

Data Quality Notes

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There are known quality issues that should be borne in mind when interpreting NRLS data. These are described within the context of the six dimensions of the European Statistical System Quality Framework below.

Dimension 1: Relevance

NRLS data are an essential component in assessing, monitoring and managing patient safety. NRLS 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 (which now includes the remit of the Health Protection Agency), the Medicines and Healthcare products Regulatory Agency (MHRA), the Care Quality Commission (CQC), the Royal College of Anaesthetists, Connecting for Health, and the NHS Wales Informatics Service.

National bodies (such as the Care Quality Commission, Monitor, and the National Audit Office) can use these datasets to build up trend analyses in order to timetable their audit and inspection functions and prioritise resources. These data also provide a context for research undertaken by academic organisations and scoping work undertaken by Royal Colleges. Additionally, they provide trend and context data to support NHS England in the development of patient safety resources, such as Safer Practice Notices (<http://www.nrls.nhs.uk/resources/type/alerts/>).

NRLS data are currently used to measure four of the outcomes within Domain 5 of the NHS Outcomes Framework (*Treating and caring for people in a safe environment and protecting them from avoidable harm*). The Outcomes Framework sets the direction of travel in the journey towards improving outcomes, and offers an opportunity for the NHS to begin to understand what an NHS focussed on outcomes means for individuals, organisations and health economies. Data from the QDS workbooks is used to calculate three of these indicators: 5a, 5b, and 5.4. The fourth indicator, 5.6 is derived from bespoke analyses of the NRLS data.

Dimension 2: Accuracy

D2a: There is no 'correct' or 'safe' number of patient safety incidents

There are known reasons for 'high' and 'low' reporting. Some organisations report daily, others quarterly. In many cases, incidents are grouped and sent 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. Even in acute care, it has been estimated that anything between 22% and 83% of incidents go un-reported locally.¹ It has also been suggested that specific incident types are under-reported (in particular medication incidents in primary care).¹

'Low' reporting

Under-reporting of patient safety incidents at a local level is a well recognised issue. Over 99% of patient safety incidents are reported to the NRLS by local organisations uploading incidents from their local risk management systems. (The upload process is via a secure website). Therefore, this potential source of bias will be embedded into the subsequent reporting to the NRLS.

A 'low' reporting rate should not be interpreted as a 'safe' organisation, and may represent under-reporting.

'High' reporting

Experience in other industries has shown that as an organisation's reporting culture matures, staff become more likely to report incidents. (Even in 'high' reporting organisations, there may still be some degree of under-reporting.)

Organisations' local risk management systems are often used for a number of reasons and not just for recording patient safety incidents. Sometimes incidents are inappropriately reported to the NRLS. There is a formal process in place for organisations to request that incidents be 'deleted', i.e. removed from the analytical layer of the NRLS database, in very specific circumstances.

A 'high' reporting rate should not be interpreted as an 'unsafe' organisation, and may actually represent a culture of greater openness.

D2b: Incidence of patient safety incidents vs reporting rates

Patient safety incidents reported to the NRLS are simply just that – incidents reported to the NRLS. They should not be presented as the number of incidents actually occurring in an organisation, especially as sometimes organisations fail to meet the NRLS submission deadlines* which can result in gaps in coverage.

D2c: The NRLS is a dynamic reporting system

The NRLS is a dynamic reporting system, and the number of incidents reported as occurring at any point in time may increase as more incidents are reported. Experience in other industries has shown that as an organisation's reporting culture matures, staff become more likely to report incidents. Therefore, an increase in incident reporting should not be taken as an indication of worsening of patient safety, but may represent an increasing level of awareness of safety issues amongst healthcare professionals and a more open and transparent culture across the organisation.

D2d: Poor recording of the patient safety incident

The quality of the data submitted to the NRLS relies on three things:

- the incident being recognised as a patient safety incident;
- sufficient detail being documented in the patient's notes; and
- adequate and consistent coding in the local risk management system prior to uploading to the NRLS.

