Medication Chart (NIMC)

Per Recommendation 3, most states and territories are continuing to implement and optimise EMM systems. Two states however, WA and Tasmania, identified that they were unlikely to transition to an EMM system in the short to medium term. Tasmania, will require a paper-based medication chart solution and WA will continue management of anticoagulant medicines using the locally developed chart.

One of the themes identified in discussion with stakeholders included potential modification of the national standard medication charts (NSMCs) to:

- accommodate an anticoagulant management section, or
- develop a separate anticoagulant medication chart.

8. Conclusion

These findings confirmed that inappropriate concomitant prescribing and administration of anticoagulants is a problem. However, lack of severity ratings meant it was difficult to understand the consequences of these incidents for patients.

For prescribers, duplicate therapy was revealed as the most frequently occurring incident. For nursing staff however, omitted dose, followed by incorrect rate of administration were the two most frequent incident types respectively.

Heparins were identified as most frequently involved in incidents. On review of the information entered, it is clear that the multiple medication management processes around the use of heparin (unfractionated) are complicated and can be easily confused. Clear and consistent communication is required to accurately prescribe, monitor and administer these medicines. Workflows relating to review, administration and documentation need to be addressed to improve safe use.

While the TGA reports identified some of the adverse outcomes from administration of anticoagulant medicines (particularly DOACs), the information and the events did not lend themselves to the classification process described. The reports did help to identify groups of medicines that had been involved in events.

Some incidents will be substantially reduced with the introduction of EMM, particularly for the top three national incident types identified. However, systems will need to be assessed to provide assurance. Other problems where there are no hard barriers in place for workflows, such as administration of unfractionated heparin are harder to address.

EMM provides an opportunity to capture this data through a medication administration report. Consideration needs to be given as to whether manual entry of these (types of) data into a separate incident management systems is the most efficient, accurate and worthwhile use of resources moving forward. In addition, these systems could be used to provide information at the point of administration on how to access the medicine after hours if it is required and staff are uncertain.

Appendix 1

Anticoagulation Incident Review Protocol

Purpose

Health Services Medication Expert Advisory Group members and other stakeholders have raised concerns that incidents involving anticoagulant medicines are on the rise.
Of particular concern is the inappropriate concomitant prescribing (and administration) of heparins and direct oral anticoagulants (DOACs). Failure to recognise medicines within the DOAC group has been, anecdotally, described as a contributing factor to this problem. While medicines of the same type can sometimes be prescribed to work together to enhance their effect, in this case to thin the blood, inadvertent and inappropriate prescribing can increase risks of severe bleeding.

The aim of this project is to describe and quantify incidents that have involved anticoagulants nationally. These incidents have been captured from hospital settings in states and territories across Australia. In the first instance, the review will focus on concomitant use of anticoagulants, that is, inappropriate therapeutic duplication of anticoagulants involving DOAC and heparin-based medicines.

Findings from this project will be used to provide an evidence-base for formulating targeted interventions in healthcare settings.

Aim

To understand current gaps in practice by identifying and describing (quantitatively and qualitatively) the incidents involving anticoagulants in Australian healthcare settings.

Method

Interrogation of incident data, both qualitative and quantitative, is to be conducted using the templates and information in Tables A, B, C and D. To facilitate comparison the incident classification definitions, types and causative factors have been adopted or adapted according to those used by WA Health.

The following information will be captured as part of the review:

- Anticoagulant medicine name and class (Table A)
- Stage at which the incident occurred in the medication management cycle. These stages will be defined according to existing WA Health definitions (Table B) with additions according to a process of harmonisation of terminologies/taxonomies
- Incident type will be allocated as classified by WA Health (Table C)
- Causative factors will be assessed and categorised in line with WA Health policy (Table D).

