Classification: Official

NRLS official statistics publications: data quality statement

Version 1.2, 29 September 2021

Contents

Introduction and background

This document provides background on the national data we collect on patient safety incidents via the National Reporting and Learning System (NRLS). It describes the quality assurance we undertake in routinely producing our official statistics publications based on this data:

- national patient safety incident reports (NaPSIR; previously the Quarterly Data Summaries – QDS)
- organisation patient safety incident reports (OPSIR)
- monthly summary data[1] on patient safety incident reports.

Each follows the principles in the code of practice for statistics. More detailed background and history are available in our guidance notes.

A new service called Learn from Patient Safety Events (LFPSE; formerly Patient Safety Information Management System (PSIMS)) will fully replace the NRLS. It will change the way information is collected to make it easier to record and learn from patient safety events, including patient safety incidents. These improvements mean any output using the patient safety data currently collected on the NRLS will also change; we are currently developing new outputs. As the current official statistic publications do not contain LFPSE data this document and all associated official statistic documentation will only refer to the NRLS. We will update documentation in due course.

[1] Although not formally an official statistic this output is included here due to its similarity to the OPSIR and NaPSIR

Impact of COVID-19 on reporting

The COVID-19 pandemic has affected society and health provision globally. The NHS in England underwent rapid changes in how services were provided to respond to the pandemic and protect the NHS (Health Foundation, 2020[2]). Data collection for some routine national NHS datasets were paused or deprioritised. We contacted all organisations who were reporting to the NRLS to continue reporting anything that concerned them and they felt others needed to know. We also made it clear there should be no criticism of staff for incident reporting decisions during this time. To date these necessary COVID-related changes have impacted on the volume and type of incidents reported to the NRLS. Our official statistic commentaries discuss specific impacts on NRLS data in more detail.

Overview of data collection

We have a statutory function to manage and operate the NRLS and use information from it 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 type of incidents to the Care Quality Commission (CQC). The NRLS is used as a reporting route to fulfil CQC's requirements by NHS trusts.

NRLS data is obtained mainly from local risk management systems (LRMS). Currently NHS acute providers submit most reports we receive. However, anyone can report an incident on the system: they may be healthcare professionals from any NHS or private provider, patients or members of the public. NRLS data is submitted voluntarily to foster openness and encourage continual increases in reporting. This means NRLS data does not, and cannot, provide the definitive number of patient safety incidents occurring in the NHS; it measures the number of incidents **reported**. The number of reported incidents has increased year on year since its inception. This reflects improved reporting culture and should not be interpreted as the NHS becoming less safe. This is in distinct contrast to many

[2] Health Foundation, November 2020. Elective care in England. Assessing the impact of COVID-19 and where next. Accessed 20 Sep. 21 < Elective care in England - The Health Foundation>

healthcare-related data collections where a reduction in numbers of the information being collected is usually a positive finding, such as a reduction in the incidence of a specific infection.

Comparability with other systems

International comparison

The World Health Organization (WHO) has run a patient safety programme since 2004.[3] Encouraging learning from reporting and sharing patient safety incidents remains a fundamental principle in the updated Global Patient Safety Action Plan.[4] These sentiments are echoed in many country-specific systems. However, to date this has been hard to achieve for several reasons: eg fears about reprisal if incidents are reported, a lack of standard definitions and a paucity of appropriate data.[5] In Europe a range of patient safety data collection systems cover a spectrum of aims, such as:

- collecting data on a specific list of patient safety incidents
- collecting all patient safety incidents with mandatory and voluntary submission criteria
- allowing anyone (healthcare professionals through to patients and the public) to submit patient safety incidents.

The situation in the United Kingdom and Ireland (Table 1) broadly reflects the range of systems in Europe. The NRLS is the most comprehensive system in terms of coverage and reporting criteria. However, as noted above, most incidents are submitted from NHS acute providers, and anecdotal evidence suggests most reporters are nurses. The NRLS is also subject to the same concerns about openness of reporting and having appropriate data, raised by WHO.

