# An Evaluation of Oral Anticoagulant Safety Indicators by England's Community Pharmacies

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# Community Pharmacy and the Medicines Safety Improvement Programme

- In 2017, WHO launched its third **Global Patient Safety Challenge 'Medication Without Harm'**, which aims to reduce the global burden of severe and avoidable medication-related harm by 50% over five years.
- The development of a Medicines Safety Improvement Programme (MedSIP) was pledged in the NHS Long Term Plan and launched in 2019.

**Aims for Community pharmacy:**

- Achieve **measurable reductions** in medication harm
- Implement an **action plan for continuous improvement** in medication safety
- **Empower patients and professionals to share decision-making**
- Focus on **patient outcomes** related to **medicine safety**
- Contribute to wider efforts to foster a **safety culture** in the NHS

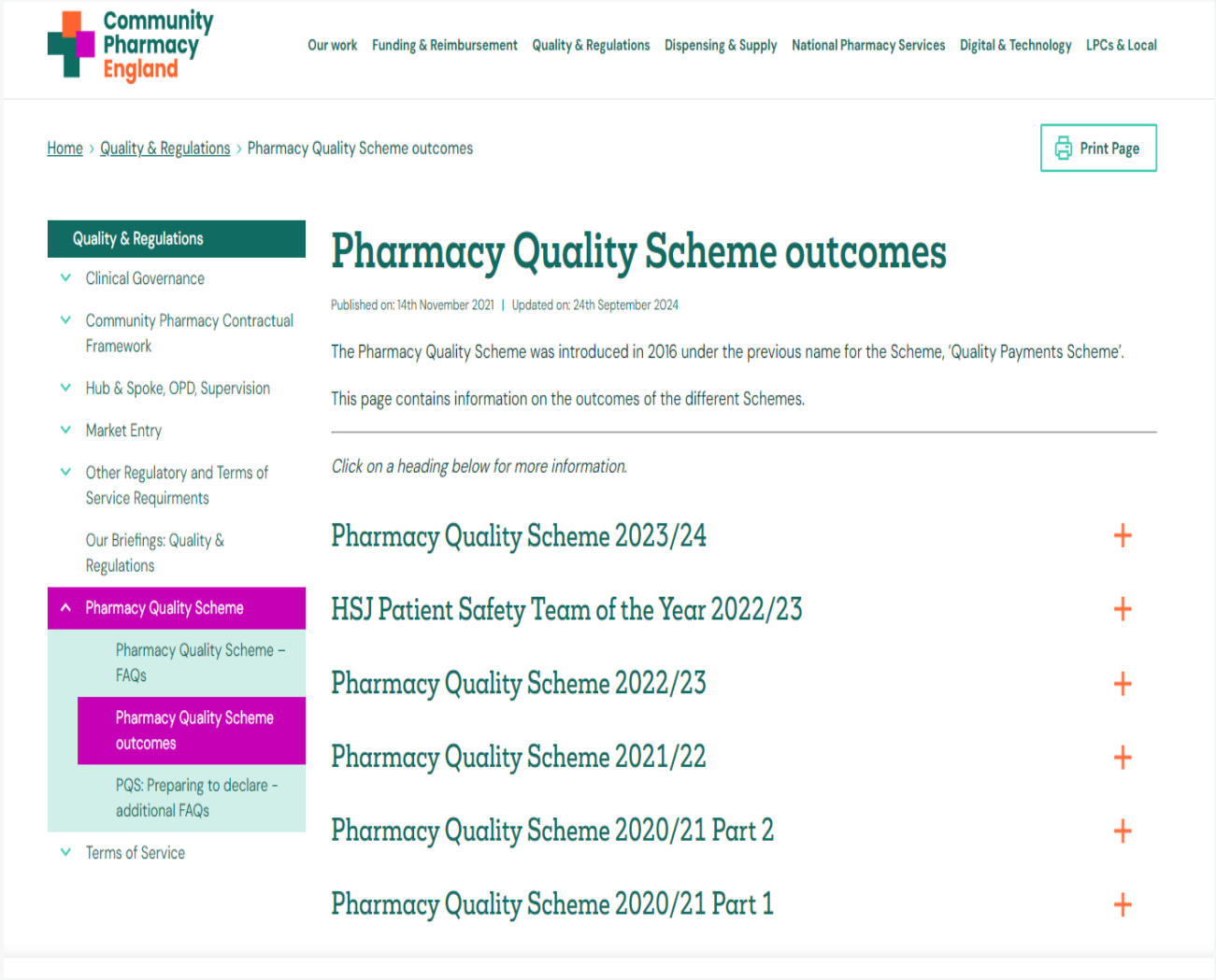
# Pharmacy Quality Scheme

- The first **quality incentive scheme** for community pharmacy introduced in 2016.
- Developing a more **clinically focussed community pharmacy service** that is better integrated with other parts of primary care.
- The scheme rewarded community pharmacies for delivering quality criteria in a number of dimensions
  - **Patient safety/clinical effectiveness**
  - **Patient Experience**
  - **Healthy living/prevention**
  - **Digital enablers**
- From 2019 – 2024, a 5-year deal was agreed where an annual £75 million was awarded to PQS
- Through PQS, progress has been made on **healthy living** advice and support, delivering the **medicines safety programme**, **integration**, **emergency preparedness** and **sustainability**.

# Pharmacy Quality Scheme and Outcomes

**Examples of Criteria**

- **Safe use of NSAIDs** in over 65s
- **Reducing harm** from high-risk medicines (lithium, methotrexate, amiodarone and phenobarbital)
- **Safeguarding antimicrobials &** promoting **Antimicrobial stewardship**
- **Anticoagulant safety**
- **Preventing asthma deaths**
- **Red flags** and **identifying Sepsis**
- Pharmacy Quality Scheme outcomes - Community Pharmacy England (cpe.org.uk);
- NHS England » Pharmacy quality scheme



