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**England and Wales data**

The NRLS Quarterly Data Summary (QDS) now presents data from England and Wales separately. This QDS includes details of reports received from NHS trusts in **England** only. A separate version including reports received from NHS organisations in **Wales** is available at: [www.npsa.nhs.uk/patientsafety/patient-safety-incident-data/quarterly-data-reports/](http://www.npsa.nhs.uk/patientsafety/patient-safety-incident-data/quarterly-data-reports/)

The workbooks for this and the last QDS present data for both England and Wales, whilst also showing the combined figures.
An overview of the key trends in the data presented in this report.

Number of incidents reported between April and June 2008

- Between 1 April 2008 and 30 June 2008, 258,209 reports of incidents (based on date of submission) in England were reported to the National Reporting and Learning System (NRLS), bringing the total number of reports received since its inception to 2,536,940.
- The number of reported incidents this quarter (1 April 2008 to 30 June 2008) was higher compared to the number reported between January and March 2008 (216,428 incidents). This increase is likely to reflect the deadline for the Organisational Feedback reports, which fell in the quarter April to June 2008.
- Of the 391 NHS organisations in England, 145 organisations (37 per cent) submitted at least one report to the NRLS every month between April to June 2008, and a further 205 organisations (52 per cent) reported at least once in the quarter, but less often than every month.

Pattern of incidents occurring between April 2007 and March 2008

- The total number of patient safety incidents reported as having occurred between April 2007 to March 2008 in England was 796,142.
- Overall, the most commonly reported type of incident was patient accidents: accounting for more than a third of all incidents that occurred in that period (34 per cent).
- Following patient accidents, the most commonly reported incident types were treatment/procedure (10 per cent), medication (nine per cent), access/admission/transfer/discharge (including missing patient) and infrastructure (including staffing, facilities, environment) (both seven per cent).
- An overwhelming majority of reported patient safety incidents occurred in acute trusts/general hospitals (73 per cent). The second most common care setting for reported incidents was mental health services (14 per cent).
- There were different patterns of incident types in the various care settings, although among care settings that take inpatients, patient accidents were consistently the most commonly reported incident type.
- The majority of incidents were reported as causing ‘no harm’ (65 per cent) to the patient, while 27 per cent were reported as causing ‘low harm’ and six per cent were reported as causing ‘moderate harm’.
- One per cent of all incidents were reported as causing ‘severe harm’, whereas the proportion of incidents reported to have resulted in death was negligible (rounded down to 0 per cent).
- The proportion of incidents causing severe harm or death varies across care settings. The highest proportion of incidents resulting in either severe harm or death was reported by general practices (2.7 per cent), followed by mental health services (1.8 per cent), community services (including community hospitals) and ambulance service (1.5 per cent and 1.4 per cent, respectively).
Patient safety incidents reported to the NRLS from NHS staff are collected and analysed. These data are fed back to the NHS and other interested parties via these Quarterly Data Summary (QDS) reports.

The QDS provides an overview of the volume of incident reports received, what sector they are from, what type of incidents they describe and the level of resulting harm to the patient/s involved.

This quarter we also provide sections highlighting incidents related to nasogastric tubes and device-related incidents.

This quarterly data summary presents data for England only. An equivalent report for Wales can be found at: www.npsa.nhs.uk/patientsafety/patient-safety-incident-data/quarterly-data-reports/

The data

The data summarised here are from the NRLS and include all patient safety incidents reported from NHS organisations in England.

For further information on the NRLS, see the appendix on page 30.

Two sets of data and analysis are presented:
Section 1 describes the level of reporting to the NRLS by quarter and uses data based on the date that the incident was reported to the NRLS.* The data cover the period from when the NRLS was first set up in October 2003 until the end of June 2008.

Section 2 contains an overview of patterns and trends in patient safety incident reports. It uses data based on the date that the patient safety incidents were reported as having occurred. The data cover the four quarters between April 2007 and March 2008.

The following notation is used when per cent is shown in the report and accompanying workbook:
• ‘0’ is used for percentages that are rounded down to zero;
• ‘-’ is used for a true zero in a row/column showing per cent, i.e. when there are no cases in a category;
• ‘*’ is used when the base number is deemed too small to provide reliable percentages (n<30). This notation may differ compared to that used in QDS reports and workbooks prior to Issue 6.
• ‘**’ is used when data is not shown for reasons relating to confidentiality.

Note: Rounded figures are presented in this report. Therefore totals may differ marginally compared to the sum of figures as stated in the text. The exact figures can be found in the workbook.

Workbook

This report summarises the NRLS data, drawing out key trends and themes. To accompany the report, a data workbook is available on our website (www.npsa.nhs.uk/patientsafety/patient-safety-incident-data/quarterly-data-reports/). As well as containing all the data underpinning the analysis in this summary (frequencies and per cent), the workbook provides charts showing trends in the data on a quarterly basis.

The workbook presents the data for both England and Wales, whilst also showing the combined figures.

Using the data

Data presented in this report and the accompanying data workbook can be used in several ways, including as an indicator to benchmark local data against national trends; provide denominator data for research; and to enable triangulation with other data sources. Notes to aid the accurate interpretation of NRLS data are provided in the appendix on page 30.

Note: Comparisons should not be made between the data in sections 1 and 2, since they are based on different datasets.

* The date the report was received by the NPSA is also referred to as ‘date of submission’.
Highlights of recent information on patient safety, including selected published literature and key patient safety initiatives.

