safety IN PRACTICE

Community Pharmacy Anticoagulants 2020-21

Every patient, every time

AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

Waitematā District Health Board
Best Care for Everyone

Contents

Why choose anticoagulants for Safety in Practice?

A key aim of the Safety in Practice programme is to work with Primary Health Care teams to reduce preventable patient harm from the care they receive. Adverse drug events (ADEs) are major causes of patient morbidity and mortality, and a source of significant costs for both organisations and patients.[1]

In New Zealand hospitals warfarin is amongst the top 10 medicines causing harm, predominantly due to bleeding.[1] Anticoagulants and antiplatelet agents are combined as a class, they are the second highest group implicated as causing patient harm by severity, with opioids being the highest.[1] Based on exploratory analysis into administrative data for 9,000 local hospital admissions, 9% of all potential ADEs detected were anticoagulant-related.[2]

This clinical module focuses on the safe use of warfarin, dabigatran and rivaroxaban including:

- Effective patient education
- Patient understanding of alarm symptoms
- Consistent documentation of education and interventions.

General practice teams are working on a module for warfarin management. During learning sessions you will be encouraged to work together with this group to share learning and experiences.

Pharmacist Scope of Practice

According to The Pharmacy Council of New Zealand, "Pharmacists ensure safe and quality use of medicines and optimise health outcomes by contributing to patient assessment and to the selection, prescribing, monitoring and evaluation of medicine therapy".[4]
Optimal medicines management and patient education are core responsibilities of pharmacy practice. It is best practice to document all interventions and recommendations made to evidence work done. This is one way pharmacists can demonstrate the work that they do, in line with Pharmacy Council of New Zealand Competence Standard O1.4.7. The process measures are evidence that best practice activities have been performed.

"Competence Standard O1.4.7
Supports and provides continuity of care with accurate and timely documentation of clinical and professional interventions and recommendations, using agreed handover protocols."

Equity

We all have a role to play in reducing inequity in health in New Zealand. Particular groups are consistently disadvantaged in regard to health, and these inequities affect us all.[5] Health inequities are avoidable, unnecessary and unjust differences in the health of groups of people.[5] This may be between socioeconomic groups, ethnic groups, different geographical regions, levels of ability or disability, and between males and females. Research indicates the poorer you are, the worse your health will be.[6] Inequalities experienced in early life influence people in later life, and inequalities take a cumulative toll on an individual's health over their lifetime.[5]

To promote equity in health, we need to understand the inequity, design interventions to reduce them, review and refine the intervention and evaluate their impact. It is important to minimise the impact of disability and illness on socioeconomic position and access to the determinants of health.[6]

In particular as health providers, we need to emphasise the power of joint decision making and trust with patients, it is important to prioritise time to listen to their health issues in their words, ideally with protected time in consultation room, involving their whānau if preferred by them. It is important they have an understanding of the treatment options, the risks involved and where to go for help.

The most effective conversations are based on a mutual trust and understanding, giving patients confidence they are in control and empowered to make informed decisions. There are significantly increased risks of avoidable medicine related harm in Māori and Pasifika, it is important we understand this and take special care to ensure optimal health outcomes for all.

Previous teams' experiences

Benefits	Challenges
•Confidence within the team that patient education is taking place •Good conversations with patients by all staff members •Improved concordance and understanding of medication •Have a better relationship with the GPs and practice nurses in the area	•Time commitment required •Frequent reinforcement needed to effect change •Took time to effect change •It is dificult to talk to everyone in detail during busy times •Contacting patients afterwards and thinking about how to best approach the conversation.

