



# Community Pharmacy Oral Anticoagulant Safety Audit

This audit has been developed with help and support from the following organisations:

- Community Pharmacy Patient Safety Group
- PharmOutcomes
- Pharmaceutical Services Negotiating Committee
- Day Lewis Pharmacy
- NHS Improvement



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## Community Pharmacy Oral Anticoagulant Safety Audit

### Introduction

Anticoagulants are high risk medicines; they have a heightened risk of causing significant harm when used in error<sup>1</sup>. This class of medicines is frequently identified as a cause of preventable harm and admission to hospital<sup>2</sup>. Ten years ago, the National Patient Safety Agency (now NHS Improvement) issued a patient safety alert with actions to improve anticoagulant safety which included providing specific patient information, regular blood monitoring and checking drug interactions<sup>2</sup>. Since then, new non-vitamin K antagonist oral anticoagulants have come into widespread use. Although the principals of the 2007 alert still apply, some aspects, such as regular International Normalised Ratio (INR) monitoring and dietary consideration, are not relevant for the newer medicines.

Warfarin, the main traditional oral anticoagulant, is widely known to health professionals, but newer agents (apixaban, dabigatran, edoxaban and rivaroxaban) may not be recognised as anticoagulants and this has contributed to various medication errors<sup>3</sup>. Reported errors include inappropriate continuation or discontinuation of anticoagulant therapy, inadvertent co-prescribing with other drugs which increase the risk of bleeding (such as non-steroidal anti-inflammatory drugs and antiplatelets), and concomitant prescribing with other anticoagulants (such as heparin or warfarin).

The safety alert advised that patients on anticoagulant therapy should always carry a standard yellow credit card sized alert card to inform health and social care practitioners that they are taking an anticoagulant. The newer anticoagulants include product specific alert cards but the format and colours are not in line with the standard card and may not be so readily identified by practitioners. NICE has highlighted that information and awareness are essential in ensuring safe and effective use of anticoagulants.

A fundamental issue with all patient held information is patient understanding and uptake. Many studies report utilisation of patient held medical records by patients is poor<sup>4</sup>. In 2013, Pharmacy Voice conducted a large audit of patients prescribed lithium, warfarin and methotrexate, all medicines where patient record books are advisable on safety grounds. However, they reported that patients frequently did not carry their medicine record books when attending the pharmacy<sup>5</sup>. Similarly a warfarin audit in West Sussex in 2009 found that access to the yellow booklet or other written dosing information in pharmacies was often difficult<sup>6</sup>.

The key drivers for this audit are:

- The recent rapid widespread adoption of non-vitamin K oral anticoagulants, alongside the continued use of vitamin K antagonists, has significant implications for patient safety
- Update on current insight from primary care on the use of anticoagulant alert cards and record books to ensure safety

### Aims

- To determine patients' awareness of key information about their anticoagulant medicine
- To audit current use of anticoagulant alert cards
- To audit compliance with national monitoring requirements for vitamin K antagonists
- To inform a national update of patient held oral anticoagulant information and alert cards

## Audit time frame

Under the NHS regulations, community pharmacies are expected to complete two clinical audits per year which should take up to 5 days work in total. This includes developing the audit, data collection, analysing the data and suggesting improvements.

- To collect a useful sample for this audit it is suggested that data is collected over approximately 2 weeks and includes a minimum of 15 patients.
- You need to speak directly to at least 10 of the patients to complete the audit

## Audit sample

Population - All patients presenting a prescription for an oral anticoagulant ie Vitamin K antagonists, Factor Xa Inhibitors or Thrombin inhibitors

Warfarin	Acenocoumarol	Phenindione	
Dabigatran	Apixaban	Rivaroxaban	Edoxaban

It is recommended that where possible data is entered directly onto PharmOutcomes. However, a paper version of the data collection tool is available on p5-8 if required.

## Audit standards

*All patients prescribed any oral anticoagulant*

- All patients are aware they are taking an anticoagulant medicine ie *a medicine to thin the blood/ prevent blood clots* (100%)
- All patients have an anticoagulant alert card (100%)
- All patients are aware they need to check with a doctor or pharmacist before taking over-the-counter medicines or herbal products (100%)

*All patients prescribed Vitamin K antagonists (Warfarin, Acenocoumarol, Phenindione)*

- INR monitoring within the last 12 weeks is confirmed for all patients (100%)

## Alert cards

Community pharmacies can obtain supplies of the standard yellow anticoagulant alert card via the Primary Care Support England website (PCSE) at [pcse.england.nhs.uk/pharmacies](http://pcse.england.nhs.uk/pharmacies) (also used to order EPS tokens etc); order code Oral Anticoagulant Therapy Alert Card ('OATALERTCARD'). Patients prescribed the newer non-vitamin K antagonists should carry an alert card to show health and social care practitioners involved in their care. The NICE Key Therapeutic Topic Advice indicates that this may be the card provided by the manufacturer or a generic card<sup>3</sup>. South London have adopted a standardised approach where all patients are issued with the traditional yellow card; you may want to confirm any similar local policy with local CCG or hospital pharmacy teams.