**Article alert**


The authors of this paper performed a systematic review of the literature on in-hospital adverse events. Studies were reviewed independently for methodology, inclusion and exclusion criteria, and endpoints. Primary endpoints were incidence of in-hospital adverse events and percentage of preventability. Secondary endpoints were adverse event outcome and subdivision by provider of care, location and type of event. Eight studies including a total of 74,485 patient records were selected. The median overall incidence of in-hospital adverse events was 9.2 per cent, with a median percentage of preventability of 43.5 per cent. More than half (56.3 per cent) of patients experienced no or minor disability, whereas 7.4 per cent of events resulted in death. Operation (39.6 per cent) and medication-related (15.1 per cent) events constituted the majority. The paper presents a summary of evidence-based interventions aimed at these categories of events.

‘What can we learn about patient safety from information sources within an acute hospital: a step on the ladder of integrated risk management?’ H Hogan, SOlsen, SScobie, E Chapman, RSachs, MMcKee, CVincent, RThomson *Quality and Safety in Health Care*, 2008; 17: 209-215

An acute hospital in southern England was the setting for this assessment of the utility of patient safety data already existing within hospitals. Following in-depth analysis of seven key data sources (clinical incident database, health and safety incident database, complaints database, claims database and inquest database, the patient administration system and case notes), the report concluded that despite issues related to the quality of coding, depth of information available and accessibility, triangulating information from more than one source can identify a broader range of incidents and provide additional information related to professional groups involved, types of patients affected and contributory factors. Such an approach can provide a focus for further work and ultimately contributes to the identification of appropriate interventions that improve patient safety.


This study investigated critical incidents in UK emergency departments (EDs) and compared the root causes of such incidents between different EDs. An observational study with semi-structured interviews and root cause analysis was conducted over 12 months. It was set in EDs in two teaching hospitals and two district general hospitals in the north-west of England. The study identified 443 critical incidents. The rate of occurrence ranged from 11.1 to 15.9 per 1,000 new patients. The most common root causes underlying these critical incidents related to organisational issues outside the EDs; internal management issues; human errors relating to knowledge of task verification and execution; and issues related to patient behaviours. In contrast, technical root causes occurred infrequently. Significant differences were shown between the EDs for three types of root causes relating to organisational issues outside the EDs and internal protocol and collective behaviour issues. The report concludes that there are significant differences, as well as common themes, in the causes of these critical incidents between different EDs.
**Initiatives**

**Patient Safety Congress 2008**
Prime Minister Gordon Brown attended this two-day event on patient safety in May, along with 90 speakers and 650 delegates.

Led by the *Nursing Times* and the *Health Service Journal*, and supported by the National Patient Safety Agency (NPSA), the Health Foundation, the NHS Institute for Innovation and Improvement, and Microsoft, the Patient Safety Congress featured presentations, debates and discussions on key aspects of patient safety.

www.patientsafetycongress.co.uk

**Rapid Response Report: Risks of chest drain insertion (ref: NPSA/2008/RRR003)**
Chest drains are used to remove air, blood, pus or fluid from the pleural cavity. They may be used in patients with collapsed lungs, malignancies, chest trauma or after surgery. This is a common procedure, which may be carried out in general wards. Most are planned, but some may need to be done as emergencies.

When they are not inserted properly, chest drains may puncture major organs such as heart, lungs, liver and spleen.

The National Reporting and Learning Service has alerted the NHS to the risks associated with inserting chest drains, and advised that the drainage tubes should only be inserted by trained staff with relevant competencies and adequate supervision.

The guidance follows reports of 12 deaths and 15 incidents of serious harm following the medical procedure over three years from January 2005 to March 2008, with several other less severe cases likely to have gone unreported.

Further information and support materials can be found at: www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr/risks-of-chest-drain-insertion/

**Safer surgery**
A new safety checklist for surgical teams to use in operating theatres has been launched by the World Health Organization (WHO) as part of a major drive to make surgery safer around the world.

The NPSA hosted the UK participation in the global launch in June and is working with key organisations representing surgeons, anaesthetists and nurses to take forward work in the UK. The WHO Safe Surgery Saves Lives initiative began in September 2006 and has seen more than 200 national and international medical societies and ministries of health working together to reduce avoidable deaths and complications in surgical care.

Between October 2006 and September 2007, over 128,000 reports of patient safety incidents from surgical specialties were reported to the NRLS. These incidents vary hugely from incorrect treatment or procedure to misplaced patient notes. Not all of these incidents are serious but some have led to patient harm or death and many could have been prevented.


**Joint report highlights high reporting as better for patient safety**
A joint briefing from the NHS Confederation and the NRLS has highlighted that trusts that report high levels of patient safety incidents may have a stronger organisational culture of safety because they take all incidents seriously and link reporting with learning from them.

The briefing is based on a workshop with 20 consistently high reporting acute trusts, as identified through the NRLS. High reporting can be a sign of a safe organisation that is keen to identify problems as soon as they occur and put plans in place to make things right. The briefing identifies five key changes that NHS organisations can make to become a high reporting organisation:

1. Give feedback to staff
2. Focus on learning
3. Engage frontline staff
4. Make it easy to report
5. Make reporting matter

This section provides an overview of the volume and frequency of patient safety incidents reported to the NRLS.

The data analysed in this section have been extracted using the date that the incident report was submitted to the NRLS. The most recent quarter covered is April to June 2008.

Number of reports and organisations reporting to the NRLS

Between October 2003, when the NRLS was first set up, and March 2008, 2,536,940 incidents reports were received in England, based on the date of submission. In the quarter April to June 2008, 258,209 incident reports were submitted. The number of incidents reported between April and June 2008 was higher compared to the previous quarter (216,428 incidents in January to March 2008). This peak in the number of reported incidents is likely to reflect the deadlines for the Organisational Feedback reports.

Overall, of the 391 NHS organisations in England,* 145 organisations (37 per cent) reported at least once every month between April and June 2008, and a further 204 organisations (52 per cent) reported at least once during the quarter, but less often than every month. Forty-two organisations (11 per cent) did not report between April and June 2008.

