

Setting Levels of Ambition for the NHS Outcomes Framework

A technical annex to support Developing the care objectives for the NHS: A consultation on the draft mandate to the NHS Commissioning Board

Chapter 7: Treating and caring for people in a safe environment and protecting them from harm

DH INFORMATION READER BOX

| | | | |
|----------------------------|--|--|---|
| Policy | Clinical HR / Workforce Management Planning / Performance | Commissioner Development Provider Development Improvement and Efficiency | Estates IM & T Finance Social Care / Partnership Working |
| Document Purpose | For Information | | |
| Gateway Reference | 17770 | | |
| Title | Setting Levels of Ambition for the NHS Outcomes Framework | | |
| Author | Department of Health | | |
| Publication Date | 4 July 2012 | | |
| Target Audience | For those interested in measuring outcomes | | |
| Circulation List | | | |
| Description | Developing our NHS care objectives: A consultation on the draft mandate explains that the Government will hold the NHS Commissioning Board to account for delivering improvements in health outcomes. This technical annex outlines the proposed methodology for setting levels of ambition against the NHS Outcomes Framework | | |
| Cross Ref | Delivering our NHS care objectives: a consultation on the draft mandate | | |
| Superseded Docs | | | |
| Action Required | N/A | | |
| Timing | | | |
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| For Recipient's Use | | | |

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First published July 2012

Published to DH website, in electronic PDF format only.

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Domain 5 - Treating and caring for people in a safe environment and protecting them from avoidable harm.

Introduction

- 7.1 This chapter sets out our proposals for calculating a level of ambition for domain 5: 'Treating and caring for people in a safe environment and protecting them from avoidable harm'. The proposed methodology is summarised in the executive summary and explained in detail in chapter 2.
- 7.2 In this chapter, we review available data for each indicator. A 'notes' section highlights some aspects which may merit further consideration. The chapter illustrates a range of factors that may affect outcomes (we use the term 'drivers' to describe these). In some cases, we refer to findings from academic literature. Such citations are not intended to be a guide to clinical practice and should not be taken as official endorsement by the Department of Health.
- 7.3 We produce 'current practice projections' where data are available. . The purpose of these projections is explained in the executive summary and in Chapter 2. They are not forecasts of performance – rather they represent benchmarks for assessing the likely NHS contribution to improving outcomes. After producing a projection, we then consider what scope there is for the NHS to improve outcomes measured by individual indicators within available resources.
- 7.4 Finally, sections 3 a and b provide examples of how these areas of possible improvement could be aggregated and used to inform a level of ambition that is set for each domain. It is important to note that this section is a partial assessment at this stage. It illustrates how we might set levels of ambition. We intend to quantify what might be possible to achieve at a national level. It would then be for the NHS Commissioning Board to decide how to meet that level of ambition.
- 7.5 Our partial assessment is based on building up a picture of what might be possible based on considering individual indicators. Our aim is to have a level of ambition that represents the goal of the domain as a whole – therefore we are clear that we may need to make some additional broader assumptions.
- 7.6 As indicated earlier in the document, this material is an analytical work in progress. It is being published in the interests of transparency, to outline our proposals, and to invite comments. Levels of ambition will be included in the final mandate.

(1) Domain 5 overview and metric of improvement

7.7 This domain comprises two overarching indicators and seven improvement indicators.

7.8 The overarching indicators (5a Patient Safety incidents reported and 5b Safety incidents involving severe harm or death) measure, respectively the readiness of NHS to report harm and to learn from it, and the number of severe incidents of harm.

7.9 Given under-reporting of safety incidents, for the time being overarching indicators 5a, the number of incidents reported, and 5b, Safety incidents involving severe harm or death, will be seen as a positive indicator of outcome – reflecting increased willingness to recognise and to address safety problems.

7.10 The improvement areas are of two sorts:

- Sub-indicator. Indicator 5.4, Incidence of medication errors causing serious harm and death, is a sub-indicator of indicator 5b. Progress in this indicator therefore provides a useful initial analysis of what accounts for progress in the overarching indicator. Here too, however, there may be under-reporting currently.
- Complementary Indicators. In several areas of poor practice, data collection is sufficiently systematic (or plans to make it so are in hand) to generate reliable information regarding incidence even when little harm may have resulted. These practices represent cases in which patients have been exposed to risk, whether or not it has materialised. Reduction in the number of such cases is sought. These are improvement areas:
 - 5.1 Incidence of hospital-related venous thromboembolism
 - 5.2.i Incidence of healthcare associated infection: MRSA bacteraemia
 - 5.2.ii Incidence of healthcare associated infection: *C. difficile*
 - 5.3 Pressure Ulcers
 - 5.5 Admission of babies to neonatal care
 - 5.6 Incidence of harm to children due to “failure to monitor”

7.11 Together, with robust data, overarching indicator 5b and the complementary improvement indicators would provide a picture of the safety of patients in the care of the NHS from iatrogenic and other avoidable harm.

