UK Statistics Authority

Assessment of compliance with the Code of Practice for Official Statistics

Patient Outcomes Statistics: Statistics on Reported Patient Safety Incidents in England and Wales

(produced by NHS England)

Assessment Report 305

June 2015

About the UK Statistics Authority
The UK Statistics Authority is an independent body operating at arm's length from government as a non-ministerial department, directly accountable to Parliament. It was established on 1 April 2008 by the *Statistics and Registration Service Act 2007*.

The Authority's overall objective is to promote and safeguard the production and publication of official statistics that serve the public good. It is also required to promote and safeguard the quality and comprehensiveness of official statistics, and good practice in relation to official statistics.

The Statistics Authority has two main functions:
1. oversight of the Office for National Statistics (ONS) – the executive office of the Authority;
2. independent scrutiny (monitoring and assessment) of all official statistics produced in the UK.

Contact us
Tel: 0845 604 1857
Email: authority.enquiries@statistics.gsi.gov.uk
Website: www.statisticsauthority.gov.uk

UK Statistics Authority
1 Drummond Gate
London
SW1V 2QQ

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NATIONAL STATISTICS STATUS

National Statistics status means that official statistics meet the highest standards of trustworthiness, quality and public value.

All official statistics should comply with all aspects of the *Code of Practice for Official Statistics*. They are awarded National Statistics status following an assessment by the Authority's regulatory arm. The Authority considers whether the statistics meet the highest standards of Code compliance, including the value they add to public decisions and debate.

It is a producer's responsibility to maintain compliance with the standards expected of National Statistics, and to improve its statistics on a continuous basis. If a producer becomes concerned about whether its statistics are still meeting the appropriate standards, it should discuss its concerns with the Authority promptly. National Statistics status can be removed at any point when the highest standards are not maintained, and reinstated when standards are restored.

Contents

1 Summary of findings

Introduction

1.1 This is one of a series of reports[1] prepared under the provisions of the *Statistics and Registration Service Act 2007*[2]. The Act allows an appropriate authority[3] to request an assessment of official statistics against the *Code of Practice for Official Statistics*[4] in order for them to gain National Statistics status. This report is in response to such a request[5] from the Secretary of State for Health in response to the Statistics Authority's *Monitoring Review: Official Statistics on Patient Outcomes in England*[6]. The report covers the following reported patient safety incidents statistics produced by NHS England and reported in:

- *NRLS Quarterly Data Workbook and Summary*[7] *(Quarterly Data Summary)*
- *NRLS Organisation Patient Safety Incident Report and Workbook*[8] *(Organisation Report)*

1.2 This report forms part of a group of assessments of patient outcomes statistics produced by the Health and Social Care Information Centre (HSCIC), the Care Quality Commission (CQC) and NHS England: the NHS Outcomes Framework, Summary Hospital-level Mortality Indicators, Patient Reported Outcome Measures and Patient Experience statistics.

1.3 This report was prepared by the Authority's Assessment team, and approved by the Regulation Committee on behalf of the Board of the Statistics Authority, based on the advice of the Director General for Regulation.

Decision concerning designation as National Statistics

1.4 The Authority recognises the importance of publishing transparent official statistics about reported patient safety incidents, for public accountability and to provide an evidence base for planning safety improvements in health services. However, the Authority judges that, due to the variability in reporting by the data collection bodies combined with the voluntary nature of reporting incidents that do not result in moderate or severe harm or death, NHS England does not sufficiently understand the coverage, completeness and accuracy of the administrative data used to produce the reported patient safety incident statistics. It is therefore impossible for NHS England to fully understand the quality of the statistics, to describe that quality to users, and to understand the extent to which the statistics meet users' needs. Until NHS England can be

[1] http://www.statisticsauthority.gov.uk/assessment/assessment-reports/index.html
[2] http://www.opsi.gov.uk/Acts/acts2007/pdf/ukpga_20070018_en.pdf
[3] Subsection 12(7) of the Act defines 'appropriate authority' as Ministers of the Crown, Scottish Ministers, Welsh Ministers, Northern Ireland departments or the National Statistician
[4] http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html
[5] http://www.statisticsauthority.gov.uk/reports---correspondence/correspondence/letter-from-rt--hon--jeremy-hunt-mp-to-sir-andrew-dilnot-170314.pdf
[6] http://www.statisticsauthority.gov.uk/assessment/monitoring/monitoring-reviews/monitoring-review-1-2014---official-statistics-on-patient-outcomes-in-england.pdf
[7] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/
[8] http://www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/directory/

assured that it is able to produce statistics to a known level of quality that meets users' needs, the potential value of the statistics is undermined – indeed, there is a risk that inappropriate decisions may be made on the basis of these statistics. We understand that NHS England is developing a new national system for recording safety incidents which it expects to provide improved coverage and completeness for reported patient safety incidents. Achieving sufficiently accurate patient safety incident statistics to meet users' needs will rely on a combination of the robust reporting of safety incidents by NHS organisations and an understanding of the nature and extent of any inaccuracies by NHS England statisticians.

1.5 The Statistics Authority judges that the statistics covered by this report do not fully comply with the *Code of Practice for Official Statistics* in the ways summarised in paragraph 1.10. The Authority judges that the statistics published in *Quarterly Data Summary* and *Organisation Report* cannot be designated as National Statistics until the Authority has confirmed that appropriate actions have been taken by NHS England to meet the Requirements listed in paragraph 1.10. As part of meeting the Requirements set out in this report, the Statistics Authority invites the Lead Official for Statistics at NHS England to submit to the Director General for Regulation a plan for implementing the Requirements listed in paragraph 1.10. Upon receiving NHS England's plan, the Authority will consider what actions would be appropriate regarding the assessment and designation of the patient safety statistics.

Summary of strengths and weaknesses

1.6 The National Reporting and Learning System (NRLS) is the largest patient safety incident reporting database in the world. It holds over 10 million reported patient safety incident records. NHS England has established quality assurance processes that help to ensure that the patient safety incidents reported by NHS-funded organisations are accurately mapped onto the NRLS. NHS England Clinical Leads review all reported patient safety incidents that result in severe harm or death, to learn from the incidents in order to make future care safer. This process also checks that the coding of the most serious reported patient safety incidents is accurate and consistent. Reporting organisations are provided with a provisional summary of the incidents that they have reported to the NRLS each month so that they have the opportunity to perform a quality assurance check before the official statistics are produced.

1.7 The primary purpose of incident reporting is learning in order to improve patient safety. NHS England is clear that the statistics cannot be interpreted as the number of incidents actually occurring in an organisation, as it knows that incidents are not recorded completely or consistently across health service providers. It is also not mandatory for NHS trusts to report patient safety incidents unless they result in moderate harm, severe harm or death. NHS England says instead that the statistics should be seen as a measure of an organisation's patient safety incident reporting culture, although it acknowledges that it cannot be automatically assumed that when an organisation reports low numbers of incidents that it is under-recording; it may just have low numbers of incidents. NHS England does not publish sufficient

information about the potential quality issues with the administrative data or about the quality assurance arrangements undertaken by the different data collection bodies. This makes it difficult to draw any meaningful conclusions from the statistics at a national level, or to make comparisons between health service providers with any level of confidence.

1.8 NHS England is undertaking a development project to establish a new system for reporting patient safety incidents – a successor to the current NRLS. NHS England is hopeful that the new system will facilitate more complete reporting of incidents but it will be incumbent on the statisticians to evaluate the suitability of the administrative data for use in producing official statistics and to determine the type of assurances that users will need.

Detailed recommendations

1.9 The Assessment team identified areas where it felt that NHS England should improve the production and presentation of the reported patient safety incidents statistics. Those which are essential for the NHS England to address in order to strengthen its compliance with the *Code* and to enable designation as National Statistics are listed – as Requirements – in paragraph 1.10, alongside a short summary of the key findings that led to each Requirement being made. Other recommended changes, which the Assessment team considers would improve the statistics and the service provided to users but which are not formally required for their designation as National Statistics, are listed – as Suggestions – in paragraph 1.11.

Requirements for designation as National Statistics

1.10 This paragraph includes those improvements that NHS England is required to make in respect of its reported patient safety incidents statistics in order to fully comply with the *Code of Practice for Official Statistics*, and to enable designation as National Statistics.

