How to Report Medication Safety Incidents from a GP Practice on the National Reporting and Learning System (NRLS)

This document provides a quick explanation of why patient safety incident reporting is necessary in healthcare and shows you how to do it. Increased patient safety incident reporting is one of the key measures in the NHS Outcomes Framework 2014-15. There is a particular focus on more reporting from primary care (e.g. GP practices, community pharmacies, care homes etc.). Increased incident reporting is included in the 2014-15 quality premiums for CCGs and many CCGs will now have appointed a local Medication Safety Officer to help with reporting.

All patient safety incidents should be reported to the NRLS - both clinical and non-clinical. It’s important to report all incidents as the learning from one patient safety incident can be shared and may benefit lots of other patients elsewhere.

Here we have used three common examples of medicine incidents identified in a GP practice to help with this.

1. **GP practice reporting error that occurred in their own practice**: Out of date GP records. Patient receiving methotrexate on advice of a hospital consultant, but prescribed by GP. The most recent hospital letters give dose as 10mg once weekly but repeat prescription records have not been updated and still printing as 15mg once weekly.

2. **GP practice reporting error made by the GP practice/ hospital prescriber**: Lack of monitoring. A patient regularly prescribed lithium but has not had any monitoring documented for 8 months.

3. **GP practice reporting error made by a community pharmacy**: Dispensing error detected by GP when patient complains that treatment is not effective. Pantoprazole 20mg daily was prescribed, but the tablets supplied are actually pravastatin 20mg.

*Reporting isn’t hard; this document is 20 pages long only because there are lots of screen shots which take up loads of space.*
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Background to reporting

The National Reporting and Learning System (NRLS) was established in 2003 to try and improve patient safety. Although patient safety incidents can never be prevented totally, there is a need to share information about adverse events to ensure lessons are learned and previous tragedies are not repeated. Since its inception, the NRLS has used the patient safety incidents reported to identify particular risks and how they might be avoided. Medicines examples include safety alerts on oral anti-cancer medicines, opioid dosing and insulin.

The definition of a patient safety incident is ‘Any unintended or unexpected incident which could have or did lead to harm for one or more person(s) receiving NHS funded care’. This means that any incident, even if the incident was prevented, can be reported.

Since July 2012, the definition of an Adverse Drug Reaction (ADR) has been extended to include harm that results from medication errors, off-label use, and abuse of the medical product. The established yellow card system for reporting ADRs to the Medicines and Healthcare Products Regulatory Agency (MHRA) will continue unchanged, but medication error incidents will be monitored via the NRLS (See Appendix 1).

It is very important to be clear that incident reporting is not about blame or retribution. In fact increasing reporting is a sign of an open and maturing safety culture. The intention is to enable everyone to learn from mistakes and help stop them happening again.

Unfortunately our increasingly litigious culture may make people reluctant to report safety incidents. This is particularly serious for medicine incidents where changes are being implemented, but dispensing and labelling errors are currently still criminal offences. There is also a capacity issue. A recent major study of prescribing errors in General Practice found that 1 in 550 prescription items had a severe error and 1 in 20 had a mild to moderate error. There are now over 1 billion prescriptions dispensed each year so severe prescribing errors alone could total nearly 2 million.

Since reporting in primary care is starting from a very low base the current aim is simply to increase reporting of any incident types. (A strategy developed to prioritise reporting of medicine incidents in NHS Trusts is given in Appendix 2.)

Most NHS provider organisations and large chain community pharmacies will use an ‘in house’ system for incident reporting (e.g. Datix) and information from such systems is up-loaded onto the NRLS or submitted to the safety team at NHS England. However, any organisation or individual (patient or professional) can report safety incidents directly to the NRLS, no additional incident reporting system is needed.

NHS Trusts receive feedback from the NRLS about reporting rates and types of incidents every 6 months, CCGs need to be registered with the NRLS to get their data. The local Quality & Safety Lead is the person to contact to find out who within the CCG is the Local NRLS Reporting Manager.

We should thank those reporting incidents because without their effort and contribution the opportunity to learn and improve safety is lost

What should be reported?

**Dispensing errors** that do reach the patient are often identified by patients, pharmacies, GP practices or hospitals. These do need to be reported to the NRLS even when the patient has not taken the medication or no harm has been done. The healthcare professional who identifies the error should generally make the report, even when the mistake was made by someone else. There should be procedures in place to feedback to the organisation and healthcare professional responsible for the mistake. A general policy for incident feedback between different NHS contactors and organisations is under development which can be adapted for local use. NRLS administrators will identify and amalgamate reports of the same incident from different sources.