7.12 Intuitively, the whole domain captures the risk that the population faces of being harmed by the NHS. A metric to allow aggregation of the contributions of each improvement area would be

- the expected QALY loss arising from unsafe care.

7.13 The aggregate metric would thus take on board what each individual indicator contributes – giving an appropriate relative weight for example to reducing incidents of severe harm or death (indicator 5b) on the one hand, or reducing the incidents of lesser harms on the other.

(2) Domain 5 Indicator Trends, Explanations, Projections and Scope for Improvement

7.14 This section sets out for each indicator or set of indicators

- a) Recent Trends and Explanations
- b) Current Practice Projections
- c) Scope for Improvement by Indicator

7.15 The number of safety incidents is determined in part by the volume of need to be addressed by the NHS. Volume will affect outcomes for all domain 5 indicators by its impact upon the availability of resources relative to caseload. However, current-practice projections for each indicator are made on the assumption that the quality of the NHS contribution to outcomes per capita is maintained at the same level as in the base-year, 2012-13 (see discussion in Chapter 2, section ii).

7.16 The indicator projections should also take account of possible bias to the extent that recording of incidents is variable. If recording systems become more robust, outcomes may appear to become worse – it will be vital to find ways to avoid creating perverse incentives not to record adverse outcomes.

Indicator 5a: Patient Safety Incidents Reported

| | |
|-----------------------|--|
| Outcome sought | Improved readiness of the NHS to report harm and to learn from it |
| Indicator definition | Patient safety incidents reported to the National Reporting and Learning Service (NRLS) by provider organisations in England, per 100,000 population |

Background to patient safety incident reporting

7.17 This indicator is based on data from the National Reporting and Learning System (NRLS), which was established by the National Patient Safety Agency (NPSA) in 2003 to enable healthcare staff to submit confidential reports to a national database about patient safety incidents (PSIs).

7.18 PSIs are any unintended or unexpected incident, which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare. By submitting PSI reports to the NRLS, clinicians can then use the aggregate data collected to identify patterns in such incidents and opportunities to reduce risks to patients.

7.19 All NHS healthcare providers are linked to the NRLS. However, the majority of PSIs are reported from acute/general hospitals – 72% of all reports in 2010/11, according to figures published by the NRLS.

(a) Indicator 5a: Recent Trends and Explanations

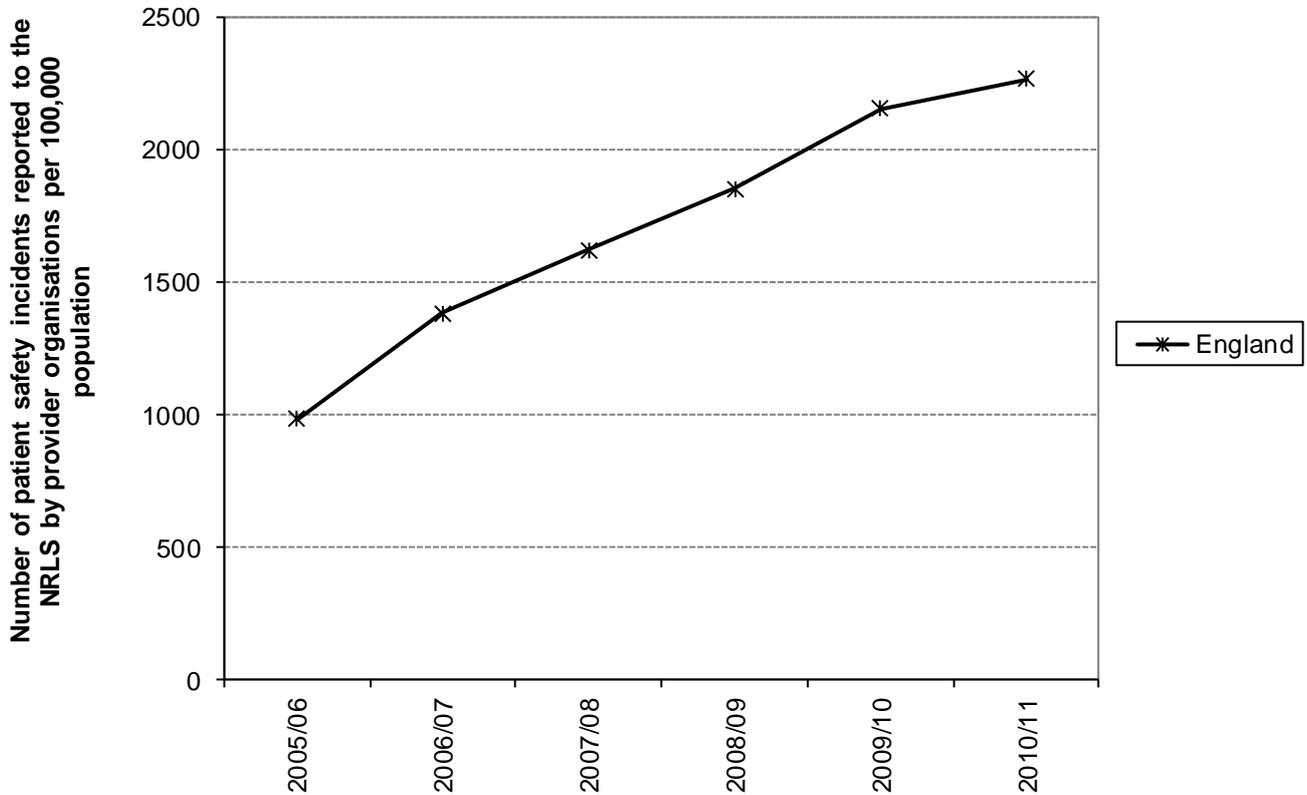
7.20 The annual PSI reporting rate increased by around 5% between 2009/10 and 2010/11 from 2,154 to 2,267 incidents per 100,000 population. The annual reporting rate has more than doubled since the end of 2005/06 when the rate was 984 per 100,000 population.