Finding	**Requirement**	
NHS England engages well with users of the NRLS and the case-level data but needs to do more to understand how the official statistics outputs are used, and what user experiences are of these statistics. NHS England should:	**1**	a) Develop a thorough understanding of the use made of the reported patient safety incidents statistics presented in *Quarterly Data Summary* and *Organisation Report,* particularly by engaging effectively with users outside NHS England, and document the types of decisions that the statistics are used to inform, including providing context for users about how they can be used in conjunction with other patient outcomes statistics b) Publish information about users' experiences of the content, presentation and timing of the statistics, and explain how

		it intends to respond to what it has learned c) Publish details of its plans for the future of reported patient safety incidents (para 3.6).
The reasons for, and extent of, any revisions to these statistics are not highlighted in the data tables. NHS England should:	**2**	a) Publish an updated revisions policy for these statistics and explain how users will be informed of any changes to the statistics b) Include a link to the revisions policy within the statistical reports c) Indicate the nature and extent of any revisions alongside the statistics (para 3.9).
The different roles and responsibilities for decision making in relation to the reported patient safety incidents statistics are unclear. NHS England should:	**3**	Publish details of the roles and responsibilities of all parties involved in the production of the reported patient safety incidents statistics, including those of the Lead Official. This should include details of the responsibilities for: a) deciding on statistical methods, standards and procedures, and on the content and timing of statistical reports b) ensuring that the professional development needs of the statisticians are met, and to a level that enables them to meet the requirements of the *Code* (para 3.11).
The published patient safety quality documentation does not provide sufficient information on the assurance arrangements for ensuring the quality of the patient safety statistics. NHS England should:	**4**	a) Ensure that reported patient safety incidents statistics are produced to a level of quality that meets users' needs b) Provide an indication of the coverage, completeness and accuracy of the data used to produce the reported patient safety incidents statistics for each care setting c) Extend the patient safety incident quality documentation to summarise the quality assurance arrangements of the NHS organisations and make clear the implications for the quality of the statistics d) Summarise the outcomes of the reviews of NHS organisations' practices by regulatory bodies with respect to the current quality of the reported patient safety incidents statistics. In meeting this requirement, NHS England should take into consideration the Authority's

		Administrative Data Quality Assurance Toolkit (para 3.22).
NHS England publishes some information about other sources of patient safety data and statistics but it does not present sufficient detail about the coherence and comparability of these sources with the NRLS. NHS England should:	**5**	Publish information about the comparability and coherence of its reported patient safety incidents statistics with similar statistics for England and Wales, the other countries of the UK, and internationally (para 3.23).
NHS could do more to draw out the key messages from the reported patient safety incidents statistics and to explain the operational context for *Quarterly Data Summary* and *Organisation Report* together. NHS England should:	**6**	Improve the commentary alongside the reported patient safety incidents statistics so that it aids users' interpretation of the statistics by: a) clarifying the key messages up front for known uses b) clarifying the linkages between NRLS organisational and national data and explaining the consequences of disparities for user interpretation c) taking particular account of the need to provide information on the wider context of patient safety reporting and on the effects of operational policy on the statistics d) including charts that are clearly presented to enhance interpretability of the statistics As part of meeting this requirement, NHS England should consider the points detailed in annex 1 and annex 2. In meeting this Requirement we suggest that NHS England work with DH and HSCIC, and with other data provider bodies as relevant, to identify the operational and policy issues that affect patient safety statistics and collaborate to provide helpful explanatory information to support the wider use of these statistics within the context of presenting statistics on patient outcomes more widely (para 3.31).
Quarterly Data Summary is not available in a format	**7**	Publish the data associated with *Quarterly Data Summary* in an open format that equates to at least a Three Star level under the Five

that meets the expectations proposed in the *Open Data White Paper: Unleashing the Potential.* NHS England should:		Star Scheme (para 3.32).
The *Organisation Report* and *Quarterly Data Summary* workbooks contain limited historical trends. NHS England should:	**8**	Investigate the user need for published historical time series data from *Organisation Report* and *Quarterly Data Summary* and take steps to meet any identified need (para 3.33).
Quarterly Data Summary and *Organisation Report are* not accessible from NHS England's website. NHS England should:	**9**	a) Ensure the reported patient safety incidents statistics are accessible from its statistics pages and search facility b) Improve the labelling and signposting of the NRLS website, to make it clear to users how the different statistical reports relate to each other and ensure that it is clear to users how to access information that is relevant to their needs (para 3.34).
The reported patient safety incidents statistics are not listed in NHS England's 12-month publication plan or on National Statistics release calendar on GOV.UK. NHS England should:	**10**	Publish a timetable of releases for these statistics 12 months in advance and ensure that these statistics can be accessed from the Statistics Release Calendar (para 3.36).
NHS England cannot guarantee the 9.30am release of *Quarterly Data Summary*, due to delays in sign off processes. NHS England should:	**11**	Ensure that reported patient safety incidents statistics are issued at 9.30am on the day of release (para 3.37).
NHS England does not publish the details of the	**12**	Publish the name and contact details of the responsible NHS England statistician in the

responsible NHS England statistician in the statistical reports. NHS England should:		statistical reports (para 3.38).
NHS England has a published policy for pre-release access to official statistics but does not publish lists of those people given restricted pre-release access to the reported patient safety incidents statistics. NHS England should:	**13**	a) Review the arrangements for granting early access to the reported patient safety incidents statistics and ensure that pre-release access is only granted where absolutely necessary b) Ensure those with access understand their obligations under the *Pre-release Access to Official Statistics Order 2008*, publish records of those who have access to the statistics prior to release and inform the Authority of the justification for each inclusion (para 3.39).
NHS England has published a Statement of Administrative Sources; however, the NRLS is not included. NHS England should:	**14**	Ensure that the NRLS is listed in its Statement of Administrative Sources (para 3.40).

Suggestions for extracting maximum value from the statistics

1.11 This paragraph includes some suggestions for improvement to NHS England's statistics on reported patient safety incidents in the interest of the public good. These are not formally required for designation, but the Assessment team considers that their implementation will improve public confidence in the production, management and dissemination of official statistics.

We suggest that NHS England:

1	Draw on examples of good practice in user consultation from other health statistics producers and the Government Statistical Service (GSS) and explore using avenues such as the Health Statistics User Group on StatsUserNet and patient representative groups to facilitate user discussions (para 3.7).
2	Review the way that the statistics are presented in *Organisation Report* and consider presenting them separately from the operational statements (para 3.8).
3	Publish a process map to illustrate the supply of the patient safety incident data, and the assurance measures and safeguards taken by

	data suppliers, regulators and the statistics producer team (para 3.22).

2 Subject of the assessment

Patient Outcomes Review and the Francis Inquiry

2.1 Following publication of the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*[9] (chaired by Robert Francis QC) in February 2013, the Statistics Authority conducted an independent review of patient outcome statistics in England to consider the extent to which the public could more readily use these statistics. In its report, *Monitoring Review: Official Statistics on Patient Outcomes in England*[10] (*Patient Outcomes Review*) which was published on 7 February 2014, the Authority recommended that the patient outcomes statistics be assessed against the *Code of Practice*. The Secretary of State for Health requested the assessment of NHS England's patient safety statistics against the *Code* in response to that recommendation.

2.2 In addition to recommending the assessment of seven sets of official patient outcomes statistics, most of which are covered by the group of assessments outlined in paragraph 1.2 of this report[11], *Patient Outcomes Review* makes other recommendations pertinent to this group of patient outcomes assessments. The Authority:

- sees a vital need for NHS England and HSCIC to disseminate consistent patient outcome statistics from all publicly-funded healthcare providers (whether NHS or independent sector) and, in the interim, to state clearly whether the current statistics do so
- recommends that NHS England and HSCIC engage closely with expert users such as in third sector organisations with a view to improving the clarity and accessibility of current patient outcome statistics for less-expert users
- recommends that: NHS England, HSCIC and CQC further research and publish the views of a wide range of users about their needs in respect of: (a) ensuring that the presentation of relevant statistics is accessible, clear and at a level of detail that supports their further use; and (b) extending the range of patient outcome statistics to address currently unmet needs

2.3 Specifically in respect of reported patient safety incidents statistics, *Patient Outcomes Review* highlighted the importance of transparent and timely non-personal data on quality and safety as underscored in the Berwick review into patient safety[12] which emphasised that such data should be 'shared in a timely fashion with all parties that want it, including, in accessible form, with the public'.

The National Reporting and Learning System (NRLS)

2.4 NHS England runs the National Reporting and Learning System (NRLS), a national compilation of patient safety incident records for NHS-funded

[9] http://www.midstaffspublicinquiry.com/report
[10] See footnote 6
[11] Decisions about the timing of assessment by the Statistics Authority of NHS Safety Thermometer: Patient Harms and Harm Free Care and Friends and Family Test are pending
[12] https://www.gov.uk/government/publications/berwick-review-into-patient-safety

organisations in England and Wales. From this system, NHS England publishes official statistics on reported patient safety incidents, in *NRLS Quarterly Data Workbook and Summary (Quarterly Data Summary)*[13] and *NRLS Organisation Patient Safety Incident Report (Organisation Report)*[14]. NHS England is currently piloting the reporting of patient safety incidents from private healthcare providers, though these data are not included in the published official statistics.

2.5 The NRLS was established in 2003 by the National Patient Safety Agency (NPSA)[15], an arm's length body (ALB) of the Department of Health (DH)[16]. The NPSA itself was formed in 2001, with a mandate to identify and reduce safety risks for patients receiving NHS-funded care and to lead on national patient safety initiatives. The NPSA set up the NRLS to help achieve this mandate. The NPSA defined a patient safety incident as 'any unintended or unexpected incident that could have, or did, lead to harm for one or more person(s) receiving NHS funded healthcare'.

2.6 When a patient safety incident occurs, staff working in NHS-funded care in England and Wales may complete a local report of the incident. These incident reports are stored electronically on Local Risk Management Systems (LRMS). Reporting teams within individual organisations submit incident returns from these systems to the NRLS. The NRLS compiles a selection of key incident fields from the separate local reporting systems into a single national patient safety incident database. LRMS submissions account for around 99 per cent of all NRLS reports, although healthcare staff, patients and members of the public can also submit safety incident returns to the NRLS via an e-form template, illustrated in Figure 1.

