



module 260

Patient safety in community pharmacy

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module 260

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Patient safety in community pharmacy

GOALS AND LEARNING OBJECTIVES

This module will help pharmacists and their teams recognise the importance of reporting patient safety incidents.

You will learn how reporting these incidents can benefit other pharmacy teams to prevent the same incident occurring in their own pharmacy.

Pharmacists will also be able to reflect on whether the patient safety incident reports their teams are currently making contribute to a supportive culture of improvement.

KEY FACTS

High reporting levels of patient safety incidents is associated with a strong safety culture

Details of an incident should be recorded and reported as soon as possible after it has taken place

Reports should be factual and include enough detail for someone who was not present to understand what happened and what the impact on the patient was

There is no 'correct' or 'safe' number of patient safety incidents

Incident reporting rates in community pharmacy range from 0 to 1.90 incidents per 10,000 prescription items dispensed

The 'Report, Learn, Share, Act, Review' wheel provides a simple framework for identifying and reporting a patient safety incident

The value of reporting incidents is not always seen immediately but reports are used at both local and national level to improve practice

Medication safety officers regularly share learning and recommended practice changes from serious or common patient safety incidents

Introduction & module overview

Patient safety is a fundamental consideration for all frontline healthcare professionals as well as their employers. All community pharmacists, pharmacy technicians and pharmacy support staff will recognise the importance of safely dispensing medication and providing appropriate advice to patients and the public. While things run seamlessly most of the time, it is important to learn the lessons when something does go wrong.

Significant progress has been made over the past decade in detecting, reporting and learning from patient safety incidents, with year-on-year incident reporting rates increasing. However, further improvements are needed across the NHS to maximise learning.

Background

A patient safety incident can be defined as any unintended or unexpected incident that could have or did lead to harm for one or more patients.¹ In community pharmacy settings, this includes both dispensing errors and other incidents, such as incorrect advice being provided for an OTC product.

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Standards for incident reporting

In November 2016, the Royal Pharmaceutical Society, Pharmacy Forum of Northern Ireland and Association of Pharmacy Technicians UK published professional standards for the reporting, learning, sharing, taking action and reviewing of incidents⁴. Barriers to reporting incidents, and potential solutions to these, were explored in the development of the standards.

Patient safety incidents are potentially preventable and can be reduced through the systematic application of procedures for identifying, reporting and learning from mistakes when things go wrong, and by making changes to practice accordingly.

Experience from other sectors and industries shows that effective learning and improvement is dependent upon the timely reporting of safety incidents via centralised, non-punitive and user-friendly systems. For the NHS in England and Wales, the National Reporting and Learning System (NRLS) has been established to meet this requirement. The NRLS enables patient safety incident reports to be submitted to a single database that covers the whole healthcare system, providing the NHS with a national perspective on risk and harm.

The organisation currently responsible for managing this system on behalf of the health service is NHS Improvement. Submitted data is analysed to identify hazards and risks, as well as opportunities to improve the safety of patient care. Trends and patterns are identified and tools or guidance developed to help create learning opportunities for healthcare professionals to improve patient safety and take action at a local level. Reporting to the NRLS has increased year-on-year since its inception in 2003, and it is anticipated this increase will continue as the culture of reporting all patient safety incidents spreads across the NHS.²

Since 2005, under the terms of the NHS Community Pharmacy Contractual Framework³, all pharmacy contractors in England and Wales have been required to report patient safety incidents to the NRLS. In Scotland and Northern Ireland, local anonymous reporting systems are used, supported by the Healthcare Improvement Scotland Adverse Events National Framework and the Health and Social Care Framework for Adverse Events in Northern Ireland.⁴

In 2014, NHS England issued a directive recommending that all community pharmacy organisations (as well as NHS trusts, homecare companies and independent providers) identify a named medication safety officer (MSO) to review medication incidents and oversee safety improvements within their organisation. Many MSOs in community pharmacy organisations are the superintendent pharmacist, or work in their team, and are also the point of contact for safety for their teams located outside of England and Wales.