Table 5a.a – Patient safety incidents reported to the National Reporting and Learning Service (NRLS) by provider organisations in England (per 100,000 population)

| | England |
|---------|---------|
| 2005/06 | 984 |
| 2006/07 | 1,386 |
| 2007/08 | 1,624 |
| 2008/09 | 1,852 |
| 2009/10 | 2,154 |
| 2010/11 | 2,267 |

Source: NRLS, Office for National Statistics, NHS Information Centre

Figure 5a.a - Patient safety incidents reported to the National Reporting and Learning Service (NRLS) by provider organisations in England (per 100,000 population)



Source: NRLS, Office for National Statistics, NHS Information Centre

- 7.21 Note that following the establishment of the NRLS in 2003, the early years of reporting data were limited by technical barriers ie the development of the capacity to submit reports based on software developers' capacity to update local risk management systems. Therefore, data submitted to the NRLS before 2007 effectively represents pilot data in which a minority of suppliers of local risk management systems implemented uploading to the database.
- 7.22 Despite the increased level of reporting in recent years, it is still likely that a significant proportion of incidents are not being reported. This is described in more detail in the following section. However, it must also be noted that incident reporting systems are not designed to measure the number of adverse incidents that occur. They are designed to gather information about the nature of adverse and patient safety incidents. It is therefore not surprising that the NRLS does not accurately reflect the number of actual incidents that occur.
- 7.23 An increase in the number of incident reports is indicative of an improving patient safety culture, hence these indicators should be viewed as reflecting the safety culture rather than the specific safety of services.

Completeness of reporting patient safety incidents (PSIs)

7.24 Patient safety experts from the NRLS team consider the following two descriptions as being broadly equivalent:

- estimates of the incidence of preventable adverse events in hospital settings and,
- the number of PSIs that are classified as reported from acute/general hospitals to the NRLS, and which are classified as resulting in harm (low harm, moderate, severe or death, ie excluding 'no harm' incidents).

7.25 This provides a basis for a direct comparison, based on available evidence, which can be made to assess under-reporting of patient safety incidents. Estimates for the incidence of adverse events is based on evidence presented in the report of an expert working group on learning from adverse events, *Organisation with a Memory* (Department of Health, 2000), which included the best available evidence known at the time about the scale and nature of the problem of patient safety.

7.26 The key findings relevant to this indicator were

- The Harvard Medical Practice Study, reported in 1991 (Brennan et al, 1991), which found that 3.7% of hospital admissions led to adverse events, based on clinical records from 1984, and
- The Australian quality in health care study, which identified adverse events in 16.6% of admissions in 1992, of which half were considered preventable (Wilson et al, 1995).

7.27 Subsequent research by Vincent et al (2001) based on a retrospective record review of medical and nursing records in two hospitals, estimated that an adverse event occurred in about 11% of hospital admissions.

7.28 Taken together these findings correspond with the broad statement in *Organisation with a Memory* that "...adverse events in which harm is caused to patients...occur in around 10% of admissions".

7.29 Further research indicates that of these adverse events, typically around 40 – 50% are considered preventable (Wilson et al, 1995; Zegers et al, 2009). Taking these estimates together, preventable adverse events are estimated to occur in around 4-5% of hospital admissions.

7.30 For comparison, and taking the upper estimate of a preventable adverse event rate of 5% to illustrate the potential shortfall in reporting:

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- There were a total of 14.89 million hospital admissions in 2010/11 according to Hospital Episode Statistics published by the NHS Information Centre
- At a rate of 5%, this suggests an approximate 'expected' total of around 744,500 preventable adverse events (resulting in harm) occurring annually
- In 2010/11, 232,168 PSIs were reported from acute/general hospitals to the NRLS, which were classified as resulting in some degree of harm

7.31 On the basis of these figures, completeness would appear to be around 31% (232,168/744,500). This estimate should be treated with extreme caution, given the uncertainty in adverse event rates quoted in the literature as outlined above.