Figure 1 – NHS Direct directions to record a patient safety incident[17]

Source: NRLS report a patient safety incident web page, NHS England

2.7 The NRLS allowed the NPSA to provide feedback and guidance to healthcare organisations to improve patient safety. Specialist clinicians and safety experts analysed the NRLS database to identify common or emerging safety risks and opportunities for improvement. This included issuing alerts[18] to address specific safety risks, providing tools[19] to build a strong safety culture, and national initiatives[20] in specific areas such as hand hygiene, nutrition, cleaning and the design of processes such as the labelling of medicines. The NPSA also

[13] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/
[14] http://www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/directory/
[15] http://www.npsa.nhs.uk/
[16] https://www.gov.uk/government/organisations/department-of-health
[17] http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/
[18] http://www.nrls.npsa.nhs.uk/resources/type/alerts/
[19] http://www.nrls.npsa.nhs.uk/resources/type/toolkits/
[20] http://www.nrls.npsa.nhs.uk/resources/collections/

provided feedback to the reporting healthcare organisations to facilitate improvements to the robustness of the submitted patient safety incident data.

2.8 The NRLS was initially established as a voluntary reporting system. However, from April 2010 it became mandatory for NHS trusts in England to report all serious patient safety incidents (those resulting in moderate harm, severe harm or death) to the CQC[21] as part of the CQC registration process[22]. To avoid the duplication of reporting, NHS organisations were required to report serious incidents to the NRLS, which were in turn passed to CQC under a separate Data Sharing Agreement (DSA).

2.9 A review of DH's ALBs[23] in July 2010 proposed the abolition of the National Patient Safety Agency (NPSA). It recommended that the NPSA's responsibilities for reporting and learning from patient safety incidents should move to the newly formed NHS Commissioning Board[24]. Section 281 of the *Health and Social Care Act 2012*[25] confirmed the change, and the key functions for patient safety developed by the NPSA transferred to the NHS Commissioning Board Special Health Authority in June 2012.

2.10 To ensure continuity of service, the previous NRLS staff and NRLS infrastructure transferred to the Imperial College Healthcare NHS Trust[26]. This was initially under a two-year contract which included scoping work for a new Patient Safety Incident Management System[27] (PSIMS) to replace the NRLS, ahead of a formal competitive tender to run the system from 2016/17. The NHS England patient safety team told us that it was considering a portal-based system that would make reporting and reviewing incidents easier, and would provide better support for commissioners and more granular information. However, during the course of the Assessment NHS England told us that responsibility for the NRLS is planned to transfer to a new organisation responsible for NHS quality in England from April 2016. Further details have not yet been announced.

Reported Patient Safety Incidents statistics

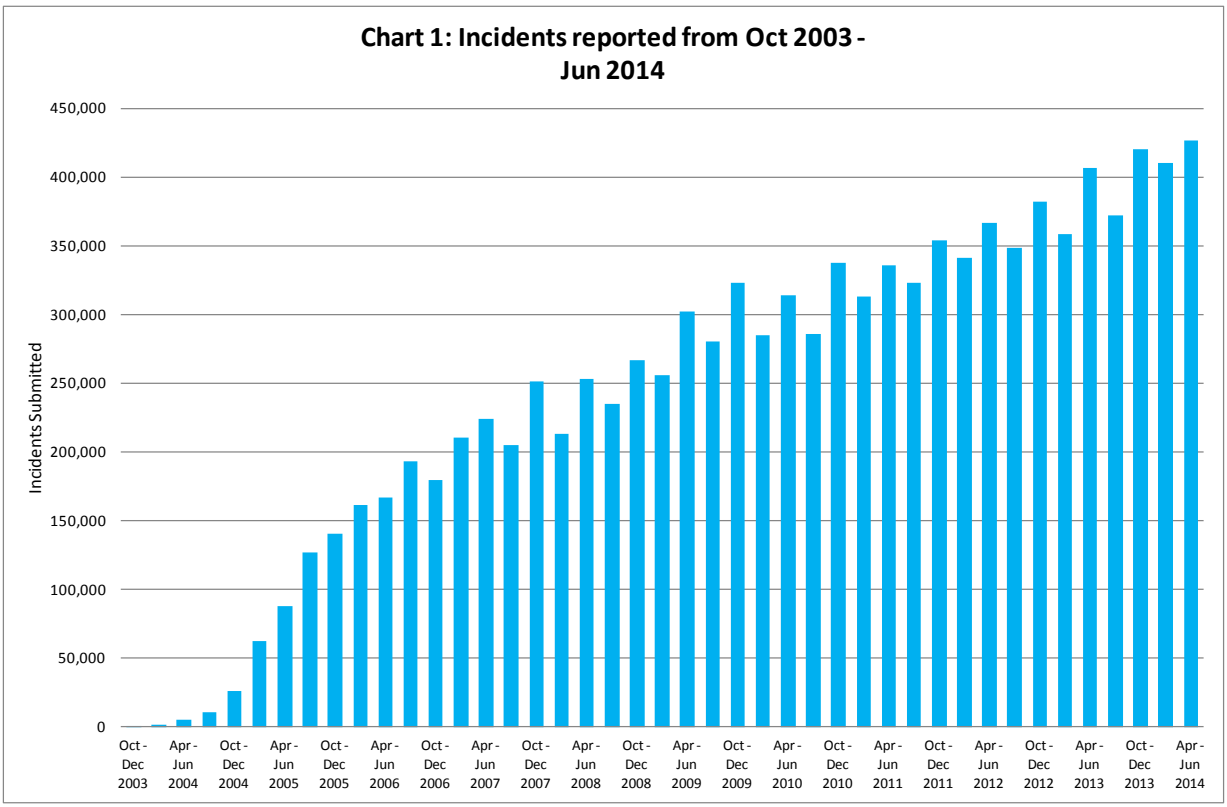
2.11 The voluntary nature of the majority of incident reporting to the NRLS means that it cannot be reliably used to derive definitive estimates for the number of patient safety incidents occurring in the NHS. The primary use of the NRLS is instead as a measure of the safety culture of NHS organisations and their organisational effectiveness. High levels of incident reporting are not necessarily indicative of poor patient care, and instead may be a reflection of a positive patient safety incident reporting culture. To date, the NRLS contains around 10 million reported incidents, with around one million new incidents being added each year (see Figure 2).

2.12 *Quarterly Data Summary* is a three-page summary report accompanied by an Excel workbook. NHS England, and its predecessor NPSA, have produced the

[21] http://www.cqc.org.uk/
[22] http://www.cqc.org.uk/content/notifications-nhs-trusts
[23] https://www.gov.uk/government/news/review-of-department-of-health-arm-s-length-bodies-update
[24] http://www.england.nhs.uk/2012/05/31/npsa-transfer/
[25] http://www.legislation.gov.uk/ukpga/2012/7/contents
[26] http://www.imperial.nhs.uk/
[27] http://www.england.nhs.uk/ourwork/patientsafety/dpsims-dev/

summary report since July 2006[28]. NPSA used to produce regular thematic commentary alongside the statistics. Each Excel workbook presents charts and tables for national trends in patient safety incident reporting since 2003, for 'incident type', 'care setting' and 'degree of harm'.

Figure 2 – Patient safety incidents reported to the NRLS, Oct 2003 – Jun 2014



Source: *Quarterly Data Summary* up to June 2014, NHS England

2.13 *Organisation Report* comprises an Excel workbook, CSV files and a separate two-page PDF report for each NHS trust. The reports are published every six-months. Each Excel workbook presents detailed cross-sectional tables for NHS organisations, and types of reported safety incidents for the latest six-month period. The workbook includes preset filters to allow results for a particular organisation to be presented, either separately, or alongside organisations with similar incident reporting profiles. Similar types of organisations are grouped together into nine distinct organisational 'clusters', presented on separate workbook tabs. The CSV files are produced for each organisational cluster, to facilitate re-use. The trust-level two-page reports are akin to performance dashboards, and are presented to encourage frequent and consistent patient safety incident reporting to the NRLS. These two-page reports can be accessed via the NRLS Patient Safety Explorer Tool[29] as well as via the 'Patient safety data' pages of NHS England's website.

2.14 The reported patient safety incidents statistics are used to produce four separate indicators in Domain 5 of the *NHS Outcomes Framework 2014/15*[30]

[28] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=59802&p=3
[29] https://report.nrls.nhs.uk/explorerTool/default.aspx
[30] https://www.gov.uk/government/publications/nhs-outcomes-framework-2014-to-2015

(NHS OF): 'Treating and caring for people in a safe environment and protecting them from avoidable harm.' They are also available from the HSCIC Indicator Portal[31] eight months after the end of the calendar year reference period. However, the new version of the NHS OF for 2015/16[32] includes only one NRLS indicator: 'Patient safety incidents reported'. The decision to have a single improvement indicator reflects the known limitations of the NRLS for measuring patient safety outcomes given the variability in the levels of patient safety incidents reported by different data collection bodies. DH acknowledges the importance of developing replacement indicators to measure avoidable harm and death at the national level, and is working to develop the expansion of Retrospective Case Record Reviews (RCRR) to potentially provide more-robust alternative indicators in the future.

2.15 The Department of Health, Social Services and Public Safety in Northern Ireland publishes official statistics about patient safety[33] including *Complaints Received by HSC Trusts, Board and Family Practitioner Services in Northern Ireland*[34]. The Scottish Government publishes statistics about patient safety – for example as part of *Scottish Inpatient Patient Experience Survey*[35].

2.16 NHS England publishes *Organisation Report* in PDF format with supplementary data tables published in Excel and CSV format; and *Quarterly Data Summary* in PDF format with supplementary data tables published in Excel format only. *Organisation Report* equates to a level of three stars under the Five Star Scheme that forms part of the Open Standards Principles proposed in the *Open Data White Paper: Unleashing the Potential*[36] and adopted as UK government policy in November 2012[37]. *Quarterly Data Summary* equates to a level of two stars under the Scheme. Five stars represent the highest star rating within the Scheme.