1.1 Getting your team ready for Safety in Practice

- Identify responsible leads to drive the programme in your pharmacy
- Organise a staff meeting to introduce the programme; it is critical to have the whole team engaged. Safety in Practice works when all team members take part and make their processes safer for all of your patients.
- Develop a Standard Operating Procedure (SOP) document for locums and new staff. Think about how you can all ensure new team members are up to speed on what you do and why. This way your results continue to show improvement when regular staff are not there.
- Decide on preferred patient resources with your team; make them readily available.
- Think about how you could make this process work for over-the-counter codeine products
- Decide how to document interventions, discussions and education; agree on this as a team.
- Decide who will be responsible for completing the data collection sheet and submitting data. Share this task so skills are developed across team members.
- Engage with your GPs, discuss the programme and the resources you will be using. If they have any questions you can refer them to the Safety in Practice website.
- Display posters in the pharmacy so patients are aware that you are a 'Safety in Practice' pharmacy. Posters will be available at the learning sessions, or you can request one from info@safetyinpractice.co.nz

1.2 Aim

All patients receiving anticoagulants will receive education about the medicine at time of medicine collection by June 2021.

1.3 Measures & rationale

This module comprises of process and outcome measures. The **process measures** are evidence the activity has taken place. This information needs to be recorded in the patient file (Toniq or RxOne).
The **patient outcome measures** assess whether the patient has understood and can recall correctly the information provided.
To assess your processes, we require data from a random sample of 10 patients each month. We do not require NHI or patient identifiable data so please ensure it is anonymous.

- Please see Table 1 for further guidance regarding these measures
- The questions relate to the patient or carer as appropriate
- The target population for data collection is patients aged 18 years and over
- For prescriptions with repeats, data collection will focus on initial dispensing encounter
- Medicine refers to either warfarin, dabigatran or rivaroxaban

For this module to be successful, it is best to start by getting to know your GPs and informing them that you are part of the Safety in Practice programme. Let them know the measures you are working on with this module, and ask them how they would prefer to be contacted if you have any queries.

Table 1: Measures and rationale

Is there documented evidence that the patient has received the following care when they had their anticoagulant dispensed (original dispensing).

	Process measure	Rationale
1.	**Is there documented evidence there was a discussion about how to use the medicine?** Yes ☐ No ☐	• Improved patient knowledge and understanding of the use of warfarin improves anticoagulation control. [4,5] Non-adherence of anticoagulant medicines appears more prevalent among those less well informed about their condition and medicines. The proportion of adherent patients is higher when they receive appropriate education and monitoring.[6]
2.	**Is there documented evidence there was a discussion about what to do if they miss a dose?** Yes ☐ No ☐	**Warfarin information:** If you forget to take a dose, take the missed dose if you remember on the same day. If not, skip the dose and carry on as normal. Do not take two doses of warfarin on the same day. Record your missed dose in your anticoagulant booklet and tell your doctor on your next visit. www.healthnavigator.org.nz/medicines/w/warfarin/ **Dabigatran information:** If you forget to take a dose, and your next dose is due in less than 6 hours, skip the missed dose and take your next dose as normal. If there are more than 6 hours until your next dose, take the missed dose as soon as you remember. DO NOT take double the dose of dabigatran - this increase your risk of bleeding. www.healthnavigator.org.nz/medicines/d/dabigatran/ www.saferx.co.nz/dabigatran-patient-guide.pdf **Rivaroxaban information:** **If you're taking rivaroxaban ONCE A DAY** If you miss a dose, take it as soon as you remember on the same day. Do not take double the dose – this increases your risk of bleeding. **If you're taking rivaroxaban 15 mg TWO times A DAY** If you forget to take a dose you can take two 15 mg tablets at the same time to get a total dose of 30 mg in one day. Continue your regular dose, morning and evening, the next day. www.healthnavigator.org.nz/media/5057/rivaroxaban-factsheet-july-2018-final.pdf www.saferx.co.nz/rivaroxaban.pdf www.healthnavigator.org.nz/medicines/r/rivaroxaban/