7.32 For instance, if the adverse event rates from the Harvard study and the Australian quality in health care study of 3.7% and 16.6% respectively were taken as the basis for the comparison described above, completeness would lie somewhere between 19% and 84%.

7.33 Although this comparison only relates to adverse events and PSIs in hospitals, these form the bulk of PSI reporting and by itself provides sufficient evidence that the reporting rate for indicator 5a underestimates the level of harm occurring.

7.34 Therefore, the trend in this indicator is very likely to reflect changes in reporting behaviour rather than changes in the level of harm occurring. This is further supported by the trend in the average proportion of trusts reporting to the NRLS in a given period, which increased from around 60% to 90% between 2007 and 2011.

7.35 Just 4,858 PSIs were reported from General Practice to the NRLS in 2010/11 – representing 0.4% of all PSIs reported. However, there is little published evidence about the overall rate of adverse events in primary care. A study by De Wet et al (2009) reported a rate of 1 event per 48 consultations, while a study by Tsang et al (2010) reported that:

- injuries due to surgical and medical care were detected in 0.72 cases per 1,000 consultations and
- adverse drug reactions were detected at a rate of 1.26 reactions per 1,000 consultations.
- The NRLS team advise that the current evidence is not sufficiently generalisable to estimate the 'expected' number of PSIs that are occurring in primary care.

Breakdown by SHA

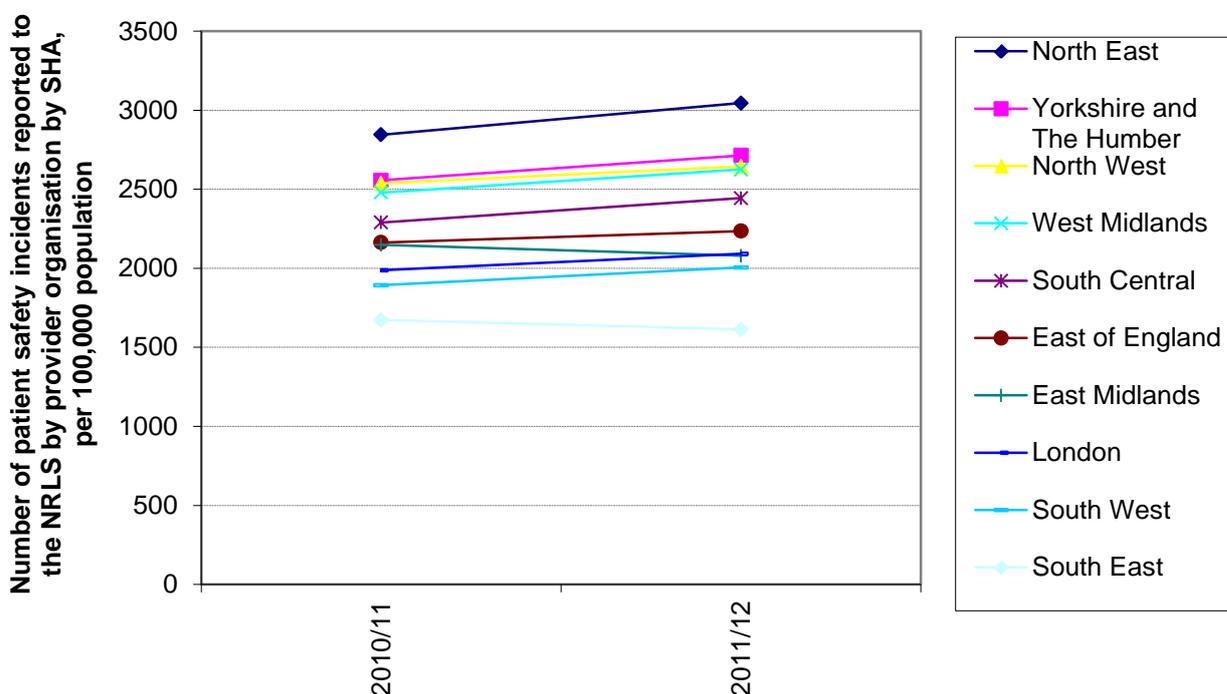
7.36 The reporting rate at SHA level varied almost two-fold in 2011/12, from around 1,600 per 100,000 population in South East Coast to around 3,050 in the North East. There are

insufficient data available at this time to ascertain trends in reporting rates at regional level.

