



**Specialist
Pharmacy
Service**

NHS

Community Pharmacy NSAID Safety Audit 2018-19

**Gastroprotection in people aged 65 years and
above Quality Payments Scheme
(February 2019 review point)
Interim Report**

**The first stop
for professional
medicines advice**

NHS England and NHS Improvement



Community Pharmacy NSAID Safety Audit 2018-19

Publishing Approval Number: 001133

Version: 1

First published: November 2019

Prepared by: NHS England and NHS Improvement with the support of the Specialist Pharmacy Service (SPS).

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Audience

- NHS leaders responsible for patient safety, medicines optimisation and primary care contracts;
- Pharmaceutical Services Negotiating Committee and other national pharmacy bodies;
- Community pharmacists, primary care pharmacists and all others responsible for prescribing, dispensing or reviewing non-steroidal anti-inflammatory drug (NSAID) use.

Purpose

- To report the key findings of the NSAID safety audit included in the 2018-19 Community Pharmacy Quality Payments Scheme (QPS);
- To make recommendations to support safety improvement and re-audit in the 2019-20 [Pharmacy Quality Scheme \(PQS\)](#)¹.

Background

In 2017, The World Health Organization (WHO) launched a [Global Patient Safety Challenge](#)² relating to medication safety. The challenge focuses on improving medication safety by strengthening systems to reduce errors. Its over-arching aim is to globally reduce the level of severe avoidable harm related to medications by 50% over five years. Contributing to this, NHS England and NHS Improvement launched its Patient Safety Strategy in July 2019 including [The Medicines Safety Improvement Programme](#)³ focusing on three specific areas: high risk drugs, high risk parts of the medicines use process and patients who are most vulnerable.

NSAIDs are widely used for both their anti-inflammatory and analgesic properties. However, this class of medication is commonly implicated in [medication associated harm](#)⁴ such as gastrointestinal (GI) bleeding, heart attacks, stroke and kidney damage. The [risk](#)⁵ of NSAID related adverse effects is increased in patients as they get older. GI adverse effects are the most common adverse effects of NSAIDs and a known cause of potentially [preventable hospital admissions](#)⁶. The National Institute for Health and Care Excellence (NICE) guidance advises that elderly patients are [co-prescribed gastroprotection](#)⁷ e.g. a proton pump inhibitor (PPI) to mitigate this [risk](#).⁸

¹ <https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-quality-payments-scheme/pqs/>

² <https://www.who.int/patientsafety/medication-safety/medication-without-harm-brochure/en/>

³ <https://improvement.nhs.uk/resources/national-medicines-safety-programme/>

⁴ <http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf>

⁵ [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(13\)61128-9.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(13)61128-9.pdf)

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2000562/> Howard RL et al. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol. 2007 Feb; 63(2): 136–147

⁷ NICE CG177 <https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#pharmacological-management> Feb 2014.

⁸ NICE CKS <https://cks.nice.org.uk/nsaids-prescribing-issues#!scenario>. Aug 2019.

Introduction

The audit was first tested by 1,278 pharmacies in 2014 and showed that some patients were unaware of the GI adverse effects of NSAID use. Patients who might benefit from gastroprotection in line with NICE guidance were identified and referred for review where appropriate. Five years on, the [national safety indicators](#)⁹ show that preventable harm is still occurring. In 2018, 654 patients aged 65 or over prescribed NSAIDs without a gastroprotective medicine were admitted to hospital for a gastric bleed. The aim of this audit was to reduce preventable patient harm from adverse effects of NSAIDs including cyclooxygenase-2 (COX-2) inhibitors.

Audit

This national audit represents the first report of specific medicines safety data collected from almost all community pharmacies in England. It was part of the QPS in which, 9,825 community pharmacies collected data for two weeks between October 2018 - February 2019. Each needed a minimum sample size of 10 patients and if more time was needed to achieve this number, pharmacies could extend their data collection to four weeks. Pharmacies had the option to submit their anonymised data using two online reporting portals, but some contractors submitted data using both portals. The data was cleansed to remove duplicate entries before being analysed. Data was collected for a total of 91,252 patients, most of whom were aged between 65 and 74 (69%), although a substantial number were 75-84 (26%) and some 85 or over (5%).

