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# Evaluation of the England Community Pharmacy Quality Scheme (2018–2019 and 2019–2020) in reducing harm from NSAIDs in older patients

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#### **ABSTRACT**

Introduction Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used for their analgesic and anti-inflammatory action, but the gastrointestinal (GI) adverse effects are a known cause of preventable harm. A medication safety audit was incentivised for community pharmacies in England in 2 successive years as part of the Pharmacy Quality Scheme (PQS) to address GI safety of NSAIDs.

**Aims** To evaluate community pharmacy's contributions to NSAID safety and determine any change between audit 1 (2018–2019) and audit 2 (2019–2020).

**Method** Patients aged 65 years or over prescribed an NSAID were included in both audits. The audit tool assessed compliance with national standards relating to co-prescribed gastroprotection, referrals to the prescriber and patient advice on long-term NSAID use and effects, with responses submitted via an online portal. Descriptive analyses were performed to explore differences between the years and tested for significance using X<sup>2</sup> tests. Qualitative data were analysed using an inductive thematic approach.

**Key findings** Data from 91 252 patients in audit 1 and 73 992 in audit 2 were analysed. More patients were prescribed gastroprotection in audit 2 (85.0%) than audit 1 (80.7%, p<0.001). More patients without gastroprotection in audit 2 had a current or recent referral (67.5%) than in audit 1 (58.8%, p<0.001). Verbal or other communications between pharmacists and patients about their NSAID medication were reported more frequently in audit 2 (76.0% vs 63.5%, p<0.001).

**Conclusion** During two audits, community pharmacists in England reported referring more than 15 000 patients at risk of preventable harm from NSAIDs to prescribers for review. The audits demonstrated significant potential for year-on-year improvement in GI safety for a large cohort of older patients prescribed NSAIDs. This evaluation provides evidence of how the PQS can effectively address a specific aspect of medicines safety and the place of community pharmacy more broadly in improving medicines safety.

#### INTRODUCTION

Medication errors are ubiquitous.<sup>1</sup> While the majority of errors do not lead to harm, some medicines are more prone to causing harm and are therefore considered 'high risk'.<sup>1</sup> High-risk prescribing in primary

#### WHAT IS ALREADY KNOWN ON THIS TOPIC

- Non-steroidal anti-inflammatory drugs (NSAIDs) are classed as high-risk medicines as they are commonly implicated in medication-associated harm.
- $\Rightarrow$  The use of gastroprotection in elderly patients mitigates against gastric bleeding.
- ⇒ There are still many elderly patients being prescribed NSAIDs without gastroprotection.

#### WHAT THIS STUDY ADDS

- Community pharmacy teams were able to identify a large cohort of patients at risk of avoidable harm from their medicines and make appropriate referrals
- The combined efforts of primary care can improve medicines safety.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND POLICY

- ⇒ Incentivisation maybe an effective tool for community pharmacy in improving medicines safety at pace.
- ⇒ A centrally coordinated and driven approach can enable quality improvement at scale.

care that causes preventable drug-related hospital admissions is a major concern for healthcare systems internationally. Examples include the prescribing of non-steroidal anti-inflammatory drugs (NSAIDs) without gastroprotection resulting in gastric bleeds.<sup>2</sup> In March 2017, the WHO launched its third Global Patient Safety Challenge: Medication Without Harm with an overarching aim to reduce severe avoidable medication-related harm globally by 50% in the next 5 years.<sup>3</sup> NSAIDs were identified by the WHO as highrisk medicines.<sup>45</sup>

NSAIDs are widely used for their antiinflammatory, analgesic and antipyretic properties. S-7 NSAID prescribing in England is common: in the first quarter (Q1) of 2018– 2019, over 450 000 patients aged 65 years or more were prescribed NSAIDs. Available on and off prescription, this class of medication is commonly implicated in medicationassociated harm such as gastrointestinal (GI)



bleeding, acute ischaemic events, stroke and kidney damage. GI bleeding is the most common adverse effect and a known cause of potentially preventable hospital admissions. In The National Institute for Health and Care Excellence guidance advises that elderly patients are co-prescribed gastroprotection such as a proton-pump inhibitor to mitigate this risk of a gastric bleed. In Italian is the strong patients are co-prescribed gastroprotection such as a proton-pump inhibitor to mitigate this risk of a gastric bleed.