Table 5a.b – Number of patient safety incidents reported to the National Reporting and Learning Service (NRLS) by provider organisations by SHA per 100,000 population

| | 2010/11 | 2011/12 |
|--------------------------|---------|---------|
| North East | 2,845 | 3,045 |
| North West | 2,537 | 2,645 |
| Yorkshire and The Humber | 2,557 | 2,714 |
| East Midlands | 2,148 | 2,080 |
| West Midlands | 2,479 | 2,625 |
| East of England | 2,163 | 2,236 |
| London | 1,987 | 2,092 |
| South East | 1,673 | 1,613 |
| South West | 1,893 | 2,005 |
| South Central | 2,290 | 2,444 |

5a.b – Number of patient safety incidents reported to the National Reporting and Learning Service (NRLS) by provider organisations by SHA per 100,000 population



International position

7.37 There are no international patient safety indicators that are directly comparable to those in the NHS Outcomes Framework. However, the Office for Economic Co-operation and Development (OECD) and the Agency for Healthcare Research and Quality (AHRQ) have

published patient safety indicators to provide an international focus on measuring a range of potentially avoidable adverse events, for instance, covering obstetric trauma and postoperative complications.

Notes:

- What accounts for the rising trend in reporting of safety incidents?
- Why is safety reporting diverging across regions?

Drivers of this indicator

7.38 The table below describes the key drivers for reporting PSIs rather than drivers of the ‘true’ rate of incidents because the indicator represents an under-estimate of the overall burden of harm from PSIs.

| KEY DRIVERS | |
|---|--|
| Healthcare need/activity | There is no direct evidence about the effect of healthcare need/activity on reporting, an increase in activity associated with an increasing population may have some effect on the overall reporting rate |
| Incentives | To report PSIs in sufficient numbers to make learning from incidents possible. The effect of sanctions for failing to report is unclear whilst sanctions for admitting error are likely to drive down reporting. |
| Changes to IT systems supporting automated or easier incident reporting | As more medical records become electronic, there will soon be an ability to detect medical errors referred to in clinical notes and e-prescribing systems for example. |

(b) Indicator 5a: Current Practice Projections Methodology

7.39 The projections in Table 5a.c and Figure 5a.c are based on the following methodology:

- A default position that recent average annual increases in the reporting rate are maintained through the current year, 2012-13, followed by projecting what would happen if no further push to increase reporting occurred ie assuming a ‘flat’ trend from 2012-13 onwards.
- This is based on an assumption that only organisations that are currently most effective and engaged with PSI reporting continue to do so.

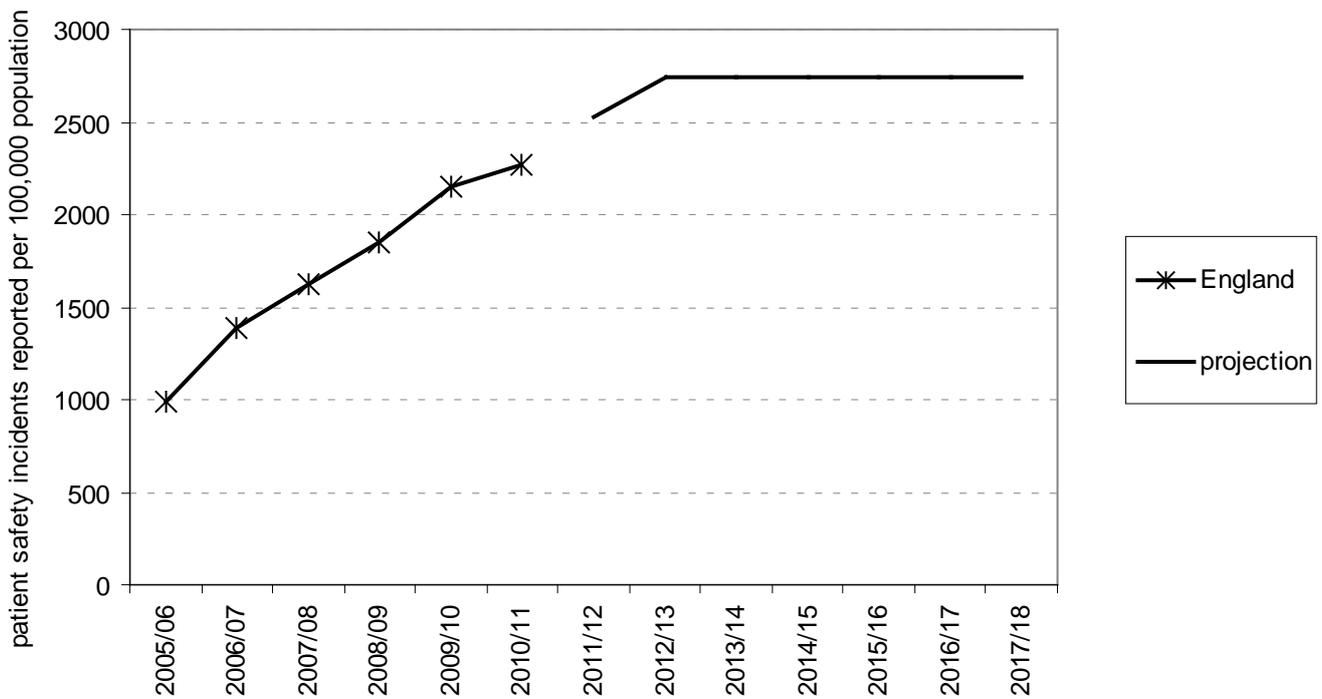
Results

Table 5a.c – Current practice projection for: number of patient safety incidents reported to the NRLS by provider organisations per 100,000 population

