NHS Improvement

NRLS official statistics publications: guidance notes

March 2018

We support providers to give patients safe, high quality, compassionate care, within local health systems that are financially sustainable.

Contents

1. Introduction

This is a guide to using and interpreting the National Reporting and Learning System (NRLS) official statistics outputs:

- national patient safety incident reports (NaPSIR, previously the quarterly data summaries – QDS)
- organisational patient safety incident reports (OPSIR)
- monthly summary data[1] on patient safety incident reports.

It gives background to the NRLS, a summary of our data publications, and the caveats and other considerations when using the data. The document should be read alongside the NaPSIR, OPSIR and monthly data tables.

Patient safety incident definition

We use the definition of 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'. This definition was developed by the National Patient Safety Agency (NPSA) in the *Seven steps to patient safety: full reference guide* (2004).

Examples 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.

[1] The monthly summary data will shortly be classified as experimental statistics and we are working to the code of practice for these statistics. Further information will become available on our webpages.

The National Reporting and Learning System

The NRLS was established by the NPSA in late 2003 as a voluntary scheme for reporting patient safety incidents; its primary function is to enable learning from these incidents and to reduce their recurrence.

All NHS organisations in England and Wales have been able to report to the system since 2005.

NHS Improvement now manages the NRLS and has statutory functions in relation to patient safety: to operate the NRLS and to use information from the NRLS and elsewhere to develop advice and guidance for the NHS to reduce risks to patients.

In April 2010, it became mandatory to report deaths in certain circumstances and some other types of incidents to the Care Quality Commission (CQC). The NRLS is used as a reporting route to fulfil CQC's requirements by NHS trusts.

To foster openness and encourage continual increases in reporting, reporting to the NRLS remains voluntary with the exception of certain severe incidents (see below). This means NRLS data does not provide the definitive number of patient safety incidents occurring in the NHS. We use information from incident reports to identify trends and develop patient safety resources such as Patient Safety Alerts.

All patient safety incident reports submitted to the NRLS coded as resulting in severe harm or death are individually reviewed by NHS Improvement clinicians to make sure we learn as much as we can from them and take action at a national level where appropriate.

NRLS incident reports and data are shared with a range of national bodies to support the identification of hazards and the development of patient safety guidance and solutions. These organisations include: NHS England, Public Health England (PHE), the Medicines and Healthcare products Regulatory Agency (MHRA), CQC and the royal colleges.

Other data sources

Other systems and organisations collect data that relates to patient safety incidents; however, the NRLS is the only national database that includes all types of patient safety incident. Many of these other data collections have been created specifically

for a particular type of incident, have a broader remit, or cover a wider geography; as such their comparability with the NRLS cannot be assumed. Other systems include the: strategic executive information system (StEIS); CQC notification database; (MHRA) 'yellow card scheme' and serious adverse blood reactions and events (SABRE); NHS safety thermometer; PHE notifications database; and serious hazards of transfusion (SHOT) scheme. More information is available in our accompanying data quality statement.

Databases are not the only source of patient safety information. The patient perspective, 'the 'voice of the patient', has been shown to be fundamental to understanding patient safety issues; for example, a key failing identified in the Mid Staffordshire NHS Foundation Trust Public Inquiry was that the trust board "did not listen sufficiently to its patients and staff". The Department of Health has instructed trusts to use the summary hospital-level mortality indicator (SHMI) in their quality accounts. Quality accounts are reports on the quality of the services provided, measured by looking at patient safety, the effectiveness of the treatments that patients receive and patient feedback about the care provided.

2. NRLS data collection

The NRLS collects data on patient safety incidents in England and Wales. Organisations are encouraged to report patient safety incidents to the NRLS regularly and consistently across the year. Frequent and regular reporting can be viewed as an indication of a positive reporting culture.

Most patient safety incident reports are submitted electronically to the NRLS from an NHS organisation's own local risk management system. These local systems are often used for a number of purposes, not just recording patient safety incidents. As a result, local definitions and classification systems often differ and must be aligned to the NRLS for accurate reporting (see Section 5 below).

A small number of incidents are reported directly using our online 'eForms' by individuals and organisations that do not have local risk management systems.