The risk of NSAID-related adverse effects increases with age, patients aged 65 years and over being at particular risk. 14 15 However, NSAID use is often necessary for older people to manage conditions associated with pain and inflammation. 15 16 Irrespective of age and other risk factors, continuous use of NSAIDs means that the potential for related adverse events to occur over time remains a concern.<sup>17</sup> Long-term NSAID prescribing in older people is associated with significantly increased costs and reduced quality-adjusted life years. 17 18 In 2010, the estimated cost of managing serious GI adverse effects of NSAIDs in the UK was in excess of £60 million per year. 19 National prescribing data over the 3 years from 2015 to 2018 show a gradual decrease in the number of patients aged 65 years and above prescribed NSAIDs without gastroprotection. Despite this trend, in Q1 2018-2019, 180918 older people were still being prescribed NSAIDs without gastroprotection and 189 such patients were admitted to hospital for gastric bleeds.8

In response to known harms from medicines, various interventions have been developed to improve safety. In the PINCER trial, a pharmacist-led information technology-based intervention was shown to effectively reduce a range of clinically important and commonly made medication errors in primary care. 13 Pharmacists are now widely employed in primary care to work directly with prescribers, but the role of community pharmacists in supporting safe prescribing is less well documented.<sup>20</sup> A randomised trial in Canada of a community pharmacist-led educational intervention increased discontinuation of inappropriate prescribed medication.<sup>21</sup> More recently, an economic evaluation of this D-PRESCRIBE intervention supported reimbursing community pharmacists' clinical professional services for deprescribing inappropriate NSAIDs in community-dwelling older adults. 122

The Community Pharmacy Quality Scheme (PQS) forms part of the Community Pharmacy Contractual Framework.<sup>23</sup> It incentivises quality improvement in community pharmacy, reflecting National Health Service (NHS) strategic priorities such as the NHS Long Term Plan, Medicines Value Programme and Medicine Safety Programme.<sup>23</sup> Since its inception in 2017, the PQS has had approximately 90% uptake for all criteria. Community pharmacists are often the last point of contact with healthcare services when taking medicines and patients report that community pharmacists have an important role in medication safety. <sup>24</sup> A study to determine whether targeted medication reviews for high-risk drugs, including NSAIDs, can be safely and effectively undertaken by pharmacists demonstrated that when recommendations were accepted, adverse events were not experienced by

the patient. In contrast, when recommendations were rejected, preventable adverse events occurred including hospital admissions. <sup>25</sup>

Clinical audits are integral for the maintenance and continuous improvement of patient care and medicines safety. A clinical audit of NSAID safety in community pharmacies in England in 2014 identified that one in four patients (2838 patients) were regularly prescribed NSAIDs without gastroprotection. The audit confirmed ongoing safety concerns with NSAID use and highlighted the potential community pharmacists have in recognising and referring high-risk patients while working collaboratively with prescribers to improve medication safety. English of the patients while working collaboratively with prescribers to improve medication safety.

#### Aim

The aim of the work reported in this paper was to evaluate community pharmacy's contributions to NSAID safety in clinical audits over 2 years and determine any change between audit 1 and audit 2.

#### **METHOD**

An audit tool and audit standards, suitable for inclusion in the 2018 national PQS, were developed from earlier work on NSAID safety. <sup>26</sup>

The audit criteria include assessment and improvement of patients' understanding of their NSAID therapy, identifying high-risk patients and contacting prescribers to advise on gastroprotection. The data collection tool included patient demographics; the name, dose and duration of NSAID prescribed; any concomitant medicines prescribed; whether gastroprotection was prescribed; conversations/contact with patients to support understanding of their medication; and whether the patient was referred to their general practitioner (GP) for a clinical review for suitable gastroprotection.<sup>27</sup> A free-text option was available for general comments and additional information.<sup>27</sup>