[3] www.who.int/patientsafety/en/ accessed 22 September 2021.
[4] World Health Organisation, 2021. Global patient safety action plan 2021-2030: towards eliminating avoidable harm in health care. Available at https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan accessed 22 September 2021
[5] Health Information and Quality Authority. *International review of patient safety surveillance systems*. 2016. Available at: https://www.hiqa.ie/sites/default/files/2017-01/International-review-patient-safety-surveillance-systems.pdf accessed 22 September 2021

Table 1: Summary of patient safety data collection systems in the UK and Ireland

Country	National/local reporting mechanism	Incidents collected	Who reports	Mandatory/voluntary
England and Wales	National	Patient safety incidents (NRLS) and Serious Incidents (STEIS)	Anyone (any healthcare professional, patients and the public)	Mandatory for Serious Incidents, voluntary for patient safety incidents
Scotland	Local NHS boards set policy for reporting A national framework for learning has been published Several specific incidents must be reported nationally or to UK-based systems	Exact dataset determined locally	Healthcare professionals	Voluntary except for specific incidents that are reported nationally or to UK-based systems
Northern Ireland	National; data submitted to the State Claims Agency Data collection not limited to patient safety incidents	Adverse incidents	State authorities	Mandatory
Ireland	Local National system under development	Set locally	Public and private providers of public health services	Voluntary except for incidents resulting in death or severe harm

National comparison

In England and Wales other organisations also collect data on patient safety. There is some overlap with the NRLS, but no other system is directly comparable in its entirety, and the NRLS remains the only single source of patient safety incidents for England and Wales (Table 2). Potentially overlapping data sources may be an obvious route to understand reporting completeness to the NRLS by comparing similar incidents across different systems. A scoping exercise to test this by linking NRLS and STEIS data on incidents relating to never events highlighted significant methodological problems in comparing two datasets where the scope and remit of submission differ. The differences meant that attempting a comparison would not provide a meaningful or reliable ascertainment estimate and would lead to confusion for users rather than increased understanding or transparency.

Table 2: Data collections which overlap with the NRLS

Organisation and/or system	Purpose, data collected and coverage	Overlap with NRLS
Strategic Executive Information System (STEIS)	**Purpose:** • Collect serious incident data for the Serious Incident Framework[6] **Data collected:** • Unexpected/avoidable death/severe harm of one or more patients/staff/public • A Never Event[7] • A scenario that prevents/ threatens to prevent an organisation's ability to continue to deliver healthcare services, including data loss/property damage/incidents in population programmes (eg screening/ immunisation) where harm may potentially extend to a large population • Allegations/incidents of physical abuse and sexual assault • Loss of confidence in the service/ adverse media coverage/public concern about healthcare/an organisation	**Yes** for the following: • Unexpected/avoidable death/severe harm • Never events • Allegations/incidents of physical abuse and sexual assault

[6] Note the Serious Incident Framework is currently being reviewed by NHS Improvement and future requirements may differ from the current framework.
[7] The Never Events policy and framework was revised in January 2018.

Organisation and/or system	Purpose, data collected and coverage	Overlap with NRLS
	Coverage: • England, from 2010	
Care Quality Commission (CQC)	**Purpose:** • CQC registration requirements **Data collected:** • Specific incidents, events and changes that affect a service or the people using it As part of these regulations, certain notifications can be submitted to the NRLS: • 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) and (b) (serious injuries to people who use the activity) **Coverage:** • NHS providers, England • Independent healthcare providers have different registration requirements	**Yes,** for incidents reported by independent sector organisations as these will be reported directly to the CQC and may also be reported to the NRLS. Incidents reported to the CQC via the NRLS as part of CQC registration requirements do not overlap as they are singly reported to the NRLS and shared with CQC.
Medicines and Healthcare products Regulation Agency (MHRA) Yellow Card Scheme	**Purpose:** • Drug safety (pharmacovigilance) and device safety **Data collected:** • Side-effects from medicines, vaccines and herbal or complementary remedies • Safety of medical devices **Coverage:** • All healthcare products in the UK • Data available from 1964	**Yes** for the following: • Medicines/medicinal device-related incidents