2.17 The NHS England patient safety team told us that the operational budget for running the NRLS in 2014/15 was £1.67 million and that a separate figure for the production of the official statistics was not available.

[31] http://www.hscic.gov.uk/indicatorportal
[32] https://www.gov.uk/government/publications/nhs-outcomes-framework-2015-to-2016
[33] http://www.dhsspsni.gov.uk/index/statistics/safetyquality/patient-safety.htm
[34] http://www.dhsspsni.gov.uk/complaints-2013-2014.pdf
[35] http://www.gov.scot/Topics/Statistics/Browse/Health/InpatientSurvey
[36] http://data.gov.uk/sites/default/files/Open_data_White_Paper.pdf
[37] https://www.gov.uk/government/publications/open-standards-principles/open-standards-principles

Assessment findings

Principle 1: Meeting user needs

The production, management and dissemination of official statistics should meet the requirements of informed decision-making by government, public services, business, researchers and the public.

3.1 NHS England engages effectively with some users – primarily those with access to case-level records – but not others. As part of its role, the statistics team oversees the NRLS, and works closely with NHS England's clinical insight, regional and local teams. These teams are not users of the reported patient safety incidents statistics, but are primarily focused on identifying emergent patient safety risks from NRLS case-level records. This is to inform preventative local and national action, such as issuing patient safety alerts[38], to mitigate further risks to patient safety. NHS England also provides CQC with case-level data about reported patient safety incidents resulting in moderate or severe harm, or death. CQC uses this for intelligent monitoring[39], and informing its decisions about when to inspect different health and care organisations. NHS England shares extracts of NRLS data with around 30 organisations under separate Data Sharing Agreements (DSAs). These include the NHS Wales Informatics Service[40], Monitor[41] and HSCIC[42].

3.2 HSCIC is a key user of *Quarterly Data Summary*. The decision to move to a single patient safety cultural improvement indicator in the NHS OF 2015/16 reflects an increased level of communication between NHS England and HSCIC about the relative strengths and limitations of the reported patient safety incidents statistics. NHS England told us that other users of *Quarterly Data Summary* include academics and NHS clinicians, who are interested in particular patient safety issues. NHS England told us that the team receives very few queries after each *Quarterly Data Summary* publication, and that it has responded to the most common requests by improving the supporting FAQs and methods documentation[43].

3.3 NHS England engages frequently with the suppliers of NRLS incident data – these organisations also use the data. The data suppliers primarily use the NRLS data to review their own safety incident reporting levels in relation to past performance and in comparison with peers. This analysis is facilitated through a limited access Interactive Analysis Tool, which is part of the NRLS. Reporting organisations receive regular communications, guidance and training from NRLS Reporting Leads, and carry out a monthly quality review of the provisional NRLS data submitted for their particular organisations. This helps to ensure the accuracy and completeness of the incidents submitted to the NRLS from LRMS before the official statistics are produced. NHS England told us that it is increasingly engaging with new data suppliers, such as small GP practices and community pharmacies. These suppliers primarily submit incident reports

[38] http://www.england.nhs.uk/ourwork/patientsafety/psa/
[39] http://www.cqc.org.uk/content/intelligent-monitoring-nhs-acute-hospitals
[40] http://www.wales.nhs.uk/sitesplus/956/home
[41] https://www.gov.uk/government/organisations/monitor
[42] http://www.hscic.gov.uk/home
[43] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/

using a new NRLS web-based e-form[44] and they are alerted to any new developments through the NRLS.

3.4 NHS England is currently engaging with users about the development of an NRLS replacement from 2016/17, the new PSIMS[45] – it has published: the outcomes of a user survey[46] that had over 600 responses from health professionals, patients and other users; a report of listening events held with health professionals[47]; and stakeholder updates[48]. NHS England told us that the new system will be similar to the NRLS, but will be more flexible and allow a greater range of NHS organisations to report patient safety incidents through web-based reporting.

3.5 However, while NHS England's consultation of users about the PSIMS, and its engagement with users and suppliers of the case-level data is positive, it does not consult users about changes to the official statistics presented in *Quarterly Data Summary* and *Organisation Report*, or publish information about their experiences of using the statistics. The statistics presented in *Organisation Report* have become less detailed in recent years and NHS England no longer presents time series information. NHS England told us that it has received requests for more-frequent publication of the statistics.

3.6 As part of the designation as National Statistics, NHS England should:

a) develop a thorough understanding of the use made of the reported patient safety incidents statistics presented in *Quarterly Data Summary* and *Organisation Report,* particularly by engaging effectively with users outside NHS England, and document the types of decisions that the statistics are used to inform, including providing context for users about how they can be used in conjunction with other patient outcomes statistics

b) publish information about users' experiences of the content, presentation and timing of the statistics, and explain how it intends to respond to what it has learned

c) publish details of its plans for the future of reported patient safety incidents statistics[49]

(Requirement 1).

3.7 We suggest that in meeting this requirement NHS England draw on examples of good practice in user consultation from other health statistics producers and the Government Statistical Service (GSS) and explore using avenues such as the Health Statistics User Group on StatsUserNet[50] and patient representative groups to facilitate user discussions.

[44] http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting/
[45] See footnote 27
[46] https://fs2.formsite.com/res/resultsReportCharts?EParam=m/OmK8apOTAd8Y4p2frd7OmbtmIuQSUj2CO%2BcxzjberWeVIiB0/mIAAl6fwFDdon2%2BycBO9iaxE%3D
[47] http://www.england.nhs.uk/wp-content/uploads/2014/10/nrls-dev-prof-wrkshps-rep.pdf
[48] http://www.england.nhs.uk/wp-content/uploads/2014/12/nrls-dev-stakeholder-update-dec14.pptx
[49] In relation to Principle 1, Practices 1, 2, 3 and 5 and Protocol 1, Practice 7 of the *Code of Practice*
[50] http://www.statsusernet.org.uk/Home/

Principle 2: Impartiality and objectivity

Official statistics, and information about statistical processes, should be managed impartially and objectively.

3.8 NHS England publishes the reported patient safety incidents statistics in an orderly and timely manner on its website; however the timetable for release is not made clear (see Protocol 2 for further details). The statistics in *Quarterly Data Summary* are presented impartially and objectively. However, the statistics in *Organisation Report* are presented alongside various operational statements that encourage a consistent and more frequent rate of safety incident reporting. We suggest that NHS England review the way that the statistics are presented in *Organisation Report* and consider presenting them separately from the operational statements.

3.9 NHS England has published a revisions policy[51] for the reported patient safety incidents statistics which is available on the web page presenting *Quarterly Data Summary*. The policy states that the statistics are not subject to scheduled revisions. However, the NRLS is a dynamic database that is updated following local investigations into the safety incidents. The numbers of incidents also change as late incidents are reported; for example, the total number of reported incidents (by reported date) in the quarters July to September 2013 and October to December 2013 both changed between their publication in *Quarterly Data Summary* for the period up to December 2013 and in the subsequent publication in *Quarterly Data Summary* for the period up to March 2014. The reason for, and extent of, the revisions in these statistics are not highlighted in the data table. As part of the designation as National Statistics, NHS England should:

a) publish an updated revisions policy for these statistics and explain how users will be informed of any changes to the statistics

b) include a link to the revisions policy within the statistical reports

c) indicate the nature and extent of any revisions alongside the statistics[52]

(Requirement 2).

[51] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/
[52] In relation to Principle 2, Practice 6 of the *Code of Practice*

Principle 3: Integrity

At all stages in the production, management and dissemination of official statistics, the public interest should prevail over organisational, political or personal interests.

3.10 No incidents of political pressures, abuses of trust or complaints relating to professional integrity, quality or standards were reported to, or identified by, the Assessment team.

3.11 The Head of Profession for Statistics (HoP) at DH is also the Lead Official for Statistics (Lead Official) at NHS England. Statistics are produced by NHS England statisticians and analysts based with the relevant policy teams, such as the patient safety team, but under the overall direction of the Lead Official. The patient safety team at NHS England has a leadership role for patient safety across the NHS, and its responsibilities include oversight of the NRLS and the publication of statistics about reported patient safety incidents. The NHS England patient safety team contracts professional statisticians in Imperial College Healthcare Trust to manage the NRLS and to produce the safety incidents statistics. During the course of this assessment, the Assessment team found that the responsibilities for statistical decision making and professional leadership between the statisticians at Imperial, the responsible statistician within the NHS England patient safety team and the Lead Official have not been clearly established. We consider that it would be beneficial to transparent decision making and to the professional development of the statisticians responsible for producing the reported patient safety incidents data to clearly document the roles and responsibilities, for example, as part of a memorandum of understanding. As part of the designation as National Statistics, NHS England should publish details of the roles and responsibilities of all parties involved in the production of the reported patient safety incidents statistics, including those of the Lead Official. This should include details of the responsibilities for:

a) deciding on statistical methods, standards and procedures, and on the content and timing of statistical reports

b) ensuring that the professional development needs of the statisticians are met, and to a level that enables them to meet the requirements of the *Code*[53]

(Requirement 3).

[53] In relation to Principle 3, Practice 3 and Principle 7, Practice 6 of the *Code of Practice*

Principle 4: Sound methods and assured quality

Statistical methods should be consistent with scientific principles and internationally recognised best practices, and be fully documented. Quality should be monitored and assured taking account of internationally agreed practices.