A re-audit has been included in the February 2020 PQS where pharmacy contractors have been asked to audit their patients embedding the findings from this report into their clinical practice. The purpose of the re-audit is to:

- Raise awareness amongst healthcare professionals of the findings of the original audit;
- Embed the learning and implement the recommendations into routine clinical practice;
- Re-audit current practice to confirm necessary changes have been put into practice.

This initiative aligns with the Prescribing Safety module of the [GP contract](#)¹⁰ Quality and Outcomes Framework (QOF). The module specifically focuses on reducing the rate of potentially hazardous prescribing, including the safer use of NSAIDs in patients at significant risk of complications such as GI adverse effects.

⁹ <https://apps.nhsbsa.nhs.uk/MOD/MedicationSafety/atlas.html>

¹⁰ <https://www.england.nhs.uk/wp-content/uploads/2019/01/gp-contract-2019.pdf>

Findings

The findings of the audit against the audit standards are shown in the table below.

Table 1: Performance against the audit standards.

Standard	Result
Standard 1A: All patients aged 65 years or over prescribed an oral NSAID or COX2 inhibitor are co-prescribed gastroprotection.	Outcome: 80% of patients aged 65 years and over were co-prescribed gastroprotection.
Standard 1B: All patients aged 65 years or over prescribed an oral NSAID or COX2 inhibitor, but <u>not</u> co-prescribed gastroprotection are referred to the prescriber for review unless such a referral has been made in the previous six months.	Outcome: 51% of patients aged 65 years and over <u>not</u> prescribed gastroprotection were referred to the prescriber for a review, a further 7% were not referred but had a previous review in the last six months.
Standard 2: Verbal advice/conversation is offered to all patients to support understanding/decision making about their NSAID/COX2 medicine.	Outcome: Verbal advice/conversation was offered to 63% of patients.

Audit standard 1A: The performance against this standard was 80% ([see Table A8](#)). In practice, 100% may not be achievable as some patients choose not to take additional medicines. However, those without gastroprotection must be fully informed of both the risks and benefits and their individual circumstances regularly reviewed.

Audit standard 1B: 51% of patients without gastroprotection were referred to prescribers for review. ([see Table A9](#)). Data on the outcomes of these referrals was not collected but these referrals should help prevent well-recognised avoidable harm from NSAIDs and the subsequent morbidity and associated healthcare cost. Of the 49% of patients who were not referred, 7% had already been referred in the last six months, a reason for not referring was given for 27% (mostly due to short courses or intermittent NSAID use) and no reason was given for 15%.

Audit standard 2: Pharmacies offered 63% of patients verbal advice about their medicines, 11% was by telephone or other remote methods of contact ([see Table A10](#)). Of the 37% who were not offered advice, the medicine had been delivered to 9% and collected by a representative for 14%. Patients not attending the pharmacy, and possibly not having easy access to other health services, may be in particular need for support with their medicines. Many patients appear to be having interactions with pharmacists outside of the pharmacy premises, possibly reflecting approaches adopted by distance selling pharmacies as well as community pharmacies contacting relevant patients for a conversation. However, there is an opportunity to use other methods of communication to improve coverage.

Other findings:

- The most frequently prescribed NSAIDs were naproxen (59%), ibuprofen (20%), meloxicam (6%), diclofenac (6%) and celecoxib (4%). Both piroxicam and indomethacin, NSAIDs with restricted indications due to the severity of side-effects, were among the top 12. Extra caution is needed when prescribing these NSAIDs for patients including ongoing monitoring.
- More than 18,000 patients (1 in 5) were not prescribed any gastroprotection. A thematic analysis of the qualitative comments for not referring patients suggests there were three main reasons for this:
 - **Clinical considerations:** The practitioner/pharmacist did not feel prescription of short-term/acute courses of NSAIDs warranted gastroprotection or the patient did not tolerate PPIs;
 - **Patient choice:** Patient did not want to take any more medication despite understanding the risks;
 - **Situational factors:** The patient's representative collected the medication on behalf of the patient and/or the patient was not contactable.
- 16,999 patients (18.6%) were prescribed NSAIDs concurrently with an anticoagulant¹¹, an antiplatelet (including aspirin) or a selective serotonin re-uptake inhibitor (SSRI). Of this group, 2,443 (2.7%) had no gastroprotection ([see Table A7](#)). Pharmacists referred 1,465 (60%) of them for a clinical review. A minority of patients, 153 (6%) of the 978 (40%) who were not referred, had already been reviewed within the last six months and another reason such as a short course was given for a further 299 (12%).
- In total, community pharmacies referred 9,222 (51%) patients prescribed an NSAID without gastroprotection to prescribers for a review, 1,091 of whom were prescribed NSAIDs for two months or more as well as medicines that increase the risk of a GI adverse effect. Pharmacists also reported from discussions with patients that some are prescribed but do not actually take gastroprotective medication.

Recommendations

Clinical risk assessment: Current research establishing the clinical risk for patients prescribed short term courses of NSAIDs or from infrequent and/or irregular use is unclear. It is recognised that it may not be appropriate for such patients to be prescribed gastroprotection, particularly those prescribed short courses. Until the exact risk is established, patients should be counselled on the risks and benefits of gastroprotection as well as periodically offered reviews for any further courses. Patients at increased risk of a GI adverse effect who are co-prescribed antiplatelets, SSRIs or anticoagulants and/or NSAIDs with the highest risk GI adverse effect should be prioritised for clinical assessment.

¹¹ As per [NICE guidance](https://cks.nice.org.uk/nsaids-prescribing-issues#!scenarioRecommendation:5), (<https://cks.nice.org.uk/nsaids-prescribing-issues#!scenarioRecommendation:5>) concomitant use of NSAIDs with anticoagulants is not recommended.

Recommendation 1: Community pharmacists should be aware of the risks versus benefits of gastroprotection in patients taking NSAIDs and where appropriate refer them to prescribers. Pharmacists should prioritise high risk patients such as those taking other medicines that increase risk of GI adverse effects concomitantly for referral to their prescriber.

Support for patients who do not attend the pharmacy: Community pharmacists need to use a range of methods to contact patients who do not collect their medicines from the pharmacy. The audit identifies pharmacists are already doing this to some extent, but clear support routes need to be established for housebound patients and those in care homes. This proactive approach can involve liaising with colleagues in other settings e.g. Primary Care Network clinical pharmacists, care home pharmacists, clinical commissioning groups (CCGs) and community pharmacy teams.

Recommendation 2: An amendment to pharmacy procedures to embed best practice into day-to-day practice would prevent these patients being missed.

Shared decisions, patient consent and referral: The qualitative data identified some confusion about obtaining patient consent to make clinical referrals. Safety information about prescribed medicines should be shared with prescribers where it has not been possible to contact the patient as this can prevent avoidable harm and is in the best interest of the patient.

Recommendation 3: Community pharmacy teams should be clear about their responsibility for liaising with the prescriber to prevent avoidable harm from medicines.

Improved visibility and integration with other primary care professionals: NSAID safety initiatives are included in both the community pharmacy and GP contracts as well as in the Academic Health Science Network led PINCER (Pharmacist-led Information technology iNtervention for the reduction of Clinically important ERrors in medicines management).

Recommendation 4: Community pharmacists should maximise the opportunities to work with multi-disciplinary teams across all sectors to promote medicines safety.

Conclusion

This national audit demonstrated that community pharmacy teams appropriately identified and referred a large cohort of patients at risk of harm from their medicines. But it also reveals that the safety of NSAID therapy could be improved in many elderly patients.

This audit highlighted the need for community pharmacists:

- to be clear in their understanding of the risks and benefits of gastroprotection for a range of patients, i.e. patients prescribed short courses of NSAIDs or those prescribed concurrent medication that increase the risk of adverse effects, to ensure patients receive appropriate personalised support in decision-making;
- to have in place clear communication and referral pathways for patients residing in care homes or receiving care at home to ensure vulnerable patients are reviewed;
- to be clear about their responsibility to share information for the safety of patients.