Organisation and/or system	Purpose, data collected and coverage	Overlap with NRLS
MHRA Serious Adverse Blood Reactions and Events (SABRE)	**Purpose:** • Haemo-vigilance **Data collected:** • Serious adverse events related to the collection or transfusion of blood /blood components **Coverage:** • UK • Data available from 2005	**Yes** for the following: • Adverse blood reactions
Public Health England (PHE) notifications and routine surveillance systems	**Purpose:** • Surveillance of specific incident types and infectious diseases **Data collected:** • Specific data collections too various to list; varies by data collection, but including relevant epidemiological data • Includes mandatory and voluntary data collections **Coverage:** • England for the purposes of health protection	**Yes,** where it is related to patient care: for example, healthcare-associated infections
Serious Hazards of Transfusion (SHOT)	**Purpose:** • Haemovigilance **Data collected:** • Serious adverse events related to the transfusion of blood • NB there is some crossover with SABRE above. **Coverage:** • UK	**Yes,** for specific blood transfusion incidents only

Data outputs

NaPSIR and OPSIR provide a national and organisational summary, respectively, of patient safety incidents reported to the NRLS. These include breakdowns that describe the type and location of the incidents reported. The monthly summary data is also published at organisation level, and shows the counts of incidents reported to the NRLS, by month and degree of harm; data is provided as a table and graphs that users can manipulate. These three publications are not directly comparable, and anyone using the data must consider their differences. More information is available in our guidance notes. The official statistics form just one aspect of our outputs that contribute to learning; for more detail, see Section 8 below under 'Users and uses of the data'.

Accessibility

All official statistics are published on our website as transparency data and are available via the publication-specific hyperlinks in Section 1 above. We publish data tables in a non-proprietary format to maximise accessibility for all users.

Timeliness and punctuality

Publication dates are announced in advance for the forthcoming year, and data is published at 9.30am. NaPSIR and OPSIR were published annually for the first time in September 2021; previously these outputs were published six-monthly in March and September. There is, and previously was also, a six-month lag between the end of a reporting period and the publication: ie the September publication reflects incidents submitted up to the end of the preceding March. This is due to internal quality assurance and processing time and delays in reporting incidents to the NRLS (see next section). By contrast the monthly summary data is published every month covering all incidents received in the previous month. This means the monthly data will reflect reporting patterns more acutely than the NaPSIR and OPSIR and there may be changes in the number of incidents in each reported category if data is updated by reporters.

Reporting delays

There are known delays and patterns in how incidents are reported to the NRLS. This affects how the data is interpreted and results in it being published either on a less timely schedule but with more stable numbers of incidents (NaPSIR and OPSIR), or – if it is more timely – with numbers that are liable to change (monthly summaries). NRLS guidance asks organisations to submit their data at least once a month, and serious incidents (incidents leading to severe harm and death) should be reported "without delay".[8] However, peaks in reporting to the NRLS still occur around the cut-offs for data extraction before NaPSIR and OPSIR publication. The six-month lag in publishing these statistics is designed to deal with this issue. We continue to work closely with reporting organisations to try to reduce reporting delays. The monthly summary data has been developed to support this work as it reflects reporting delay and provides reporting organisations with a timely view on their reporting patterns.

Operational context

Users and uses of the data

The NRLS data and associated outputs are used for a range of purposes by organisations and individuals in the UK, Ireland and internationally. A summary of key stakeholders and how they use the data is provided below. This has been informed by our daily interactions with our users, analysing data requests on the NRLS data we receive and a survey during winter 2017/18 (see below). This includes input from the public and patients.