The audit standards were as follows:

- ► Standard 1a: all patients aged 65 years or over prescribed an oral NSAID or COX-2 inhibitor are co-prescribed gastroprotection.
- ▶ Standard 1b: all patients aged 65 years or over prescribed an oral NSAID or COX-2 inhibitor, but not co-prescribed gastroprotection, are referred to the prescriber for review unless such a referral has been made in the previous 6 months.
- ► Standard 2: verbal advice/conversation is offered to all patients to support understanding/decision-making about their NSAID/COX-2 medicine. 22

The study settings were community pharmacies across England. The audit population was all patients aged 65 years or over who presented a prescription for any oral NSAID or COX-2 inhibitor.<sup>20</sup> Long-term use was defined as a patient prescribed the medicine for more than 2 months on a regular use or when required; regular use was defined as taking the medicine on at least 3 days each week.



All community pharmacy contractors in England are eligible to participate in this voluntary incentivised scheme and were invited to participate. Pharmacy contractors were asked to collect data for 2 weeks to reach a minimum sample size of 10 patients. If they were unable to achieve 10 patients over the 2 weeks, the audit was extended for a further 2 weeks to try to achieve the minimum sample size. Pharmacies conducted audit 1 between October 2018 and February 2019. Data were submitted online either directly to the NHS Business Services Authority (NHSBSA) portal or via pharmacy computer systems able to feed directly to the NHSBSA.

Data from audit 1 were reviewed to produce an interim report with recommendations to support quality and safety improvement for the reaudit in 2019–2020 (audit 2).<sup>27</sup> Recommendations from the interim report included improving contact with patients who were housebound or could not attend the pharmacy in person and clarifying patient consent for interventions to prevent patient harm.<sup>27</sup> For audit 2, minor revisions were made to the data collection tool reflecting these recommendations. Additional response fields were included for patient contact (eg, discussion with a carer, email contact) and reasons for not referring patients without gastroprotection. The reaudit data were collected between October 2019 and February 2020.

#### **Data analysis**

Data were collated for both years and downloaded onto Microsoft Excel and imported into SPSS V.27 package for data analysis. Data were cleansed to remove duplicate entries, erroneous entries and major data absence. Data were coded as nominal values and descriptive analyses were used to explore the data. Cross-tabulations and tables were made for a side-by-side analysis of different variables by the year of the audit to compare changes. This included age groups, gender differences, the number of patients prescribed gastroprotection and number of referrals made. Other outcomes of interest were whether there were significant changes in the number of referrals and conversations with patients.  $\chi^2$  tests were used to test differences in key outcomes between the two audits.

Qualitative analysis using an inductive thematic approach was undertaken manually to explore the freetext comments section from each year by SP. Codes were grouped into themes following discussion with CL and YHI.

#### **RESULTS**

A total of 165 244 patients were included: 91 252 patients in audit 1 and 73 992 in audit 2. A total of 10 532 pharmacies participated in audit 1 (total contractor list size 11 603; 90.8% participation rate) and 10 225 in audit 2 (total contractor list size 11 472; 89.1% participation rate). The mean recruitment rate was 8.7 patients per pharmacy in audit 1 and 7.2 patients per pharmacy in audit 2.

Overall, the patient age and gender distribution were similar in the two audits, with a mean age of 73 years for female patients and 72 for male patients (table 1). There were more female than male patients in both audits. The frequency and duration of NSAID use, including regular and long-term use, were greater in audit 2 (table 1).

The five most commonly prescribed NSAIDs were the same across both years and accounted for more than 93% of all prescribing. Naproxen was the most widely used agent (audit 1, 58.8%; audit 2, 64.7%), then ibuprofen (19.5%; 16.1%) meloxicam (6.0%; 5.3%), diclofenac sodium (5.1%; 4.2%) and celecoxib (3.7%; 3.3%). There was some use of piroxicam (audit 1, 0.3%; audit 2, 0.2%) and ketoprofen (0.2%; 0.2%) in both audits.