**Prescribing errors** where a prescription has been issued with a mistake that has potential to cause harm, this should be entered on the NRLS. Pharmacies routinely identify such errors and will intervene and contact the prescriber so no harm occurs. Nevertheless reporting to the NRLS is necessary and should be done by the pharmacy that identifies the problem unless the prescriber wishes to do this. As for dispensing errors, a clear policy for incident feedback would help to overcome the inter-professional difficulties of reporting other professionals’ mistakes.

A legal problem, such as a CD prescription not written correctly, is not a safety incident unless it results in a patient not receiving necessary medication or being harmed in some other way.

**Pharmacists working in GP practices** will often pick up prescribing problems when doing medication reviews or routine audits. Issues such as non-synchronised medicine quantities, medicines prescribed ‘As directed’, use of non-formulary products may indicate poor practice, but would not generally be reported to the NRLS.

However, the following examples would be appropriate to report:

- Patients without necessary safety monitoring e.g. INRs on warfarin
- Incorrect repeat medicine lists e.g. not updated following a hospital admission
- Prescribed medicines that are incompatible with a documented allergy status

**What does not need to be reported to the NRRLS?** In community pharmacy or dispensing surgeries there is no need to report to the NRLS any incidents or errors that are corrected during the normal dispensing processes before being issued to a patient. So if a picking or labelling error is made (e.g. wrong strength, wrong medicine) this should be highlighted to the staff involved so they are aware and learn from the mistake, but this does not need to be reported nationally. Keeping a record of this type of ‘near miss’ in the pharmacy or dispensary is a useful learning tool.

**Time pressures?** Anyone can enter information onto the NRLS. For example, repeat medicines staff or a medicines counter assistant could use this guide to enter incidents onto the NRLS if the pharmacist, nurse or doctor jots down the key points.

Using the NRLS - where do you start?

**Step one:** Go to: [https://report.nrls.nhs.uk/GP_eForm](https://report.nrls.nhs.uk/GP_eForm)

Or use the icon on your desk top

Find out how to download the icon at:

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**NRLS report: GP PRACTICE REPORTING MEDICINE ERROR MADE BY THE GP PRACTICE OR HOSPITAL PRESCRIBER**

**Example one:** GP practice reporting error made by the same GP practice – 1] Methotrexate: Out of date GP records. Patient receiving methotrexate on advice of a hospital consultant, but prescribed by GP. The most recent hospital letters give dose as 10mg once weekly but repeat prescription records have not been updated and still printing as 15mg once weekly. Incident identified by CCG pharmacist working at the GP surgery doing audit work. Patient contacted; patient knew correct dose was 10mg not 15mg, and was taking 10mg.

**Example two:** GP practice reporting error made by the GP practice/ hospital prescriber – 2] Lithium: Lack of monitoring. A patient regularly prescribed lithium but has not had any monitoring documented in GP records for 8 months. The practice nurse identifies this when the patient attends a smoking cessation clinic.
Step two – General Practice Patient Safety Incident Form

There are several questions to be completed on this page.

*Don’t worry, if you think you have selected the wrong option for any of the questions, you can always go back and change your entry right up until you submit.*

**Q1 ODS Practice Code**
If you are unsure of your practice’s ODS code then ask your practice manager or you can look it up on [https://odsportal.hscic.gov.uk/Organisation/Search](https://odsportal.hscic.gov.uk/Organisation/Search). You will need to click on the XLS download for General Medical Practices towards the bottom of the page. Open the excel file and use the find function to narrow down your search.

When you have put your ODS code in click on the box **Click here to verify code**

The Practice name should now appear

Don’t forget to tick the box to share with the CCG.
Q2 If this incident is a safeguarding, whistleblowing or other Serious Incident it needs to be reported both on this form and according to your local Serious Incident Policy.

Neither of our examples would be considered in this category

Q2 (continued) Describe what happened.

Make sure you include the name of the medicine concerned, a lot of medication incident reports manage to miss this. Describe clearly what happened without apportioning blame and without naming names. Concentrate on the facts and describe events in the sequence in which they occurred. Do not enter any person identifiable information such as names, ages or dates of birth. Use of initials is acceptable.

Example of how to describe what happened:

A patient regularly prescribed lithium attended our smoking cessation clinic at the surgery. He asked whether stopping smoking could have any effect on his medication. I was unsure so asked the GP and she asked me to check what the patient’s last lithium level was. On checking, we found we had no records of lithium monitoring since November last year (8 months ago) and the patient couldn’t recall any recent blood tests. The patient did not feel unwell or think he had any problems.

The GP completed the blood test forms and I took blood samples so we could check levels and do blood safety monitoring as quickly as possible.