National users and uses

- **NHS England and NHS Improvement:** statutory functions to develop advice and guidance and share learning nationally to reduce the risk to patients, which includes review by clinical leads, publication of patient safety alerts, review and response alerts; the production of official statistics; responses to Freedom of Information requests and parliamentary questions.
- **NHS England:** internal use; to inform policy; support ongoing project work.

[8] CQC registration regulations 2009, www.cqc.org.uk/guidance-providers/registration-notifications/notifications

- **Department of Health and Social Care (DHSC):** NHS England and NHS Improvement works with DHSC to respond to Freedom of Information requests and parliamentary questions.
- **CQC:** specific incidents relating to CQC registration requirements are shared with the CQC.
- **Public Health England:** data is shared with the Medical Exposures Group to support its surveillance of radiotherapy errors and near misses.
- **MHRA:** to understand issues and risks associated with products regulated by MHRA.
- **Healthcare Safety Investigation Branch:** to trigger and run investigations.

Local users

- **NHS providers**, including acute trusts and clinical commissioning groups (CCGs): monitoring their own reporting trends; local learning and quality improvement programmes; comparison with peers for learning, assurance, planning and efficiency monitoring.
- **Ad hoc users**, such as academic departments, industry, healthcare product and service companies, private healthcare providers, international organisations, charities and the media.

The main external users of our data are providers, commissioners and regulators of NHS care. However, we have a wide user base, which means our routine official statistics and other outputs cannot address all needs of all users. We have a formal data request process to manage this. In brief, users can submit a data request and where possible we will respond using available published resources; if this is not possible, we will undertake a bespoke analysis. If the NRLS data is not suitable for the user's needs, we tell them as soon as we can and provide potential alternatives where possible.

Assurances to users and data suppliers

We provide these assurances to the users of our official statistics and data suppliers:

- to publish our statistics on time on the pre-announced date

- to place the minimum burden on suppliers of data
- to promptly assist when technical problems occur in providing data to us
- to treat all information provided in accordance with the security of information statement (see Section 16)
- to provide an easily accessible route for feedback and comments, questions and complaints about the statistics
- to respond in a timely and accurate manner to questions or complaints.

User engagement

We work closely with data suppliers to ensure data submission is as timely, accurate and as minimal a burden to them as possible. We maintain close working relationships with our routine data users so that appropriate and relevant data is continually provided. All users are invited to supply feedback at every publication; our contact details are available for all our publications on our webpages and in the publications themselves.

Engaging with users forms an integral part of the development of LFPSE. We carried out a survey on current access to and uses of NRLS statistics, other outputs and future ways users would like to interact with the data. Frontline staff, patients and the public were invited to take part. We will use the results to assess our current official statistics and other outputs. Future developments may include updated official statistics and other mechanisms to access data.

Users are encouraged to contact us if they have any comments or questions about our statistics and their presentation: nrls.datarequests@nhs.net. We will post information on any developments to our OPSIR and NaPSIR statistics on the relevant webpages.

Quality assurance processes

Most data is submitted to the NRLS via batch upload from LRMS with a small amount submitted via the manually entered eForm. Quality assurance processes are applied locally where the data is entered and uploaded to the NRLS, and nationally where data from all data suppliers is collated, stored, cleansed, analysed and published. The quality assurance steps and processes are outlined below.

Local data collection

Initial verification of NRLS compliance

Local providers of LRMS must show that their system is NRLS-compliant so users can connect to and submit data to the NRLS. Compliance encompasses validation and sign-off of the mapping of local fields to NRLS, and successful and correct uploading of test files. We check and approve both the mapping and uploads. As LRMS can be modified locally, we must validate and approve each data supplier's mapping before users are allowed to submit data. We must also approve any subsequent local changes to LRMS before use. Additionally, we recommend mappings are checked at least every three years, and we invite data suppliers for a mapping review.

Upload of data

Each upload of data is automatically validated before incorporation into the NRLS to ensure it contains the required fields with no errors and a minimum dataset is provided. If these fields are not uploaded or they contain errors, the data upload is rejected and the user notified. We support users to rectify problems with upload and data quality. We give data suppliers documentation to help them successfully upload their data.