A community pharmacy clinical audit has value in identifying patients at risk of adverse events, as through this, pharmacists may also identify adherence and self-medication issues, and provide a final safety net should other strategies fail. This approach, through the PQS, has the potential to drive improvement across community pharmacies on important medication safety issues.

The case for re-auditing NSAIDs safety is clear and has, therefore, been included in the February 2020 PQS. It also aligns with the [GP contract](#)¹² requiring practices to audit the quality of their prescribing for patients at significant risk of GI adverse effects who in the preceding six months have been prescribed a non-selective NSAID without co-prescribed PPI. Community pharmacy teams working closely with colleagues in Primary Care Networks, GP practices and secondary care can reduce the potential for medicine-related harm.

Community pharmacies will complete the audit cycle in the second half of 2019-20 and data will be collected in February 2020. This, along with the general practice activity through PINCER and the GP QOF quality improvement modules contributes to NHS England and NHS Improvement's medicines safety programme to reduce harm from medicines. The overall impact will be monitored through the [NHS Business Services Authority Medicines Safety Dashboard](#)¹³.

¹² <https://www.england.nhs.uk/wp-content/uploads/2019/01/gp-contract-2019.pdf>

¹³ <https://apps.nhsbsa.nhs.uk/MOD/MedicationSafety/atlas.html>

Appendix: NSAID audit data summary tables

Table A1: Data cleansing before analysis

Total number of patient entries submitted	96,003
Removals to obtain clean data	
Non-logical responses	526
Non-NSAID entries/non-oral prescriptions	37
Patients removed due to age criteria (i.e. under 65 or reported as 117 and above years of age)	42
Non-sensical dose (100, 500 mg)	1
Incorrect date entries (2002, 2003, 2014)	6
Total	612
Removal of duplicate entries	4,139
Total number of entries removed	4,751
Total number of entries in final analysis	91,252

Table A2¹⁴: Patients by region

Region	Number of patients
East England	8,819
East Midlands	9,721
London	14,204
North East	10,011
North West	16,857
Scotland	50
South East	11,628
South West	9,654
Wales	363
West Midlands	9,945
Total	91,252

¹⁴ Includes pharmacies located on the England/Scotland and England/Wales borders which are remunerated in England.

Table A3: Patient age and gender

Age	Male	Female	Gender not confirmed	Total	
65–69	16,242	19,151	65	35,458	38.8%
70–74	12,329	14,930	19	27,278	29.9%
75–79	6,647	8,635	11	15,293	16.8%
80–84	3,609	4,845	9	8,463	9.3%
85–89	1,351	2,131	2	3,484	3.8%
90–94	328	649	0	977	1.1%
95+	89	210	0	299	0.3%
Total	40,595	50,551	106	91,252	100%

Table A4: Top 12 prescribed NSAIDs

Name of prescribed NSAID/COX-2 inhibitor	Number of patients	Percentage
Naproxen	53,622	58.8
Ibuprofen	17,807	19.5
Meloxicam	5,442	6.0
Diclofenac sodium	4,648	5.1
Celecoxib	3,340	3.7
Etoricoxib	2,632	2.9
Indomethacin	1,200	1.3
Etodolac	788	0.9
Diclofenac potassium	511	0.6
Nabumetone	274	0.3
Piroxicam	271	0.3
Ketoprofen	187	0.2
Total	90,722	99.4

Table A5: Number of patients regularly prescribed NSAIDs for more than two months by age

Age	Total	
65–69	22,333	24.5%
70–74	17,717	19.4%
75–79	9,829	10.8%
80–84	5,316	5.8%
85–89	2,175	2.4%
90–94	612	0.7%
95+	184	0.2%
Total	58,166	63.7%

Table A6¹⁵: Number of patients co-prescribed anticoagulants, antiplatelets or SSRIs by age