Local risk management systems are the dominant route for report submissions: between April and June 2008, 99 per cent of incidents received in England were reported this way, whereas one per cent of incidents were reported via eForms.

* Since the start of the quarter April to June 2008, there have been two mergers overall resulting in 423 NHS organisations in England and Wales as of 1 July 2007. NHS Direct is not included in this number.
Figure 1:
Number of incidents reported in England, October 2003 to June 2008*

*Following a review of the data, this chart contains a slightly modified data set to the previous issues of the QDS.
This section provides an overview of the patterns and trends in patient safety incidents in England, focusing primarily on incident types and care settings.

The data presented in this section covers April 2007 to March 2008, based on the date when the incidents were reported as having occurred.

Interpreting the data
The data presented in this issue cover the four consecutive quarters from 1 April 2007 to 31 March 2008. The three month time lag in publishing this data allows time for the majority of incidents to be reported, uploaded to the NRLS and processed.

The data were extracted as of 1 July 2008. Further incidents which occurred during the period January to March 2008 that have been sent to the NRLS since this date will be included in subsequent quarterly data summary reports. Accordingly, the figures presented in this report for the three quarters between April 2007 and December 2007 may also vary to a small extent compared to previous issues of the report, since additional incidents have been submitted since then.

Data in this section have been through data quality measures to eliminate duplicate data and blank reports.

The data in this section is generally presented on a 12 month basis, which is followed, where relevant, by a description of trends and changes in the patterns seen across the four individual quarters. Furthermore, the primary focus of the text in this section is the data expressed in term of per cent. Figures and charts display the number of incidents while also aiming to provide a visual overview of relevant patterns.

NOTE: Data presented in this section should not be compared with data in Section 1 of this report, as it is not based on the same time period. Care should also be taken when comparing data with previous issues of the quarterly data summary reports, since the number of incidents reported as having occurred in each quarter may vary to some extent in the different issues of the report.

Volume of patient safety incidents
Between April 2007 and March 2008, a total of 796,142 patient safety incidents occurred in England and were reported to the NRLS, based on the date when incidents were reported as having occurred. The incidents reported in England accounted for 93 per cent of all incidents reported to the NRLS in this time period. Of the reported incidents, 199,939 incidents (25 per cent) were reported as having occurred between April and June 2007, while the equivalent figures were 202,251 incidents (25 per cent) between July and September 2007, 205,953 (26 per cent) between October and December 2007, and 187,999 incidents (24 per cent) between January and March 2008.

This pattern is similar to that seen at the time of publication of previous QDS reports, reflecting the time lag with which some incidents are reported.
Reported incident types

Overall, in England, between April 2007 and March 2008, the most commonly reported type of incident was patient accident, which accounted for 34 per cent of all incidents.

Following patient accidents, the next most commonly reported incident types were treatment/procedure (10 per cent) and medication (nine per cent). Access/admission/transfer/discharge and infrastructure (including staffing, facilities, and environment) both accounted for seven per cent, and documentation (including records and identification) and clinical assessment (including diagnosis, scans, tests, and assessments) both accounted for five per cent.

Disruptive/aggressive behaviour, and consent/communication/confidentiality accounted for four per cent each, whereas medical device/equipment, implementation of care andongoing monitoring/review, and self-harming behaviour, each accounted for three per cent of all incidents. The least commonly reported incident types were infection control and abuse of patient (by staff/third party), which accounted for two per cent and one per cent of all incidents, respectively. Four per cent of all incidents were categorised as ‘other’.

The pattern of reported incident types within each care setting reported between April 2007 and March 2008 show that there was substantial variation across the different care settings. Yet patient accident was consistently the most commonly reported incident type in care settings taking inpatients – ranging from 32 per cent in both acute/general hospitals and learning disabilities services, to 52 per cent in community services (including community hospitals). The pattern of incident types within in each care setting is described on the following pages.

Analysis of reports of two specific types of incidents relating in particular to acute/general hospitals can be found on page 14. The analysis of nasogastric and device-related incidents describes emerging themes and issues, and give examples of typical incidents.
Figure 2:
Reported incident types in England, April 2007 to March 2008

- 28,627 Consent, communication, confidentiality
- 93,825 All other incident types
- 271,230 Patient accident
- 78,104 Treatment, procedure
- 70,178 Medication
- 58,116 Access, admission, transfer, discharge (including missing patient)
- 40,329 Documentation (including records, identification)
- 36,258 Clinical assessment (including diagnosis, scans, tests, assessments)
- 32,886 Disruptive, aggressive behaviour
- 33,098 Other
- 53,491 Infrastructure (including staffing, facilities, environment)
- 796,142 Total no. of incidents
Overall, in England, between April 2007 and March 2008, an overwhelming majority of reported patient safety incidents occurred in acute trusts/general hospitals (73 per cent).

The second most common care setting for reported incidents was mental health services (14 per cent), followed by community services* (including community hospitals) which were combined with community pharmacy, community and general dental services, and community optometry/optician services (eight per cent). Among the community services, community hospitals accounted for the majority of incidents.

Learning disabilities services accounted for three per cent of all reported incidents, while ambulance services accounted for a negligible proportion (rounded down to 0 per cent). This pattern was similar across all four quarters.

Acute/general hospitals

In England, between April 2007 to March 2008, the most commonly reported type of incident in acute/general hospitals was patient accident (32 per cent).

Treatment/procedure was the second most commonly reported incident type (13 per cent), followed by medication (nine per cent), infrastructure (including staffing, facilities, environment) (eight per cent), and access/admission/transfer/discharge (including missing patient) (seven per cent).

Clinical assessment (including diagnosis, scans, tests, assessments), documentation (including records, identification), consent/confidentiality, medical device/equipment, implementation of care and ongoing monitoring/review, and incidents coded as ‘other’ ranged between six per cent and three per cent. Incidents categorised as infection control accounted for two per cent of all incidents. The remaining incident types (disruptive/aggressive behaviour, self-harming behaviour, and patient abuse (by staff/third party)) each accounted for a negligible proportion (each rounded down to 0 per cent). A similar pattern was seen in all four quarters.