Method for interrogation of data:

- All incident data consolidated to one spreadsheet where possible
- Harmonise medication management cycle terms across states and territories

- Randomly select 350 records to review[13]
- Allocate/confirm medicine(s) involved in the incident (primary and secondary)
- Allocate/confirm stage at which incident occurred in the medication management cycle
- Allocate/confirm causative factors where possible
    - Special consideration: Use of enoxaparin and warfarin can be used appropriately in practice. Incidents involving these two medicines will be classified according to their relationship to enoxaparin (LMWH). Enoxaparin will be the classified as the primary medicine involved in the incident, warfarin the secondary medicine
- One project officer will be responsible for review and allocation/confirmation of each of these incidents
- On completion of this task, a second project officer will randomly select 5% of these incidents to confirm that classifications have been recorded appropriately.

Questions for interrogation of data:

a. How many incidents have involved inappropriate concomitant prescribing and administration of DOAC and heparin-based medicines?
b. How many warfarin related incidents have occurred? What were the top three incidents that occurred with this medicine?
c. How many DOAC incidents, including those involved in concomitant prescribing?
d. How many LMWH incidents have occurred?
e. How many heparin incidents?

[13] Ong M, Magrabi F, Coiera E. Automated categorization of clinical incident reports using statistical text classification. Qual Saf Health Care 19 (2010) 1–7.

Table A: Anticoagulant medicine names grouped by medicine class

Medicine class	Anticoagulant medicines with this class (trade name)[14]
Direct Oral Anticoagulant (DOAC)	Apixaban (Eliquis)
	Dabigatran (Pradaxa)
	Rivaroxaban (Xarelto)
Heparins	Heparin [Unfractionated heparin]
	Heparinised saline
Low Molecular Weight Heparins (LMWH)	Enoxaparin (Clexane)
	Danaparoid (Orgaran)
	Dalteparin (Fragmin)
	Nadroparin (Fraxiparine)
Vitamin K antagonists	Warfarin (Coumadin and Marevan)
Factor Xa Inhibitor[15]	Fondaparinux (Arixtra)

[14] Note that not all states and territories searched for the same medicines in their incident management systems.

[15] It is acknowledged that Apixaban and Rivaroxaban have a mode of action that corresponds to classification as a Factor Xa inhibitor. However, for the purposes of reporting, these medicines have been classified as DOAC medicines.

Table B: Incident definition related to the medication management process involved (adapted from WA Health definitions)

Process	Description
Administration process	This step encompasses re-assessment of the need for the medicine, the selection of the correct medicine and appropriate preparation and administration of the medicine by a suitable skilled clinician to the correct patient on each occasion. This includes a record of administration as well.
Prescribing process	This step relates to the prescriber and their need for accurate, comprehensive, complete and up-to-date patient specific information to assess the most suitable treatment option in light of the best available evidence and the patient's treatment goal. This step also includes the record of the medicine order on the medication chart or prescription by the prescriber. The medicine order needs to be legible, unambiguous and contain enough information to support the use of the medication as intended. Where a medication history or co-morbidities dictate use of a medicine that has not been charted or recharted, these incidents are included under prescribing process. Medicine orders that do not document the administration times in the administration section of the order have been included as part of a prescribing process problem for an incomplete order.
Dispensing process	This step includes the process of dispensing the medication from a pharmacy undertaken by a pharmacist. The correct medicine should be manufactured or selected, then labelled fully and clearly, in line with legislative requirements and a record is made in the pharmacy's dispensing software.
Supply process	This step involves the distribution of medication to the ward or unit.
Storage process	This process relates to the storage of the medication and encompasses any special storage conditions related to stability of the medication or legislative requirements.
Self-administration process	This process relates to a patient self-administering a medication.
Post monitoring process	The step encompasses a suitable skilled clinician to assess the patient and the effect that the prescribed medication is having.
Documentation process	This step relates to incomplete or incorrect documentation in the medical record or the medication order/prescription.
Consumer advice and information	This process relates to the provision of information to the patient.