# Methodology

Two audits were incentivised for England's community pharmacies in

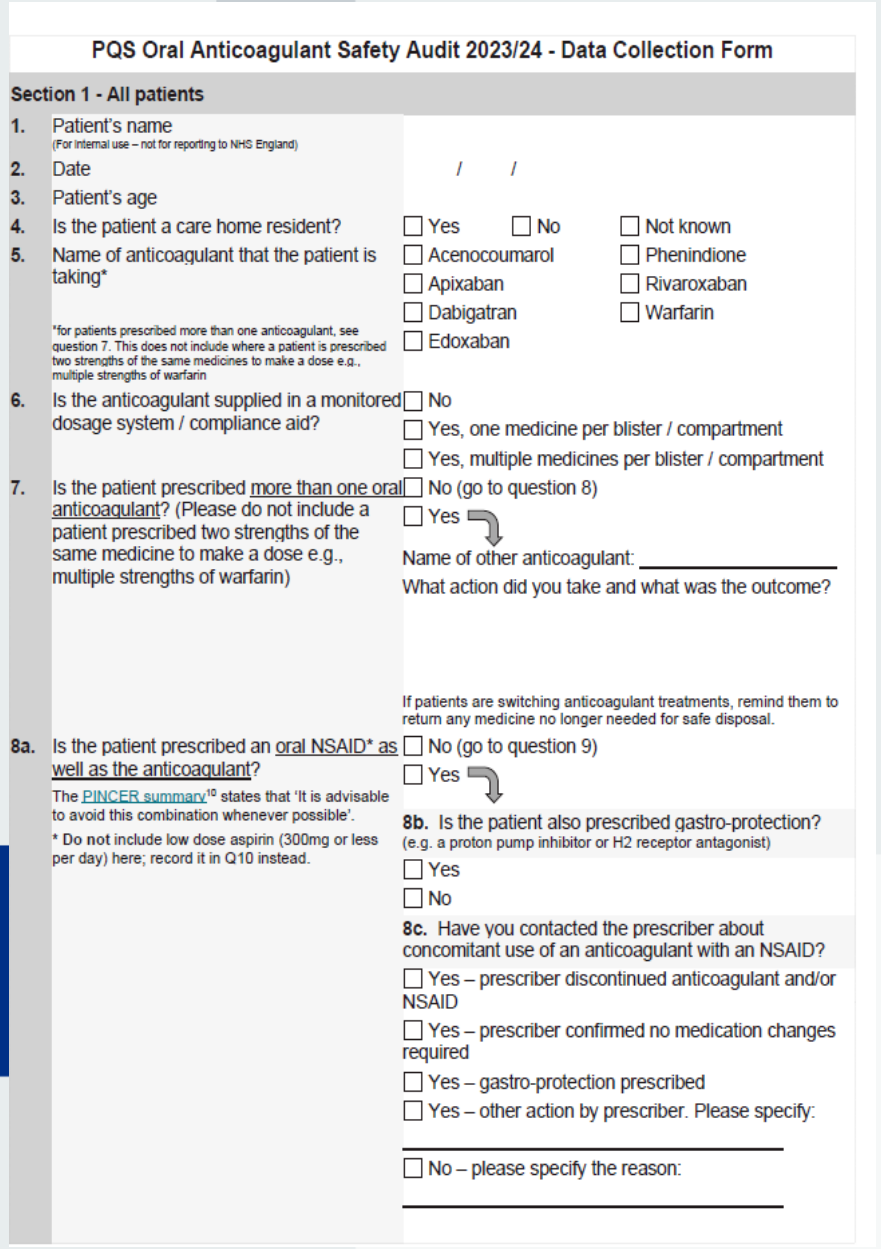
- **2021–2022** and
- **2023–2024**

under the **Community Pharmacy Contractual Framework** and the **Pharmacy Quality Scheme (PQS) commissioned by NHS England**.

These audits were built on a **voluntary audit conducted in 2017/2018**, was aimed at determining **patient awareness of key information about anticoagulants**.

The **audit questionnaire** consisted of **17 questions:**

- **assessing and improving patients' understanding of anticoagulant therapy**,
- **identifying high-risk patients**, and
- **contacting prescribers when clinically appropriate**.



**PQS Oral Anticoagulant Safety Audit 2023/24 - Data Collection Form**

**Section 1 - All patients**

1. Patient's name
(For internal use – not for reporting to NHS England)
2. Date / /
3. Patient's age
4. Is the patient a care home resident? ☐ Yes ☐ No ☐ Not known
5. Name of anticoagulant that the patient is taking*
☐ Acenocoumarol ☐ Phenindione
☐ Apixaban ☐ Rivaroxaban
☐ Dabigatran ☐ Warfarin
☐ Edoxaban
*for patients prescribed more than one anticoagulant, see question 7. This does not include where a patient is prescribed two strengths of the same medicines to make a dose e.g., multiple strengths of warfarin
6. Is the anticoagulant supplied in a monitored dosage system / compliance aid?
☐ No
☐ Yes, one medicine per blister / compartment
☐ Yes, multiple medicines per blister / compartment