* Community services include community nursing, medical and therapy services.
Figure 3:
Care setting of incident reports in England, April 2007 to March 2008

- 2,354 Ambulance service
- 2,150 General practice
- 67,047 Community nursing, medical and therapy service (incl. community hospital)
- 26,356 Learning disabilities service
- 114,060 Mental health service
- 583,567 Acute / general hospital
- 796,142 Total no. of incidents
- 131 Community and general dental service
- 3 Community optometry / optician service
Figure 4:
Reported incident types in acute/general hospitals in England, April 2007 to March 2008

- **Total no. of incidents**: 583,567
- **Patient accident**: 189,251
- **Treatment, procedure**: 73,745
- **Medication**: 55,135
- **Access, admission, transfer, discharge (including missing patient)**: 40,525
- **Infrastructure (including staffing, facilities, environment)**: 48,651
- **Documentation (including records, identification)**: 37,292
- **Clinical assessment (including diagnosis, scans, tests, assessments)**: 34,669
- **Medical device / equipment**: 23,146
- **Consent, communication, confidentiality**: 25,632
- **Implementation of care and ongoing monitoring / review**: 21,271
- **All other incident types**: 34,250
Nasogastric feeding can be vital to the survival and recovery of patients who are unable to eat normally. An estimated 271,000 nasogastric tubes are supplied to the NHS annually (NHS Supply Chain 2008).

However, nasogastric feeding, as with any clinical treatment, carries risks. Nasogastric feeding into a tube misplaced into the lungs instead of the stomach can be fatal.

In February 2005, the NPSA issued a Patient Safety Alert, Reducing the harm caused by misplaced nasogastric feeding tubes, followed by an Alert related specifically to neonates in August 2005, and provided additional recommendations to Directors of Nursing in February 2007 (www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/nasogastric-feeding-tubes/).

The key advice from the Alerts was regarding the correct and incorrect methods to test the position of nasogastric tubes:

- **Do not use** the following methods:
  - the ‘whoosh’ test (injecting air and listening with a stethoscope for exit sounds);
  - observation for bubbling at the tube end;
  - use of litmus paper to test acidity/alkalinity of aspirate.

- **Do use** the following methods:
  - measure the pH of aspirate using pH indicator strips/paper to ascertain position (a pH aspirate of 5.5 or lower); or
  - a chest x-ray to confirm placement.

Analysis of NRLS data

The aim of this analysis was to review nasogastric tube related incidents reported to the NRLS since the Alert was issued in February 2005. Incidents received between 31 August 2005 and 29 February 2008 were searched for relevant keywords, including nasogastric, pH, whoosh, and equivalent terms.

These reports suggest that in the vast majority of tube placements, staff were implementing NPSA advice, no longer using litmus paper or ‘whoosh’ tests, and carrying out pH paper checks and x-rays with care and with a clear awareness of the risk of tube misplacement. However, a small number of reports indicate that problems still exist.

There were 2,397 incidents reported, of which 210 related to nasogastric tube placement.

The diagram on the next page illustrates the results of the analysis, both in terms of the issues identified and the number of incidents involved.

Most of these reports were made shortly after feeding into the lungs was suspected or confirmed, and before investigations had been completed, so there is inevitably missing information. In some cases checks on initial tube placement may have been correctly carried out, but the tube was later displaced by vomiting, suctioning, or patient movement.

We are currently contacting all trusts who have reported apparent feeding into the lungs or serious near misses, including incidents reported since the analysis above, to obtain more detailed information on how tube placements were checked, and what the eventual outcome was for the patient.

The analysis above suggests that although a majority of NHS organisations had implemented the Alerts, there are still areas of concern in the following areas:

- Some staff (including doctors and nurses) do not know that injecting air and listening for exit sounds is unreliable, for example:
  - ‘Night SHO had inserted a nasogastric tube and tested its location by syringing air through the tube. Dr was advised on two occasions prior not to do this as it is not policy. However, the Dr did not listen and proceeded with the air in the syringe twice…..[nursing staff ensured the patient was not fed until tube position confirmed by x-ray]’

- Some staff appear unaware of what is the safe pH reading for feeding, for example:
  - ‘Nasogastric tube inserted aspirate pH 6. Feed commenced. Pt coughing through Trachy tube ……aspirate from Trachy tube containing feed. Feed stopped………….’

- X-rays are only the ‘gold standard’ for confirming tube placement if interpreted by staff who have the competencies to interpret them correctly. Otherwise interpretation errors can occur, for example:
  - ‘I received patient with nasogastric tube. Chest x-ray was done and reviewed by Dr X. I was told by her that the nasogastric tube is in right place. At 15.00 hrs feeding started. At 16.30 hrs doctors managing patient came and reviewed the chest x-ray and I was told the nasogastric tube is in the lung.’

Organisations also need to ensure that whilst their checking procedures are robust, they are also efficient: 89 reports described avoidable and sometimes prolonged delays whilst patients waited without nutrition or medication, due mainly to:

- Delays in checking x-rays to confirm tube position
  - ‘Patient waiting since 1400hrs for x-ray for check of NG tube position. So patient was unable to be fed via NG tube until next day when x-ray was done. Patient also could not receive his medication orally.’

- Delays in reporting and reviewing of x-rays
  - ‘NG tube placed and aspirated, CXR performed and required medical review prior to feed being commenced. CXR performed at approx 14.30 hours, medics bleeped to review at 15.00hrs, 17.00hrs, 19.00hrs and 20.00hrs …..’
The NRLS will provide further information after following up these incidents with individual organisations and reviewing the findings of their local investigations. If any organisation has any additional relevant investigations that would help national learning, we would be grateful for information.