Table C: Incident type

Omitted dose	Illegible prescription
Incorrect dose	Supplied without prescription
Incomplete prescription	Medication not prescribed
Premature dosing	Incorrect strength
Incorrect rate of administration	Failure to administer
Duplicate dose	Contraindication
Administered when should have been withheld	Bolus dose given when not required
Incorrect patient	Blood level monitoring not actioned
Wrong formulation	Unclear labelling
Delayed dose	Unclear
Incorrect frequency	Unauthorised self medication
Incorrect dilution	Medication withheld inappropriately
Infusion stopped inappropriately	Medical assessment issue
Contraindication due to medical condition	Incorrect storage
Incorrect medication	Incorrect quantity
Duplicate therapy	Incorrect labelling
Incorrect formulation	Incorrect duration of treatment
Administered without prescription	Incorrect dose calculation
Incorrect route of administration	Incorrect documentation
Incorrect bolus dose	Incorrect abbreviation
Failure to monitor post dose	Extravasation
Estimated patient weight – not patient actual weight used to determine dosing/rate of administration	Documentation error – no dose
Contraindication due to monitoring result	Bolus not administered
Administered when order ceased	Wrong medication chart used (National Inpatient Medication Chart instead of Anticoagulant Chart)
Administered but not signed	Other

Table D: Incident causative factors

Not checking properly	Misreading
Documentation	Multiple charts active
Handover	Medication not available on ward
Lack of knowledge – clinical	Patient factor
Lack of knowledge – unfamiliar with process/protocol	Incorrect nomogram
Misinterpretation	Poor supervision
Chart filed incorrectly	Chart design issue
Non-compliance with policy	ePrescribing vs paper transfer
Lack of medication history	LASA
Not checking patient ID	Selection error
Busy/Time pressure/Reduced staff	Incorrect chart used
Confusion between brands	Equipment failure
Dilution confusion	Incorrect patient folder taken to room
Distracted/Disruption/Interruption	Lack of knowledge – patient
Miscommunication	Lack of resources
Lack of standardisation	Incorrect estimation of patient weight
Lack of VTE risk assessment	Incorrect labelling
Medical device issue	Incorrect medication in patient locker
New equipment	Lack of knowledge – unfamiliar with equipment
Storage process	Lack of experience
Used IV instead of dialysis dilution	Lack of double checker
Confusion between heparin and enoxaparin	Incorrect sampling
Forgot to administer	Incorrect pump programming
Incorrect estimation of patient weight	Incorrect preparation

Appendix 2

Anticoagulant resources – June 2020

Initiation

- Guidelines for the diagnosis and management of atrial fibrillation: National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand: Australian Clinical Guidelines for the Diagnosis and Management of Atrial Fibrillation 2018. 6.3. Stroke Prevention with Anticoagulation. Heart, Lung and Circulation (2018) 27, 1209–1266. www.heartlungcirc.org/article/S1443-9506(18)31778-5/pdf
- Safe prescribing of non-vitamin K antagonist oral anticoagulants:
    - *Clinical Guideline: Safe prescribing of new oral anticoagulants: apixaban, rivaroxaban and dabigatran*. SA Health. July 2015
    - Clinical Excellence Commission (CEC). *NOAC Guidelines – Non-vitamin K Antagonist Oral Anticoagulant*. Sydney: CEC: 2017
- Clinical Practice Guidelines for Anticoagulation therapy – The Royal Children's Hospital Melbourne: Available from: www.rch.org.au/clinicalguide/guideline_index/Anticoagulation__therapy/
- Warfarin Administration and Dosage Adjustment. The Royal Hospital for Women. South-eastern Sydney Local Health District. February 2018. Available from: www.seslhd.health.nsw.gov.au/sites/default/files/documents/warfadminanddosageadjust.pdf.

Monitoring

- Oral anticoagulants:
    - NPS MedicineWise. Oral anticoagulants: Safety checks. November 2017. Available from: https://www.nps.org.au/professionals/anticoagulants/oral-anticoagulants-safety-checks
    - Queensland Health and the Royal Flying Doctor Service. Queensland Health. 2016. *Guidelines for Warfarin Management in the Community*
- Tips for prevention and management of haemorrhagic disorder due to circulating anticoagulants: Australian Commission on Safety and Quality in Health Care (ACSQHC). Hospital-Acquired Complication 10 Medication Complications. Diagnostic Group 2: Haemorrhagic disorder due to circulating anticoagulants. Available from: www.safetyandquality.gov.au/sites/default/files/migrated/SAQ730_HAC_Factsheet_MedicalComplications_LongV2.pdf.