3.	**Is there documented evidence there was a discussion about possible side effects?** Yes ☐ No ☐	With **warfarin**, bleeding can still occur when the INR is between 2 and 3, but is more likely with higher INRs. **Note:** Some medicines and supplements can increase bleeding risk without increasing INR. Illness can also affect INR, and an adjustment in warfarin dosing may be required for patients who develop diarrhoea, fever, heart failure, hyper or hypothyroidism or liver disease. Tell patients about the following symptoms to report immediately to a health care professional if they are taking **warfarin, dabigatran or rivaroxaban**. These could indicate **over** anti-coagulation: • Red or brown urine • Red or black stools • Severe headache • Unusual weakness • Excessive menstrual bleeding • Prolonged bleeding from gums or nose • Dizziness, trouble breathing or chest pain • Unusual pain, swelling or bruising • Dark, purplish or mottled fingers or toes • Vomiting or coughing up blood **Important:** *Refer any patient with symptoms of bleeding to their GP or directly to A&E.* Symptoms of **under** anti-coagulation (ie from non-compliance, or a dose that is too low) can also signal a life threatening situation: • Bluish toes or fingers • Chest pain or severe back pain • Blurred vision • Symptoms of DVT .

4.	**Is there documented evidence there was a discussion about interactions with other medicines supplements, food and alcohol?** Yes ☐ No ☐	Inform patients about other medicines and products that can interact with oral anticoagulants and increase the bleeding risk, these include SSRIs, aspirin and NSAIDs. Refer to the New Zealand Formulary for a complete list. www.nzf.org.nz **Warfarin** For patients taking warfarin, advise them to check with their doctor or pharmacist before making major dietary changes, before starting or stopping any other medicines especially antibiotics, OTC, herbal, or complementary medicines. A consistent and balanced diet is recommended to maintain a stable INR. Excessive alcohol or large quantities of cranberry-based products can increase the risk of bleeding. Supplements including fish oil, gingko, garlic and ginger can also interact with warfarin. Refer to Auckland Regional Health Pathways information the warfarin red book, the Waitemata DHB warfarin counselling checklist and interactions list (see reference section), and the resources on www.saferx.co.nz and www.healthnavigator.org.nz **Dabigatran** The combination of amiodarone or verapamil with dabigatran increases the amount of dabigatran absorbed, increasing the risk of bleeding. **Rivaroxaban** Medicines that can increase rivaroxaban plasma concentrations include itraconazole and ritonavir. The anticoagulant effect of rivaroxaban may be decreased by St John's Wort and some anticonvulsants including phenytoin and carbamazepine.
5.	**Is there documented evidence the patient was offered written information about their medicine?** Yes ☐ No ☐	"Offered written information" means: The patient/carer has been actively asked if they would like to receive written information. Examples of patient information: **Warfarin** • Patient-held anticoagulation record *'Red Books'* are free via Medidata. These have patient information about warfarin and space to document INR levels and dose. Encourage patients to take them to appointments. • Contact Medidata on 09 488 4271 or email

		gmouldey@medidata.co.nz with the name of your pharmacy, your delivery address and the number of '*Red Books'* you require. • SafeRx® warfarin guides available in English, Chinese, Tongan, Samoan, Niuean, Korean www.saferx.co.nz/patient-guides • Health Navigator www.healthnavigator.org.nz/medicines/w/warfarin/ **Dabigatran** • SafeRx® dabigatran patient guide www.saferx.co.nz/dabigatran-patient-guide.pdf **Rivaroxaban** • PHARMAC and Health Navigator leaflet www.healthnavigator.org.nz/media/5057/rivaroxaban-factsheet-july-2018-final.pdf

Outcome Measures

From the 10 random patients selected, ask the following questions. This can be via follow up phone call or when they return for a repeat. Use open questions and listen carefully to their answers.

If you are unable to locate a patient after 2 attempts, document as N/A in the spreadsheet and note this in the comments column.