3.12 In light of the de-designation of police recorded crime statistics in January 2014 (in Assessment report 268), the Statistics Authority published[54] a regulatory standard that confirms the quality assurance arrangements that are required for statistics compiled using administrative data to comply with the *Code of Practice*. The *Administrative Data Quality Assurance Toolkit*[55] is the mechanism that the Authority is using to determine compliance in relation to four areas of practice:

- Operational context and administrative data collection
- Communication with data supply partners
- QA principles, standards and checks by data suppliers
- Producers' QA investigations & documentation

3.13 The judgment by statistical producers about the suitability of the administrative data for use in producing official statistics should be pragmatic and proportionate. It should be made in the light of an evaluation of the likelihood of quality issues arising in the data that may affect the quality of the statistics. It should also reflect the nature of the public interest served by the statistics. Statistical producers should determine the types of assurance and documentation required to inform users about the quality assurance arrangements for administrative data.

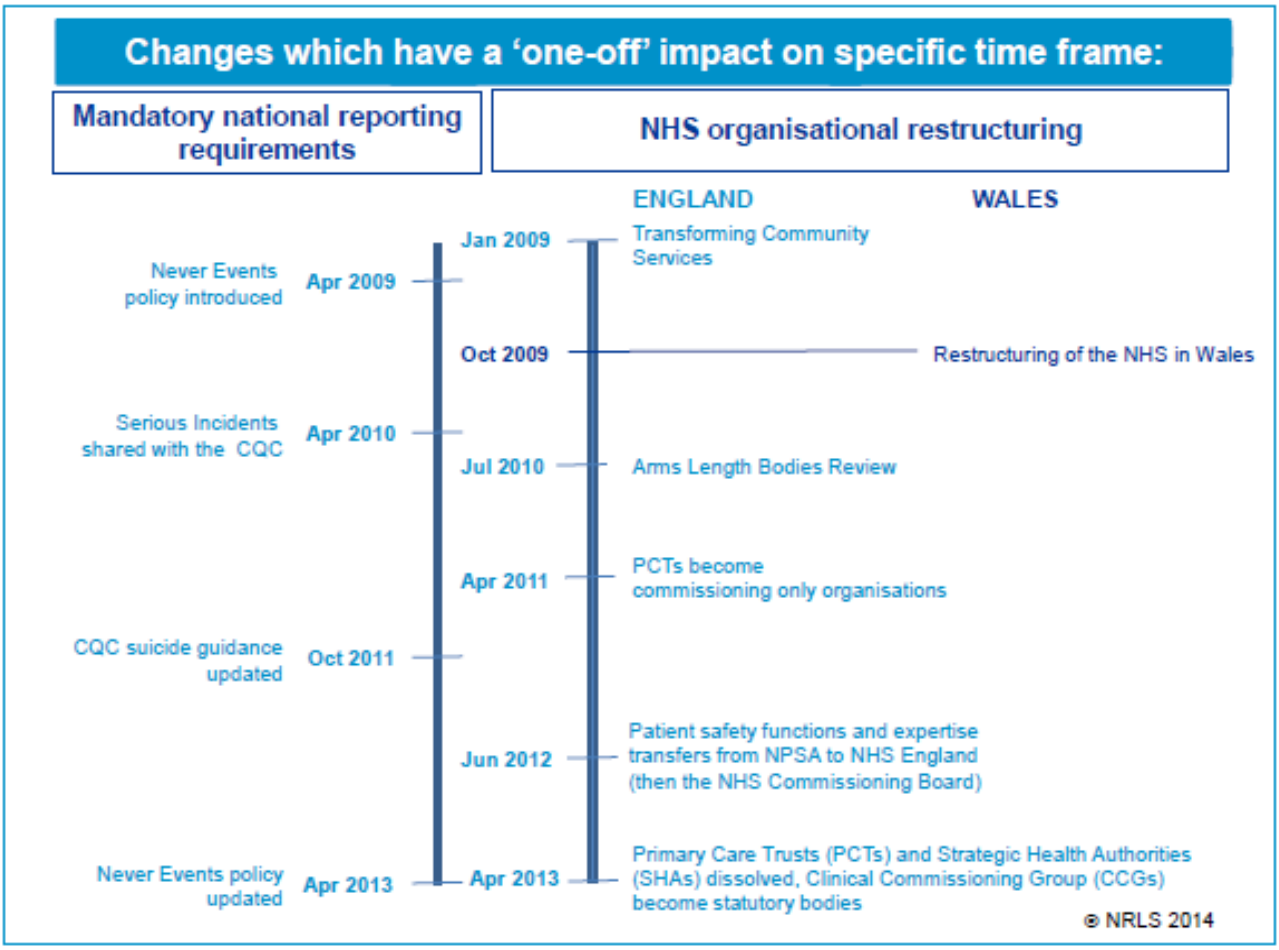
3.14 NHS England produces a Data Quality Note[56] to accompany *Quarterly Data Summary* which states that patient safety incidents reported to the NRLS should not be interpreted as the number of incidents actually occurring in an organisation, but should instead be seen as a measure of an organisation's patient safety incident reporting culture. The distinction has been acknowledged by the decision to use the statistics as a measure of patient safety cultural improvement in the NHS OF 2015/16, rather than as a measure of incidents, as in previous years. However, this interpretation is also potentially misleading – it cannot be automatically assumed that when an organisation reports low numbers of incidents that it is under-recording due to a poor safety culture, it may just have low numbers of incidents. An organisation reporting very high numbers may be potentially overzealous rather than proportionate in their reporting.

3.15 The Data Quality Note presents a summary quality assessment of the NRLS using the European Statistical System Quality Framework dimensions[57]. It also

[54] http://www.statisticsauthority.gov.uk/assessment/monitoring/administrative-data-and-official-statistics/index.html
[55] http://www.statisticsauthority.gov.uk/assessment/monitoring/administrative-data-and-official-statistics/quality-assurance-toolkit.pdf
[56] http://www.nrls.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=135288
[57] The European Statistical System Quality Framework has five quality criteria: relevance; accuracy and reliability; timeliness and punctuality; coherence and comparability; accessibility and clarity: http://ec.europa.eu/eurostat/web/quality/quality-reporting

summarises historical changes in the mandatory incident reporting requirements, to illustrate institutional changes that could explain particular variations in the level and types of incidents reported. The Data Quality Note states that users should take care when making comparisons over time because of such events (see Figure 3).

Figure 3 – Chart presented by NHS England to illustrate that users should give careful consideration to 'one-off' impacts – Data Quality Note



Source: *Quarterly Data Summary Data Quality Note*, NHS England

3.16 While this summary information is useful, the Data Quality Note does not provide enough detail for users to come to an informed judgment about the potential sources of error and bias in the statistics. For example – certain organisations may have maintained consistent levels of incident reporting over time, whereas the reporting by others may have varied more substantially. NHS England does not publish sufficient information about the potential quality issues with the administrative data or about quality assurance arrangements to clarify how far this is the case. This makes it difficult to draw any meaningful conclusions from the reported patient safety incidents statistics at a national level, or to make comparisons between health service providers with any level of confidence.

3.17 The Data Quality Note highlights a marked variability in the coverage and completeness of reporting of patient safety incidents by NHS organisations:

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[58]. It has also been suggested that specific incident types are under-reported (in particular medication incidents in primary care). [Page 1]

The reference in the Data Quality Note is to the House of Commons Health Committee's report *Patient Safety* (sixth report of the 2008-09 session), which cited evidence of under-reporting from a census of NHS trusts by the National Audit Office[59] and from the Committee of Public Accounts[60], both from 2005. These sources highlight important weaknesses in the reporting of patient safety incidents by NHS organisations. However, they reflect the health service a decade ago; the current scale and nature of under-reporting is not clear.

3.18 The Data Quality Note indicates that the scale of NRLS data completeness and accuracy are influenced by three factors:

- the incident being recognised as a safety incident (reflecting the subjective nature of the decision and basis of the data)
- sufficient detail being recorded in patient notes (relying on extracting information from textual information written for other purposes with judgment required by the recorder and the one extracting the information)
- adequate and consistent coding in the local system before submission to the NRLS

The Data Quality Note does not describe the scale and extent to which these factors impact upon the safety incident reporting for different types of care setting and types of incident. NHS England told us that checks are carried out locally to minimise the risks of inconsistencies and subjectivity in data recording. For example, all incident reports may be checked by a local risk management officer to ensure that they are accurate before submission. The details of the frequency, consistency and prevalence of the checks carried out within NHS organisations, and quality indicators demonstrating the robustness of the data, are not published. A recent review of case notes concluded that patient safety statistics on the incidence of harm to children due to 'failure to monitor' are not capturing the intended type of incidents specified for the NHS OF[61] – only 3 incidents out of 50 cases reviewed referred to 'failure to monitor' in the sense intended. This issue was initially raised by the NRLS team and its finding has led to DH removing the associated NHS OF indicator (ID5.6) from the NHS OF for 2015/16[62]. Similar case notes review for other patient safety records would provide valuable insight into the accuracy and completeness of the data.