Transitions of care

- Non-vitamin K antagonist oral anticoagulants:
    - *Clinical Guideline: Safe prescribing of new oral anticoagulants: apixaban, rivaroxaban and dabigatran*. SA Health. July 2015
    - Clinical Excellence Commission (CEC). *NOAC Guidelines – Non-vitamin K Antagonist Oral Anticoagulant*. Sydney: CEC: 2017.

De-escalation

- Management of patients with atrial fibrillation undergoing surgical procedures: National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand: Australian Clinical Guidelines for the Diagnosis and Management of Atrial Fibrillation 2018. Brieger DA, et al. Heart, Lung and Circulation, Volume 27, Issue 10, 1209–1266. www.heartlungcirc.org/article/S1443-9506(18)31778-5/fulltext
- For patients on anticoagulants to prevent venous thromboembolism (VTE): Australian Commission on Safety and Quality in Health Care (ACSQHC). *Venous Thromboembolism Prevention Clinical Care Standard*. Sydney: ACSQHC; 2018
- Perioperative management of patients on anticoagulants: Clinical Excellence Commission (CEC). *Guidelines on Perioperative Management of Anticoagulant and Antiplatelet Agents*. Sydney: CEC; 2018.

Appendix 3

Summary of state and territory interview responses

New South Wales (July 2019)

Question	Response
What do you understand to be the biggest problems with anticoagulant management in NSW health services currently	From a 2013/14 report on anticoagulants: • Anticoagulant use around surgery considered problematic (bridging errors) • Heparin use • Not recognising or familiar with use of Non-Vitamin K antagonist Oral Anticoagulants (NOACs).
What is NSW data saying?	See above and 2013/14 summary report

What interventions have been put in place?	Since 2013/14 incident review:
	• *NOAC Guidelines – Non-vitamin K Antagonist Oral Anticoagulant* (July 2017)
	• *Guidelines on perioperative management of anticoagulant and antiplatelet agents* (December 2018)
	• IV Unfractionated Heparin Recommended Standard (December 2018)
	• Education and training resources:
	  ○ VTE risk assessment (covers off on technical and clinical aspects of VTE risk assessment)
	  ○ Safe use of Anticoagulants
	  ○ EMR interventions: VTE Risk assessment for adult admitted patients
	• At a local level LHDs have incorporated in their EMM guidance on prescribing of VTE prophylaxis (e.g. PowerPlan).

Has any data or is data being captured about the interventions that have been made?	No measures/outcomes being captured at this time due to limited resourcing
What work plans are in place? What risk mitigation strategies, what education or forms?	While support for safe anticoagulant use is ongoing, NSW will be focusing future work on opioids at this time

Question	Response
Anticoagulant work in the EMM system	For further discussion with eHealth NSW
What do you feel the Commission could be doing to assist with improving safety of anticoagulant management/use?	Assisting with measurement – e.g. National QUM Indicators for Australian Hospitals Set 1: Antithrombotic therapy
Further ideas	Australianising the 2017 Institute for Safe Medication Practices (ISMP) *Medication Safety Self Assessment (MSSA) for Antithrombotic Therapy*
Other notes	–

Victoria (August 2019)

Question	Response

What do you understand to be the biggest problems with anticoagulant management in Vic health services currently	• Difficult to pinpoint due to Victoria being so devolved
	• Suggested that the following are the most problematic:
	  ○ perioperative management
	  ○ therapeutic duplication.

What is Vic data saying?	–
What interventions have been put in place /are ongoing?	Establishment of a Melbourne Health working group and changes to the medication chart
Has any data or is data being captured about the interventions that have been made?	–

Question	Response
What work plans are in place? What risk mitigation strategies, what education or policy/protocols etc.?	• Holding regular events: for instance, repeating 2019 roundtable jointly hosted by Safer Care Victoria and Victorian Therapeutic Advisory Group (VicTAG) • Review of incident data and scoping strategies: Melbourne Health and Safer Care Victoria collaboration • Considering use of ICD-10 codes to quantify and look at costs associated with anticoagulants.
Anticoagulant work in the EMM system	–
What do you feel the Commission could be doing to assist with improving safety of anticoagulant management/use?	–
Further ideas	• Indicators for appropriateness of anticoagulant use • Development of a standardised tool to assess appropriateness.