* the NRLS sets two 'submission' deadlines a year, for data to be included in the Organisation Patient Safety Incident Reports (NRLS Official Statistics) workbooks: the last Friday in May and the last Friday in November.

D2e: Harm as a direct result of the patient safety incident

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’.

Reporters may code the degree of harm as ‘severe’ when the patient is expected to suffer severe but temporary harm (for example, severe bruising), instead of the NRLS definition of significant and permanent harm.

A report on Patient Safety by the House of Commons Health Committee¹ refers to earlier work showing that “incidents leading to serious harm were among the least likely to be reported”.

As organisations use their local risk management systems for a number of purposes, some incidents that are reported to the NRLS are not patient safety incidents, and this can also confound this data.

Dimension 3: Timeliness and Punctuality

D3a: Known delays in reporting to the NRLS – the time lag between the incident occurring to the incident being reported to the NRLS

Organisations are encouraged to report patient safety incidents to the NRLS at least once a month, and the CQC guidance for the reporting of serious incidents recommends reporting “without delay”.

However, in practice there is a delay between an incident occurring and it being reported to the NRLS. The NRLS team monitor the average (median) number of days delay for both serious incidents and all incidents, and feed these data back to NHS organisations. Every month, provisional data are shared back with the submitting organisation to help identify possible data quality problems with data uploaded to the NRLS. This gives organisations the opportunity to check the data that the NRLS has received and compare them with data in their local risk management system. Detailed guidance on what to look for and known reporting issues is given in an online FAQ document, along with the option to contact the Patient Safety Reporting Leads for further support if needed.

As this delay is well known, we always allow a minimum of two months lag in defining our ‘Occurring Dataset’ (the data set used to analyse patient safety incident characteristics, based on the date the incident is reported to have actually occurred, rather than the date that the incident was reported to the NRLS).

D3b: Frequency of publication

The intention is to publish these statistics quarterly to a time table agreed with NHS England. As stated above, a minimum two month time lag is factored into the definition of the 'Occurring Dataset'. A comprehensive and rigorous quality assurance process is undertaken prior to any analysis.

As a result, there is a delay between the submission deadline and publication of the data, in order to maximise the usefulness/accuracy of the data whilst minimising the delay in publication.

Dimension 4: Accessibility and Clarity

D4a: Accessibility

These data are available for free via a public website (<http://www.nrls.nhs.uk/resources/>).

D4b: Clarity

Since October 2014, the documentation has been increased and improved in order to be much clearer about the context, interpretation, scope, methods, reasoning, and known quality issues of the data.

All releases are now accompanied by a range of documentation in order to support user(s) by providing a commentary on trends and changes. Background information is also provided to help clarify the context of the data, and the limitations in the use of the data are explicitly documented.

Dimension 5: Comparability

D5a: Comparing over time

When comparing NRLS data across time periods, it is important to compare data to the same time period in the previous year(s). This is to take into account known 'seasonality' in the data. (Seasonality is due to the fact that patterns, variations and fluctuations in patient safety incidents are caused by the season, month, day of the week, or some other time period they occur in.) There are at least two causes of seasonality in the reporting of patient safety incidents to the NRLS: 'administrative seasonality' and incident seasonality.

['Administrative seasonality'](#)

There are large spikes in the reporting of patient safety incidents to the NRLS every six months (at the end of May and the end of November), as organisations upload substantial batches of data in order to meet the cut-off dates for submission to the NRLS for inclusion in the Organisation Patient Safety Incident Report (NRLS UK Official Statistics) workbook*.

[Incident seasonality](#)

Research suggests that higher rates of postsurgical morbidity and mortality relate to the time of the year, with systems of care within academic medical centres sufficiently disrupted with the beginning of a new academic year to affect patient outcomes.²

* the NRLS sets two 'submission' deadlines a year, for data to be included in the Organisation Patient Safety Incident Reports (NRLS Official Statistics) workbooks: the last Friday in May and the last Friday in November.