We are also hoping to learn from a major piece of research commissioned by the Department of Health’s Patient Safety Research Programme on best available evidence for checking nasogastric tube placement.

Most of the incidents analysed suggest a failure to implement existing advice consistently. Organisations are urged to use the audit tools available on the NPSA website (www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/nasogastric-feeding-tubes/) to check their local policies are implemented in practice.
Between April 2006 and March 2007, three per cent of all incidents reported to the NRLS related to medical devices; a total of 24,207 incident reports.* Of these, 500 incidents were reported as causing severe harm to the patient or death. These incidents were screened to remove duplicates or non-device related incidents, resulting in 303 incident reports being analysed. The free text of the 303 incidents was analysed to identify the device or devices that were involved, and the type of incident. This analysis identified 326 individual device incidents due to multiple devices and multiple incident types within some reports.

Devices involved
Devices cited in the incident reports were grouped into larger categories of similar device type or function. For example, infusion, epidural, and diamorphine pumps were grouped together; as were crash trolley and resuscitation equipment. Figure A shows the five most frequently cited device types.

Incident types
The reported incidents were grouped into different categories. The five most frequently listed categories are shown in Figure B (page 17).

Contributing factors
The analysis suggests that aspects of both the design of devices and the system for managing devices contributed to incidents. The key findings from each of the top five types of devices are highlighted below.

Pumps and accessories
Nearly half the total number of incidents involving pumps and accessories (19 out of 45) were categorised as ‘equipment not operating as intended’.

Although it was difficult in some cases to establish whether the device was faulty, or whether the design of the device had contributed to inappropriate programming, it was often apparent that the design of the device could have played a part in the incident.

‘On checking progress of syringe driver at 22:00, I discovered the syringe empty. The syringe driver was commenced at 15:00 hours to run over 24 hours and should be set to run at 2mm per hour but was set at 20mm per hour. The syringe driver contained diamorphine 30mg and cyclizine 100mg. The patient was receiving this for pain control in palliative care.’

Device-related incidents: reports of serious harm

* A search of NRLS data was conducted that returned all incidents where the incident type was device/equipment, and incidents where common device types or names were mentioned in the free text.
Trusts can help to minimise risks by identifying devices with inconsistent designs, and reducing their use in the same location, or with the same patient. Procurement decisions can also take into consideration potential design inconsistencies, as well as evaluate how easy it is to determine the current infusion status of the device by involving end users in selection and evaluation.

Catheters and cannulae

In nine of the 21 incidents involving catheters and cannulae, an inappropriate type of catheter or cannula was used. This suggests that these devices are not readily distinguishable from each other and identification of the correct type of device is not clear. It may be that it is easy to distinguish between different types or sizes of devices when viewed side by side, but such comparators are not necessarily available at the point of care.

‘I was called to a patient with an epidural in situ who had had 2 episodes of high block. Further assessment by me revealed that the epidural catheter was in fact intrathecal / spinal.’

‘Patient was complaining of pain in lower abdomen, on investigation the catheter in situ was a female size catheter length.’

By recognising that such equipment can be difficult to distinguish, trusts can incorporate ease of identification as a factor in procurement decisions for new equipment. Trusts can also assess whether their storage of such equipment encourages picking errors.

Beds, mattresses and hoists

Of the 23 incidents involving beds, mattresses and hoists, 14 were categorised as ‘equipment unavailable’. In these incidents the device management systems contributed to the incident, rather than the design of the device itself.

‘Request to stores on 19 April for pressure mattress & cushion. Not delivered. Same requested on 26 April on new form. Not delivered by 4 May. Patients skin now broken down.’

By mapping common tasks and situations with existing systems that support device management, trusts can start to understand where additional measures might need to be taken to ensure the robustness of the systems in place.

Surgical

As with beds, mattresses and hoists, ‘equipment unavailable’, rather than the equipment itself, contributed to incidents involving surgical equipment (five out of 23 incidents).

In all five cases, surgery was planned and the systems to provide for the availability of the required equipment contributed to the incidents. This demonstrates that equipment availability is problematic, even in planned, non-emergency procedures:

‘Patient on elective list for wrist surgery with requirement for vista image intensifier on list. Patient anaesthetised on table when told vista machine not available.’

Similar to the systems supporting device management relating to beds, mattresses, and hoists, trusts can increase the understanding of the systems underpinning surgical device management, and the potential for increased safety, by walking through frequently performed tasks and common situations with the systems currently in place to identify possible risks.

Figure B:

Most frequently reported incident types, April 2006 to March 2007

Base: Devices related to incidents resulting in death or severe harm

- **46** Other
- **32** Equipment not operating as intended
- **34** Equipment not set up properly
- **326** Total no. of incidents
- **90** Equipment unavailable
- **92** Faulty equipment
There were also five surgical device incidents where the patient was unintentionally harmed by the equipment. All cases involved electrically induced heating devices, such as diathermy: three incidents involved the diathermy burning the patient directly, and the other two cases involved the diathermy setting light to other surgical artefacts (drapes and operation site spray).

Six of the 23 surgical device incidents related to equipment that failed during use. It is important that incidents involving medical devices that are faulty or not operating as intended are reported to the MHRA via their website www.mhra.gov.uk including incidents relating to a device’s instructions for use or labelling. Trusts need to ensure they have a clear policy for reporting incidents relating to faulty medical devices to the MHRA.

Crash trolley equipment and resuscitation

Of the 21 incidents involving crash trolley equipment and resuscitation, 11 related to ‘equipment unavailable’. In these incidents, processes to plan and check the required equipment contributed to the incidents. However, such incidents also raise other questions such as how easy it is to check crash trolleys for completeness, and how staff know what equipment a crash trolley should be stocked with.