Comparison of concomitant use of three drug classes known to increase the GI risk showed that prescribing of an NSAID with an anticoagulant was unchanged between the two audits. There were reductions in NSAID prescribing with an antiplatelet or selective serotonin reuptake inhibitor (SSRI) between audit 1 and audit 2 (table 2).

#### **Gastroprotection and referrals**

The number of patients prescribed gastroprotection increased from 80.7% of patients in audit 1 to 85.0% in audit 2. Referral of patients without gastroprotection

Table 1 Patient demographics and NSAID usage						
	2018/2019 audit 1		2019/2020 audit 2		P value (X <sup>2</sup>	
	N	%	N	%	test)	
Male; mean age in years (SD)	40 595; 72 (±6)	44.5	32 762; 72 (±6)	44.3		
Female; mean age in years (SD)	50 551; 73 (±6)	55.4	41 142; 73 (±6)	55.6		
Duration of NSAID therapy						
NSAID used regularly	71 215	78.0	59215	80.0	<0.001	
NSAID used for more than 2 months	65 786	72.1	54026	73.0	<0.001	
NSAID prescribed for regular use for more than 2 months	58166	63.7	48618	65.7	<0.001	
NSAID, non-steroidal anti-inflammatory drug.						



Table 2 Patients co-prescribed antiplatelets, anticoagulants or SSRIs

	Audit 1		Audit 2		
	N	%	N	%	P value (X <sup>2</sup> test)
Antiplatelet	9719	10.7	7066	9.5	<0.001
Anticoagulant	2122	2.3	1641	2.2	ns
SSRI	5843	6.4	4426	6.0	<0.001
Any 1 or more of the medicine classes above	16 999*	18.6	12 807*	17.3	<0.001

\*Some instances where more than one medicine class concurrently prescribed. ns. not significant: SSRIs, selective serotonin reuptake inhibitors.

increased from 58.8% in audit 1 to 67.6% in audit 2 (table 3).

The subset of patients prescribed an NSAID with an antiplatelet, anticoagulant or SSRI was more frequently prescribed gastroprotection in both audits than in the full cohort. Referral rates in this patient group when gastroprotection was not prescribed were higher in audit 2 than audit 1 (table 3).

Thematic analysis of free-text comments (13720 in total across both years) for non-referral of patients was similar in both audits (see box 1).

#### **Conversations and communication with patients**

More patients were contacted by the pharmacist about their NSAID medicine in audit 2 (76.0%) than audit 1 (63.5%) (table 4). In both audits, the most common communication route was a face-to-face conversation between the patient and pharmacist in the pharmacy (audit 1, 52.5%; audit 2, 61.8%). Patients who did not attend the pharmacy were contacted by telephone (audit 1, 10.9%; audit 2, 14.2%). In the second audit, there were a few occasions (42) where communication by email or video link was reported.

#### DISCUSSION

This national primary care study involving pharmacist-led audit and review of approximately one in five of the total population of older people in England prescribed NSAIDs showed a year-on-year improvement in identifying patients at risk of medication-related harm. The majority of those at increased risk of GI adverse effects were referred to the prescriber. A minority of patients who had already been referred and had a conversation in the last 6 months (and had subsequently declined any gastroprotection) were not referred.

Approximately 90% of all pharmacies in England took part in this component of the voluntary PQS. Fewer eligible patients were reported in the second audit suggesting less older patients were prescribed NSAIDs in 2019–2020. This finding is in line with national prescribing data where the number of older patients prescribed NSAIDs has declined in recent years.<sup>8</sup>

Ibuprofen and naproxen, which are first-line agents in national guidelines, were the most commonly prescribed NSAIDs in both audits. <sup>12</sup> Small numbers of patients were reported as being prescribed piroxicam or ketoprofen