7. Is the patient prescribed more than one oral anticoagulant? (Please do not include a patient prescribed two strengths of the same medicine to make a dose e.g., multiple strengths of warfarin)
☐ No (go to question 8)
☐ Yes
Name of other anticoagulant: _____
What action did you take and what was the outcome?
If patients are switching anticoagulant treatments, remind them to return any medicine no longer needed for safe disposal.
8a. Is the patient prescribed an oral NSAID* as well as the anticoagulant?
The PINCER summary[10] states that 'It is advisable to avoid this combination whenever possible'.
* Do not include low dose aspirin (300mg or less per day) here; record it in Q10 instead.
☐ No (go to question 9)
☐ Yes
8b. Is the patient also prescribed gastro-protection? (e.g. a proton pump inhibitor or H2 receptor antagonist)
☐ Yes
☐ No
8c. Have you contacted the prescriber about concomitant use of an anticoagulant with an NSAID?
☐ Yes – prescriber discontinued anticoagulant and/or NSAID
☐ Yes – prescriber confirmed no medication changes required
☐ Yes – gastro-protection prescribed
☐ Yes – other action by prescriber. Please specify:
_____
☐ No – please specify the reason:
_____

# Results

A total of **245,719 patients** were audited, with **6,605** community pharmacies participating in **both audits** and **10,899 pharmacies** participating **in either of the two audits.**

The distribution of data from the regions is the same for both audit years, with the Midlands collecting the most patient data, followed by **Northeast and Yorkshire, and Northwest Regions**, where the most patient data were collected.