The results were all fine and we have now put a pop up message on the system reminding about regular blood tests.
In both our examples there is not a clear date when the incident occurred, so enter the date the incident was discovered.

Both the examples happened in the GP surgery. You can then choose ‘GP Surgery - Treatment/consulting room’ or ‘GP Surgery - other’.

Remember, you are entering where the incident actually happened, not where it was detected.

Categorising the incident
Assume it’s as easy as it looks.

These are ‘Medication’ incidents.

The first example with methotrexate is a “Prescribing” incident. The second example with lithium is a “Monitoring/ follow-up of medicines use” incident.

The first example with methotrexate is a “Wrong / unclear dose or strength”. The second example with lithium is “Other” with “Failure to monitor Lithium” added in the free text box.
Step three – Additional information for Patient Safety Incident involving medication

At this point a new screen opens with Q5a – Q5h which are optional. Remember the more information you can give about the incident the better. So please answer as many questions as you can.

Q5a Asks you to indicate what other factors were important and more than one can be selected. If you click the ? then all the options are shown with scenarios of possible incidents.

For our methotrexate incident “Poor transfer / transcription of information between paper and / or electronic forms” could be chosen but “other” could also be chosen and a brief description inserted. For our lithium incident “Failure in monitoring / assessing medicines therapy” is the most appropriate choice.

Q5b - Q5h are self-explanatory and will be generated depending on the category selected in Q5.2, for example in our methotrexate incident we selected “Wrong / unclear dose or strength”; this will result in questions about what the dose was and what it should have been.

At the end of this section click close

If you need to change anything you can Click here at Q5
Step four – returns to the main question page

Q5.3 What is the approved drug name of the medicines?*

Approved drug name

Q5.3 Asks for the approved name of the drug involved, this is the generic name. The proprietary (trade) name can be given in Q5b and must be included for drugs where the brand needs to be specified (as in our lithium example) or where the error involved the brand name.

If the incident involved more than one drug, try to choose the drug which caused the incident and avoid “all drugs”.

Q6 Never Events

Click the ? button on the right to see a list of never events. Medicine never events include specific errors where harm resulted e.g. with insulin, opioid, chemotherapy etc. Methotrexate given once daily when it should be once weekly is a never event, but our Methotrexate example is not a never event so the no should be ticked (More information on ‘Never events’: http://www.england.nhs.uk/ourwork/patientsafety/never-events/)

Q7 Asks if the patient, carer and/or their family has been informed about the incident
Q8: This is the actual harm the patient suffered from the incident

In the methotrexate example, the patient did not take the wrong dose so it was a *No Harm* incident.
The actual harm from failing to monitor lithium in our example was *Low Harm* as an unplanned blood test was needed but the results came back within normal range.

Click the ? button to get further information about grading incidents.

Q9 & Q10: Are self-explanatory

Q11 & Q12: These questions are not about blame or checking up on anyone.

If you enter your email address, you’ll get a Significant Event Audit template which you can use to reflect on your learning and add to your CPD.

All that remains is to click the Submit button.

Once you have submitted the incident, a Patient Safety incident Report will appear. This can be saved or printed by clicking on the appropriate icon at the bottom left of the screen.
**NRLS reports: GP PRACTICE REPORTING MEDICINE ERROR MADE BY A COMMUNITY PHARMACY**

**Example three:** This incident is where a GP surgery picks up an error made by a pharmacy - 3] Dispensing error detected by GP when patient complains that treatment is not effective. Pantoprazole 20mg daily was prescribed, but the tablets supplied are actually pravastatin 20mg

(See page 5 for Step one)

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**Step two – General Practice Patient Safety Incident Form**

There are several questions to be completed on this page.

*Don’t worry, if you think you have selected the wrong option for any of the questions, you can always go back and change your entry right up until you submit.*

**Q1 ODS Practice Code**

If you are unsure of your practice’s ODS code then ask your practice manager or you can look it up on [https://odsportal.hscic.gov.uk/Organisation/Search](https://odsportal.hscic.gov.uk/Organisation/Search). You will need to click on the XLS download for General Medical Practices towards the bottom of the page. Open the excel file and use the find function to narrow down our search.

When you have put your ODS code in click on the box

**Click here to verify code**

The Practice name should now appear

Don’t forget to tick the box to share with the CCG.
Q2 Please describe what happened?
If this incident relates to safeguarding, whistleblowing or other Serious Incident where separate policies and local arrangements exist, these must be followed in addition to completing this form.

Do not include patient or person identifiable information

Q2 If this incident is a safeguarding, whistleblowing or other Serious Incident it needs to be reported both on this form and according to your local Serious Incident Policy. Our example would not be considered to be in this category.