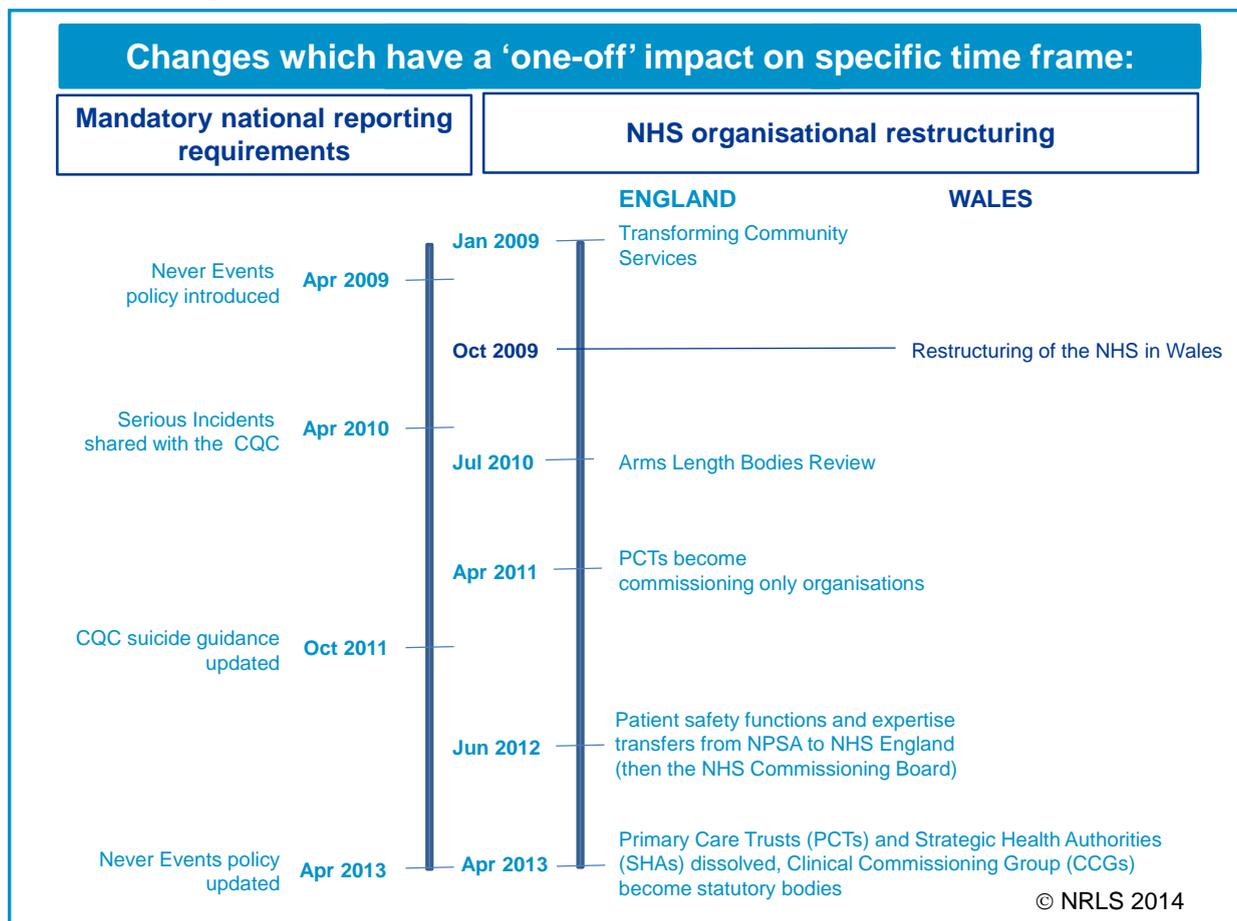
Seasonality also has an impact on some of the national mandatory reporting requirements. For example, suicides have been found to have at least two seasonal peaks.³ In October 2011, the Care Quality Commission revised its guidance on the reporting of apparent and actual suicides. This is now a wider definition to include all actual or apparent suicides of people with an open episode of care in specialist mental health services (either inpatient or community patients) at the time of death, i.e. no longer restricted to deaths related to patient safety incidents.