| Year | England | Projection |
|---------|---------|------------|
| 2005/06 | 984 | |
| 2006/07 | 1,386 | |
| 2007/08 | 1,624 | |
| 2008/09 | 1,852 | |
| 2009/10 | 2,154 | |
| 2010/11 | 2,267 | |
| 2011/12 | | 2,524 |
| 2012/13 | | 2,744 |
| 2013/14 | | 2,744 |
| 2014/15 | | 2,744 |
| 2015/16 | | 2,744 |
| 2016/17 | | 2,744 |
| 2017/18 | | 2,744 |

Source: NRLS, ONS, NHS Information Centre

Figure 5a.c – Current practice projection for: number of patient safety incidents reported to the NRLS by provider organisations per 100,000 population



Source: NRLS, ONS, NHS Information Centre

c) Indicator 5a: Scope for Improvement

- 7.40 This section considers whether there is scope for further improvement in this outcome indicator beyond that captured in the current practice projection. As outlined in section (a), the PSI reporting rate may only be about 31% complete. This implies that there is considerable further scope for more PSIs to be reported. However, it should be borne in mind that the NRLS was established primarily as a learning tool for analysing trends rather than as a surveillance tool.
- 7.41 The technological barriers to data collection in the early years of the NRLS were outlined in section (a). Over time the NPSA has worked with healthcare providers to overcome these barriers. Therefore, increases in reporting rates during the last five years are more a reflection of reporting behaviour than the capability of providers to submit PSI reports. If the average annual increases in the recent trend from 2006/07 to 2010/11, were maintained, then the reporting rate would continue to increase by around 5 – 13% per year. Influences on that might be improvements in effective reporting by organisations that report relatively fewer incidents, thus reducing the variation of effective reporting across care providers, and further increases in the average proportion of trusts who are reporting to the NRLS in future.
- 7.42 Individual providers would be expected over a period of time to go through a trajectory where reporting increases, followed by a plateau when reporting is comprehensive and then reductions from increased safety of care. However, because individual organisations are at different stages in this journey, then at national level, neither increases, decreases nor a steady state definitively represents better outcomes – any of these could actually represent negative or positive changes to patient care. An appropriate national level of ambition may be a narrowing of the range between the lowest and highest reporting providers, as this would cover both an increase in reporting in low reporters and a decrease in harm in good reporters.

References

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Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al., (1991) Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*; 324, 370-376

Wilson, RM, Runciman WB, Gibberd, RW, Harrison BT, Newby L, Hamilton JD (1995) The quality in Australian health care study. *Med J Aust.*; 163: 458-71

Vincent C, Neale G, & Woloshynowych, M. (2001). Adverse events in British hospitals: preliminary retrospective record review. *British Medical Journal*; 322, (7285) 517 – 519

Zegers M, de Bruijne MC, Wagner C, Hoonhout LHF, Waajiman R, Smits M et al. (2009) Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care*; 18:297-302

De Wet C, Bowie P. (2009) The preliminary development and testing of a global trigger tool to detect error and patient harm in primary care records. *Postgrad Med J*, 85:176-80

5b – Safety incidents involving severe harm or death

| | |
|-----------------------|---|
| Outcome sought | Reduced extent of severe harm or death caused or contributed to by the NHS |
| Indicator definition | Patient safety incidents reported to the National Reporting and Learning Service (NRLS), where degree of harm is recorded as “severe harm” or “death”, by provider organisations in England, per 100,000 population |

Background to grading patient safety incidents

7.43 Like indicator 5a, this indicator is based on patient safety incidents (PSIs) reported to the National Reporting and Learning System (NRLS), as established by the National Patient Safety Agency (NPSA) in 2003.

7.44 PSIs reported to the NRLS are graded according to the following definitions provided by the NPSA:

| Degree of harm | Definition |
|-----------------------|---|
| No harm | <ul style="list-style-type: none"> • Impact prevented – any PSI that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. • Impact not prevented – and PSI that ran to completion but no harm occurred to people receiving NHS funded care. |
| Low | Any PSI that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS funded care. |
| Moderate | Any PSI that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS funded care |
| Severe | Any PSI that appears to have resulted in permanent harm to one or more persons receiving NHS funded care. Permanent harm directly related to the incident and not to the natural course of the patient’s illness or underlying condition is defined as a permanent lessening of bodily functions, sensory, motor physiologic or intellectual, including removal of the wrong limb or organ or brain damage. |

| | |
|-------|---|
| Death | Any PSI that directly resulted in the death of one or more persons receiving NHS funded care. |
|-------|---|

7.45 This indicator is based on PSIs which are graded as involving severe harm or death. In 2010/11 0.87% (9,942) of PSIs reported from all care settings involved severe harm or death.