	Audit 1	Audit 1		Audit 2			
Gastroprotection prescribed	N	%	N	%	P value		
Proton-pump inhibitor	70 484	77.2	60884	82.3	<0.001		
H2 receptor antagonist	2747	3.0	1817	2.5	<0.001		
Misoprostol	407	0.4	170	0.2			
Total with gastroprotection	73 638	80.7	62871	85.0	<0.001		
Referral of patients without gastroprotection							
Total without gastroprotection	17614	19.3	11 121	15.0			
Current or recent referral	10358	58.8	7512	67.5	<0.001		
Referral of patients co-prescribed antiplatelets, anticoagulants or SSRIs without gastroprotection (audit 1, n=16999*; audit 2, n=12807*)							
Total with gastroprotection	14556	85.6	11370	88.8	<0.001		
Total without gastroprotection	2443	14.4	1437	11.2			
Current or recent referral	1618	66.2	1099	76.5	<0.001		



#### Thematic analysis of free-text comments

Three main themes were identified across both years from the qualitative analysis of the reasons for not referring patients.

⇒ Patient views

It was commonly reported that patients were aware of potential gastrointestinal (GI) side effects but did not wish to take gastroprotection. Some patients (3098) refused referral since they 'did not want to take more medication'. Others reported taking non-steroidal anti-inflammatory drugs (NSAIDs) long term without experiencing any problems.

⇒ The role of the community pharmacist

There were reports of advice being given in place of referral, such as taking the NSAID after food and explaining warning signs of a GI bleed to patients. Short-term acute NSAID use was often cited as a reason for not referring for gastroprotection. There were also instances where the pharmacist reported uncertainty about referring as the patient had not agreed to it.

⇒ Communication with the prescriber

It was reported that some prescribers did not implement pharmacy advice on gastroprotection or that gastroprotection had already been reviewed by the prescriber. Some patients chose to speak to the prescriber directly without a formal pharmacy referral. Other reasons included: short-term use, no consent for referral, other advice given, not a regular customer.

despite significant safety warnings.<sup>29</sup> Regular and prolonged NSAID use increases the risk of potential harm and was more common in the second audit. The reasons for this are not clear, but as overall NSAID use reduces, the cohort remaining may be those requiring long-term treatment. Pharmacists are well placed to optimise the choice of agent and dose regimens for these patients, and this could be an area of future improvement and safety initiatives.

The increase in prescribing of gastroprotection after the first audit (4.3%) is slightly greater than that reported in national prescribing data (3.4% increase July-September 2019 compared with July-September 2018). The prescribing statistics include all prescriptions submitted to the NHS for payment (some will be from nonpharmacy sources); the audits use a time-limited convenience sample, self-reported by pharmacists. Overall, the reduction in the numbers of patients at risk of preventable harm is clear in both datasets. Following the second audit, the national data (July-September 2020) show a further 6.1% increase in prescribing of gastroprotection. Although the national data have shown a gradual reduction in the number of older patients prescribed NSAIDs

without gastroprotection since 2015, in the measurement period after the first audit, there was a notable increase in the rate of reduction which continued through into 2021.<sup>8</sup>

National statistics also report actual harm for older patients prescribed NSAIDs as hospital admissions for gastric bleeding. While these numbers are comparatively small, the annualised figures drop from 658 admissions in the year before the first audit, to 500 in the year after audit 1 and 329 in the year after audit 2. Alongside audit 2 in 2019-2020, there were additional NHS initiatives on NSAID safety included in the GP Quality and Outcomes Framework and Academic Health Science Network (AHSN) safety programme which are likely to have contributed to the observed improvement. The AHSN programme aided national rollout of the PINCER intervention which includes identification of older patients prescribed NSAIDs without gastroprotection. 18 Coordinating multiple healthcare initiatives with a common safety improvement goal was intended to support interprofessional working and potentially confer greater patient benefit.<sup>20</sup>

In both audits, pharmacists identified more than 10000 older patients prescribed NSAIDs without gastroprotection and the majority of these patients were referred to the prescriber for a safety review. The referral rate for patients not taking gastroprotection increased in the second year. The analysis from audit 1 found that pharmacists were sometimes reluctant to refer when they were unable to contact the patient.<sup>27</sup> Additional guidance was provided for audit 2 (that where it was not possible to contact the patient, a referral could still be made in the best interest of the patient to prevent avoidable harm), which may have increased the referral rate.