Reporting to the NRLS has increased year on year since its inception in 2003, and it is anticipated that 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 a number of factors.

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, it is recommended that:

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



D5c: Comparing between countries

These statistics relate to NHS organisations in England and Wales, and there are no directly comparable figures to allow international comparison.

Dimension 6: Coherence

Coherence does not necessarily imply full numerical consistency, rather consistency in methods and collection standards.

D6a: Consistency (dataset and methods)

The statistics in this release are all drawn from the same data source (the NRLS), using a coherent and consistent method to define the datasets used, and a rigorous quality assurance process.

Although it is possible for NHS organisations to use different methods to report to the NRLS (uploading from their local system or by completing an eform on the NRLS website), almost all – more than 99% – upload their incidents directly from their local risk management systems. The data fields from these commercial local risk management systems (or bespoke locally developed systems) have been mapped to the NRLS national dataset by the Patient Safety Reporting Leads in a consistent and systematic way. This provides a high degree of assurance regarding the uniformity of reporting of categorical data.

D6b: Consistency (changes in mandatory reporting requirements)

National changes to reporting requirements add to the complexity of data interpretation. These should be taken into consideration when making any comparisons over time.

D6c: Comparability with other sources of information

There are many ways to measure ‘safe’ care, each with unique perspectives, and specific strengths and limitations. Individual organisations are encouraged to apply their local knowledge and expertise – in addition to considering these other related sources of patient safety information (such as ‘the patient voice’, their local complaints data, their CQC reports, and their local serious incidents requiring investigation) alongside their NRLS data, in order to check that the messages from each data source are consistent before prioritising areas for action. Please also see D6d: Statistical coherence below.

D6d: Statistical coherence

Statistical coherence has been defined as “the degree to which data about the same phenomenon are similar although derived from different sources or methods”⁴.

There are many other patient safety incident databases. These include: the Department of Health Strategic Executive Information System (STEIS); the Care Quality Commission (CQC) notifications 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; and the Serious Hazards of Transfusion (SHOT) scheme. A brief

description of each is given below, and Table 6d1b summarises the similarities between these databases and the NRLS.

STEIS

April 2002 saw the launch of a system for collecting management information from the NHS: STEIS. In March 2013, the then NHS Commissioning Board (now NHS England) published a revised and updated framework for the responsibilities and actions required following a serious incident. All serious incidents should be recorded on STEIS. A “serious incident” was defined⁵ as an incident that occurred during NHS funded healthcare¹ (including in the community), which resulted in one or more of the following:

- unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
 - a never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death;
 - a scenario that prevents, or threatens to prevent, an organisation’s ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
 - allegations, or incidents, of physical abuse and sexual assault or abuse;
- and/or
- loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

As is clear from the list above, the reporting required by STEIS is far wider than the patient safety remit (and includes – but is not limited to – reporting to the Health & Safety Executive, the police, and NHS Protect*)

Care Quality Commission (CQC) notification ([/www.cqc.org.uk/content/notifications](http://www.cqc.org.uk/content/notifications))

Regulations 12, 14, 15, 16, 17, 18, 20, 21 and 22 of the Care Quality Commission (Registration) Regulations 2009 make requirements that the details of certain incidents, events and changes that affect a service or the people using it are notified to CQC.

The regulations also say that NHS bodies can submit certain notifications to the NRLS. These notifications are then shared with the CQC under an information sharing agreement.

* NHS Protect (www.nhsbsa.nhs.uk/Protect.aspx) leads on work to identify and tackle crime across the health service. The aim is to protect NHS staff and resources from activities that would otherwise undermine their effectiveness and their ability to meet the needs of patients and professionals.