(a) Indicator 5b: Recent Trends and Explanations

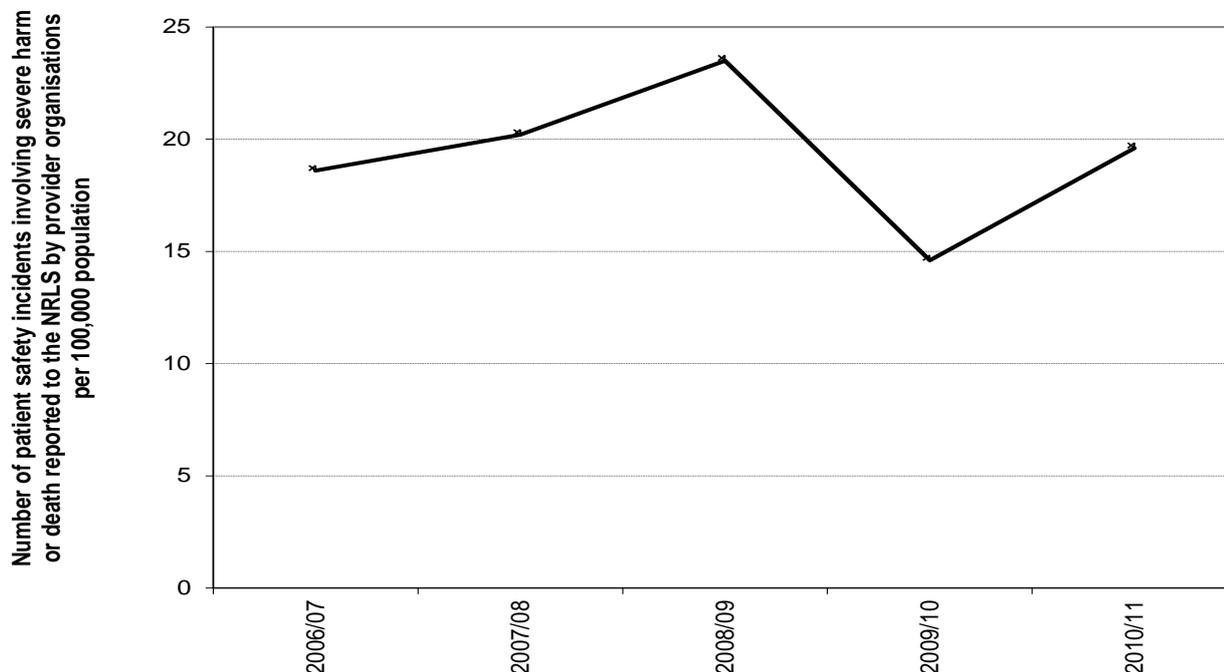
7.46 The reporting rate for patient safety incidents involving severe harm or death in 2010/11 was around 20 per 100,000 population, an increase of 27% compared to 2009/10. The rate has fluctuated since 2006/07, and peaked during 2008/09 at around 24 per 100,000.

7.47 As mentioned earlier, the majority of PSIs involving severe harm or death (71% in 2010/11), are reported from acute/general hospitals. This is also true of PSIs involving severe harm or death, with 67% in 2010/2011 being reported from acute/general hospitals.

Table 5b.a – Number of patient safety incidents involving severe harm or death reported to the National Reporting and Learning Service (NRLS) by provider organisations in England per 100,000 population

| | England |
|---------|---------|
| 2006/07 | 18.6 |
| 2007/08 | 20.2 |
| 2008/09 | 23.5 |
| 2009/10 | 14.6 |
| 2010/11 | 19.6 |

Figure 5b.a – Number of patient safety incidents involving severe harm or death reported to the National Reporting and Learning Service (NRLS) by provider organisations in England per 100,000 population



Source: NRLS, ONS, NHS Information Centre

Completeness of reporting PSIs involving severe harm or death

7.48 Under indicator 5a, estimates for adverse event rates in hospital admissions were described. The same key research based on The Harvard Medical Practice Study and the Australian quality in health care studies also set out estimates for the rate of adverse events in hospital admissions which resulted in at least permanent harm. However, this is not directly comparable with reported PSIs involving severe harm or death. Therefore, the same type of analysis cannot be carried out.

7.49 Looking in more detail at the incidents underpinning this indicator, specifically at deaths in hospital, studies by Hayward & Hofer (2001) and Zegers et al (2009) report respectively that 4.1% and 6.0% of deaths in hospital were probably contributed to by preventable adverse events. In 2011, there were 264,112 deaths in NHS hospitals. Therefore based on Zegers' and Hayward's estimate, somewhere between 10,800 and 15,800 deaths in hospital annually might be contributed to by preventable adverse events. In 2011, 1,453 deaths in hospitals were reported to the NRLS and so on the basis of these figures, completeness would be around 9% to 13%.