Although the referral rate was higher in the second audit, there was still a significant minority who were not referred. The qualitative analysis indicated that shortterm NSAID use was a common reason for not referring.<sup>27</sup> There were also instances where patients refused referral because they did not want to take any additional medicines or had been taking an NSAID long term without a problem.<sup>27</sup> There is some uncertainty in clinical practice about the risk-benefit of co-prescribing gastroprotection for acute NSAID use. However, if NSAID use is continued, then this change needs to be identified. It may be useful for pharmacists to include an alert in the patient's medication record to identify when acute NSAID therapy is extended and prompt timely review of high-risk patients.

Table 4 Pharmacist-nations communication

Table 4 Tharmacist-patient communication						
	Audit 1		Audit 2			
	N	%	N	%	P value (X <sup>2</sup> test)	
Patient contacted	57919	63.5	56 263	76.0	<0.001	
Patient not contacted	28310	31.0	15715	21.2		
Unknown/not recorded	5023	5.5	2014	2.7		

Co-prescribing of medicines, which further increase the risk of GI adverse events with NSAIDs (eg, SSRIs, anticoagulants and antiplatelets), was slightly less in the second audit.<sup>30 31</sup> In both years, gastroprotection was more commonly prescribed in these very high-risk patients, with almost 90% having protection in the second audit. Referral rates for those in this group without gastroprotection were greater in the second audit, reaching over 75%. Overall, this suggests both prescribers and pharmacists recognise the need for particular caution with these drug combinations.<sup>8</sup> The significant reduction in concomitant prescribing of NSAIDs with antiplatelets and SSRIs between audits 1 and 2 could be because such patients were more frequently referred to prescribers during audit 1. However, even if coincidental, the observed reduction in co-prescribing reduces potential harm in this patient group.

The project described an incentivised intervention. Community pharmacy contractors who participated were asked to embed these interventions into day-to-day practice. Essentially, key areas of medicines safety are initially incentivised within the PQS to facilitate new working patterns to become established normal practice. The incentive for this initiative has not been continued but monitoring of this patient cohort is ongoing via the Medicines Safety Indicators, and the number of patients 'at risk' has continued to fall in the most recent data available for 2021–2022. <sup>19</sup>

Specific action taken by prescribers in response to pharmacy referrals was outside the scope of this study but has been reported elsewhere. A preliminary study of pharmacy referrals for older patients prescribed NSAIDs found that 59% were subsequently prescribed gastroprotection and for 11% the NSAID was discontinued. <sup>18</sup> General reports of referrals by community pharmacists have shown prescriber acceptance rates of over 50%. <sup>25</sup> <sup>32</sup>

Communication with the prescriber is a recurring problem identified by pharmacists, seen both in the qualitative analysis and in existing literature.<sup>33</sup> This is especially due to the fast-paced nature of the community pharmacy setting and the barriers in being able to speak directly to prescribers while they have appointments.

Ensuring patient safety is a key responsibility for all healthcare staff. Safe use of medicines is particularly relevant to prescribers and pharmacists, and patients agree that pharmacists are responsible for medication safety.<sup>24</sup> The second audit showed an increase in pharmacist-patient interactions about NSAID use and safety. Patient contact can be difficult when patients are unable to attend the pharmacy to collect their medicines. In the second audit, pharmacists were encouraged to use other contact routes such as telephone or email for vulnerable people (such as housebound patients and care home residents), which is likely to have contributed to the improved performance. In England, NSAIDs are available to buy in many shops with the consequent danger of patients inadvertently taking two NSAIDs concurrently, one prescribed and another purchased from a retail outlet. Community

pharmacists are in a unique position to help prevent this through regular patient contact.

A recent review of community pharmacist interventions found that patients considered pharmacists important healthcare providers, helping decision-making in terms of medication use and adherence. The Patient counselling by community pharmacists on medication adherence and quality use of medicines while dispensing medication influences patients' health outcomes. Poor adherence to prescribed gastroprotection has been reported so pharmacist interactions with patients may have safety benefits beyond those reported here. The repeated interactions between community pharmacists and patients prescribed regular medication offer an important opportunity to involve and empower patients in safe use of NSAIDs.