## QUICK GUIDE

**What's the point?** To make sure people taking anticoagulants know that the medicines affect blood clotting and to check on relevant safety issues. NHS advice on safe anticoagulant therapy is more than 10 years old, and a number of new types of anticoagulant are now in common use in primary care. Whilst the new agents do not require INR monitoring, errors such as inadvertent co-prescribing with other medicines which can also cause bleeding have been reported to cause potentially avoidable harm.

### Include all patients prescribed these medicines

Acenocoumarol  
Apixaban  
Dabigatran  
Edoxaban  
Phenindione  
Rivaroxaban  
Warfarin

**Can I use this audit to meet contractual requirements for clinical audit?** Yes and collecting data on the PharmOutcomes system will help document the national contribution made by community pharmacy to patient safety.

A paper data collection form is provided on p5-8 as some people prefer to use paper forms and then enter data on PharmOutcomes later. You will need to print at least 15 copies of the form.

### When talking to patients for this audit, what do I need to find out?

Do they know that the medicine is an anticoagulant? ie *thins blood to prevent clots*

Do they know to check with you or the doctor before taking over-the-counter medicines?

Do they have an anticoagulant alert card and where is it?

Have they been given other information about their anticoagulant such as the Yellow Book?  
(*not the manufacturer's PIL*)

Do they find the alert card and other information useful?

**Why ask patients what they think of anticoagulant alert cards?** Much of the audit concerns actions required by the patient safety alert on making anticoagulant therapy safer. However, nationally available patient materials are currently being reviewed so this extra information will help inform that process.

DATA COLLECTION FORM (complete 1 per patient) **Circle choices where necessary.**  
Please familiarise yourself with the questions; some cannot be completed from the prescription or pharmacy records. The form has 4 pages; this is Page 1 of 4

## Section 1 All patients

### Patient information

1. Date: 2. Patient Name:  
3. Date of Birth: 4. Gender:  
5. Postcode:  
6. Is the patient a care home resident?    Yes    No    Not known

### Prescribed medicines

7. Name of anticoagulant:  
8. Dose in mg:                      or 'As Directed' or 'Dose not consistent eg alternate day dosing'  
9. Number of doses per day:  
10. Is the anticoagulant supplied in a monitored dosage system/compliance aid?  
    No      Yes one drug per blister      Yes multiple drugs per blister  
11a. Is the patient taking more than one anticoagulant? ie more than one of the medicines included in this audit      Yes      No  
11b. Is the patient taking any other medicines that might cause bleeding?  
*Consider NSAIDs, antiplatelets, SSRIs, high dose steroids*

Circle ALL that apply:

Ibuprofen	Naproxen	Diclofenac	Celecoxib
Aspirin (antiplatelet - low dose)	Aspirin (daily dose over 300mg)	Clopidogrel	Ticagrelor
Prasugrel	Dipyridamole	Prednisolone	
Citalopram	Sertraline	Fluoxetine	
Other (please specify):			

**11c.** Is the patient taking a proton pump inhibitor or H<sub>2</sub> receptor antagonist?    **Yes**    **No**

**12.** Which category best describes how the audit was completed for this patient?

Conversation with the patient in the pharmacy - Go to Section 2

Conversation with the patient by telephone - Go to Section 2

Patient's representative in pharmacy, patient not contacted - Go to Section 3 or Section 4

Medicine delivered by pharmacy, patient not contacted - Go to Section 3 or Section 4

## **Section 2 – Patient feedback (only complete this section if you were able to speak to the patient)**

**13.** Was the patient already aware that they are taking an anticoagulant? ie a medicine to prevent blood clots?

**Yes**                      **No**

**14.** Were they already aware of the need to check with the doctor or pharmacist before taking over-the-counter medicines or herbal products?

**Yes**                      **No**

**15.** Did they have a traditional yellow anticoagulant alert card like this?

*Yes, card seen by pharmacy staff*

*Yes, verbal confirmation that they have this card*

*No card or unaware of card*

*Not known/Not reported*



**Anticoagulant Alert Card**

This patient is taking anticoagulant therapy  
This card should be carried at all times and shown to healthcare professionals

Name of patient: A N Other  
Address: 1 A Street, South London  
Postcode: SE1 2AB Telephone: 07123 456 789  
Name of next of kin: B C Other Tel: 07987 654 321  
Hospital number: 100100 NHS Number: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

**Details of anticoagulant therapy:**

Name of anticoagulant: Rivaroxaban 20mg daily  
Indication for treatment: Atrial Fibrillation  
Therapeutic range (IMV): Not required for this drug  
Treatment started: 09/08/2016 Duration of treatment: Indefinite  
Name and address of anticoagulant clinic: Name of prescriber or organisation  
Telephone number of clinic: Contact details of the above

**16.** Did they have any other anticoagulant alert card?

**Yes, manufacturer's card**

**Yes, other card**

**No**

**Not known/Not reported**

17. On a scale from 1 'not useful' to 5 'very useful' – how useful do they think alert cards are?  
1      2      3      4      5      Not known/Not reported

Any comments from patient about anticoagulant alert cards?