Community pharmacy context

Community pharmacies use several different channels and platforms to regularly upload patient safety incident data to the NRLS. Some will upload their incident data directly to the NRLS as each incident occurs. Others will report their data to their MSO, who will then work with a central office team to collate incident data

Reflection exercise 1

Think about a patient safety incident that occurred in your pharmacy:

- Was it reported?
- Are the procedures for reporting incidents clear?
- Was adequate time taken to reflect on what the contributory factors were?
- What actions were taken to mitigate the risk of the same (or a similar) incident occurring again?

centrally in order to conduct internal trend analysis. The central office teams will then upload all their reports to the NRLS in batches, usually every few months. Unfortunately, due to the way in which the current NRLS is set up, this can sometimes result in data going missing or batches being rejected, which skews the overall national reporting picture.

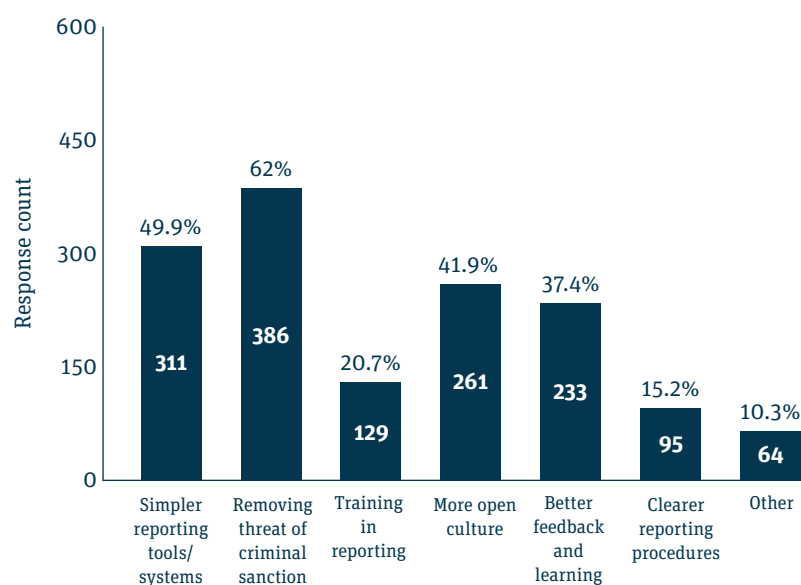
Barriers and enablers

In January 2016, the MSOs ran an anonymous survey to gather insight from frontline teams on safety culture and incident reporting. Respondents to the survey indicated that their company procedures for reporting incidents were generally clear but said there were still a number of barriers that prevented them from effectively embedding a culture of reporting and learning from patient safety incidents.

The two most significant barriers highlighted were time constraints and a fear of criminal prosecution. Removal of the threat of criminal prosecution may go some way to encouraging community pharmacy teams to embed a reporting and learning culture, but it is not the only solution. Around half of survey respondents (n=311) indicated that simpler reporting tools and systems would encourage them to report more patient safety incidents, while 42 per cent felt a more open culture at their place of work would help.



Figure 1: What would encourage you to report more dispensing incidents?⁵



The Report, Learn, Share, Act, Review framework

Based on the insights gained from their survey of frontline pharmacy teams, the MSOs developed a set of patient safety incident reporting principles, which are presented in the Report, Learn, Share, Act, Review (RLSAR) wheel. This provides a simple framework that pharmacy teams can use to structure their actions when identifying and reporting a patient safety incident.

The wheel has been embedded into professional standards⁴ for pharmacists, pharmacy technicians and the wider pharmacy team, as well as NHS England's recommended templates for monthly and annual patient safety incident logs, in line with quality payment criteria.⁶

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Figure 2: Report, Learn, Share, Act, Review (RLSAR) principles wheel for patient safety incidents



How reporting contributes to incident management

The process of reporting incidents of any nature as soon as they are identified may be critical to the immediate safety of the patient concerned. It also allows for a full investigation to commence in an appropriate time frame, ensuring that full details are available and lessons are learned as soon as is possible. Each pharmacy will have its own incident management standard operating procedure (SOP) and should conduct an internal review to understand the underlying causes or events which led to the incident, as well as any contributory factors.