#### **Strengths and limitations**

The study had high ecological validity being conducted in the community pharmacy setting. The data were both widespread for all of England as well as large in quantity. Using both quantitative and qualitative data enabled a comprehensive evaluation between the years. The qualitative data provided insight on areas of concern, such as consent to refer and short-term use. Data were selfreported by pharmacists so inconsistent reporting cannot be ruled out and the time frame was variable, dependent on the number of eligible patients. There were minor changes to the audit tool between audit 1 and audit 2. While these were intended to improve clarity, the changes may have resulted in different interpretation of the audit questions. The study only addressed one aspect of GI safety and there are multiple known risk factors which may predispose patients to gastric bleeding and ulceration, such as comorbidities, excessive alcohol consumption and smoking. Follow-up of the outcome of patient referrals for gastroprotection from each audit was outside the scope of the current study. However, other studies have reported on the effectiveness of pharmacist interventions to improve prescribing safety, including one specifically using the method reported here. <sup>18</sup> The contribution of other concurrent initiatives addressing NSAID safety to the observed prescribing change could not be determined.

#### CONCLUSION

National data from two consecutive medicines safety audits have shown that community pharmacists are able to identify a large cohort of patients at risk of avoidable harm from their medicines and make appropriate referrals. Prescribing statistics linked to patient outcomes support the reported improvement in performance against practice standards. Overall, this work has demonstrated how the PQS can be used as an effective lever to address specific clinical safety concerns and deliver measurable improvement. Such initiatives, ideally across multiple organisations and professionals, with an aligned



data collection process could allow achievable, evidenced delivery on the challenge set by the WHO to reduce severe avoidable medication-related harm.

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Patient consent for publication Not required.

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**Data availability statement** Data are available upon reasonable request. Data can be made available after contacting the authors.

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#### REFERENCES

- 1 Elliott RA, Camacho E, Jankovic D, et al. Economic analysis of the prevalence and clinical and economic burden of medication error in England. BMJ Qual Saf 2021;30:96–105.
- 2 Dreischulte T, Donnan P, Grant A, et al. Safer prescribing—a trial of education, informatics, and financial incentives. N Engl J Med 2016;374:1053–64.
- 3 Organization WH. Medication safety in high-risk situations World Health Organization; 2019.
- 4 Rosenbloom CJ, Morley FL, Ahmed I, et al. Oral non-steroidal antiinflammatory drug use in recreational runners participating in Parkrun UK: prevalence of use and awareness of risk. Int J Pharm Pract 2020;28:561–8.
- 5 TNw-N. NSAIDs NSAIDs NHS, 2021. Available: www.nhs.uk
- 6 Cashman JN. The mechanisms of action of NSAIDs in analgesia. Drugs 1996;52 Suppl 5:13–23.
- 7 Vane JR, Bakhle YS, Botting RM. Cyclooxygenases 1 and 2. *Annu Rev Pharmacol Toxicol* 1998;38:97–120.
- 8 Authority NHSBS. NHSBSA Catalyst public insight portal Catalyst: 03 Dashboards - Medication Safety Indicators GIB01:[Increased risk of hospital admission] Prescribed NSAID without gastro-protection 2020.: NHSBSA, 2021. Available: https://www.nhsbsa.nhs.uk/ access-our-data-products/catalyst
- 9 Care DoHaS. The report of the short life Working group on reducing medication-related harm, 2018. Acute care and Workforce/Acute care and Quality/CQC laQP