Q2 (continued) Describe what happened. Make sure you include the name of the medicine concerned, a lot of medication incident reports manage to miss this. Describe clearly what happened without apportioning blame and without naming names. Concentrate on the facts and describe events in the sequence in which they occurred. Do not enter any person identifiable information such as names, ages or dates of birth. Use of initials is acceptable.

Example of how to describe what happened:

AB attended the practice with a packet of tablets which had been prescribed for him 2 weeks ago. He had on-going indigestion and reflux and had been prescribed pantoprazole 20 mg each morning. The tablets he had been given by the pharmacy were actually pravastatin 20 mg but were labelled pantoprazole. AB had been taking them regularly but his gastric symptoms had continued.
Q3 This is the date the GP identified the dispensing error.

Q4
The incident occurred outside the GP Practice and the most appropriate answer for our example is “Primary care setting”
Then choose “Other” and in the free text box add “Community Pharmacy”
**Q5 Categorising the incident**

**This is a ‘Medication’ incident**

**Q5.1** Our example is a “Preparation of medicines in all locations / dispensing in a pharmacy” incident.

**Q5.2** this would be a “Wrong drug / medicine”
Step three – Additional information for Patient Safety Incident involving medication

At this point a new screen opens with Q5a – Q5h which are optional. Remember the more information you can give about the incident the better. So please answer as many questions as you can.

Q5a Asks you to indicate what other factors were important and more than one can be selected. If you click the ? then all the options are shown with scenarios of possible incidents.

For our incident “Medicines with similar looking or sounding names” is the most appropriate choice.

Q5b - Q5h are self-explanatory and will be generated depending on the category selected in Q5.2, for example in our incident we selected ”Wrong drug / medicine” ; this will result in questions about which drug was intended and the wrong drug in the incident.

At the end of this section click close

If you need to change anything you can Click here at Q5
Step four – returns to the main question page

Q5.3 Asks for the approved name of the drugs involved, these are the generic names of the intended drug and the wrong drug.

Q6 Never Events
Click the ? button on the right to see a list of never events. Medicine never events include specific errors where harm resulted e.g. with insulin, opioid, chemotherapy etc.

This pantoprazole/ pravastatin dispensing error is not a never event.

(More information on 'Never events': http://www.england.nhs.uk/ourwork/patientsafety/never-events/)

Q7 Asks if the patient, carer and/or their family has been informed about the incident
**Q8**

This is the actual harm the patient suffered from the incident

The patient did have ongoing reflux symptoms, likely due to no pantoprazole, but pravastatin did no apparent harm. We selected *Low Harm* here as the incident probably resulted in additional visit to GP because of poor symptom control. However, there was no significant or permanent harm.

Click the ? button to get further information about grading incidents

**Q9 & Q10**

Are self-explanatory

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**Q11 & Q12**

These questions are not about blame or checking up on anyone.

If you enter your email address you’ll get a Significant Event Audit template which you can use to reflect on your learning and add to your CPD

All that remains is to click the Submit button

Once you have submitted the incident a Patient Safety incident Report will appear. This can be saved or printed by clicking on the appropriate icon at the bottom left of the screen.
Appendix 1

How the medication incidents reported to the NRLS are reviewed:
NHS England and the Medicines Healthcare Regulatory Agency are both involved in reviewing medication incidents. This diagram describes the process:

1. **Preventable medication error reported to NRLS**
   - No harm occurred to the patient but there was potential for harm, or
   - Where harm resulted from omission or delay in using a medicine
   - NHS England review

2. **Preventable medication error reported to NRLS**
   - Where harm occurred to a patient when the medicine was used
   - NHS England review and share with MHRA

3. **Adverse drug reactions reported directly to the MHRA’s Yellow Card Scheme**
   - Where medication was used correctly according to the product licence, or
   - Unlicensed and 'off-label' use, or
   - Where no medication error has occurred, or
   - Associated with abuse or deliberate abuse
   - MHRA review
Appendix 2

Stepped strategy for prioritising medication incident reports

1. Report all medication incidents that actually result in patient harm, even when other work pressures are high (possibly report very brief information initially then add more detail later).

2. Report all incidents (i.e., including those where harm was prevented) which are considered to have the potential for severe harm or fatality.

3. Report all incidents (i.e., including those where harm was prevented) directly related to pharmacy processes, which are detected after the final internal checks.

4. Carry out intensive reports for all incidents (i.e., including those where harm was prevented) with all potential levels of harm for ‘high risk’ medicines or processes (e.g., anticoagulants, opiates, ward transfer, discharge) over appropriate periods.

Livingstone C, Nicholls J. What kind of medication incidents should pharmacists be reporting? Clinical Pharmacist vol 3 Jan 2011