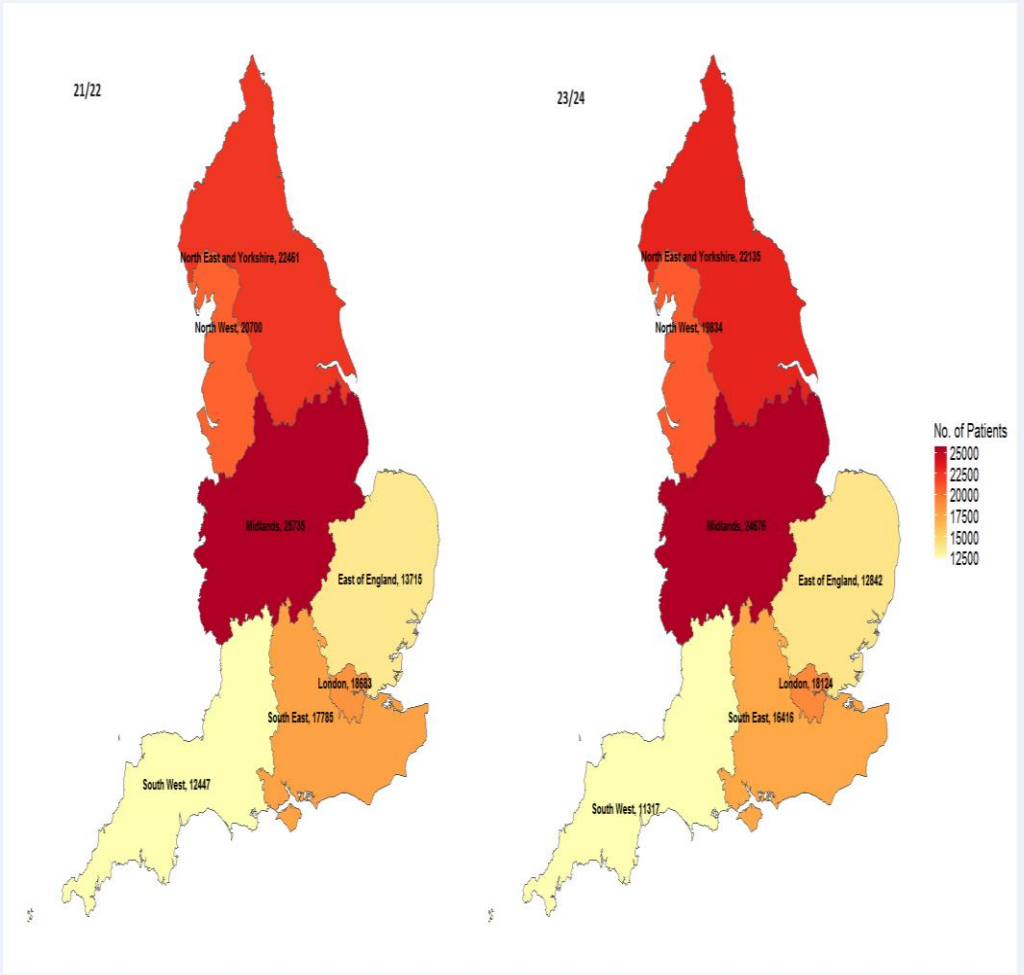
The majority of the data for both audits were collected:

- when the **patient attended the pharmacy** to collect their medication 49.5% (64,991) in 2021–2022 vs. 55.3% (69,354) in 2023–2024;
- **conversation with the patient by telephone** 34.9% (45,809) in 2021–2022 vs. 28.0% (35,074) in 2023–2024
- **representatives collecting medication** on behalf of patients for 7.9% (10,349) in 2021–2022 and 8.6% (10,843) in 2023–2024

Some data entries **contained blank data** as representatives collected medication for patients, and they did not always know patient details/could not complete the audit for the patient.

Therefore, **complete data were included in the final analysis.** Incomplete data entries were excluded.

The final analysis consisted of **111,195 patients from 2021–2022 (audit 1)** and **104,677 from 2023–2024 (audit 2).**