- 10 Howard RL, Avery AJ, Slavenburg S, et al. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol 2007;63:136–47.
- 11 Andrew Moore R, Phillips CJ. Cost of NSAID adverse effects to the UK National health service. J Med Econ 1999;2:45–55.
- 12 NICE C. NSAIDs-prescribing issues; 2015.
- 13 Avery AJ, Rodgers S, Cantrill JA, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and costeffectiveness analysis. *Lancet* 2012;379:1310–9.
- 14 Griffin MR. High-dose non-steroidal anti-inflammatories: painful choices. *Lancet* 2013;382:746–8.
- 15 McDonald J, McBain L, Dowell AC, et al. GPs' views and experiences of prescribing non-steroidal anti-inflammatory drugs: a qualitative study. BJGP Open 2017;1:bjgpopen17X100869.
- 16 UK NCGC. Osteoarthritis: care and management in adults; 2014.
- 17 Cameron C. Non-Steroidal anti-inflammatory drugs (NSAIDs): making safer treatment choices. Best Practice Journal 2013.
- 18 Livingstone C, Patel C. Evaluation of targeted MURs in preventing avoidable harm from NSAIDs. *International Journal of Pharmacy Practice* 2012;20.
- 19 Belsey J. The cost impact of NSAID-induced gastrointestinal adverse events. *Managing Pain in Practice* 2010;1:3–11.
- 20 Alderwick H, Dixon J. The NHS long term plan. British Medical Journal Publishing Group, 2019: I84.
- 21 Martin P, Tamblyn R, Benedetti A, et al. Effect of a pharmacist-led educational intervention on inappropriate medication prescriptions in older adults: the D-PRESCRIBE randomized clinical trial. JAMA 2018;320:1889–98.
- 22 Elliott RA, Putman K, Franklin M, et al. Economic evaluation of a pharmacist-led IT-based intervention with simple feedback in reducing rates of clinically important errors in medicines management in general practices (PINCER). University of Birmingham: Department of Health Patient Safety Research Portfolio Birmingham, 2013.
- 23 Improvement NEa. Pharmacy quality scheme. Available: https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-quality-payments-scheme/
- 24 Hartung DM, Hall J, Haverly SN, et al. Pharmacists' role in opioid safety: a focus group investigation. Pain Med 2018;19:1799–806.
- 25 Morrison C, MacRae Y. Promoting safer use of high-risk pharmacotherapy: impact of pharmacist-led targeted medication reviews. *Drugs Real World Outcomes* 2015;2:261–71.
- 26 Service SP. Community pharmacy NSAID safety audit 2015, 2014. Available: https://www.sps.nhs.uk/articles/community-pharmacy-nsaid-safety-audit-2014-d-national-data-from-pharmoutcomes/ [Accessed 07 Oct 2019].
- 27 Improvement NEa. Community pharmacy NSAID safety audit 2018-19; 2019.
- 28 NHSBSA. Pharmaceutical list. Available: https://www.england.nhs. uk/futurenhs-platform/2019-20
- 29 GOV.UK. Piroxicam: new restrictions, including specialist initiation: medicines and healthcare products regulatory agency; 2014 [Accessed 11 Dec 2014].
- 30 Dalton SO, Johansen C, Mellemkjaer L, et al. Use of selective serotonin reuptake inhibitors and risk of upper gastrointestinal tract bleeding: a population-based cohort study. Arch Intern Med 2003:163:59–64.
- 31 Mellemkjaer L, Blot WJ, Sørensen HT, et al. Upper gastrointestinal bleeding among users of NSAIDs: a population-based cohort study in Denmark. Br J Clin Pharmacol 2002;53:173–81.
- 32 Bhat S, Kroehl M, Yi WM, et al. Factors influencing the acceptance of referrals for clinical pharmacist managed disease states in primary care. J Am Pharm Assoc 2019;59:336–42.
- 33 Phipps DL, Noyce PR, Parker D, et al. Medication safety in community pharmacy: a qualitative study of the sociotechnical context. BMC Health Serv Res 2009;9:1–10.
- 34 Rajiah K, Sivarasa S, Maharajan MK. Impact of pharmacists' interventions and patients' decision on health outcomes in terms of medication adherence and quality use of medicines among patients attending community pharmacies: a systematic review. *Int J Environ Res Public Health* 2021;18:4392.
- 35 Babelghaith SD, Alarifi MN, Wajid S, et al. Knowledge of patients on safe medication use in relation to nonsteroidal anti-inflammatory drugs. Saudi J Anaesth 2019;13:106.