Other notes	• Presentations on anticoagulants website from the 2019 Roundtable on Medication Safety available on the VicTAG website:
	  ○ Reducing anticoagulant-related patient harm – the way forward
	  ○ Raising the bar for improvement in VTE prevention
	• Research by a UK network of three National Health Service Trusts presented from NZ on measuring medication safety and patient harm using existing data including data on anticoagulants: A qualitative study exploring how routinely collected Medication Safety Thermometer data have been used for quality improvement purposes using case studies from three UK hospitals.

Queensland (July 2019)

Question	Response
What do you understand to be the biggest problems with anticoagulant management in Qld health services currently?	• Safe use of heparins are high on QLD Health priority list • Incident data is being utilised to answer specific questions • Anticoagulant management concerns include understanding/recognising a DOAC, duplicate therapy. Initiation of VTE prophylaxis is reported by HHS clinicians as completed reasonably well, however, documentation of VTE risk assessment has been sub-optimal on the National Standard Medication Chart (NSMC) • Other findings are believed to be consistent with findings from the national anticoagulation incident analysis. It is anticipated that improvements will occur following availability and implementation of state-wide VTE prevention resources (*Guideline for the Prevention of Venous Thromboembolism (VTE) in Adult Hospitalised Patients*; VTE risk assessment tool and VTE prevention flowchart) which can be found on the QLD Health Medication Safety webpage along with other anticoagulant-related guidelines • Perioperative management of anticoagulants is an area of difficulty for clinicians. Advice on timing of anticoagulant administration (in relation to catheter removal) is a particular topic that clinicians have requested and current QLD Health guidelines include this topic.
What is Qld data saying?	Whilst a comprehensive review of all anticoagulants incidents not completed, elements of data that have been reviewed in relation to anticoagulants are consistent with national findings.
What interventions have been put in place/are ongoing?	A digital anticoagulant group has been established by the team leading the integrated medical record (ieMR) rollout. Monthly reporting and discussion provides more detail on any incidents that are potentially related to the EMM system.
Has any data or is data being captured about the interventions that have been made?	• QLD Health uses RiskMan as the incident management system. There have been more efficient ways introduced to aggregate and review data using themes and word-search techniques • There is a plan to measure how well VTE guidelines and risk-assessment tools are being utilised. In addition, the VTE risk assessment tool in a Smart PDF format, is planned for incorporation into the integrated electronic medical record (ieMR).

Question	Response
What work plans are in place? What risk mitigation strategies, what education or policy/protocols etc.?	• The current version of the QLD Health VTE guidelines and risk assessment tool were released at the beginning of 2018. Good consensus and engagement was experienced from stakeholders in the process • Anticoagulant guidelines have been created and released for different medicines within this class at different times in history are due for review with the intent for all anticoagulant guidelines to be merged into a single web-based document. This is expected to have a two-year project timeline • Ongoing risk mitigation strategy includes review of SAC 1 incidents and RCAs at a QLD Health state-wide level to determine whether these have state-wide impacts which need to be addressed • Heparin infusion form has been in place since 2008 and is reviewed on a regular basis and as need arises • Warfarin end-of-bed guidelines have been available since 2006 and are reviewed on a regular basis, and as the need arises • Harmonisation across QLD Health of medicines/medicine groups included as part of the High-risk medicines (APINCH) list is required. Currently, there are different interpretations of what is included across QLD hospitals.
Anticoagulant work in the EMM system	• Heparin dashboards: Available for implementation if sites choose and can be used to optimise medicines use • Discharge Summary Program: This program flags any patient that has had warfarin mentioned in their medical record or medicines list. The discharge summary program will flag that this patient may or may not need to be on warfarin at discharge and allows input of information required by the clinician taking over the patient's care (usually the patient's general practitioner). Only some mandatory elements for completion are included in this program (trying not to be too burdensome for the clinicians entering the information). There is a proposal to further develop this tool by expanding the scope to include all anticoagulants not just warfarin.
What do you feel the Commission could be doing to assist with improving safety of anticoagulant management/use?	• Need to look at addressing anticoagulant safety in hospitals with and without EMM systems in place • Review of VTE prophylaxis section of the chart. Would there be benefit in this being an anticoagulation section instead? • Standard indicators in EMM systems: For example: If the indication is mandatory is the anticoagulant being used appropriately? • Look at anticoagulant stewardship.
Further ideas	–

