Reporting and learning from patient safety events in EQA

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1. Scope

The purpose of this policy is to assist learning from patient safety events (PSEs) in external quality assurance (EQA) programmes, to share learning via national reporting systems and to formulate a process for learning from these incidents. This will provide an opportunity for laboratories and the EQA system to continuously improve the quality and safety of patient care.

The policy may also be used to inform reporting into the National Reporting and Learning System (NRLS), at the time of writing, and its successor, the Learning from Patient Safety Events (LFPSE) service.

The policy is not intended for the escalation of investigation of the persistent poor performance of individual laboratories, which is managed through the Escalation policy (document WS20501), but dovetails with this policy. Note that an actual or potential PSE in EQA is poor performance; however, poor or persistent poor performance is not necessarily a PSE.

2. Introduction

Patients can be inadvertently harmed by any event that occurs during their care, including those related to errors in laboratory medicine. Pathology results are vital to the patient's diagnostic pathway, ensuring that the patient receives the correct healthcare services at the correct time and in the correct place.

Poor quality laboratory test results have the potential to cause harm. The volume of test requesting means that a single adverse quality event may have an impact on hundreds if not thousands of patients over a relatively short period of time. The impact of events may result in missed or delayed diagnosis, delayed assessment of care or the administration of incorrect care.

Reporting patient safety concerns identified through EQA provision can allow reflection by the EQA provider, the laboratory and suppliers of laboratory equipment and kits, and enhance the service provided to and by clinical laboratories.

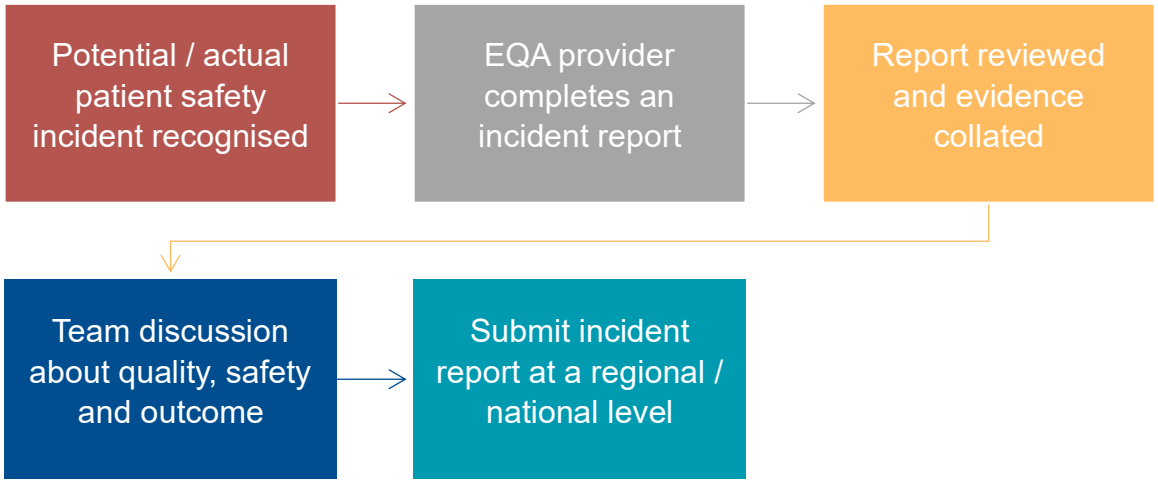
Investigation of poor performance, persistent poor performance and PSEs in EQA may highlight important issues and risks, which require improvement (at both a local and national level) and identify areas of concern to all laboratories.

Escalating PSEs allows healthcare providers to share learning from serious incidents.

The reporter should describe what happened in terms of the stages leading to an unsafe outcome for a patient or patients, and the potential contributory factors underpinning the incident. If the factors are identified and the processes are optimised, then patient safety incidents would be less likely to occur. Collating incidents at a national level can reveal issues that might have been overlooked at a local level. A volume of national reports can allow the modelling of the relationship between processes and any relevant contributing factors and would then allow opportunities for intervention.

The duty of candour applies to PSEs identified through the course of EQA monitoring and requires EQA providers to demonstrate an open culture, transparency of information and to inform where necessary.

3. Stages of the patient safety learning for improvement



The various stages should be considered in detail.

Stage 1

The EQA provider understands and identifies a performance issue that might represent a PSE in their EQA scheme.

Stage 2

The EQA provider knows how to report a PSE with confidence and without fear of blame. The overall aim is to identify ways in which to improve processes and ensure that such an incident does not re-occur.

Stage 3

The EQA provider collates essential information about the incident. Scheme advisors, manufacturers or other sources should be involved at this stage as appropriate. The severity of harm and the risk of recurrence are determined, and a risk score assigned, ranging from low to extreme risk. The EQA organiser decides whether all the facts have been determined and whether a more structured investigation is required.

Stage 4

The incident is escalated to the National Quality Assurance Advisory Panel (NQAAP) by the EQA provider and by the NQAAP chair to the Quality Assurance in Pathology Committee (QAPC). Decisions taken and the risk to patient safety (potential or actual) are reviewed.

Stage 5

The event is reported through the NRLS (at the time of writing), and the LFPSE in the future, if it is considered a potential PSE. The event is reported as an actual PSE if a lookback has shown that patients were affected.

For reference, further information is available from NHS England – Patient Safety Incident Response Framework.

4. Procedure

Potential and actual PSEs identified by EQA providers are reported using an SBAR style template (Situation, Background, Assessment, Recommendation), as shown in Appendix 1: Patient safety event reporting form template.

The completed SBAR report is escalated to the chair of the discipline-specific NQAAP for the analyte concerned and to the QAPC by the NQAAP chair.

The QAPC chair will share the SBAR report with members of the QAPC, which includes representatives from the MHRA, and will consider whether the incident should be shared with the Care Quality Commission (CQC) or equivalent across the devolved nations.

Further investigation/actions will be decided by the QAPC chair, including the reporting of the PSE to the NRLS (at the time of writing), as illustrated in **Appendix 2**: National Reporting and Learning System, and its successor, the LFPSE framework.

References

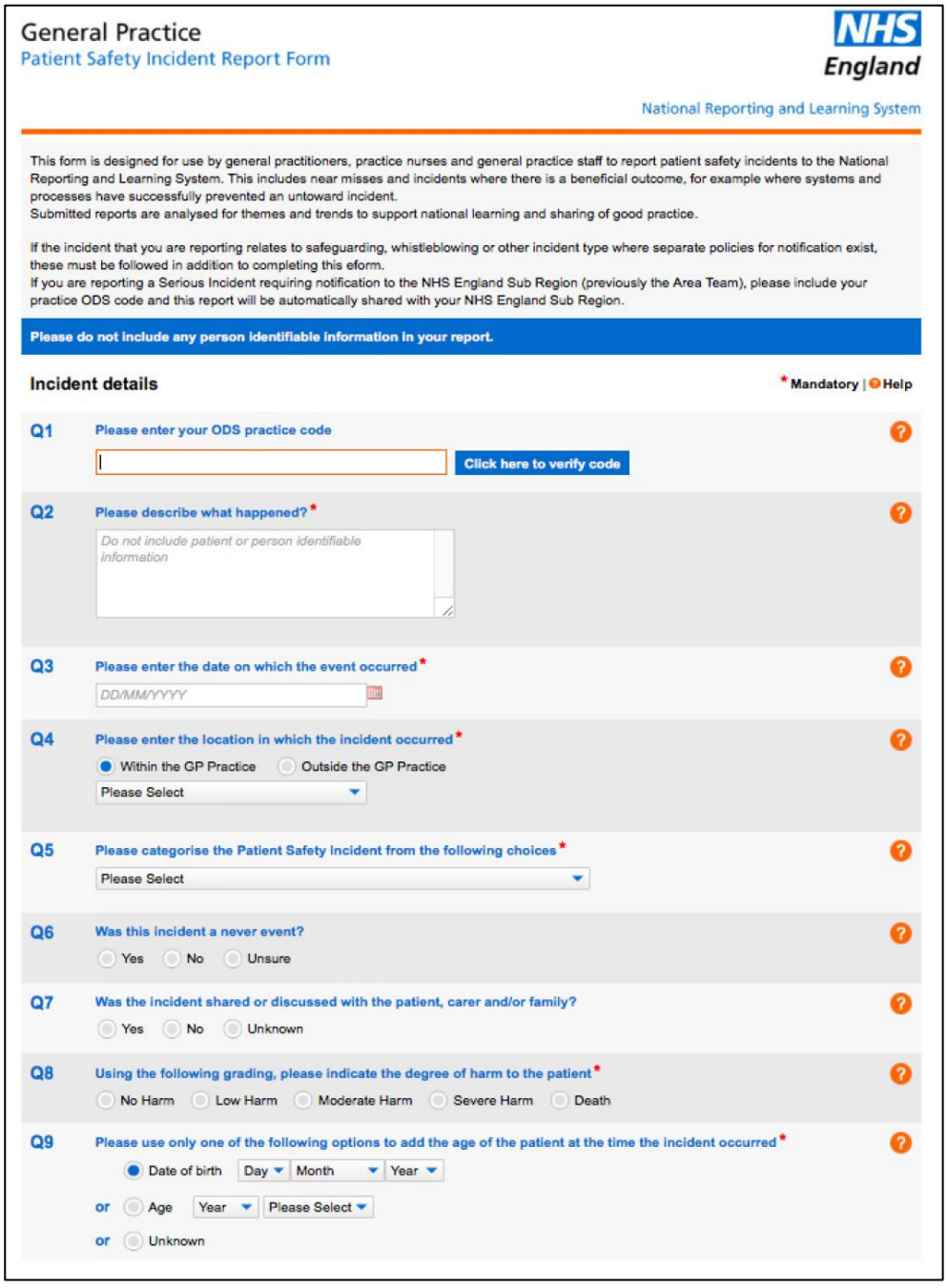
1. Carson-Stevens A, Hibbert P, Williams H, Evans HP, Cooper A, Rees P *et al*. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice. *Health Services and Delivery Research*. 2016;4:1–76.
2. The Royal College of General Practitioners. *Reporting and learning from patient safety incidents in general practice: A practical guide*. London, UK. Published April 2017. Available at: elearning.rcgp.org.uk/pluginfile.php/170665/mod_book/chapter/421/Reporting%20and%20learning%20from%20patient%20safety%20incidents.pdf

Appendix 1: Patient safety event reporting form template

S	**Situation:** Who (EQA provider details, laboratory type, manufacturer) What (analyte, summary of concern) When (timeframe)
B	**Background:** What happened? Immediate actions taken How was the incident investigated? Contributing factors Root cause analysis outcome
A	**Assessment:** Outcomes Actual / potential patient harm Severity Probability of recurrence *Assessment of risk*
R	**Recommendations:** Actions taken to prevent recurrence Escalation via the EQA Governance Framework Is a lookback exercise required for patient safety purposes?

Appendix 2: National Reporting and Learning System

The National Reporting and Learning System (NRLS) is a central repository of incident reports from healthcare organisations in England and Wales. Healthcare professionals can submit an incident report directly to NRLS in NHS England. The other UK countries have their own arrangements for reporting incidents.



General Practice
Patient Safety Incident Report Form

NHS England
National Reporting and Learning System

This form is designed for use by general practitioners, practice nurses and general practice staff to report patient safety incidents to the National Reporting and Learning System. This includes near misses and incidents where there is a beneficial outcome, for example where systems and processes have successfully prevented an untoward incident.
Submitted reports are analysed for themes and trends to support national learning and sharing of good practice.

If the incident that you are reporting relates to safeguarding, whistleblowing or other incident type where separate policies for notification exist, these must be followed in addition to completing this eform.
If you are reporting a Serious Incident requiring notification to the NHS England Sub Region (previously the Area Team), please include your practice ODS code and this report will be automatically shared with your NHS England Sub Region.

Please do not include any person identifiable information in your report.

Incident details

* Mandatory | Help

Q1 Please enter your ODS practice code
Click here to verify code

Q2 Please describe what happened? *
Do not include patient or person identifiable information

Q3 Please enter the date on which the event occurred *
DD/MM/YYYY

Q4 Please enter the location in which the incident occurred *
Within the GP Practice | Outside the GP Practice
Please Select

Q5 Please categorise the Patient Safety Incident from the following choices *
Please Select

Q6 Was this incident a never event?
Yes | No | Unsure

Q7 Was the incident shared or discussed with the patient, carer and/or family?
Yes | No | Unknown

Q8 Using the following grading, please indicate the degree of harm to the patient *
No Harm | Low Harm | Moderate Harm | Severe Harm | Death

Q9 Please use only one of the following options to add the age of the patient at the time the incident occurred *
Date of birth Day Month Year
or Age Year Please Select
or Unknown

Illustrated above is an example of the General Practice Patient Safety Incident reporting form used by NRLS. The system is available online.

Patient safety incidents can take many forms within the broader healthcare setting. The following list presents those identified in *Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice* as being most commonly encountered.[1] Clearly some are going to be more relevant to EQA-related incidents than others.

- Communication with patients
  - Miscommunication, e.g. inadequate safety netting advice.
  - Difficulties accessing clinical services, e.g. telephone triage, message handling and appointments.
  - Parent-held records unavailable.
- Communication between professionals
  - Unavailable or inaccurate medical records, e.g. paper notes from previous practice.
  - Delayed referrals, e.g. erroneously completed referral, delayed decision to refer.
  - Information transfer between care providers, e.g. delayed discharge summary or clinic letter.
- Diagnosis and assessment
  - Missed or delayed diagnosis.
  - Delayed assessment of care.
  - Delayed assessing of patients with serious mental health conditions.
  - Not identifying patients at risk of deterioration.
- Medication and vaccine
  - Errors in prescribing, dispensing and administering medicines and vaccines.

  - Complications with therapeutic drug monitoring processes.
- Investigations
  - Ordering inappropriate investigations to inform differential diagnosis.
  - Incorrect collection, or transfer, of specimens.
  - Administrative failures leading to delays, wrong results or failure to receive results.
  - Incorrectly interpreted results, e.g. blood tests, imaging, other investigations.
- Treatment and equipment
  - Complications of procedures.
  - Malfunctioning and unavailability of care equipment, e.g. pressure mattresses, oxygen, walking aids.

The Royal College of General Practitioners' *Reporting and learning from patient safety incidents in general practice: A practical guide*[2] suggests reporting a patient safety incident can allow:

- reflection on the incident by the reporter and enhanced professional development
- identification of opportunities to undertake significant event analyses
- collated reports at a Health Board or Clinical Commissioning Group to highlight local systems issues for change
- collated reports to help identify exceptional issues at the national level.