In-house data cleansing and quality assurance before publication – six-monthly publications

We undertake a rigorous schedule of quality assurance and communication with data suppliers before publishing the official statistics. Table 3 outlines these steps.

Table 3: Overview of quality assurance checks

Timescale	Task
Six months before publication	Communicate publication date to data suppliers
Four months before publication	Data submission cut-off for publication
Four months before publication until publication day	Data checking and cleansing Preliminary data checks Provisional data shared with data suppliers to identify errors and for confirmation of any organisational changes or changes to service provision Finalise organisational details and incorporate updates from data suppliers
One month before publication onwards	Quality assure final data tables
Two weeks before publication onwards	Draft, quality assure and finalise associated documentation

In-house quality assurance before publication – monthly publication

The monthly data summaries are designed to be timely and are published around two weeks after the end of the period being reported. For example January's data on the number of incidents reported is published in the middle of February. This

means the monthly data cannot have the same amount or type of quality assurance as the six-monthly publications. The following quality assurance processes are undertaken:

- Any relevant changes in organisational structure are checked, confirmed and reflected in the final data tables
- Data table production is automated with inbuilt error checking and validation
- Final data tables are manually checked for errors.

Feedback to users on data quality

Reporting organisations are supplied with their own provisional data to allow them to improve data quality to reduce reporting delay, rectify errors in uploaded data and reduce the risk of uploading patient-identifiable information.

The newly developed monthly summary data has been available on our website since July 2017. It provides timely, publicly available data. Our aim is to encourage data suppliers to submit data in a more timely and consistently manner across the year.

Documentation regarding the NRLS compliance process, expectations of local data suppliers and field definitions are made available to individuals and organisations. This includes an explanation of the key fields required for data upload and the need for the other fields to be completed for the purposes of learning and data quality.

Outline of the eForm process

Approximately 1% of patient safety incidents are reported to the NRLS via eForm. EForm data undergoes a separate data quality process as the forms have inbuilt validation checks. Users have access to help files, guidance and definition documents. Not all functionality is available for eForm submissions, however. For example, it is not possible for users to update the record if more information about the incident becomes available. Improved functionality for this route of reporting has been implemented as part of LFPSE and this is the first element of LFPSE to go live.

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.

Source of reports

In England 98% of incidents are reported by NHS acute/general hospitals, mental health service, and community nursing, medical and therapy service care settings. The NRLS data is likely to under-represent patient safety incidents happening elsewhere in the healthcare sector, for example in general practice, dental surgeries, community pharmacies and independent providers.

Organisational restructuring within the NHS may impact on who reports incidents. For example, in 2013 primary care trusts were dissolved and replaced by CCGs. CCG reporting requirements had not been established at this point and, historically, the reporting of incidents by the non-acute setting is likely to have been affected by this. Further examples are given in Figure 1. We are working with non-acute/non-NHS providers of NHS-commissioned care to improve their reporting; LFPSE is expected to improve the recording of patient safety events.