[58] http://www.publications.parliament.uk/pa/cm200809/cmselect/cmhealth/151/151i.pdf
[59] *A safer place for patients:* http://www.nao.org.uk/wp-content/uploads/2005/11/0506456.pdf
[60] http://www.publications.parliament.uk/pa/cm200506/cmselect/cmpubacc/831/831.pdf
[61] https://indicators.ic.nhs.uk/download/Outcomes%20Framework/Specification/NHSOF_5.6_I00681_Q_V3.pdf
[62] https://www.gov.uk/government/publications/nhs-outcomes-framework-2015-to-2016

3.19 NHS England told us that it reduces the likelihood of inconsistent coding by directly mapping the NRLS onto an individual organisation's LRMS. The Imperial team facilitates the mapping and operates a help desk to support data suppliers in returning information appropriately. Reporting Leads within the Imperial team are required to sign off that the mapping is correct before an organisation can report its incident data to the NRLS. NHS England Clinical Leads also review every death and severe harm incident reported to the NRLS and provide feedback to reporting organisations on any issues that they identify with the accuracy or consistency of recording. This feedback is included in a monthly provisional organisational report which is shared with each organisational supplier. The provisional reports include data quality indicators for the completeness of the reported incident data and the inclusion of personal identifiable information. NHS England told us that each supplier should also perform a quality assurance check on the provisional patient safety incident data reported on the NRLS for their individual organisation. The team told us that it typically receives 40 to 50 queries from data suppliers in response to these communications. Each query is investigated and any necessary amendments are made before the official statistics are produced. The team told us that it works with data suppliers on the appropriate coding of incidents and to encourage more frequent incident reporting. These processes do provide some reassurance regarding the uniformity of reporting of the categorical data, ensuring the validity of the records for these types of reported patient safety incidents. They do not, however, provide insight into the accuracy of the recording of the incidents within NHS organisations. The NRLS Data Quality Standard advises trusts to audit their own patient safety incident processes against the standards and to implement action plans to address weak areas. The patient safety quality documentation does not provide sufficient information about the steps taken by NHS organisations to assure the quality of their data.

3.20 In addition to the NRLS, NHS England uses other administrative data sources to produce the reported patient safety incidents statistics. For example, *Organisation Report* uses secondary sources (such as Hospital Episode Statistics (HES)) as denominators in the calculation of incident reporting rates presented in the Excel workbook. The separate Data Handling Note[63] includes some useful information about limitations in these secondary sources but it does not include details of the quality assurance processes used to reach these conclusions or provide links to HES's supporting documentation describing the assurance approach.

3.21 The NHS Trust Development Authority is responsible for providing assurance that non-foundation trusts have effective arrangements to record data. Monitor is responsible for ensuring that foundation trusts are well-governed and have effective arrangements to ensure that data are recorded accurately. The Chief Inspector of Hospitals in the Care Quality Commission has a responsibility for overseeing the regulatory activity and assessments of quality of care provided by NHS Trusts, private providers or the voluntary sector[64]. The patient safety quality documentation does not make clear whether these regulatory activities demonstrate that the NHS organisations are performing effectively. It also does

[63] http://www.nrls.npsa.nhs.uk/resources/?entryid45=135262
[64] http://www.cqc.org.uk/content/how-we-inspect

not make sufficiently clear whether there are any implications for the quality of the patient safety statistics.

3.22 As part of the designation as National Statistics, NHS England should:

a) ensure that the reported patient safety incidents statistics are produced to a level of quality that meets users' needs

b) provide an indication of the coverage, completeness and accuracy of the data used to produce the reported patient safety incidents statistics for each care setting

c) extend the reported patient safety incident quality documentation to summarise the quality assurance arrangements of the NHS organisations and make clear the implications for the quality of the statistics

d) summarise the outcomes of the reviews of NHS organisations' practices by regulatory bodies with respect to the current quality of the reported patient safety incidents statistics[65] (Requirement 4).

In meeting this requirement, NHS England should take into consideration the Authority's *Administrative Data Quality Assurance Toolkit*[66]. We further suggest that NHS England publish a process map to illustrate the supply of the patient safety incident data, and the assurance measures and safeguards taken by data suppliers, regulators and the statistics team.

3.23 The Data Quality Note contains a section on the coherence of the NRLS with other patient safety-related data sources; however this information does not provide sufficient information about the comparability of the data from these sources with the NRLS data. Also, *Quarterly Data Summary* and *Organisation Report* do not include details of related patient safety databases or other similar statistics, either for England and Wales or for Northern Ireland or Scotland. Including references, links and summary comparisons to other sources of patient safety data and statistics would further increase the utility of NRLS data for users, particularly where these sources can be used to offer possible explanations for any changes observed. These sources may also provide a useful indication of the likely level of coverage, completeness and accuracy of the patient safety statistics. As part of the designation as National Statistics, NHS England should publish information about the comparability and coherence of its reported patient safety incidents statistics with similar statistics for England and Wales, the other countries of the UK, and internationally[67] (Requirement 5).

[65] In relation to Principle 4, Practice 2 and Principle 8, Practice 1 of the *Code of Practice*
[66] http://www.statisticsauthority.gov.uk/assessment/monitoring/administrative-data-and-official-statistics/quality-assurance-toolkit.pdf
[67] In relation to Principle 4, Practices 3 and 6 of the *Code of Practice*

Principle 5: Confidentiality

Private information about individual persons (including bodies corporate) compiled in the production of official statistics is confidential, and should be used for statistical purposes only.

3.24 The NHS England and Imperial teams assured us that they take all necessary steps to protect the confidentiality of the patient safety data collected on the NRLS. The Imperial team requests that data suppliers remove identifiable data from the free text parts of the incident report form before uploading their data. It uses specialist software to check and flag any personal information that is provided. The team then removes any personal information. The data are held in a secure part of the system until the cleaning has been completed. NHS England has published a document, *Scope, method and reasoning*[68], which sets out the arrangements for protecting confidential information.

3.25 NHS England and Imperial staff sign an acceptable use policy form and have to undertake information governance training, to ensure that they appropriately handle the patient sensitive information. Researchers can request access to the incident safety records; they are required to sign a data sharing agreement (DSA). These agreements are reviewed regularly by Imperial. The team reminds researchers with DSAs to destroy the data as they approach their deadline for access – at that point researchers may request to extend the deadline or they will confirm destruction of the data.

[68] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/

Principle 6: Proportionate burden

The cost burden on data suppliers should not be excessive and should be assessed relative to the benefits arising from the use of the statistics.

3.26 NHS England told us that the annual cost of running the NRLS is £1.67 million. It has estimated[69] that around 99 per cent of returns are taken from LRMS via a secure website. This approach minimises the cost to the data suppliers. NHS England has developed e-forms for groups without an LRMS, such as small GP practices and community pharmacies. Organisations can upload forms in batch to further reduce the burden. NHS England told us that its previous stakeholder engagement highlighted that some data suppliers did not report incidents because of the burden of filling in the forms. It is aiming to simplify this supply process in the development of the new safety incident system.

[69] See Data Quality Note: http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/

Principle 7: Resources

The resources made available for statistical activities should be sufficient to meet the requirements of this Code and should be used efficiently and effectively.

3.27 NHS England told us that it does not have a single consolidated statistical work programme since statistical operations are not centralised, statisticians are embedded in teams across the organisation, and priorities and resources are assessed as part of normal business planning. The Imperial team told us that is resourced to continue managing the NRLS and producing the reported patient safety incidents statistics. The NHS England patient safety team told us that it is seeking funding for the development of the new safety incident system in 2015/16. It is looking for the system to become more flexible in order to enable users to create their own reports from the data and so reduce the burden on the central team in answering queries.

Principle 8: Frankness and accessibility

Official statistics, accompanied by full and frank commentary, should be readily accessible to all users.

3.28 NHS England produces a three-page commentary report for *Quarterly Data Summary,* with an accompanying Excel workbook. It contains summary findings under several sub-headings and a time series for four quarters. To examine the longer quarterly time series back to October to December 2003 it is necessary to cross-refer to the Excel workbook. *Organisation Report* contains little commentary presented around three charts and one table showing cross-sectional reported patient safety incidents statistics for the latest six-month period only (see annex 1 for further details on the commentary included with the reported patient safety incidents statistics).

3.29 NPSA used to produce regular detailed thematic commentary reports[70] with a richer narrative – these reports were also called NRLS Quarterly Data Summary. NHS England did not continue to publish this detailed commentary when it took over responsibility for the reported patient safety incidents statistics. NHS England told us that it has plans for the future development of the publications, following a discussion with the Head of Insight team at NHS England. It is working on providing more comprehensive guidance on how organisations can use patient safety data to improve their own opportunities for learning. However, NHS England told us that it is not intending to produce more thematic reports due to resource constraints, and that it is instead focusing on making the data more accessible to experts in the health field, academics and researchers. One example of this is the establishment of Patient Safety Collaboratives[71], led by the Academic Health Science Network[72]. NHS England said that it intends to continue producing the three-page *Quarterly Data Summary* reports, but has no plans to develop them further than this.

3.30 From our own review of *Quarterly Data Summary* and *Organisation Report*, and reflecting on what users told us as part of this Assessment, key areas for development include: drawing out the key messages from the statistics and using charts to enhance the narrative; better explaining how the statistics presented in *Quarterly Data Summary* and *Organisation report* (and supplementary data) fit together; and placing the statistics in their wider operational context (see annex 1 and annex 2 for examples in these areas).