‘...Patients condition deteriorating so medical registrar was called, he saw the patient and asked for external pacing to be put on despite all efforts none could be found. The patient… went into cardiac arrest… Crash team arrived … no drugs available on ward … to put ET tube in and despite most of drugs available in crash boxes some vital drugs were missing.’

Information about the follow-up investigation was provided with this incident (see below). The investigation demonstrated that the crash trolley was stocked according to trust policy. So although staff reported equipment to be missing from the crash trolley, it was stocked as required, as highlighted below. This also meant staff were unaware of where to find particular equipment in an emergency situation.

‘External pacing facility is not available on any of the defibrillators in the block. The crash trolley was fully stocked as per the trust policy / contents requirements. The drugs in question are not a requirement on the trolley. They are paralytic agents which need to be stored in a fridge. There is currently a set in the fridge on [ward name] for use within block.’

Trusts should review staff knowledge of where equipment can be found in an emergency situation, and should also identify ways in which this information can be readily and easily found to assist staff in pressurised situations to prevent them needing to rely on memory.

Ambiguous contributory factors

It was often difficult to establish what the contributory factors were from the incident text. In some incidents the device might have been faulty, poorly maintained or not designed to help identify errors, whilst in other incidents multiple contributing factors can be recognised.

‘Patient with chest pain called 999. Ambulance attended. Pt says ECG machine in ambulance didn’t work. Reassured by crew & left at home. Today GP referred with complete inferior MI.’

In the incident above, several factors could have contributed to the incident:

• Was there a system to check whether the ECG equipment was operational? If so, it could have failed?
• The design of the ECG machine may make it difficult to check whether or not it is working;
• The initial communication to the ambulance crew may not have included information about chest pain, increasing the need for an operational ECG machine;
• If the ambulance crew did not themselves carry out the checks on the ECG machine they may have been unaware that it was not working;
• The system failed to recognise the requirements for the 999 call and distributed an ill-equipped ambulance.

By highlighting the role of systems and design in patient safety incidents, it is hoped that frontline staff will start to recognise these factors in incidents and increase their reporting of design and system-related issues so that broader learning can be achieved.

Conclusion

The importance of design, and the role it can have on user error, needs to be recognised by trusts, frontline staff and manufacturers, to improve procurement decisions, the scope of reporting and the availability of well-designed devices.

Similarly, the prevalence of incidents related to the failure of systems that support device management demonstrates that safe design philosophies, such as understanding user requirements, context of use and potential usage scenarios need to be adopted with these systems. Guidance on the management of medical devices has been produced by the MHRA* and this may be of help with initiating such activities.

*MHRA. DB 2006(05) Managing Medical Devices. Available at: www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142
Mental health and learning disabilities services

The pattern of incident types in mental health services was somewhat different compared to other care settings, although patient accidents still accounted for the largest proportion of incidents (34 per cent) reported between April 2007 and March 2008.

In contrast to other care settings, disruptive/aggressive behaviour was the second most commonly reported incident type (19 per cent), which was followed by self-harming behaviour (15 per cent). Incidents categorised as access/admission/transfer/discharge (including missing patient) accounted for 10 per cent of all incidents, while ‘other’ incidents accounted for nine per cent. Medication accounted for six per cent, and patient abuse (by staff/third party) accounted for three per cent. The remaining incident types each accounted for two per cent or less. This pattern was similar in all four quarters.

Similarly to mental health services, in learning disabilities services, patient accidents (32 per cent), disruptive/aggressive behaviour (28 per cent) and self-harming behaviour (17 per cent) were the most commonly reported incident types between April 2007 and March 2008. Incidents coded as ‘other’ accounted for 10 per cent while medication accounted for five per cent. Patient abuse (by staff/third party) accounted for four per cent and the remaining incident types accounted for two per cent or less.

There was no substantial change in the pattern of incident types seen in learning disabilities services across the four quarters.
Figure 5: Reported incident types in mental health services in England, April 2007 to March 2008

- Patient accident: 6,867
- Medication: 10,036
- Access, admission, transfer, discharge (including missing patient): 11,024
- Disruptive, aggressive behaviour: 17,252
- Self-harming behaviour: 38,468
- Other: 3,596
- Patient abuse (by staff / third party): 4,736
- All other incident types: 114,060
- Total no. of incidents: 114,060
Figure 6:
Reported incident types in learning disabilities services in England, April 2007 to March 2008

- **26,356** Total no. of incidents
- **8,460** Patient accidents
- **7,394** Disruptive, aggressive behaviour
- **4,416** Self-harming behaviour
- **2,591** Other
- **1,323** Medication
- **992** Patient abuse (by staff / third party)
- **424** Access, admission, transfer, discharge (including missing patient)
- **756** All other incident types
Community services (including community hospitals), community pharmacies, community and general dental services, and community optometry and optician services

Overall, between April 2007 and March 2008, the most commonly reported type of incident in community services* (including community hospitals) was patient accident, which alone accounted for 52 per cent of all incidents.

None of the remaining categories accounted for more than 10 per cent: medication accounted for nine per cent, access/admission/transfer/discharge (including missing patient) accounted for eight per cent, and incidents coded as treatment/procedure and ‘other’ both accounted for five per cent.

Implementation of care and ongoing monitoring/review accounted for four per cent, while the remaining categories each accounted for between one per cent and three per cent.

The pattern of incident types in community services (including community hospitals) was similar in all four quarters.

In community pharmacies, the vast majority of reported incidents between April 2007 and March 2008 related to medication (95 per cent). Incidents coded as ‘other’ accounted for two per cent of all incidents. Neither of the remaining incidents types (i.e. consent/communication/confidentiality, documentation (including records, identification), medical device/equipment, infrastructure (including staffing, facilities, environment), treatment/procedure, disruptive/aggressive behaviour, patient abuse (by staff/third party), and patient accidents) accounted for more than one per cent.