Type of incidents reported

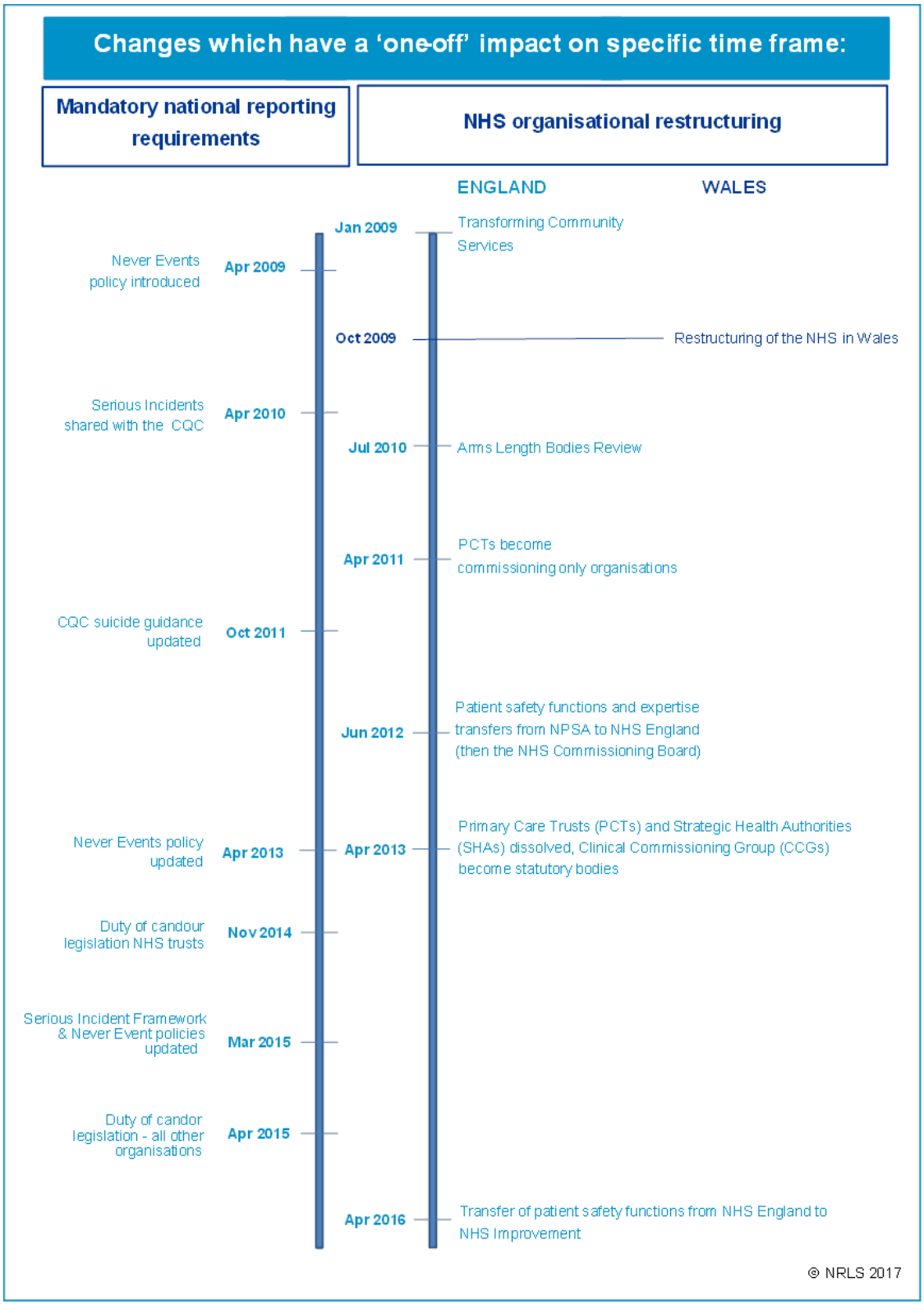
National and local initiatives on patient safety have often focused on certain staff groups and attitudes to reporting incidents may also differ between staff groups. This can impact on the types of incidents that are reported, such as falls being over-represented in reported incidents. The level of harm reported for an incident may consciously or unconsciously be modified depending on the local or national profiles of specific incident types. Again the direction and size of any resulting bias is impossible to estimate.

Changes in policy

Changes in policy may affect the type of incidents reported, with an increase in the reporting of particular incidents if their profile is raised (see Figure 1 above). For example, from April 2010 it became mandatory to report serious incidents to the CQC. STEIS is the main mechanism for reporting such incidents, but as NHS acute and mental health organisations can fulfil this requirement by reporting via NRLS reporting (such incidents are then shared with CQC), this policy change may have affected serious incident reporting to the NRLS.