Table 6d.1a: CQC notifications that can be submitted to the NRLS

Regulation	Notification
16	Certain deaths of people using the service
18(2)(e)	Allegations of abuse
18(2)(g)	Events that stop or may stop the service from running safely and properly
18(2)(a)&(b)	Serious injuries to people who use the activity

Source: Care Quality Commission, July 2013. Notifications required by the Health and Social Care Act 2008: Guidance for English NHS providers. The live document can be accessed at: www.cqc.org.uk/content/legislation

Submitting the notifications in Table 6d1.a is mandatory, and reporting the relevant incident(s) to the NRLS meets this requirement. All notifications must be submitted within a required timescale and include all the information required

MHRA (www.mhra.gov.uk/)

Since the 1990s, the MHRA has had a ‘Yellow Card Scheme’ for collecting and collating side-effects data on medicines, vaccines, and herbal or complementary remedies which acts as an early warning system for the identification of previously unrecognised adverse reactions.

Also within the remit of the MHRA is the reporting of Serious Adverse Blood Reactions & Events (SABRE) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood

NHS Safety Thermometer (www.safetythermometer.nhs.uk/)

Since May 2013, the Health & Social Care Information Centre (HSCIC) has published statistics on four adverse outcomes that make up the *NHS Safety Thermometer: Patient Harms and Harm Free Care*. The four adverse outcomes are:

- pressure ulcers
- falls
- Urinary Tract Infections in patients with a catheter
- new venous thromboembolisms

These four were chosen as the clinical consensus is that they are all largely preventable through appropriate patient care.

Public Health England notifications

Registered medical practitioners must notify Public Health England (which now includes the remit of the Health Protection Agency) about certain suspected infection cases, and incidents. In March 2010, Public Health England and the Department of Health published *The Health Protection Legislation (England) Guidance 2010*, which explains what needs to be notified to Public Health England.

(www.webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_

consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_114589.pdf)

Serious Hazards of Transfusion (SHOT) (www.shotuk.org/)

Set up in 1996, SHOT is the UK’s independent, professionally-led haemovigilance scheme.

As can be seen in table 6d1b below, there are varying degrees of overlap between all of the above patient safety incident databases and the NRLS.

However, the NRLS is the only national patient safety incident database that comprises **all** types of patient safety incident.

Table 6d1b – Alternative patient safety incident databases

Database	Overlap with the NRLS?	Notes
STEIS	✓ ^P (for three of the five incident types)	
CQC	✓ ^P (for the incidents listed in Table 6d1a only)	Since April 2013, all patient safety incidents reported to the NRLS have been shared with the CQC.
MHRA	✓ ^P (for medicines and medicinal device incidents, and adverse blood reactions only)	
NHS Safety Thermometer	✓ ^P (for falls and pressure ulcers only)	
Public Health England	✓ ^P (for specific infection control incidents only)	
SHOT	✓ ^P (for specific blood transfusion incidents only)	

Key: P = partial overlap with the NRLS, for the types of incidents specified

References:

¹ *An open, reporting and learning NHS* Chapter 5 in: House of Commons Health Committee, 2009. *Patient Safety: Volume 1* (Sixth Report of Session 2008-09). HC 151-I. London: The Stationery Office Ltd.

² Englesbe MJ, Pelletier SJ, Magee JC *et al.* *Seasonal variation in surgical outcomes as measured by the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP)*. *Ann Surg* 2007;Sept 246(3):456-62.

³ Christodoulou C, Douzenis A, Papadopoulos FC *et al.* *Suicide and seasonality*. *Acta Psychiatr Scand* 2012; Feb 125(2):127-46.
doi: 10.1111/j.1600-0447.2011.01750

⁴ UK Statistics Authority. *Monitoring Review: Official Statistics on Patient Outcomes in England*, February 2014.

⁵ NHS Commissioning Board, March 2013. *Serious Incident Framework: An update to the 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*.