Organisations vary in how their local systems are set up, how many incidents are reported locally and how frequently they upload data to the NRLS.

To reduce the burden on local organisations of having to manually enter data both locally and nationally, the NRLS enables the national submission of digital reports stored on local systems.

There can be a time lag between an incident occurring and being reported to the NRLS for a variety of reasons (see Section 5 below). Regular reporting is encouraged to minimise this lag.

3. NRLS data publications

Purpose

NHS Improvement publishes three different but complementary routine data outputs using the NRLS data, all of which are classified as official statistics: the national patient safety incident reports (NaPSIR), organisation patient safety incident reports (OPSIR) and monthly summary data. Note, as the monthly data summaries are new statistics and being tested with users, they will be classified as experimental statistics; this is a subset of official statistics.

The NaPSIR, OPSIR and monthly summaries are designed to make NRLS data more accessible and they contribute to the pan-government initiative for transparency in data. Specifically, increased transparency together with more thorough reporting and analysis of patient safety-related incidents provides a real opportunity for the NHS at a local and national level to share experiences and learn from these incidents.

Increased transparency is key to:

- improving the safety of services for patients
- 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.

As mentioned above, the NRLS and patient safety incidents are not the only source of information relating to patient safety and our published data must be considered alongside other local and national intelligence.

Frequency and format

NaPSIR and OPSIR data is published every six months in March and September, and the monthly summaries are published monthly. All data is available on the NHS Improvement website. Publication dates are announced in advance for the forthcoming year and data are published at 9.30 am on these dates as workbooks in Excel and CSV formats.

Official statistics

By definition official statistics, including experimental statistics, are statistical outputs produced by the UK Statistics Authority's executive office (the Office for National Statistics), by central government departments and agencies or the devolved administrations in Northern Ireland, Scotland and Wales, and by other Crown bodies (over 200 in total). The UK Statistics Authority Code of Practice for Statistics guides their production, management and dissemination to ensure high standards are met, and their content is well explained in a subjective and impartial manner. We continually look to improve the way we produce and publish our official statistics in line with requirements of the Code of Practice.

4. Interpreting the data

Many factors have to be considered when interpreting the NRLS data to reduce the chance of misinterpretation. Additionally, the three statistical outputs discussed in this document have different purposes and any reported numbers are not directly comparable (see Table on page 10). These factors and the steps we take to reduce their impact on the data and our learning are detailed below; some of these factors have already been alluded to above.

Data quality assurance

Assurance happens at both the local (validation at point of data collection and submission) and national (validation at the point of data collection and submission) levels. As most patient safety incident data is collected on local systems (see Section 3 above) and then uploaded to the NRLS, we need to ensure local

information is correctly mapped to the NRLS fields. Thus all systems used to supply data to the NRLS must be approved as NRLS compliant by NHS Improvement before routine uploading can start. Submitted data uploads are only accepted onto the NRLS if essential fields have been entered, to ensure a core minimum dataset is captured.

During production of the NaPSIR and OPSIR a range of quality assurance processes are undertaken, including regular feedback of reporting data for local verification by data suppliers, verification of denominator information and complete quality/cross-checking of the final data tables and associated documentation. This ensures the published outputs reflect the information reported to us.

The monthly data summaries are designed to reflect reporting to the NRLS in a timely way. Therefore data suppliers do not verify the data locally. However, quality assurance of the final tables is undertaken.

More detailed information on our quality assurance processes are available in our accompanying data quality statement.

Sources of error and bias

Patient safety incident data in general is prone to reporting error and bias and NRLS data is no exception to this. Error and bias will affect the number, type and temporality of reported incidents and how the data is interpreted. Users must also remember that as the number of incidents reported reflects reporting culture rather than the definitive number of patient safety incidents occurring. Known sources of error and bias are discussed in our accompanying data quality statement.

The reported and occurring datasets

To present NRLS patient safety incident data as accurately as possible, two different datasets are used. This helps to mitigate the issues discussed above around reporting lags and seasonality in the data. The number of reported and occurring incidents for a given period will not be, and should not be expected to be, the same.