3.31 As part of the designation as National Statistics, NHS England should improve the commentary alongside the reported patient safety incidents statistics so that it aids users' interpretation of the statistics by:

a) clarifying the key messages up front for known uses

b) clarifying the linkages between NRLS organisational and national data and explaining the consequences of disparities for user interpretation

c) taking particular account of the need to provide information on the wider context of patient safety reporting and on the effects of operational policy on the statistics

[70] http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=65320
[71] http://www.england.nhs.uk/ourwork/patientsafety/collaboratives/
[72] http://www.england.nhs.uk/ourwork/part-rel/ahsn/.

d) including charts that are clearly presented to enhance interpretability of the statistics[73]

(Requirement 6).

As part of meeting this requirement, NHS England should consider the points detailed in annex 1 and annex 2. In meeting this Requirement we suggest that NHS England work with DH and HSCIC, and with other data provider bodies as relevant, to identify the operational and policy issues that affect patient safety statistics and collaborate to provide helpful explanatory information to support the wider use of these statistics within the context of presenting statistics on patient outcomes more widely.

3.32 The *Organisation Report* workbooks are available in Excel and CSV format. The *Quarterly Data Summary* workbook is available in Excel format only and this is not in line with the minimum expectation of the Open Standards Principles proposed in the *Open Data White Paper: Unleashing the Potential*[74]*,* which requires government datasets to achieve a level of three stars under the Five Star Scheme. As part of the designation as National Statistics, NHS England should publish the data associated with *Quarterly Data Summary* in an open format that equates to at least a Three Star level under the Five Star Scheme[75] (Requirement 7).

3.33 The *Organisation Report* workbook includes data only from the latest six-month reference period. It is therefore not possible to assess changes in the levels or types of incidents reported at the trust level over time, without accessing the historical *Organisation Report* workbooks. NHS England told us that organisations reporting patient safety incidents to the NRLS can access organisational patient safety incident data back to 2011 via an Interactive Analysis Tool, but that this is not publicly available. The *Quarterly Data Summary* workbook includes quarterly overall trends in numbers of incidents reported back to 2003, but includes the quarterly trends only for the last four quarters for type of incident, care setting and degree of harm. This means that it is not possible to assess longer term changes in the types and levels of incidents reported nationally without accessing the historical *Quarterly Data Summary* workbooks. As part of the designation as National Statistics, NHS England should investigate the user need for published historical time series data from *Organisation Report* and *Quarterly Data Summary* and take steps to meet any identified need[76] (Requirement 8).

3.34 *Quarterly Data Summary* and *Organisation Report* are published to a standalone patient safety website and are not accessible from NHS England's website. As part of the designation as National Statistics, NHS England should:

a) ensure that the reported patient safety incidents statistics are accessible from its statistics pages and search facility

b) improve the labelling and signposting of the NRLS website, to make it clear to users how the different statistical reports relate to each other and how they can access information that is relevant to their needs[77]

(Requirement 9).

[73] In relation to Principle 8, Practice 2 of the *Code of Practice*
[74] http://data.gov.uk/sites/default/files/Open_data_White_Paper.pdf
[75] In relation to Principle 8, Practice 6 of the *Code of Practice*
[76] In relation to Principle 8, Practice 6 of the *Code of Practice*
[77] In relation to Principle 8, Practice 4 of the *Code of Practice*

Protocol 1: User engagement

Effective user engagement is fundamental both to trust in statistics and securing maximum public value. This Protocol draws together the relevant practices set out elsewhere in the Code and expands on the requirements in relation to consultation.

3.35 The requirements for this Protocol are covered elsewhere in this report.

Protocol 2: Release practices

Statistical reports should be released into the public domain in an orderly manner that promotes public confidence and gives equal access to all, subject to relevant legislation.

3.36 The reported patient safety incidents statistics are not listed in NHS England's 12-month publication plan[78] or on the Statistics Release Calendar on GOV.UK[79]. As part of the designation as National Statistics, NHS England should publish a timetable of releases for these statistics 12 months in advance and ensure that these statistics can be accessed from the Statistics Release Calendar[80] (Requirement 10).

3.37 NHS England told us that it releases *Organisation Report* at 9.30am. Since the quarterly statistics were not regarded as official statistics until the Assessment began, NHS England did not seek to comply with the *Code* in this respect. The patient safety team told us that it aims for 9.30am release but occasionally there are delays in getting sign-off confirmation within NHS England. As part of the designation as National Statistics, NHS England should ensure that reported patient safety incidents statistics are issued at 9.30am on the day of release[81] (Requirement 11).

3.38 *Quarterly Data Summary* includes the name of the lead statistician in the Imperial team but does not give the name or contact details of the lead statistical official responsible for the reported patient safety incidents statistics in NHS England. As part of the designation as National Statistics, NHS England should publish the name and contact details of the responsible NHS England statistician in the statistical reports[82] (Requirement 12).

3.39 NHS England has published a policy[83] for pre-release access to official statistics but does not publish lists of those people given restricted pre-release access to the reported patient safety incidents statistics. The patient safety team told us that it maintains a list of officials who are given advance access to the reported patient safety incidents statistics and that it will review its pre-release access procedures. As part of the designation as National Statistics, NHS England should:

a) review the arrangements for granting early access to the reported patient safety incidents statistics, ensuring pre-release access is only granted where absolutely necessary

b) ensure that those with access understand their obligations under the *Pre-release Access to Official Statistics Order 2008*[84], publish records of those who have access to the statistics prior to release and inform the Authority of the justification for each inclusion[85]

(Requirement 13).

[78] http://www.england.nhs.uk/statistics/12-months-statistics-calendar/
[79] https://www.gov.uk/government/statistics/announcements
[80] In relation to Protocol 2, Practices 2 and 3 of the *Code of Practice*
[81] In relation to Protocol 2, Practice 4 of the *Code of Practice*
[82] In relation to Protocol 2, Practice 6 of the *Code of Practice*
[83] http://www.england.nhs.uk/statistics/code-compliance/
[84] http://www.statisticsauthority.gov.uk/external-links/pre-release-access-to-official-statistics-order-2008.html
[85] In relation to Protocol 2, Practice 7 of the *Code of Practice*

Protocol 3: The use of administrative sources for statistical purposes

Administrative sources should be fully exploited for statistical purposes, subject to adherence to appropriate safeguards.

3.40 NHS England has published a Statement of Administrative Sources[86]; however, the NRLS is not included. As part of the designation as National Statistics, NHS England should ensure that the NRLS is listed in its Statement of Administrative Sources[87] (Requirement 14).

[86] http://www.england.nhs.uk/statistics/code-compliance/
[87] In relation to Protocol 3, Practice 5 of the *Code of Practice*

Annex 1: Compliance with Standards for Statistical Reports

A1.1 In November 2012, the Statistics Authority issued a statement on *Standards for Statistical Reports*[88]. While this is not part of the *Code of Practice for Official Statistics*, the Authority regards it as advice that will promote both understanding and compliance with the *Code*. In relation to the statistical reports associated with NHS England's reported patient safety incidents statistics, this annex comments on compliance with the statement on standards. The comments included in this annex are based on a review of *Quarterly Data Summary* up to June 2014[89] and *Organisation Report* up to September 2014[90].

A1.2 In implementing any Requirements of this report (at paragraph 1.10) which relate to the content of statistical reports, we encourage NHS England to apply the standards as fully as possible.

Include an impartial narrative in plain English that draws out the main messages from the statistics

A1.3 The commentary in *Quarterly Data Summary* presents results for the latest quarter and compares these with results from the same quarter in the previous year. A summary of key points is not included, and the findings are reported sequentially under several themed headings. The commentary does not present the statistics for the 'incident type' or 'care setting' in sufficient detail to convey the relevance of the findings. Neither does it sufficiently explain the longer term trends in patient safety incident reporting that are presented in the supporting Excel workbook.

A1.4 *Quarterly Data Summary* is largely presented in plain English. However, the definition of seasonality (including the referenced 'administrative', 'artificially-created' and 'incident' seasonality types) could be more clearly defined. Terms such as 'cluster', 'median' and 'comparative reporting rate' are not defined when first introduced. The term 'significant' is used several times, but it is not clear whether this is always intended to be a statistical or semantic use of the term.

A1.5 *Organisation Report* is produced every six months and includes brief standard commentary for each organisation in two-page reports that are presented in a consistent format from one reporting period to the next. The two-page reports are addressed to the individual NHS trust and as well as presenting headline statistics, they pose questions like: 'Are you actively encouraging reporting of incidents?'; and 'How regularly do you report?'. Much of the text is operational in nature, and is specifically included to encourage frequent and consistent patient safety incident reporting to the NRLS. The remainder of the text presents cross-sectional figures for an organisation's reported patient safety incidents over a six-month period. These are presented alongside the overall average rates for a 'cluster' of similar organisations. As the reports cover only the latest six-month period, they offer limited value in terms of explaining trends

[88] http://www.statisticsauthority.gov.uk/news/standards-for-statistical-reports.html
[89] http://www.nrls.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=135304
[90] http://www.nrls.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/directory/

in incident reporting for particular organisations in relation to their peers. *Organisation Report* would benefit from a full explanation of the main messages, particularly in relation to changing organisational trends over time, and with reference to the overall national averages.

Include information about the context and likely uses of the statistics

A1.6 The introductory text in *Quarterly Data Summary* provides some useful information about the main uses of the NRLS and its relationship to the overall NHS OF. It also includes a description of the separate 'Reporting' and 'Occurring' datasets, and this helps users to interpret the statistics. *Quarterly Data Summary* up to June 2014 included useful information about a previous change to the reporting criteria, to help explain changes in reporting levels since the previous year. However, this is the only example of contextual information being used to help explain the annual changes presented in the report. In addition, there is no discussion or reference to other related databases, or similar statistical sources, that might help explain changes in levels of incident reporting.