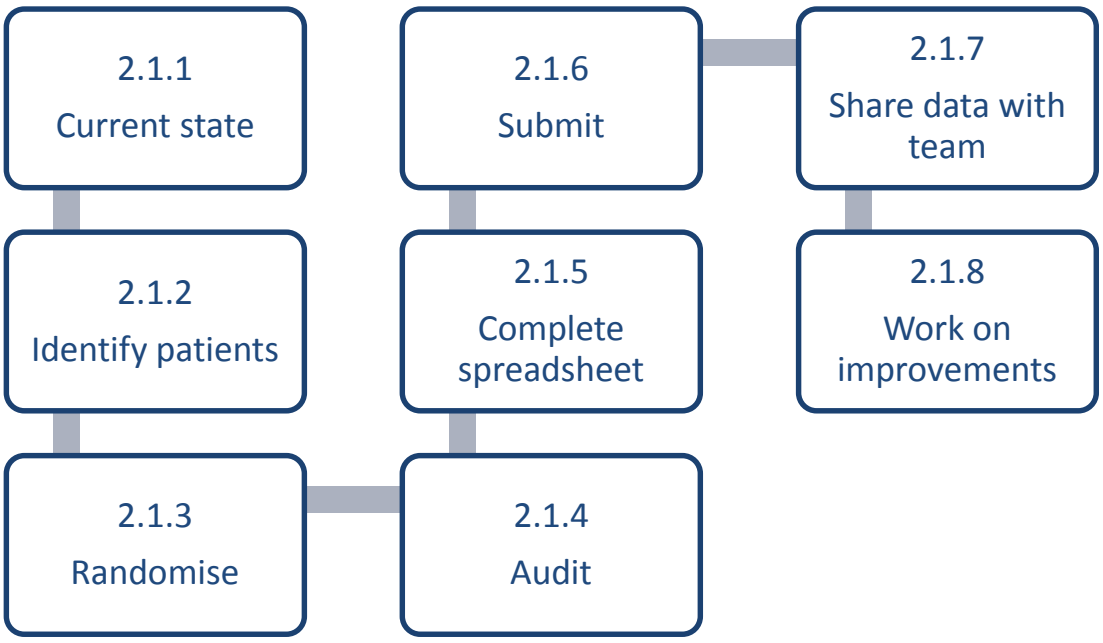
6.	**Was the patient able to correctly describe (dose and frequency) how to take their medicine?** Yes ☐ No ☐ N/A ☐	***'Tell me, how do you usually take your warfarin/dabigatran/rivaroxaban?'*** Answer guidance - warfarin: • Yes – if the patient knows to take it once daily, ideally at the same time each day. • No – if they couldn't explain how to take warfarin Answer guidance - dabigatran: • Yes – if the patient knows to take it twice daily (for AF), or once daily for VTE prevention, ideally at the same time each day. • No – if they couldn't explain how to take dabigatran Answer guidance – rivaroxaban: • Yes – if the patient knows to take it once daily for AF, or to prevent clots post-operatively. If they are taking it to treat blood clots, they will need to take it twice daily for 3 weeks, then once daily. • No – if they couldn't explain how to take rivaroxaban • N/A – if you could not get hold of the patient

7.	**Was the patient able to identify a possible side effect of their medicine?** Yes ☐ No ☐ N/A ☐	***'Do you know any side effects that might happen?'*** This is to find out if the education provided was effective. Refer to Question 3 above. Answer guidance: • Yes - if they could identify a possible side effect • No - if they couldn't name any side effects • N/A – if you could not get hold of the patient

2.0 Instructions

When you receive a script for warfarin, dabigatran or rivaroxaban, go through the Process Measures for “Every patient, every time”.
Document the information in the patient file e.g. in Toniq as an intervention or in RxOne as an event audit, so it can be found easily. To upload a checklist onto Toniq, there is a guide in the resources section of your clinical module on the website here. If you are using RxOne, the checklists have been incorporated for you.