Alongside managing the incident at a local level, reporting what happened and what action was taken in the pharmacy to prevent a similar incident happening again raises awareness of potential risks and allows other pharmacy teams to learn from something that has gone wrong. Teams can then reflect on their own practice to consider whether any changes should be made to minimise risks to patients.

What does 'good' reporting look like?

Data gathered by the MSOs in January 2017 found that the number of reported patient safety incidents per 10,000 items dispensed in community pharmacy in

Reflection exercise 2

- Approximately how many incidents did your pharmacy report in 2016?
- Are you confident that you and your team reported everything you should have?
- How do you ensure all pharmacy team members are aware of the incident and actions taken?
- How could your incident reports and reporting processes be improved?

2016 ranged from 0 to 1.90, with a mean average of 1.05 reported incidents per 10,000 items dispensed.

There is no 'correct' or 'safe' number of patient safety incidents. A 'low' reporting rate should not be interpreted to mean that a pharmacy is 'safe' and may in fact represent under-reporting. Similarly, a 'high' reporting rate should not be interpreted to mean a pharmacy is 'unsafe' and may actually indicate a culture of greater openness and a commitment to patient safety improvement.

In order to reduce the variation in reporting rates and introduce some standardised approaches to reporting, the MSOs have developed some best practice recommendations for submitting individual patient safety incident reports and logging monthly or annual trends.

Pharmacists and their teams should always follow their own company's SOP for reporting an incident, but some general best practice recommendations for submitting individual incident reports include:

- All patient safety incidents should initially be handled at pharmacy level, including discussing the incident with those individuals involved and the immediate pharmacy team
- Details of the incident should be recorded and reported as soon as possible after it takes place

Table 2: Understanding the NRLS patient harm definitions⁷

Degree of harm	Definition	Practice example
No harm	Any patient safety incident where no harm was caused	A patient is given someone else's medication. They notice the medication is not theirs, do not take any and return it to the pharmacy
Low harm	Any unexpected or unintended patient safety incident that required extra observation or minor treatment and caused minimal harm to one or more persons	A patient is given someone else's medication. The medication is the same as they normally take, but at a slightly higher dose. They take the medication and need to go to bed earlier due to drowsiness
Moderate harm	Any unexpected or unintended patient safety incident that resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused short-term harm to one or more person	A patient is given someone else's medication. The medication is stronger than their own and they suffer prolonged drowsiness for a week. The patient needs frequent observation of their respiratory rate
Severe harm	Any unexpected or unintended patient safety incident that caused permanent or long-term harm to one or more persons	A patient is given someone else's medication. They have an allergic reaction to it, have a cardiac arrest and suffer brain damage as a result of receiving the medication
Death	Any unexpected or unintended patient safety incident that caused the death of one or more persons	A patient is given someone else's medication. They have an allergic reaction to it, have a cardiac arrest and die as a result of taking the medication



Next month's CPD module...

Community pharmacy and palliative care: developments in practice

Learning scenario 1

Sophia Hussain's GP has recommended that she purchase salicylic acid gel 12% for a recent flare-up of facial warts along her jawline. The only OTC products available are a treatment gel that contains 4% lactic acid + salicylic acid and an extra strength treatment gel that contains 26% salicylic acid, but they are not recommended for use on the face. Ms Hussain insists on purchasing the lower strength product, saying she has used it before. You sell her the product but she returns two days later with inflamed and damaged skin along her jawline.

Which would be the most appropriate course of action?