Question	Response
Other notes	• Majority of hospitals in south-east Queensland have EMM implemented • Many small sites may continue with paper-based medication charts for the foreseeable future.

Tasmania (July 2019)

Question	Response

What do you understand to be the biggest problems with anticoagulant management in Tas health services currently	• Anticoagulation not the most problematic in terms of incident prevalence at the time of interview
	• Persistent issues related to anticoagulants include:
	  ○ VTE prophylaxis (VTE risk assessment and prescribing)
	  ○ Recognising VTE prophylaxis and use of other anticoagulant agents (duplicate therapy prescribing).

What is Tas data saying?	No recent review of anticoagulant incident data undertaken. However, a number of sources/ongoing projects point to omitted doses, duplicate therapy and wrong dose being the main issues (consistent with findings from the national incident analysis).

Question	Response
What interventions have been put in place/are ongoing?	• VTE prevention: a best practice implementation project (2016): Interventions focused toward clinicians (targeted education) and consumer engagement. Clinical champions included vascular surgeon and haematologist. Positive outcome – clinician engagement, with clinicians from different specialties agreeing on a single standard. Interventions from the project showed minimal impact. Clinicians consistently suggested electronic support could assist improvements. Integrating an electronic intervention into the existing system would be challenging and is unfunded. • The Royal Hobart Hospital has had a pharmacy resident focus their residency research activities on the duplication of anticoagulation treatment with VTE prophylaxis. The outcomes of this research are published: Jones BA, Paine MJ. Duplication of pharmacological venous thromboembolism prophylaxis or therapeutic anticoagulants with direct oral anticoagulants. Pharmacy GRIT SHPA. Volume 3, Issue 2 (Winter 2019). The project raised questions around whether the NIMC needed to be modified to adequately reflect DOACs and mitigate risks. • High risk medicines (HRM) procedures and risk mitigation strategies in place. • HRM eLearning modules to be implemented (review showed inconsistencies between module and state-based information). Preference for this education to be mandatory, however a lot of education already that clinicians must undertake (conflicts with time and clinical responsibilities). • Project looking at Tasmania's web-based incident reporting system (Safety Reporting & Learning System (SRLS), trying to understand incidents and reporting culture, as well as hospital acquired complications (HACs). Outcome showed HACs are not necessarily reflected through incidents, due to methods applied to HAC data collection as opposed to a thorough review of the HAC by a clinician.
Has any data or is data being captured about the interventions that have been made?	See above

Question	Response
What work plans are in place? What risk mitigation strategies, what education or policy/protocols etc.?	• Pharmacy Resident work on VTE prophylaxis (refer above) • Safer Med Practice Unit currently being formed including four pharmacy staff with other clinicians to join (medical and nursing) • Looking to undertake a project around duplicate therapy and VTE prescribing, based on established methods at Alfred Health in Melbourne: Partnered Pharmacist Medication Charting.
Anticoagulant work in the EMM system	–
What do you feel the Commission could be doing to assist with improving safety of anticoagulant management/use?	• Examine alternative VTE prophylaxis support models: for example, Anticoagulant stewardship programs, WA Health anticoagulants charting models • Gathering evidence to understand how anticoagulant prescribing could be included more holistically into the national standard medication chart.
Further ideas	–
Other notes	Barriers to implementation with two of three recommendations in preliminary report. In particular, electronic medication management (EMM) not applicable as Tasmania unlikely to implement EMM within the foreseeable future.