In community optometry/optician services, only two incidents were reported to have occurred in England and Wales combined in the quarter January to March 2008 and the overall number of incidents received between April 2007 and March 2008 remained very low (n=3). Therefore, no conclusions can be drawn with respect to incident patterns in this care setting.

In community dentistry, patient accident was the most commonly reported type of incidents between April 2007 and March 2008 (27 per cent), and 17 per cent of incidents were coded as ‘other’. The next most commonly reported incident type was medical device/equipment and treatment/procedure (both 11 per cent), infrastructure (including staffing, facilities, environment), and medication (both eight per cent). The remaining incident types ranged between four per cent and one per cent.

Although there are large fluctuations in the pattern of incident types, the number of reported incidents remains low for this sector, which is likely to explain the inconsistent pattern.

* Community services include community nursing, medical and therapy services.
Figure 7:
Reported incident types in community services (including community hospitals) in England, April 2007 to March 2008

- Patient accident: 34,584
- Treatment, procedure: 5,757
- Medication: 5,436
- Infrastructure (including staffing, facilities, environment): 2,140
- Documentation (including records, identification): 2,302
- Medical device / equipment: 1,547
- All other incident types: 4,330
- Implementation of care and ongoing monitoring / review: 3,466
- Consent, communication, confidentiality: 1,931
- Access, admission, transfer, discharge (including missing patient): 5,436
- Other: 3,099

Total no. of incidents: 67,047
**Ambulance services**

There is a single ambulance trust in Wales. Therefore, to protect confidentiality, the combined figures for England and Wales are presented, rather than for England alone.

The most commonly reported incident type in ambulance services was access/admission/transfer/discharge (including missing patient), which accounted for 22 per cent of all reported incidents between April 2007 and March 2008.

Medical device/equipment (18 per cent), patient accident (14 per cent) and consent/communication/confidentiality (12 per cent) were the next most commonly reported incident types, followed by infrastructure (including staffing, facilities, environment) (10 per cent). Treatment/procedure accounted for nine per cent, while incidents coded as ‘other’ accounted for seven per cent.

The pattern of incident types fluctuated notably during the four quarters between April 2007 and March 2008, which may be explained by the relatively low number of total incident reports received from this care setting. It is notable, however, that the proportion of incidents categorised as access/admission/transfer/discharge (including missing patient) continued to decrease in January to March 2008 (from 25 per cent in April to June 2007, to 18 per cent in January to March 2008).

**General practice**

The pattern of incident types in general practices showed a markedly different pattern compared to care settings that take inpatients.

Between April 2007 and March 2008, the most commonly reported incident type in general practice in England was medication (26 per cent), followed by documentation (including records, identification) (14 per cent), consent/communication/confidentiality (11 per cent), and access/admission/transfer/discharge (including missing patient; 10 per cent).

Treatment/procedure accounted for eight per cent, and clinical assessment (including diagnosis, scans, tests, assessments) and incidents coded as ‘other’ both accounted for seven per cent of all incidents. Patient accident accounted for six per cent, and the remaining incident types each accounted for four per cent or less.

Some variation was seen across the four quarters in the pattern of incident types, although no consistent trends were evident. The notable fluctuations are likely to be the result of the relatively low number of total incident reports submitted by general practices.
Figure 8:
Reported incident types in ambulance services in England and Wales, April 2007 to March 2008

- **All other incident types**: 202
- **Access, admission, transfer, discharge (including missing patient)**: 600
- **Medical device / equipment**: 495
- **Patient accident**: 390
- **Consent, communication, confidentiality**: 321
- **Infrastructure (including staffing, facilities, environment)**: 283
- **Treatment, procedure**: 232
- **Other**: 199

**Total no. of incidents**: 2,722
Figure 9:
Reported incident types in general practice in England, April 2007 to March 2008

- **80** Infrastructure (including staffing, facilities, environment)
- **120** Patient accident
- **147** Clinical assessment (including diagnosis, scans, tests, assessments)
- **142** Other
- **177** Treatment, procedure
- **207** Access, admission, transfer, discharge (including missing patient)
- **229** Consent, communication, confidentiality
- **304** Documentation (including records, identification)
- **557** Medication
- **2,150** Total no. of incidents
Degree of harm

Between April 2007 and March 2008, 65 per cent of incidents in England were reported as resulting in no harm to patients. Twenty-seven per cent were reported as causing low harm, and six per cent were reported as causing moderate harm. One per cent of all incidents were reported as resulting in severe harm or death, with the majority of these incidents being classified as severe harm rather than death. This pattern was similar across the four quarters.

Severe harm or death by care setting

Since the proportion of incidents resulting in either severe harm or death is very low, the proportions discussed in this section will be referred to using one decimal point.

The proportion of incidents reported as causing severe harm or death in England showed some variation across care settings. The proportion of incidents causing either severe harm or death between April 2007 and March 2008 was highest in general practices (2.7 per cent), followed by mental health services (1.8 per cent), community services (including community hospitals) and ambulance services (1.5 per cent and 1.4 per cent, respectively). The equivalent proportion was 1.2 per cent in acute/general hospitals and 0.8 per cent in community and general dental service. In both learning disabilities services and community pharmacies the equivalent proportion was 0.4 per cent.

It is likely that the relatively high proportion of incidents reported as resulting in either severe harm or death in general practices reflects a different reporting culture compared to other care settings: fewer incidents are reported overall but incidents that result in severe harm or death are most likely to be reported.