- Reports should be factual and include enough detail for someone who was not present to understand what happened and what the impact on the patient was
- Incident descriptors should be aligned to the NRLS or other reporting system codes
- Each report should identify contributing factors and actions planned to prevent the incident from happening again
- Each report should categorise the actual degree of harm caused to a patient as a direct result of the safety incident.

Reporting systems should be set up in a way that is 'user friendly' for the pharmacy team but still ensures sufficient information is gathered from every patient safety incident, including those which do not result in actual or serious harm for the patient involved. Table 2 provides some practice examples for how medication incidents should be categorised.

Alongside work to improve reporting systems and tools for individual patient safety incident reports, the MSOs have worked with NHS Improvement, NHS England and PSNC to create templates to record the learning and improvement actions that have been taken on both a monthly and annual basis. These reports are designed to support community pharmacies achieve the quality criteria set out in the 2017/18 community pharmacy contractual framework. Further information is available in NHS England's Quality Criteria guidance⁸ and on the PSNC website.

What happens to incident reports?

Incident reports are used in a variety of ways to help individuals and the system as a whole to identify safety risks and address them. Although you may not always receive formal feedback on an individual incident you report, you can be assured that by feeding into the national system you are making a difference to the bigger picture of patient safety.

MSOs also meet every other month to share the learning and recommended practice changes from serious or regular patient safety incidents. Details of serious incidents and actions taken within community pharmacy are also shared

- Suggest she gets a prescription to treat the inflammation.
Report the incident as 'no harm'
- Phone her GP to explain what has happened. Report the incident as 'low harm' and arrange a team meeting to discuss how the situation could have been better handled
- Offer her a topical cream to treat the inflammation and make a record in her PMR that she should not be sold salicylic acid
- Phone her GP to explain that salicylic acid was not licensed for the indication that Ms Hussain presented with and therefore he should report the incident as 'incorrect advice given'

Learning scenario 2

A prescription for omeprazole 20mg dispersible tablets is brought into your pharmacy for a nine-month old baby called Peter Hopkins. The prescription is received and labelled in accordance with the prescriber's directions, 'one to be taken daily', and assembled. As the responsible pharmacist you are currently checking prescriptions for the local care home in a separate area of the dispensary. One of your team places Peter's waiting basket among the care home baskets. You check this item and it is given to Peter's mother. Less than five minutes later she returns as she has noticed the medication inside the dispensing bag has a different name to that written on the prescription. The medication dispensed is olanzapine 20mg dispersible tablets. This would have made Peter very drowsy and he probably would have ended up in hospital, depending on how many doses were administered.

How would you classify this incident?

- A near-miss
- No harm
- Low harm
- Moderate harm

 Answers on page vi



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with a national network of MSOs from across the health system through regular webinars.

After a patient safety incident report has been submitted to the NRLS, it is entered into a national database, which is analysed by national patient safety experts to spot trends, specific incidents of concern, or emerging risks to patient safety. When a trigger incident or group of incidents of particular concern is identified, action is taken to help address the identified issues/risks through advice and guidance, which is disseminated as appropriate across the NHS.⁹

Incident reports submitted directly into reporting systems and/or raised by the MSOs will also feed into the National Patient Safety Response Advisory Panel, which determines when a NHS-wide alert should be issued relating to a safety risk. The panel recently issued alerts following serious incidents relating to the risks of extracting insulin from pen devices and the risks of valproate medicines for girls and women of child-bearing age.

The MSOs also share incident trends and aggregated data with the MHRA, which can be valuable should any packaging changes be recommended to mitigate the risk of selection errors. As a result of sharing data and effective collaboration, a recent change was made to the packaging for chloramphenicol ear drops to reduce the likelihood of being selected instead of chloramphenicol eye drops.

Summary

In order to provide high quality care and continually improve safety, community pharmacies should have robust, simple systems in place for staff to use when an incident occurs. The value of reporting patient safety incidents is not always seen immediately but this does not mean that these reports are not used at both a local and national level to improve practice. Alongside their internal incident review and management systems, all pharmacy teams should embed the Report, Learn, Share, Act, Review principles into their practice and use them to guide their response to every patient safety incident that occurs, even those which do not cause actual harm to the patient.