2.1 Monthly data collection and submission



2.1.1 Current state

To assess your processes you will collect data from 10 *random* patients every month. As a team, you will then reflect on your results, look for opportunities for improvement and use PDSA cycles (Plan, Do, Study, Act)
Your first set of data (baseline data) is relating to the month of August and is due on September 10th.
Note: we expect low scores for the baseline, or 'Current State' August data.

2.1.2 Identify patients

Run a report on Toniq or RxOne for all of the relevant medicines dispensed during the month.
(Refer to www.safetyinpractice.co.nz for detailed instructions on how to generate a report)

2.1.3 Randomize

From the report select a **random sample of 10 patients** using an online random number generator.
Note the SiP programme does not endorse any advertising that comes with these online tools.

2.1.4 Audit

For the 10 **randomised** patients, find **documented** evidence that the Process Measures occurred and record responses into the spreadsheet.

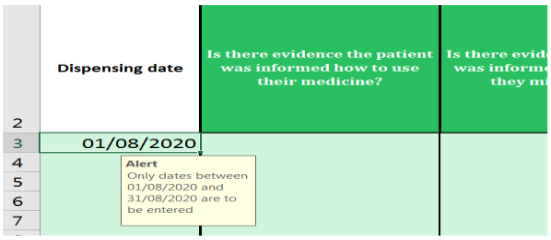
Contact the 10 patients and go through the Outcome Measures with them. Record their responses into the spreadsheet. If you are unable to locate a patient after 2 attempts, select NA and note this in the comments column on the spreadsheet.

> Advise patients you may contact them to ask two questions because you are taking part in Safety in Practice. Let them know this is to check how you and the team are working; it is not to test them.
>
> Having this information scripted may help e.g. *"We are now providing a follow-up service for people who are taking anticoagulant medicines. We select 10 patients each month and give them a quick phone call about their medicine. This is to check how we as a pharmacy team are working; it is not to test you"*

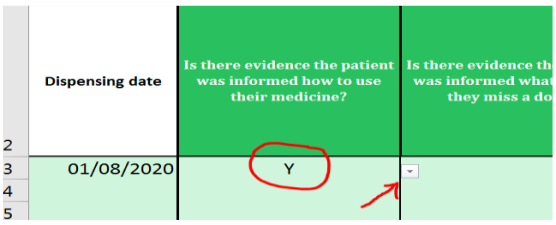
2.1.5 Complete the spreadsheet

> Tip: Your first set of data (baseline data) is relating to the month of August so this is due on September 10th.
> ***Please note: we expect low scores for the baseline August 2020 data, prior to the Safety in Practice programme beginning***

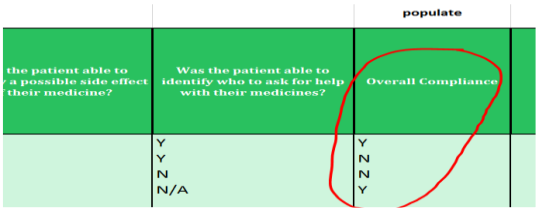
Download the spread sheet for your module in the Resources section of www.safetyinpractice.co.nz



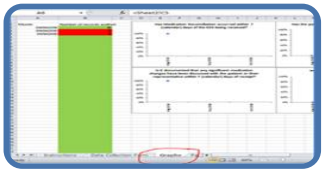
Record the date of dispensing in a DD/MM/YY format in the left column. (Alert boxes in yellow will guide you). For your first data from dispensings in August (reported in September) this is 1/8/20



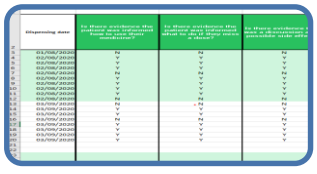
Mark Y, N or N/A by clicking on the dropdown menu, against for each measure and each patient according to your findings in the previous section.



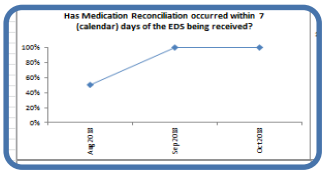
The final measure "Overall compliance" will auto-populate.