In almost all care settings, the proportion reported as resulting in severe harm was higher than the proportion reported as causing death. For example, in general practice the proportion reported as resulting in severe harm was 1.7 per cent, whereas the proportion reported as causing death was 1.0 per cent. In community services (including community hospitals) the equivalent proportions were 1.1 per cent and 0.4 per cent, respectively. The exception to this pattern was mental health services where 1.1 per cent of incidents were reported to have caused death, compared to 0.7 per cent of incidents resulting in severe harm. This pattern was largely similar in the four quarters.

All incidents where the harm to a patient is reported as death or severe harm are reviewed.

From analysis of incidents reported as resulting in death, the NRLS has found that only about a third of these incidents are events in which the death of the patient was, or might have been, directly related to patient safety. Some incidents may be coded based on the potential harm to the patient, rather than the actual harm. In other cases, the patient may have died, but not as a result of a patient safety incident: organisations often capture events in the local risk management system where patients have died, even if there was no patient safety incident, for example, still births and neonatal deaths, and outpatient suicides. Furthermore, even following investigation, the relationship between any incident which occurred and the outcome for the patient is often unclear, as many incidents happen during the care of patients with life-threatening illness. For further information on incidents reported as deaths from maternity services, see the Quarterly Data Summary Issue 6.1

Coding of degree of harm to patients is an important aspect of data quality which we are working with NHS organisations to improve.
Figure 10:
Reported degree of harm to patients in England, April 2007 to March 2008

<table>
<thead>
<tr>
<th>Harm Level</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low harm</td>
<td>218,188</td>
</tr>
<tr>
<td>Moderate harm</td>
<td>48,951</td>
</tr>
<tr>
<td>Severe harm</td>
<td>7,101</td>
</tr>
<tr>
<td>Death</td>
<td>3,282</td>
</tr>
<tr>
<td>Total no. of incidents</td>
<td>796,108</td>
</tr>
</tbody>
</table>

Note: The total number of incidents (796,108) is lower than that quoted elsewhere, as it excludes those incidents where degree of harm was not stated.
Figure 11:
Reported incidents resulting in severe harm or death in England, by care setting, April 2007 to March 2008

Percentage of all incidents in each care setting (number of incidents shown at the end of each bar)

- General practice: 36% (1,702 incidents)
- Community nursing, medical and therapy service: 709% (275 incidents)
- Acute/general hospital: 5,440% (1,702 incidents)
- Ambulance service: 20% (13 incidents)
- Mental health service: 806% (1,251 incidents)
- Community and general dental service: 1% (19 incidents)
- Learning disabilities service: 2% (87 incidents)
- Community pharmacy: 0% (2 incidents)
The National Reporting and Learning System

The reporting of patient safety incidents is essential to improving safety. One of the NPSA’s National Reporting and Learning Service’s core functions has been the development of the NRLS to collect reports of patient safety incidents. Incident reporting enables the types and causes of safety problems to be identified so that practical solutions can be developed to prevent harm to patients.2,3

The publication by the Department of Health of Safety First4 in December 2006 has provided the NRLS with a set of recommendations, one of which is to improve the current reporting systems and feed back actionable learning to the NHS. In light of this, we are currently reviewing the mechanisms for collecting reports of patient safety incidents.

Although incident reports are fundamental to understanding patient safety, on their own they cannot tell us all that we need to know. There are a number of reasons for this. Incident reporting systems are not comprehensive due to under-reporting, biases in what types of incident are reported, and the existence of several reporting systems. For example, in the UK, in addition to the NRLS there are separate reporting systems for medical device incidents,5 adverse drug reactions,6 healthcare associated infections,7 and suicide and homicide of people with mental illness.8 Also, serious incidents are rare, and information on them is often distributed across the healthcare system.

The NRLS data set is designed to collect a notification report of a single patient safety incident soon after it occurs. It focuses on what happened, when and where it happened, the characteristics of the patient(s) involved (such as age, gender and ethnicity) and the outcome for the patient(s).

The data set includes contributory factors and factors that might have prevented harm. Reports contain free text that explains what happened in varying degrees of detail. Additional detail is provided in reports involving medication and medical devices.

There are a number of notes of caution in interpreting the data from the NRLS:

- NHS organisations have provided data to the NRLS for varying lengths of time, so data included within this report may not be representative of the rate of incidents across all of England and Wales.
- Reports made to local risk management systems may not capture all types of incidents that occur.
- The data are confidential. We do not seek to hold information on the identities of individual staff or patients, and this means that the data are not routinely checked with the reporter. However, steps are usually taken to maximise the quality of the data held by, for example, checking for duplicate reports and feeding back to individual trusts if there are problems with their reports.
- Incident reports are often made soon after the incident occurs but before the incident has been investigated locally. Therefore, reports to the NRLS may not contain complete information about the incident, especially findings of more detailed investigations such as root cause analysis.
- No reports from the public or patients are included in this analysis, although since April 2006 patients and the public have been able to report incidents via a dedicated reporting form.
- A higher number of reported incidents from a trust, specialty or location, does not necessarily mean that the trust, specialty or location has a higher number of incidents; it may instead reflect greater levels of reporting.
- Some incidents recorded in local risk management systems and subsequently forwarded to the NRLS may not technically be patient safety incidents. For example, deaths from natural causes which occurred in hospital, and also deaths where patients died unexpectedly, are sometimes reported to local risk management systems, for local audit purposes, and hence are reported to the NRLS.
- The data are likely to include incidents where the impact on the patient or whether the incident could have been avoided, is not clear. For example, suicides are often reported to local risk management systems in cases where the event could not have been prevented by health services.
- The level of detail collected locally varies. For example, some organisations and local data collection systems do not currently collect contributing factors or the ethnicity of the patient(s) involved. At the present time, there is insufficient information on the age and gender of patients involved in incidents to allow analysis of this information, but the quality of demographic data is improving.

Organisations reporting higher numbers of patient safety incidents may have a better developed safety culture, resulting in greater reporting and learning from reports.9


To reference this report and the data presented, the following citation is suggested: