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1. What is a patient safety incident?

In July 2004, the National Patient Safety Agency (NPSA) defined a patient safety incident as: ‘any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare’.\(^1\)

Examples of patient safety incidents include:

- a patient has a severe allergic reaction to a medication
- a patient’s breathing is suppressed after a syringe driver’s flow rate is set inappropriately high
- an incision is made on the wrong limb of a patient scheduled for a joint replacement.

2. Can patient safety incidents be prevented?

Some types of incident can be prevented, but in other cases, specific incidents are unavoidable. In general, there are five types of patient safety incident:

- ‘near misses’: an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention
- serious incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. These incidents are known as Never Events
- incidents where there is clinical consensus that, with the appropriate care, they are ‘largely preventable’ (for example, the four adverse outcomes that make up the NHS Safety Thermometer)
- incidents where the emphasis has shifted from preventing the incident to reducing the harm suffered as a result of the incident (for example, falls)
- incidents which are unpreventable where, given the current knowledge base, there is no way of predicting that such an incident was likely to occur (for example, unpreventable adverse (drug) events).\(^2\)

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\(^1\) www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787

\(^2\) The World Health Organisation’s Conceptual Framework for the Classification of Patient Safety: Technical Annex 2 Glossary of Patient Safety Concepts and References, published in January 2009 defines “unpreventable adverse event” as “an adverse event resulting from a complication that cannot be prevented given the current state of knowledge”. It defines an “unpreventable adverse drug event” as “an adverse drug event that does not result from an error but reflect the inherent risk of drugs and cannot be prevented given the current state of knowledge”.
3. Is the National Reporting and Learning System the only database of patient safety incidents?

No. The National Reporting and Learning System (NRLS) is the only national patient safety incident database that includes all types of patient safety incident. There are other databases of patient safety incidents but many of these have been created specifically for a particular type of incident or have a broader remit. These include: the Strategic Executive Information System (STEIS); the Care Quality Commission (CQC) notification database; the Medicines and Healthcare products Regulatory Agency (MHRA) ‘Yellow Card Scheme’ and Serious Adverse Blood Reactions & Events (SABRE); the NHS Safety Thermometer; the Public Health England notifications database; and the Serious Hazards of Transfusion (SHOT) scheme.

There is more information on these here.

4. Are patient safety incidents the only measures of patient safety?

No. There are many sources of patient safety data: each has a unique perspective, with specific strengths and limitations. Each data source may detect a separate set of safety issues, with little or no overlap between sources. The ‘voice of the patient’ has been shown to be fundamental to understanding patient safety issues. (A key failure identified in the Mid Staffordshire NHS Foundation Trust Public Inquiry was that the trust board “did not listen sufficiently to its patients and staff...“)³ The Department of Health has instructed trusts to use the Summary Hospital-level Mortality Indicator (SHMI)⁴ in their quality accounts (These are reports on quality of the services provided, measured by looking at patient safety, the effectiveness of treatments that patients receive and patient feedback about the care provided.)⁵

5. What is the purpose of the NRLS?

The primary purpose of the NRLS is to enable learning from patient safety incidents occurring in the NHS. The NRLS was established in late 2003 as a voluntary scheme for reporting patient safety incidents, and therefore it does not provide the definitive number of patient safety incidents occurring in the NHS.

For more information on the NRLS click here.

³ The full Mid Staffordshire NHS Foundation Trust Public Inquiry report (including the executive summary) can be found at: www.midstaffspublicinquiry.com/report
⁴ More information on the SHMI is available at: www.hscic.gov.uk/SHMI
⁵ More information on quality accounts is available at: www.nhs.uk/aboutNHSChoices/professionals/healthandcareprofessionals/quality-accounts/Pages/about-quality-accounts.aspx
6. How are the NRLS data collected?

The NRLS collects data on patient safety incidents in England and Wales. Most patient safety incident reports are submitted electronically from local NHS organisation risk management systems. Organisations vary in how their local systems are set up, how many incidents are reported locally and how frequently they send data to the NRLS.

For more information on how the data are collected click here

7. Why are these data published?

A greater level of transparency, together with more thorough reporting and analysis of safety-related incidents, provides a real opportunity for the NHS at a local level and the NRLS at a national level to share experiences and learn from them. The transparency agenda is a pan-government initiative, in which healthcare data figure prominently. These quarterly dataset summary (QDS) workbooks are made available to the public to make data on patient safety incident reports from the NRLS more accessible. Patients, the public, academics, NHS commissioners and other organisations can all access the data and make comparisons that enable more informed choices, and help hold organisations to account (both locally and nationally).

Increased transparency is key to:

- improving outcomes and productivity in NHS services
- promoting higher quality and more efficient services, choice and accountability
- facilitating enhanced commissioning
- driving economic growth by enabling the development of tools to support users, commissioners and providers of NHS services.

8. In what format are the data published?

Since January 2009, these data have been published as Excel data workbooks, which comprise a year's worth of data, presented by quarter. When analysing the data we recommend you compare with the same quarter in the previous year. This is because there is seasonality within patient safety data.

For more information on seasonality click here

9. How often are the data published?

The intention is to publish every quarter but for practical reasons we tend to publish them every six months.
10. What steps does the NRLS take to ensure that the data are as accurate and consistent as possible?

Accuracy

Every month, NRLS shares back provisional data received with the submitting organisation to help identify possible data quality problems. This gives organisations the opportunity to check the data the NRLS has received and compare it with data in their local risk management system in a timely manner.

Consistency

The datasets underpinning the QDS workbooks are derived using coherent and consistent definitions. The workbooks are also subject to a rigorous quality assurance process. However, the NRLS is a dynamic database, and figures for previous quarters may change slightly when the workbook is updated.

For more information on a range of NRLS data quality issues click here

11. Why are some numbers ‘hidden’ (ie there is a * not a value in the table)?

The numbers are what they are, and some types of incidents are, thankfully, rare. Where the numbers involved are small, statistics (such as percentages) are not calculated and comparisons are not made. This is because statistics based on small numbers are unreliable, as it is almost impossible to distinguish random fluctuation from true changes in the statistic.

For the purposes of the QDS workbooks, ‘small’ has been defined as 30 incidents or fewer.

12. Can the data be broken down into the individual NHS organisations?

This dataset gives an overall picture of patient safety incident reporting across England and Wales, and therefore has never been presented on an organisation level basis. The Organisation Patient Safety Incident Reports (OPSIR) (NRLS UK Official Statistics) do present NRLS data on patient safety incident reporting, and the characteristics of patient safety incidents, for individual NHS organisations. They can be found here.)
13. What are the differences between the QDS workbooks and the Organisation Patient Safety Incident Reports (NRLS UK Official Statistics) workbooks?

The key differences between the two workbooks are summarised in Table 1 below.

Table 1: Key features of the QDS and Organisation Patient Safety Incident Report workbooks

<table>
<thead>
<tr>
<th>Feature</th>
<th>QDS</th>
<th>OPSIR: (NRLS UK Official Statistics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>To provide a national picture of the reporting of patient safety incidents, and of the characteristics of incidents (type, care setting, degree of harm). This dataset forms the basis of three of the four NRLS indicators within Domain 5 of the NHS Operating Framework ('Treating and caring for people in a safe environment and protecting them from avoidable harm')</td>
<td>To provide comparative data on individual organisations reporting and patient safety characteristics.</td>
</tr>
<tr>
<td>Dataset type</td>
<td>Dynamic*</td>
<td>Fixed/Static</td>
</tr>
<tr>
<td>Time period covered</td>
<td>A rolling year (in quarters)*</td>
<td>Six months</td>
</tr>
<tr>
<td>Updated</td>
<td>Every quarter*</td>
<td>Every six months</td>
</tr>
<tr>
<td>Units</td>
<td>By country (England or Wales)**</td>
<td>By individual NHS organisation</td>
</tr>
<tr>
<td>Exclusions</td>
<td>• reports from the public or patients</td>
<td>• reports from the public or patients</td>
</tr>
<tr>
<td></td>
<td>• reports from non-NHS organisations reports from clinical commissioning groups</td>
<td>• reports from non-NHS organisations reports from clinical commissioning groups</td>
</tr>
<tr>
<td></td>
<td>• reports from social enterprises</td>
<td>• reports from social enterprises</td>
</tr>
<tr>
<td></td>
<td>• reports from community pharmacies</td>
<td>• reports from community pharmacies</td>
</tr>
</tbody>
</table>

* Figures for previous quarters may change slightly (figures for four consecutive quarters are given in each workbook for incidents ‘occurring’, ie from tab 5 onwards in the workbook) as the NRLS is a dynamic system (and incidents can be reported, or updated, at any time after the event takes place)

** The ‘total’ numbers may exceed the sum of England and Wales, as in some cases the location of the patient safety incident is unidentifiable (eg where the incident location is missing or unknown, or the incident has been reported from a large pharmacy chain, such as Boots or Lloyds, with branches in both England and Wales).
14. Why are two datasets used?

To describe NLRS patient safety incident data as accurately as possible, two different datasets are used.

The ‘reported dataset’ is used to look at patterns in reporting. It contains incidents that were reported to the NRLS within a specified time period.

The ‘occurring dataset’ is used to look at patient safety incident characteristics. It contains incidents that have been reported as actually taking place in a specific time period (because, for range of legitimate reasons, there are often time lags between an incident occurring and being reported to the NRLS). There is also seasonality in patterns of patient safety incidents. So, to reduce the effects of ‘administrative seasonality’, when looking at the characteristics of patient safety incidents, we base the dataset on the date that the incident was reported to have actually taken place. This is done to minimise any artificially-created seasonality, while recognising inherent incident seasonality.

For more information on seasonality in patient safety incidents click here

15. What types of incident are reported?

There are currently 15 NLRS codes for type of incident:

1. Access, admission, transfer, discharge (including missing patient)
2. Clinical assessment (including diagnosis, scans, tests, assessments)
3. Consent, communication, confidentiality
4. Disruptive, aggressive behaviour
5. Documentation (including records, identification)
6. Infection Control incident
7. Implementation of care and ongoing monitoring / review
8. Infrastructure (including staffing, facilities, environment)
9. Medical device / equipment
10. Medication
11. Patient abuse (by staff / third party)
12. Patient accident
13. Self-harming behaviour
14. Treatment, procedure
15. Other
16. What types of care setting are there?

There are currently nine NRLS codes for the type of care setting:

1. Acute/general hospital
2. Mental health service
3. Community nursing, medical and therapy service (including community hospital)
4. Learning disabilities service
5. Ambulance service
6. General practice
7. Community pharmacy
8. Community and general dental service
9. Community optometry/optician service

17. Which is the safest care setting?

There is no ‘correct’ or ‘safe’ number of patient safety incidents: a ‘low’ reporting rate should not be interpreted as ‘safe’, and may represent under-reporting; a ‘high’ reporting rate should not be interpreted as ‘unsafe’, and may actually represent a culture of greater openness.

Low reporting rates do not necessarily mean that care is ‘safe’ or ‘good’, nor does it follow that high reporting rates are a reflection of ‘unsafe’ or ‘bad’ care. There are known reasons for ‘high’ and ‘low’ reporting. Some NHS organisations report to the NRLS daily, others quarterly. In many cases, incidents are grouped and submitted to the NRLS in large batches. It should never be assumed that the total numbers of patient safety incidents are representative of totals across the NHS. The reporting culture varies between organisation types: reporting in secondary care is far more common than in primary care; ambulance and mental health organisations have the most varied reporting patterns.

For more information on issues affecting the number of incidents reported (including changes in national reporting requirements) click here

18. What does degree of harm mean?

The degree of harm in the NRLS is intended to record the actual degree of harm suffered by the patient as a direct result of the patient safety incident. However, this is not always the case. Sometimes reporters provide the potential degree of harm of an incident instead of the actual degree of harm that occurred. For example, in the case of ‘near misses’ (where no harm resulted as the impact was prevented) the resulting degree of harm is occasionally coded as ‘severe’.
In addition, reporters may code the degree of harm as ‘severe’ when the patient is expected to suffer severe but temporary harm (for example, severe bruising), which conflicts with the NRLS definition of significant and permanent harm.

There are currently five NRLS codes for the degree of harm:

- no harm
- low
- moderate
- severe
- death.

19. How should NRLS data be compared over time?

Reporting to the NRLS has increased year on year since it began in 2003, and it is anticipated this will continue to increase as the culture of reporting all incidents spreads more widely and deeply across the NHS. Comparisons over time are confounded by several factors. The NRLS is a dynamic database, and although organisations are encouraged to report promptly, with the option to update incident(s) at a later date (eg once the local investigation is complete), it remains common for organisations to upload their data in large batches.

Careful consideration should be given to the dates of changes in mandatory reporting requirements, as these may have a ‘one-off’ impact, affecting a specific time frame. Organisational change should also be borne in mind, as newly created and newly merged organisations take time to mature and set up their systems and processes.

Therefore, when reviewing changes over time, we recommended:

- proportions or percentages are used rather than actual numbers (to allow for the differences in the underlying numbers of incidents)
- either the same time period in the previous year, or a full year’s worth of data are used (to take seasonality into account)
- checks are made that any ‘change/difference’ is not due to new/amended national mandatory reporting requirements or organisational restructuring.

For more information on mandatory national reporting requirements click here

For more information on NHS organisational restructuring click here
20. Where can I find other related information/resources?

For board members:
www.nrls.npsa.nhs.uk/resources/?EntryId45=59885

Data quality standards (to support organisations in uploading data to the NRLS):
www.nrls.npsa.nhs.uk/resources/?entryid45=62099

General patient safety information/resources: www.nrls.npsa.nhs.uk/patient-safety-data/
improvement.nhs.uk/resources/patient-safety-alerts/
www.england.nhs.uk/ourwork/patientsafety/
21. How can I give feedback?

Please contact us at: nrls.datarequests@nhs.net

About NHS Improvement

NHS Improvement is the operational name for the organisation that brings together Monitor, NHS Trust Development Authority, Patient Safety, the National Reporting and Learning System, the Advancing Change team and the Intensive Support Teams.

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