The **‘reported dataset’** is used to look at patterns in reporting, such as frequency and timeliness. It contains incidents reported to the NRLS within a specified time period. It may include incidents that occurred a long time before they were reported.

The **‘occurring dataset’** is used to look at patient safety incident characteristics. It contains incidents reported as actually taking place in a specific time period. This dataset reflects seasonality in when incidents occur; analysis based on this dataset may be biased by fluctuation in numbers over time due to reporting delays.

Comparability over time

All of the factors discussed above in relation to bias affect how NRLS data is interpreted over time.

In general, reporting is increasing over time. This is a positive finding as it reflects a maturing of the reporting culture and maximises the potential for learning. However, it can be difficult to disentangle patterns in specific incidents from the general trend of increased reporting. Therefore, when reviewing changes over time, we recommend users:

- use proportions or percentages rather than actual numbers (to allow for the differences in the underlying numbers of incidents)
- either use the same time period for the previous year or a full year’s worth of data (to take seasonality into account)
- check that any ‘change/difference’ is not due to new/amended national mandatory reporting requirements or local organisational restructuring
- consider that reporting delay and reporting seasonality may influence any apparent dips in reports for more recent periods.

Understanding the degree of harm of patient safety incidents

The degree of harm reported to the NRLS should 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 give the **potential** degree of harm of an incident instead. For example, the resulting degree of harm is occasionally coded as ‘severe’ for ‘near misses’ where no harm resulted as the impact was prevented.

Reporters may also code the degree of harm as ‘severe’ when the patient is expected to suffer severe but temporary harm (eg severe bruising), which conflicts

with the NRLS definition of significant and permanent harm (see below). For some incidents, particularly those affecting patients with multiple co-morbidities or those near the end of their life, it may be difficult to determine at the time of reporting if the level of harm recorded was a direct result of the patient safety incident.

There are five NRLS codes for the degree of harm:

- no harm – a situation where no harm occurred: either a prevented patient safety incident or a no harm incident
- low harm – any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons
- moderate harm – any unexpected or unintended 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 persons
- severe harm – any unexpected or unintended incident that caused permanent or long-term harm to one or more persons
- death – any unexpected or unintended event that caused the death of one or more persons.

Differences between the NaPSIR, OPSIR and monthly summaries

The three official statistic releases fulfil different purposes and differences between them must be appreciated if they are compared (see Table). By definition the NaPSIR provides a national perspective. Summary data is provided by the date the incident was reported to the NRLS, with more detailed analysis by date of occurrence and care setting. In contrast the OPSIR provides organisation-level breakdowns that show the number and rate of incidents, based on the date incidents occurred. The NaPSIR and monthly summaries cover a rolling historical period therefore the data is ‘dynamic’ and will reflect any data changes to historic periods. By contrast the OPSIR publishes the most recently available six-month

period only; the data is therefore static and cannot reflect changes to historic periods. Data quality indicators based on patterns of reporting are included. Due to the impact of organisation type on the anticipated level of patient safety incidents, the OPSIR groups organisations by type.

Table: Main features of the NaPSIR, OPSIR and monthly workbooks

Feature	NaPSIR	OPSIR	Monthly summaries
Purpose	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 the indicator 'Improving the culture of safety reporting' in Domain 5 of the NHS outcomes framework (*Treating and caring for people in a safe environment and protecting them from avoidable harm*)	To provide data on individual organisation's reporting and patient safety characteristics. Different NHS organisations provide different services and serve different populations. Therefore, to make comparisons as meaningful as possible, the NRLS groups NHS organisations into 'clusters' of similar organisations.*	To provide timely data on reporting to the NRLS to encourage more consistent reporting and support organisations to monitor potential under-reporting of incidents. Data is provided by organisation, degree of harm and month of report to the NRLS. Organisations are not grouped into 'clusters'.
Dataset type	Dynamic†	Fixed/static	Dynamic
Dataset used	Reported and occurring datasets‡	Reported and occurring datasets‡	Reported dataset‡
Period covered	Reported dataset: Rolling quarters from October to December 2003 to the most recent quarter available. Occurring dataset: Rolling quarters covering the last four available quarters.	The most recent six months only	A rolling 12-month period covering the preceding 12 complete months of available data.
Updated	Every six months	Every six months	Every month