Graphs will be automatically generated in the next tab in the spread sheet.



Next month, add your data to the same spread sheet.



This means you can track your progress over time.

2.1.6 Submit

Submit your data on the 10th of each month to audit@safetyinpractice.co.nz

Tip: Please ensure all data sent to Safety in Practice in anonymised

2.1.7 Share data with your team

Safety in Practice works when all team members take part. Make the data available for everyone to see. Print the graphs and put them up in the tea room so the whole team can see the progress being made and have the opportunity to make suggestions on how to improve.

2.1.8 Work on improvements

As a team, look for opportunities for improvement and use PDSA cycles (Plan, Do, Study, Act). Refer to the Quality Improvement Workbook for other quality improvement tools.

2.2 Change idea examples

The following ideas have been tested and implemented by previous teams:

General	• Discuss results of baseline data collection at a team meeting and include SiP as a regular agenda item at team meetings • Arrange education session for pharmacy team about anticoagulants and patient education • Get to know the local GP teams and let them know you are part of the Safety in Practice programme.
Clinical processes	• As a team, identify barriers that will prevent you from providing education to patients and look for ways of addressing them
Documentation	• Use measures templates in Toniq and RxOne
Discussion with patient	• Create prompt card for education points • Optimise use of Self Care Cards • Utilise SafeRx® patient information leaflets • Arrange education session for pharmacy team about atrial fibrillation and thrombosis • Provide information to patients/carers about their reason for being on an oral anticoagulant eg information about atrial fibrillation, or thrombosis. See www.healthnavigator.org.nz for resources • Advise patients that you are doing random follow-ups as part of your new service and they may be contacted and asked two short questions. Let them know this is about checking how you and the team are working, not to test them.

Resources

3.1 Contacts

- Questions, feedback or general enquiries: info@safetyinpractice.co.nz
- Submitting data: audit@safetyinpractice.co.nz
- Website: www.safetyinpractice.co.nz

3.2 Resources

General

- BPAC article: An update on antithrombotic medicines www.bpac.org.nz/BPJ/2015/April/antithrombotic.aspx
- BPAC article: The safe and effective use of dabigatran and warfarin in primary care www.bpac.org.nz/2017/anticoagulants.aspx
- Health Pathways information about Atrial Fibrillation (includes patient information) https://aucklandregion.healthpathways.org.nz/index.htm?18972.htm
- Health Navigator www.healthnavigator.org.nz/medicines/a/anticoagulants/

Warfarin

- Pharmac Online Resources – www.pharmaconline.co.nz "Starting on Warfarin" leaflet and DVD.
- Health Pathways information https://aucklandregion.healthpathways.org.nz/index.htm?18972.htm
- Waitemata DHB – Warfarin Counselling Checklist and List of Interactions https://aucklandregion.healthpathways.org.nz/Resources/PWarfarin-CounsellingChecklistListofInteractionsMay13.pdf
- BPAC Guidelines: INR for Monitoring Warfarin Treatment www.bpac.org.nz/BT/2010/November/inr.aspx
- New Zealand Formulary: Warfarin www.nzf.org.nz/nzf_1493
- SafeRx® leaflets. "Warfarin: What you need to know" leaflets are available at www.saferx.co.nz in English, Chinese, Korean, Niuean, Samoan, and Tongan
- Anticoagulant Treatment Booklet "Red Book" – available free from Medidata on 09 488 4271 or email gmouldey@medidata.co.nz with the name of your pharmacy, your address and number you require.
- Health navigator www.healthnavigator.org.nz/medicines/w/warfarin/