References

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2. NHS Improvement (September 2016). Guidance notes on NRLS quarterly data summary publications: improvement.nhs.uk/uploads/documents/QDS_FAQs_Sept_2016.pdf
3. Pharmaceutical Services Negotiating Committee (December 2014). Patient safety incident reporting: psnc.org.uk/contract-it/essential-service-clinical-governance/patient-safety-incident-reporting
4. Royal Pharmaceutical Society (November 2016). Professional standards for the reporting, learning, sharing, taking action and review of incidents: rpharms.com/support-pdfs/rslar-standards-nov-2016.pdf
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6. NHS England (February 2017) Pharmacy Quality Payments – Quality Criteria Guidance: england.nhs.uk/wp-content/uploads/2017/02/quality-payments-quality-criteria-guidance-1.pdf
7. Created using National Reporting and Learning Service (NRLS) e-form definitions of degrees of harm: eforms.nrls.nhs.uk/staffreport/help/AC/Dataset_Question_References/Patient_details/Individual_patient/Impact_on_patient/PDO9.htm
8. NHS England (February 2017). Pharmacy Quality Payments – Quality Criteria Guidance: england.nhs.uk/wp-content/uploads/2017/02/quality-payments-quality-criteria-guidance-1.pdf
9. NHS England (February 2015). Guide for general practice staff on reporting patient safety incidents to the NRLS: england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/02/gp-nrls-rep-guide2.pdf



Answers: learning scenario 1

- Suggest she gets a prescription to treat the inflammation. Report the incident as 'no harm'.**
INCORRECT. The incident resulted in actual harm for the patient and, although it did not cause permanent harm, it will have caused unnecessary distress and discomfort – so should not be classified as 'no harm'. The salicylic acid should not have been sold for use on the face, even though the patient said she had used it before. This learning should be shared with both the pharmacy team and the GP.
- Phone her GP to explain what has happened. Report the incident as 'low harm' and arrange a team meeting to discuss how the situation could have been better handled.**
CORRECT. Sharing the incident details with the GP and explaining what has happened, as well as reporting the incident to the central system and discussing what happened with other team members, should help to prevent similar incidents from occurring again.
- Offer her a topical cream to treat the inflammation and make a record in her PMR that she should not be sold salicylic acid.**
INCORRECT. An appropriate course of action would include involving, or at the very least notifying, the GP of what has happened, especially as the product was unlicensed for the patient's indication.
- Phone her GP to explain that salicylic acid was not licensed for the indication that Ms Hussain presented with and therefore he should report the incident as 'incorrect advice given' and arrange to see her later that day.**
INCORRECT. Although it is correct that the product was not licensed for the indication which Ms Hussain presented with, the incident should be reported as a patient safety incident in the pharmacy, as it was the pharmacist who chose to supply the product. It would still be helpful to notify the GP of what has happened, as well as discussing with the other pharmacy team members.



Answers: learning scenario 2

- A near-miss**
INCORRECT. The wrong item left the dispensary with the patient/carer and therefore should be treated as a dispensing incident, not a near-miss, even though the medication itself was not taken and no actual harm was caused as a direct result of the incident.
- No harm**
CORRECT. As the mother noticed the mistake before giving any of the medicine to her child, no actual harm was caused and it should therefore be classified as 'no harm'. The incident should still be reviewed and reported to raise awareness of the risk and allow the pharmacy team to discuss how to prevent it occurring again.
- Low harm**
INCORRECT. Although the incident could have caused harm to such a young patient, in this case the mother spotted the mistake before giving any of the medicine to her child – so no actual harm was caused as a direct result of the incident.
- Moderate harm**
INCORRECT. Although the incident could have caused moderate harm to such a young patient, in this case the mother spotted the mistake before giving any of the medicine to her child – so no actual harm was caused as a direct result of the incident.

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