Feature	NaPSIR	OPSIR	Monthly summaries
Geography/ breakdown	All geographical locations, by care setting	England, by individual NHS organisation (organised by cluster)	England, by individual organisation
Inclusions	The following care settings: acute/general • mental health service • community nursing, medical and therapy service • learning disabilities service • ambulance service • general practice • community pharmacy • community and general dental service • community optometry/ optician service	The following organisation types: • acute/general hospital • mental health service • community trusts • ambulance service	The following organisation types: • acute/general hospital • mental health service • community trusts • ambulance service • integrated care organisation

*Information on clusters is available in or accompanies the relevant publication.

†Figures for previous quarters may change slightly (figures for four consecutive quarters are given in each workbook for incidents 'occurring', 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).

‡ The reported dataset refers to incidents reported by, or within, a certain time period. The occurring dataset refers to incidents occurring by, or within, a certain time period. See above for more information.

Suppression of statistics based on small numbers

The number of incidents an organisation reports varies both over time and compared to other organisations. The reasons for this are varied and may, for example, reflect real differences in the number of incidents or problems with data upload functionality.

Statistics such as percentages and rates are unreliable measures when the underlying numbers are small as differentiating random fluctuation (the role of

chance) from true changes in the statistic can be impossible. Where an organisation reports 10 or fewer incidents as occurring during the specific time period (OPSIR), reporting rates and medians are not calculated or published and comparisons are not made. For both the NaPSIR and OPSIR publications, percentages are not calculated where fewer than 30 incidents in total (over the most recently available preceding four quarters (NaPSIR) and six months (OPSIR) are reported as occurring. Monthly summaries present numbers only, rather than percentages.

Understanding ‘high’ and ‘low’ reporting rates

Incidents are reported to the NRLS voluntarily and for the purposes of learning. The number reported by each organisation therefore reflects reporting culture, and is not necessarily the actual number of incidents occurring. A ‘low’ reporting rate for an organisation should not necessarily be interpreted as a ‘safe’ environment; it may represent under-reporting. Conversely a ‘high’ reporting rate should not be interpreted as ‘unsafe’; it may represent a more open culture. 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, while ambulance and mental health organisations have the most varied reporting patterns. NHS Improvement’s guidance is that organisations should be reporting incidents to the NRLS on a regular basis and at least once a month.

Calculation and interpretation of NRLS reporting rates

A rate is the frequency of occurrence of a phenomenon in the population under study – that is, how often an event happens in a given period of time in the population at risk of the event. For example, if the event is a patient falling in ‘ward A’ in a given hospital, the population at risk could be all patients admitted to ‘ward A’ in that hospital. Rates are important in comparing different patient populations and have always been given for the NRLS reporting data. We calculate a reporting rate as:

$$\frac{\text{Reported number of patient safety incidents (numerator)}}{\text{Potential opportunities for these incidents to occur (denominator)}}$$

Using the example above, this would be calculated as:

$$\frac{\text{Number of falls in ward A}}{\text{Number of patients admitted to ward A}}$$

For this rate to be valid, reliable and therefore meaningful, both the number of patient safety incidents (numerator) and the potential opportunities for those incidents to occur (denominator) need to be as accurate as possible. The falls example above is simplistic for the purposes of illustration; as discussed above known factors affect the number of incidents reported and this will affect the accuracy of the numerator. Additionally there are issues with identifying the denominator that best captures the population at risk; for example, the type of service(s) provided by an organisation and the patient safety incident being examined both affect the population at risk, thus the choice of denominator.

NRLS statistics use quarterly KH03 data on average daily overnight bed occupancy (published by NHS England) to estimate total number of bed days for the specified time period of the analysis. Due to the nature of KH03 data this denominator is only appropriate for acute and mental health trusts and a rate currently cannot be calculated for NHS ambulance and community trusts.

5. Contact us for help

If you have any questions about the NRLS data collection, the published data or your organisation's data please contact the NRLS team: nhsi.nrls.datarequests@nhs.net

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