Another example is when the requirements for reporting suicides were widened to encompass actual or apparent suicides of people with an open episode of care in specialist mental health services. Previously only suicides relating to patient safety incidents were required to be reported.

Figure 1: Example of changes with a one-off impact on reporting



Seasonality

The NRLS dataset is subject to two types of seasonality:

- **Incident seasonality** reflects real differences across the year in when certain types of incident occur. For example, postsurgical morbidity and mortality appear to vary over the year.[9]
- **Reporting (or 'administrative') seasonality** is an artefact of when reports are received by the NRLS: notable peaks every six months coincide with the historical cut-off deadlines for data submission for the NaPSIR and OPSIR publications. Annual publication may smooth out these peaks.

Users should be aware of incident seasonality when examining data across time, but this should not be controlled for as it reflects real fluctuations in incidents.

However, reporting seasonality reflects patterns of reporting rather than when incidents occur. The monthly summary data is designed to encourage and support a more even distribution of reporting over time.

Reporting delay

Users are encouraged to report their incidents to the NRLS regularly, at least once a month. However, there are known reporting delays with batches of incidents being sent close to the cut-offs for the NaPSIR and OPSIR publications. Users may also only report or update incidents once a full investigation has been completed, often a considerable time after the incident occurred. Due to its timely nature the monthly summary data will be more prone to reporting delay for more recent months.

Cost and burden

NRLS data is populated mainly from existing administrative sources, minimising the burden on data suppliers. We keep the number of mandatory fields to a practical minimum, balancing the submitted data's usefulness in improving patient safety with reducing the burden on data suppliers. A key part of LFPSE is developing a minimum dataset and assessing cost/benefit to data suppliers. A more formal assessment of cost and burden will be available in the future.

[9] Englesbe MJ, Pelletier SJ, Magee JC et al (2007) Seasonal variation in surgical outcomes as measured by the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP). *Ann Surg* 246(3): 456–462.

Strengths and weaknesses of the NRLS data collection

The NRLS data collection has known strengths and weaknesses. Its strengths include:

- the use of national definitions, which ensure consistency of reported data across organisations
- data is collected centrally to support consistency in analyses
- clinical review of all incidents resulting in death or severe harm to identify and monitor serious incidents and highlight them to medical professionals to reduce their recurrence
- routine statistical outputs ensuring transparency and clarity in outputs and their publication timescales
- ad hoc alerts relating to specific safety issues to enable rapid response and sharing of learning.

Discussion on the known weaknesses is available in our accompanying guidance notes.

Security of information

We have organisational guidance and policies to ensure confidentiality and disclosure control; these are augmented by local guidance/policies on accessing NRLS data.

Data is transferred to us securely using Secure Sockets Layer (SSL) transmissions. This means the submitted data is encrypted on our network. Data is stored on a secure password-protected server. Only relevant staff have access to the data. Before they can access it, they must complete information governance training and read and agree to NRLS-specific policies on data use. No patient-level data is

published. We expect that the risk of deductive disclosure from the published data is minimal due to the level of detail in our publications.

Data suppliers can only have access to upload and view NRLS data once their system has been approved as NRLS-compliant. We maintain a list of registered users. The local NRLS reporting manager is responsible for local access to the NRLS and must ensure:

- local users requesting access to the system are valid employees of their organisation
- appropriate levels of access are provided
- accounts are disabled when the user leaves the organisation
- they notify us of any security incidents relating to access to the NRLS and associated data, such as when a password has been compromised.

Confidentiality

We abide by the principle of confidentiality outlined in the code of practice for statistics. The confidentiality of personal and other information in administrative and management data systems is paramount. The national system does not intend to retain any patient or staff personal identifiable information; this is stated in our reporting guidance. In the event that such information is submitted in error, we take steps to anonymise the data. We provide monthly feedback on the number of incidents flagged as potentially containing personal identifiable information.

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: nrls.datarequests@nhs.net

Contact: nrls.datarequests@nhs.net

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