Dabigatran

- Health Pathways information https://aucklandregion.healthpathways.org.nz/index.htm?18972.htm
- New Zealand Formulary: Dabigatran www.nzf.org.nz/nzf_1504
- SafeRx® bulletin www.saferx.co.nz/dabigatran.pdf
- Safe Rx® patient guide www.saferx.co.nz/dabigatran-patient-guide.pdf
- Health Navigator www.healthnavigator.org.nz/medicines/d/dabigatran/
- App to manage patients taking dabaigatran and rivaroxaban https://itunes.apple.com/nz/developer/healthobs-ltd/id498413740

Rivaroxaban

- New Zealand Formulary: Rivaroxaban https://nzf.org.nz/nzf_1508
- SafeRx® bulletin www.saferx.co.nz/rivaroxaban.pdf
- Health Navigator www.healthnavigator.org.nz/medicines/r/rivaroxaban/
- Pharmac information: www.pharmac.govt.nz/medicines/my-medicine-has-changed/rivaroxaban/
- BPAC article: Rivaroxaban, a fully subsidised anticoagulant medicine https://bpac.org.nz/2018/rivaroxaban.aspx
- App to manage patients taking dabaigatran and rivaroxaban https://itunes.apple.com/nz/developer/healthobs-ltd/id498413740

3.3 References

1. Robb, G, Loe E, Maharaj A et al. Medication-related patient harm in New Zealand hospitals. New Zealand Medical Journal 2017;130(1460):21-32 www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2017/vol-130-no-1460-11-august-2017/7328 (Accessed 06-05-19)
2. Ng, J (2017), Personal communication: Potential Adverse Drug Events identified from administrative data. Auckland, Institute for Improvement and Innovation, Waitemata District Health Board.
3. Pharmacy Council of New Zealand. Scope of Practice. http://www.pharmacycouncil.org.nz/Pharmacists-wanting-to-register-in-New-Zealand/Qualifications-and-training/Scopes-of-Practice (Accessed 06-05-19)
4. Ministry of Health, Reducing Inequalities in Health. 2002, Ministry of Health: Wellington. www.health.govt.nz/publication/reducing-inequalities-health (Accessed 06-05-19)
5. Signal L, Martin J, Cram F, Robson B. The Health Equity Assessment Tool (HEAT): A user's guide. 2008. Wellington, Ministry of Health. ISBN 978-0-478-31747-3 www.health.govt.nz/system/files/documents/publications/health-equity-assessment-tool-guide.pdf (Accessed 06-05-19)
6. Tang EO, Lai CS, Lee KK, Wong RS, Cheng G, Chan TY. Relationship between patients' warfarin knowledge and anticoagulation control. Ann Pharmacother. 2003 Jan; 37(1):34-9.

Appendix 1: Anticoagulant checklist

Process measures

1. **Is there documented evidence there was a discussion about how to use the medicine?**

   Yes ☐ No ☐

2. **Is there documented evidence there was a discussion about what to do if they miss a dose?**

   Yes ☐ No ☐

3. **Is there documented evidence there was a discussion about possible side effects?**

   Yes ☐ No ☐

Symptoms of over-anticoagulation *(e.g. excessive bruising, epistaxis, bleeding gums, severe headache, haematuria, haemoptysis, melena, excessive menstrual bleeding, etc)*
Symptoms of under-anticoagulation *(bluish toes/fingers, chest/severe back pain, blurred vision or symptoms of DVT etc) may signal a life threatening situation.*

Important: Refer any patient with any presenting symptom(s) to their GP or directly to A&E; especially bleeding or unexplained bruising.

4. **Is there documented evidence there was a discussion about interactions with other medicines (prescription, OTC and complementary), supplements, food and alcohol?**

   Yes ☐ No ☐

5. **Is there documented evidence the patient was offered written information about their medicine?**

   Yes ☐ No ☐

Patient outcome measures

6. **Was the patient able to correctly describe (dose/frequency) how to take their medicine?**

   Yes ☐ No ☐ N/A ☐

7. **Was the patient able to identify a possible side effect of their medicine?**

   Yes ☐ No ☐ N/A ☐