Northern Territory (July 2019)

Question	Response
What do you understand to be the biggest problems with anticoagulant management in NT health services currently	• Omissions and duplications (involving DOACs) consistent with national data. Incorrect dose is not highly reported in the NT incident management system • VTE risk assessment not available within the current electronic medication management and administration (EMMA) system • Documentation of a VTE risk assessment is poor.
What is NT data saying?	See above

<table>
<tr>
<td>What interventions have been put in place/are ongoing?</td>
<td>

Reporting functionality is currently very limited with the EMMA system. A new end-to-end system will be implemented into NT health services over the next five or so years, and reporting functionality will be included. The new system should make it possible to capture and report on omissions and duplications (if desired), once implemented. The system of reporting is meant/intended to be fairly smart, and also be able to report on a combination of patient information (e.g. if GRF<X or pt X age, and what was prescribed outside of the recommended guidelines)
Currently, the reporting system is reliant on clinicians detecting omissions manually and reporting these to the incident management system
The new systems will include an in-built VTE risk assessment (with prompts for completion). Despite documentation of the VTE risk assessment being poor, collection of QUM indicator data suggests that patients who require VTE prophylaxis are having it prescribed and it is prescribed at the correct dose
An alert was introduced in 2009 into the EMMA system to fire when potential anticoagulant prescribing duplication was occurring. This is an ‘information only’ alert that fires if either enoxaparin or heparin are already charted, and a clinician is trying to prescribe heparin or enoxaparin in addition to the existing orders
Drug-interaction alerts have been included in EMMA since 2016. These drug interaction alerts can only be over-ridden when a prescriber enters a comment. Alerts are fired when prescribers try to order any of the combinations shown below:
<table>
<tr><th></th><th>enoxaparin</th><th>heparin</th><th>warfarin</th></tr>
<tr><td>apixaban</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>dabigatran</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>rivaroxaban</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
</table>

A link to the HRM Register (see below) is included in these alerts. An NT-wide initiative
To address problems with duplicate therapy, face-to-face education sessions (with medical and nursing staff) have been implemented. Information about duplicate therapy was also circulated in the NT health service newsletters. Top-end and Central included similar key messages:

Did you know these are DOACs? Rivaroxaban and apixaban are anticoagulants. Use these with caution with other anticoagulants. Timely administration of these medicines is important and they should not be omitted (arrangements are in place to ensure stock can be accessed for use after hours)

</td>
</tr>
</table>

Question	Response
	• Policy guideline centre is NT-wide and includes an HRM register which refers to the APINCH classification and specific medicines within these classification groups. Embedded hyperlinks to various guidelines and procedures for heparin, dabigatran, enoxaparin, rivaroxaban and warfarin are included • Anticoagulation and antiplatelet administration guidelines have been updated to include rivaroxaban. For example, guidelines on perioperative management of anticoagulants which are NT-wide • VTE Prevention in Adult Patient Guidelines were reported to be under-development and include information on specific DOACs.
Has any data or is data being captured about the interventions that have been made?	Alerts have been implemented into EMMA for therapeutic duplication. Data is not available on how many alerts are being triggered. However, there had been a recent reduction in incident reports involving duplicate anticoagulant therapy.
What work plans are in place? What risk mitigation strategies, what education or policy/protocols etc.?	Tools will be built into the new EMM system to: • Support documentation of VTE risk assessment (including prompts) • Capture administration data (as described above) • Enable reporting on specific information about DOACs.
Anticoagulant work in the EMM system	See above
What do you feel the Commission could be doing to assist with improving safety of anticoagulant management/use?	• HRM eLearning module on perioperative management of anticoagulants would be useful and would reduce requirement for local education • Guidance for EMM and EMM SAT need to include in functionality specifications for VTE risk assessment and documentation. Given that VTE risk assessment is not a medication order, the assessment tool more likely needs to be included within EMR system functionality rather than EMM • Measurement: advising on indicators for anticoagulants • Difficult for NT to justify an anticoagulant stewardship program. NT health services do well where patients need dose adjustments and prescribing of appropriate VTE prophylaxis. The main problem is primarily with the documentation of the VTE risk assessment.
Further ideas	–
Other notes	Apixaban dosing: requires manual data entry Rivaroxaban: a quick-list is available that includes dose options.

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au