18. Do they have any other information about anticoagulant therapy (not including the manufacturer's PIL), such as the 'yellow book'?

Yes, yellow book    Yes, other information    No    Not known/Not reported

19. Any comments from patient about other anticoagulant information?

20. Did you issue the patient with a traditional yellow anticoagulant alert card while doing this audit?  
Yes                      No

Go to Section 4 if not prescribed a vitamin K antagonist

### Section 3 Patients prescribed vitamin K antagonists only

21. Did the patient/representative show you their INR record?  
Yes                      No

22. Does the patient/representative know when the last INR test was?  
Less than 4 week    4-12 weeks    More than 12 weeks    Not known

23. Does the patient/representative know what their last INR value was?  
Less than 2          2-5          More than 5          Not known
24. Is INR information recorded in the pharmacy records?  
Yes          No
25. Does the patient have to cut tablets in half to get the required dosage?  
Yes          No          Not known
26. Does the patient have an alternate day dosing regime ie not constant daily dosing?  
Yes          No          Not known
27. Was the patient aware that dietary change could affect their anticoagulant medicine?  
Yes          No          Not known
28. Did you contact the prescriber because of any safety concerns about this medicine?  
Yes          No  
If yes, what was the problem?

#### Section 4

29. Any other general comments/information

END

Any problems or queries about the audit? Please contact [carina.livingstone@nhs.net](mailto:carina.livingstone@nhs.net), phone 01903 708432

Any problems or queries about data entry on PharmOutcome? Please contact [helpdesk@phpartnership.com](mailto:helpdesk@phpartnership.com)

**Thank you for doing this audit**

### Audit results and actions

	Dates of audit	
<b>A</b>	Total number of patients in audit	
<b>B</b>	Number where the patient was asked about the anticoagulant [Q13-20 completed]	
<b>C</b>	Number of patients aware they were taking an anticoagulant [Yes to Q13]	
<b>D</b>	Number of patients aware they need to check with a doctor or pharmacist before taking over-the-counter medicines or herbal products [Yes to Q14]	
<b>E</b>	Number of patients with an alert card [Yes to question 15 or 16]	
<b>F</b>	Number of patients taking a vitamin K antagonist [Q21-28 completed]	
<b>G</b>	Number of patients known to have had an INR test within the last 12 weeks [Q22]	

### Were the audit standard met?

#### All patients prescribed any oral anticoagulant

- All patients are aware they are taking an anticoagulant medicine ie *a medicine to thin the blood/ prevent blood clots* (100%)  
C/B x 100 =
- All patients have an anticoagulant alert card (100%)  
E/B x 100 =
- All patients are aware they need to check with a doctor or pharmacist before taking over-the-counter medicines or herbal products (100%)  
D/B x 100 =

#### All patients prescribed Vitamin K antagonists (Warfarin, Acenocoumarol, Phenindione) (100%)

- INR monitoring within the last 12 weeks is confirmed for all patients  
G/F x 100 =

### Audit actions

Is there a problem ensuring anticoagulant safety because patients are not present in the pharmacy? Do you have procedures in place to manage this problem? For agents that do need INR monitoring, are you familiar with local systems for this and what to do if you find a problem?

Record your audit actions here:

- 1
- 2
- 3



NHS Specialist Pharmacy Service  
[www.sps.nhs.uk](http://www.sps.nhs.uk)

#### References

1. Key definitions. Institute for Safe Medication Practices 2011  
<http://www.ismp.org/selfassessments/hospital/2011/definitions.pdf> (accessed 22.6.17)
2. Actions that can make anticoagulant therapy safer. Patient Safety Alert 18.NPSA March 2007  
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814> (accessed 22.6.17)
3. Anticoagulants, including non-vitamin K antagonist oral anticoagulants (NOACs). Key therapeutic topic. NICE Jan 2017 <https://www.nice.org.uk/advice/ktt16> (accessed 22.6.17)
4. Ko H et al. Patient-held medical records for patients with chronic disease: a systematic review. Qual Saf Health Care 2010;19:e41.
5. Practice Based Audit 2012/13.Pharmacy Voice [http://pharmacyvoice.com/wp-content/uploads/2016/03/PBA\\_final\\_report.pdf](http://pharmacyvoice.com/wp-content/uploads/2016/03/PBA_final_report.pdf) (accessed 6.9.17)
6. Lambert J. Warfarin Audit 2008/9. NHS West Sussex. Personal communication