Age	Anticoagulant		Antiplatelet (including Aspirin)		SSRI	
65–69	530	0.6%	2,823	3.1%	2,815	3.1%
70–74	611	0.7%	2,817	3.1%	1,657	1.8%
75–79	455	0.5%	1,952	2.1%	748	0.8%
80–84	321	0.4%	1,296	1.4%	391	0.4%
85–89	134	0.1%	605	0.7%	163	0.2%
90–94	65	0.1%	185	0.2%	53	0.1%
95+	6	0.0%	41	0.0%	16	0.0%
Total	2,122	2.3%	9,719	10.7%	5,843	6.4%

¹⁵ 485 incidences where more than one other medication was concurrently prescribed.

Table A7¹⁶: Referral for review of patients co-prescribed anticoagulants, antiplatelets and SSRIs but not gastroprotection by age

Age	NSAID + anticoagulant/ antiplatelet (including aspirin)/SSRI		No gastroprotection prescribed		Referral Details		
					Yes	No referred in previous 6 months	No (other)
65–69	5,912	6.5%	839	0.9%	498	57	284
70–74	4,888	5.4%	677	0.7%	403	42	232
75–79	3,045	3.3%	438	0.5%	264	25	149
80–84	1,934	2.1%	305	0.3%	186	19	100
85–89	876	1.0%	138	0.2%	90	7	41
90–94	283	0.3%	36	0.0%	17	3	16
95+	61	0.1%	10	0.0%	7	0	3
Total	16,999		2,443		1,465	153	825
Percentage	100%	18.6%		2.7%	60%	6%	34%

¹⁶ No (other) – Of the 825 that were not referred, 299 had a qualitative response.

Table A8¹⁷: Gastroprotection co-prescribed

	Total no of patients audited	Gastroprotection co-prescribed	Choice of PPI prescribed at licensed dose				Other gastroprotection prescribed	Choice of gastroprotection		
			Omeprazole	Lansoprazole	Esomeprazole	Pantoprazole		H ₂ receptor antagonist	Miso-prostol	PPI not listed
Male	40,595	31,906	18,085	11,382	593	386	2,007	1,089	178	740
Female	50,551	41,153	23,876	13,786	882	559	2,820	1,654	228	938
Gender not confirmed	106	81	42	31	3	0	7	4	1	2
Sub-total			42,003	25,199	1,478	945		2,747	407	1,680
Sub-percentage			46.0%	27.6%	1.6%	1.0%		3.0%	0.4%	1.8%
Total	91,252	73,140*				69,625*	4,834*			4,834
Total percentage	100%	80.2%				76.3%	5.3%			5.3%
Gastroprotection NOT co-prescribed										
Total	91,252	18,112								
Total percentage	100%	19.8%								

¹⁷ *1,319 incidences where more than one gastroprotective agent was reported.

Table A9: Referral details for patients without gastroprotection

Age	Number of patients without gastroprotection	Referral details			
		Yes – patient referred	Patient NOT referred as was reviewed in the last 6 months	No – qualitative reason given	No –no reason stated
65–69	7,473	3,722	560	1,948	1,243
70–74	5,143	2,659	375	1,396	713
75–79	2,912	1,508	188	814	402
80–84	1,642	866	92	449	235
85–89	682	350	45	184	103
90–94	180	78	9	70	23
95+	80	39	4	31	6
Total	18,112	9,222	1,273	4,892	2,725
Percentage (%)		51%	7%	27%	15%

Table A10: Conversations with patients about their prescribed NSAID

Conversation with patient about their NSAID/COX-2 inhibitor	Number of patients	Percentage
Yes – conversation with the patient in the pharmacy	47,928	52.5
No – patient's representative attended pharmacy, patient not contacted	12,690	13.9
Yes - conversation with the patient by telephone/ remotely	9,991	10.9
No – medicine delivered by pharmacy, patient not contacted	8,341	9.1
No – other	7,279	8.0
Data not recorded (e.g. forgot, prescription not collected during the audit period)	5,023	5.5
Total	91,252	100.0



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