# Results

**Table 1.** Audit results against audit standards.

| | Audit Results | | |
|---|---|---|---|
| **Standard** | **2020–2021** | **2023–2024** | ***p* Value** |
| **Standard 1: All patients are aware of or are provided with the following key information:**<br>• the medicine is an anticoagulant, i.e., a medicine to thin the blood/prevent blood clots;<br>• the symptoms of over anticoagulation, e.g., unexplained bruising, nose bleeds;<br>• to check with a doctor or pharmacist before taking OTC medicines, herbal products, or supplements.<br>• If taking a VKA, that dietary change can affect their anticoagulant medicine. | 106,255 (95.6%) of patients knew they were prescribed an oral anticoagulant<br>85,029 (76.5%) of patients prescribed an oral anticoagulant knew the symptoms of anticoagulation<br>89,171 (80.2%) of patients<br>were aware they need to check with a doctor or pharmacist before taking OTC medicines, herbal products, or supplements.<br>16,764 (67.4%) knew that dietary change can affect their anticoagulant medicine. | 101,006 (96.5%) of patients knew they prescribed an oral anticoagulant<br>83,902 (80.2%) of patients prescribed an oral anticoagulant knew the symptoms of anticoagulation<br>85,071 (81.3%) of patients. were aware they need to check with a doctor or pharmacist before taking OTC medicines, herbal products, or supplement<br>12,594 (73.9%) knew that dietary change can affect their anticoagulant medicine | (*p* value < 0.001).<br>(*p* value < 0.001).<br>(*p* value < 0.001).<br>(*p* value < 0.001). |
| **Standard 2: Alert Cards**<br>All patients have a standard yellow anticoagulant alert card or are offered one. | 73,901 (66.5%) of patients have a standard yellow anticoagulant alert card.<br>24,576 (96.5%) of those without a card were offered one. | 76,735 (73.3%) of patients have a standard yellow anticoagulant alert card<br>26,427 (94.6%) of those without a card were offered one. | (*p* value < 0.001).<br>(*p* value < 0.001). |
| **Standard 3: Safe use with other prescribed medicines—antiplatelets**<br>Contact the prescriber about all patients prescribed an anticoagulant with an antiplatelet but not co-prescribed GI protection unless referral has been made in the last 6 months or the patient has already discussed with their prescriber. | 6021 (4.6%) of patients were also prescribed an antiplatelet, of which 748 (12.4%) were not co-prescribed GI protection. Contact with the prescriber was made in 429 (57.4%) of these cases for review of the patient's GI protection. | 4975 (4.0%) of patients were also prescribed an antiplatelet of which 547 (11.0%) were not co-prescribed GI protection.<br>Contact with the prescriber was made in 309 (56.5%) of these cases for review of the patient's GI protection | (*p* value < 0.001),<br>(*p* value < 0.05).<br>(*p* value = 0.800) |
| **Standard 4: Safe use with other prescribed medicines—NSAIDs**<br>The prescriber is contacted about all patients prescribed an anticoagulant with an NSAID. | 0.9% (1201) of patients were concomitantly prescribed an NSAID.<br>927 (77.2%) of these patients were co-prescribed GI protection.<br>79.5% of patients taking anticoagulants and NSAIDs were referred to the prescriber. | 1.4% (1732) of patients were concomitantly prescribed an NSAID.<br>1457 (84.1%) of these patients were co-prescribed GI protection.<br>80.5% of patients taking anticoagulants and NSAIDs were referred to the prescriber. | (*p* value < 0.001)<br>(*p* value < 0.001)<br>(*p* value = 0.576) |
| **Standard 5: INR monitoring and recording**<br>INR monitoring within the last 12 weeks is confirmed for all patients prescribed VKAs. | 18,446 (99.3%) of patients had INR monitoring within the last 12 weeks. | 11,730 (99.1%) of patients had INR monitoring within the last 12 weeks. | (*p* value = 0.246) |

*p* values of <0.05 or less indicate a statistically significant data result.

# Significant Findings

**4 out of every 5** patients knew about the **symptoms of over anticoagulation**

There was a **significant increase** from 66.5% of patients (in 2021–2022) to **73.3%** (in 2023–2024) having a **standard yellow anticoagulant alert card**.

Fewer patients were prescribed **antiplatelets concurrently**. Furthermore, when these patients were concurrently prescribed an antiplatelet agent, a greater percentage were also **prescribed gastroprotection**.

**More than half of the patients** who were not prescribed gastroprotection were **referred** to their GPs for a review; of which half of the patients in 2023–2024 patients were prescribed gastroprotection as a result of the intervention.

There was also an **increase** in the number of patients **co-prescribed** an NSAID and an anticoagulant **with gastroprotection**

# Conclusions

Community pharmacy teams were **proactive in counselling and educating patients** about their medication.

Over the course of the two audits**, pharmacists and their teams provided 148,376 interventions** to the **245,719 patients**.

Moreover, embedding the **recommendations of the first audit significantly improved safety over time between audits.**

They offered patients key advice to patients regarding:

**their indication** for being prescribed an anticoagulant, **symptoms of over anticoagulation** e.g., unexplained bruising and nose bleeds, reminders to **check** with an appropriate healthcare professional before taking **OTC medicines, herbal products, or supplements**

In accordance, to national guidelines, **all patients on anticoagulants should receive a standard yellow anticoagulant alert card.** As a result of the audits, there was a **statistically significant increase in patients with a standard yellow anticoagulant alert card**

As a result of audits, **fewer patients were prescribed concurrent antiplatelets with an anticoagulant** Although there was **an increase in the number of patients prescribed NSAIDs with anticoagulants, more of these patients were also prescribed gastroprotection concurrently.**

Community pharmacy teams have also been **proactive in identifying patients** who are **prescribed two anticoagulants simultaneously most likely as a result of switching to DOACs**

# Thank You

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