A1.7 *Organisation Report* includes no information about the context or likely uses of the statistics, although it does include links to the 'patient safety data'[91] and 'patient safety alert'[92] web pages to provide a degree of operational context. The contextual information in *Quarterly Data Summary* and *Organisation Report* could usefully be expanded to provide: more background information about the NRLS operational and policy context including the types of decisions that the reported patient safety incidents statistics are used to inform; and links to relevant web pages and supporting documentation.

Include information about the strengths and limitations of the statistics in relation to their potential use

A1.8 NHS England does not include, or reference, information about the strengths and limitations of the statistics in either *Quarterly Data Summary* or *Organisation Report*. The *Organisation Report* Excel workbook includes a link to useful supporting documentation on the NRLS website[93], but this is not directly available from *Quarterly Data Summary*.

A1.9 The Data Handling Note published alongside *Organisation Report* includes a helpful assessment of the NRLS in relation to the European Statistical System Quality Framework dimensions, and this provides useful context for users about the strengths and limitations of the NRLS case-level data. Similar information is presented in a separate Data Quality Note presented alongside *Quarterly Data Summary*. This information could go further, both in terms of highlighting the limitations of the reported patient safety incidents statistics in relation to their potential uses and in relation to a more detailed appraisal of the procedures NHS England undertakes to assure itself of the quality of the administrative source data used to produce the statistics.

[91] http://www.nrls.npsa.nhs.uk/patient-safety-data/
[92] http://www.england.nhs.uk/ourwork/patientsafety/psa/
[93] http://www.nrls.npsa.nhs.uk/resources/?entryid45=135262

A1.10 *Quarterly Data Summary* refers to statistically significantly changes but no explanation of the statistical methods used is included. It is also not clear how any revisions made to the 'Occurring data set' are accounted for, or how these revisions impact the statistics.

Be professionally sound

A1.11 The names of the lead statistician and senior analyst from Imperial College Healthcare NHS Trust are included in *Quarterly Data Summary*, but the name and contact details for the responsible statistician in NHS England do not appear in *Quarterly Data Summary* or *Organisation Report*.

A1.12 *Quarterly Data Summary* would benefit from including charts from the accompanying workbook in the report with supporting commentary. It is not helpful to have to switch between the *Quarterly Data Summary* report and the workbook to see the illustrations of the trends. The charts currently included in the workbook are quite clear, although some are difficult to interpret when printed in black and white.

Include, or link to, appropriate metadata

A1.13 The layout and labelling of the NRLS web pages and statistical reports could be improved. *Quarterly Data Summary* would also benefit from including 'reported patient safety incidents' in the title.

A1.14 It is not clear why *Quarterly Data Summary* and *Organisation Report* are in separate areas of NHS England's website. Bringing them together in the same area would improve user accessibility for both sets of reported patient safety incidents statistics and allow supporting methods and quality documentation to be shared.

A1.15 *Organisation Report* includes Excel workbooks and CSV files to facilitate re-use of the organisational NRLS data, whereas *Quarterly Data Summary* includes an Excel workbook only. Including a CSV file for *Quarterly Data Summary* would facilitate greater re-use of national NRLS data.

A1.16 *Quarterly Data Summary* and *Organisation Report* do not include links to the supporting Excel workbooks and CSV files or the supporting quality and methods information. Providing better links between the reports, workbooks and quality and methods documents would better facilitate re-use of NRLS data and make it easier for users to appreciate the relative strengths and limitations of the statistics.

A1.17 The *Organisation Report* workbook includes data from only the latest six-month reference period. This means that it is not possible to assess changes in the levels or types of incidents reported at the trust level over time, without accessing the historical *Organisation Report* workbooks. The *Quarterly Data Summary* workbook includes quarterly overall trends in numbers of incidents reported back to 2003, but includes the quarterly trends only from the last four quarters for type of incident, care setting and degree of harm. This means that it is not possible to assess longer-term changes in the types and levels of incidents reported nationally without accessing the historical *Quarterly Data Summary* workbooks.

A1.18 *Quarterly Data Summary* and *Organisation Report* do not include details of related patient incident databases or other similar statistics, either for England and Wales or for Northern Ireland or Scotland. Including references, links and summary comparisons to these sources would further increase the utility of the NRLS statistics for users, particularly where these sources can be used to offer possible explanations for changes observed in the reported patient safety incidents statistics, or to provide a useful indication of the likely level of coverage, completeness and accuracy of the patient safety statistics.

Annex 2: Summary of assessment process and users' views

A2.1 This assessment was conducted from October 2014 to June 2015.

A2.2 The Assessment team – Oliver Tatum and Penny Babb – agreed the scope of and timetable for this assessment with representatives of the NHS England in October 2014. The Written Evidence for Assessment was provided on 21 November 2014. The Assessment team subsequently met NHS England during January 2015 to review compliance with the *Code of Practice*, taking account of the written evidence provided and other relevant sources of evidence.

Summary of users contacted, and issues raised

A2.3 Part of the assessment process involves our consideration of the views of users. We approach some known and potential users of the set of statistics, and we invite comments via an open note on the Authority's website. This process is not a statistical survey, but it enables us to gain some insights about the extent to which the statistics meet users' needs and the extent to which users feel that the producers of those statistics engage with them. We are aware that responses from users may not be representative of wider views, and we take account of this in the way that we prepare Assessment reports.

A2.4 As it was known that some of the users that we planned to approach would have an interest in the range of patient outcomes statistics we invited comments about all of the sets of statistics in this group of assessments as part of a single user consultation. We received 29 responses and the respondents were grouped as follows:

NHS England	4
NHS trusts	4
Department of Health	3
Professional/Membership Bodies	3
Regulators	2
Public Health England	2
Office for National Statistics	2
Commercial	2
Charities	1
Academics	1
Data suppliers	5

Common Themes

A2.5 Users of patient outcomes statistics identified with some common themes:

- Volume of statistics and data – Users appreciated the availability of statistics and data about patient outcomes and experiences and said that this is an area of increasing policy and operational focus within the health sector (see Section 2). However, users indicated that the range and volume of different data and statistics available from different sources can be overwhelming. Users said that it is difficult to know what statistics best

serve particular needs and to determine the coherence and comparability of the different statistics

- Accessibility – users told us that they found it difficult to locate and navigate the range of patient outcomes statistics and supporting datasets. Users told us that they would welcome better search functionality and one user suggested that an app be developed that would explain what statistics and data are available for different themes and where to find them. Users were particularly critical of HSCIC's website and the layout and functionality of its indicators portal. Some users also highlighted that often the greatest value lies in the individual record-level data, which is more difficult to access, though they noted the importance of protecting confidentiality
- Commentary – some users only used the data and did not refer to the commentary; others found the commentary helpful; but some users told us that they would welcome more insightful commentary and trend analysis to aid interpretation
- Timeliness – some users in NHS trusts told us that hospitals thrive on real time information, and that the delayed availability of statistics reduces their relevance
- Assurance of source data – suppliers provided details of a range of checks carried out on the data but some users and suppliers raised potential concerns about the quality of the data and administrative processes that underpin the statistics – issues raised included: patchy response rates to patient surveys; limitations caused by the different organisational structures in the NHS; the potential for different interpretations of definitions; and the lack of information available to inform the sign off processes by trusts and CCGs
- Engagement with producer bodies – those users who had direct contact with the teams producing the statistics were positive about their experiences and the helpfulness of the statisticians

Quarterly Data Summary and *Organisation Report*

A2.6 Users also provided specific feedback in relation to *Quarterly Data Summary* and *Organisation Report.* Key points were:

- Users recognised that NHS-funded organisations were currently divided in terms of whether it was in their interest to report patient safety incidents to the NRLS. This means that it is not straightforward to imply from the reported patient safety incidents statistics that particular organisations had better or worse cultures around patient safety. It was recognised that organisations with the highest levels of reporting were often those with stronger patient safety cultures
- In line with general feedback, users said that the presentation of *Quarterly Data Summary* could be improved. In particular, the commentary could be made more meaningful by including the interpretation of longer term trends with explanations for outliers in terms of organisations, settings, and types of harm. There was also interest in including more information about the

broader patient safety policy and operational context, for example whether national patient safety advice was having an impact on the levels of incidents reported

- For *Organisation Report*, one user told us that it would be helpful if NHS England could include better comparisons (with similar organisations and with the national picture) for the top degree of harm categories. Another user stated that while *Organisation Report* was useful at provider and trust level to assess the level of reporting and harm for their own reported incidents over time, it was difficult to draw reliable conclusions between trusts because of the large variation in reporting behaviour between them. In line with general user feedback, one user said that the six-month lag in publishing *Organisation Report* reduced its relevance due to the health system increasingly requiring more timely information
- Some users primarily use the NRLS data rather than statistics presented in *Quarterly Data Summary* and *Organisation Report*. One of these users said that the NRLS data were not presented in a tidy or interactive way and that analysts spent a considerable amount of time interpreting patient safety profiles for particular organisations across the various themes in relation to the aggregate national picture. Another user said that combining data from the NRLS with other data sources, such as claims data held by the NHS Litigation Authority[94], could lead to a better understanding of the claims made in relation to reported safety incidents. This would help organisations to better understand whether they were failing to report the types of safety incidents for which claims were being made, and vice versa

Key documents/links provided

Written Evidence for Assessment document

[94] http://www.nhsla.com/Pages/Home.aspx

www.statisticsauthority.gov.uk