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

The first stop for professional medicines advice
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. This class of medicines is frequently identified as a cause of preventable harm and admission to hospital. 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. 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 Internalised 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 mediation errors. 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. 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. 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.

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

<table>
<thead>
<tr>
<th>Warfarin</th>
<th>Acenocoumarol</th>
<th>Phenindione</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dabigatran</td>
<td>Apixaban</td>
<td>Rivaroxaban</td>
</tr>
<tr>
<td>Edoxaban</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 (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 card3. 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.

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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

<table>
<thead>
<tr>
<th>Acenocoumarol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apixaban</td>
</tr>
<tr>
<td>Dabigatran</td>
</tr>
<tr>
<td>Edoxaban</td>
</tr>
<tr>
<td>Phenindione</td>
</tr>
<tr>
<td>Rivaroxaban</td>
</tr>
<tr>
<td>Warfarin</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Ibuprofen</th>
<th>Naproxen</th>
<th>Diclofenac</th>
<th>Celecoxib</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin (antiplatelet - low dose)</td>
<td>Aspirin (daily dose over 300mg)</td>
<td>Clopidogrel</td>
<td>Ticagrelor</td>
</tr>
<tr>
<td>Prasugrel</td>
<td>Dipyridamole</td>
<td>Prednisolone</td>
<td></td>
</tr>
<tr>
<td>Citalopram</td>
<td>Sertraline</td>
<td>Fluoxetine</td>
<td></td>
</tr>
<tr>
<td>Other (please specify):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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11c. Is the patient taking a proton pump inhibitor or \( \text{H}_2 \) 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

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, phone 01903 708432

Any problems or queries about data entry on PharmOutcome? Please contact helpdesk@phpartnership.com

Thank you for doing this audit
Audit results and actions

<table>
<thead>
<tr>
<th>Dates of audit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> Total number of patients in audit</td>
<td></td>
</tr>
<tr>
<td><strong>B</strong> Number where the patient was asked about the anticoagulant [Q13-20 completed]</td>
<td></td>
</tr>
<tr>
<td><strong>C</strong> Number of patients aware they were taking an anticoagulant [Yes to Q13]</td>
<td></td>
</tr>
<tr>
<td><strong>D</strong> 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]</td>
<td></td>
</tr>
<tr>
<td><strong>E</strong> Number of patients with an alert card [Yes to question 15 or 16]</td>
<td></td>
</tr>
<tr>
<td><strong>F</strong> Number of patients taking a vitamin K antagonist [Q21-28 completed]</td>
<td></td>
</tr>
<tr>
<td><strong>G</strong> Number of patients known to have had an INR test within the last 12 weeks [Q22]</td>
<td></td>
</tr>
</tbody>
</table>

**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 this the blood/ prevent blood clots* (100%)
  
  \[
  \text{C/B} \times 100 =
  \]

- All patients have an anticoagulant alert card (100%)
  
  \[
  \text{E/B} \times 100 =
  \]

- All patients are aware they need to check with a doctor or pharmacist before taking over-the-counter medicines or herbal products (100%)
  
  \[
  \text{D/B} \times 100 =
  \]

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

- INR monitoring within the last 12 weeks is confirmed for all patients
  
  \[
  \text{G/F} \times 100 =
  \]

**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
References

   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)