7.50 However these retrospective studies do have limitations and potential bias issues leading to significant uncertainty about their accuracy. Hayward in particular point out that using median figures, rather than mean, to reduce to the skewing of results from ‘outlier’ opinions of whether an incident contributed to a death leads to an estimate of 1.3% of deaths probably being contributed to by preventable adverse incidents (ie potentially 3,433 deaths, meaning an indicator completeness of 43%).

7.51 The above studies also look at cases where death is potentially contributed to by a preventable adverse incident, which is not necessarily the same thing as a death being caused by a preventable adverse incident, which is what providers are expected to contribute to the NRLS. Detailed results of another study, potentially providing a more definitive estimate of preventable deaths in hospital, is due to be published in the British Medical Journal shortly (Hogan et al, 2012).

7.52 Drawing together these studies suggests that, as with indicator 5a, the reporting rate for this indicator may potentially be an under-estimate of the actual number of patient safety incidents resulting in severe harm or death. The trend in the number of reports received is therefore as likely to reflect changes in reporting behaviour as reflect changes in the amount of harm occurring. This is not surprising given the fact that, as mentioned earlier, incident reporting systems are not designed to report the true number of incidents, but rather gather information on the nature of those incidents to facilitate learning and improvement.

Breakdown by SHA

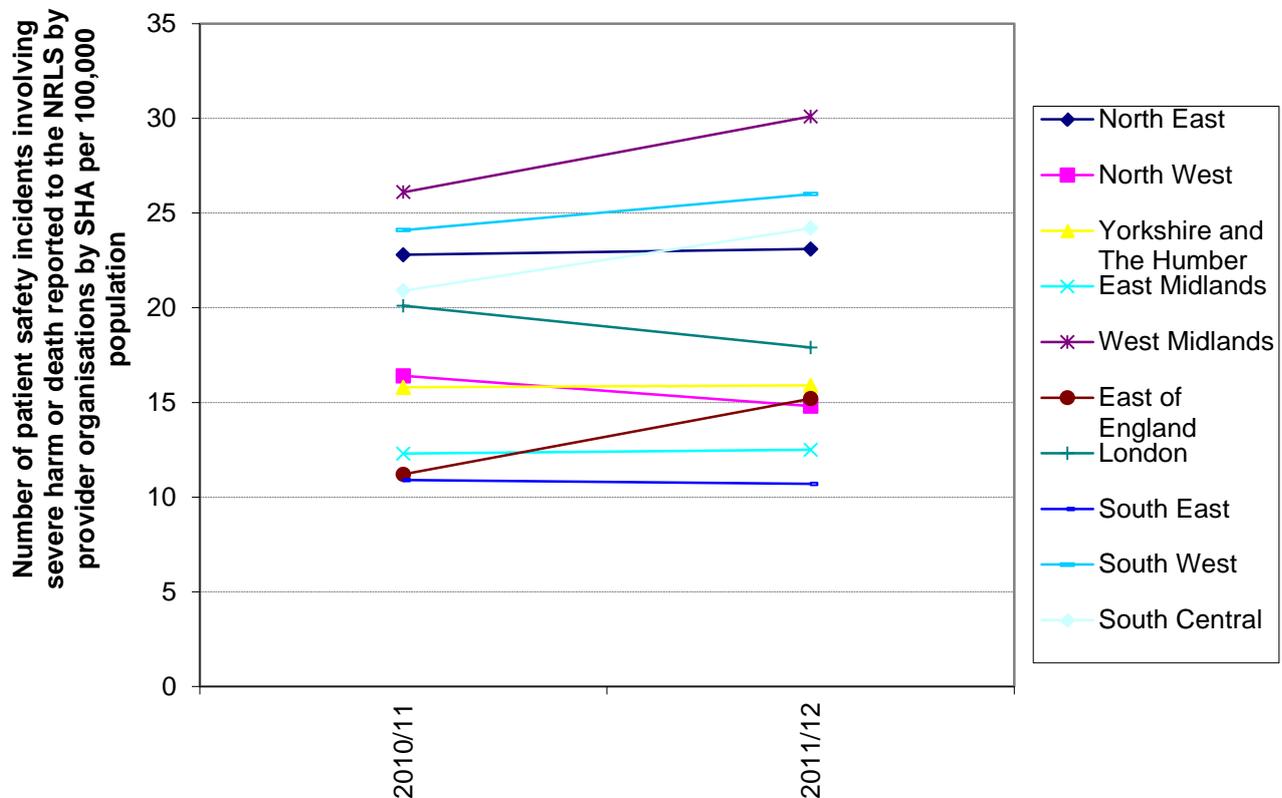
7.53 The reporting rate at SHA level varied almost three-fold in the year ending Q1 2011/12, from around 11 per 100,000 population in South East Coast to around 30 in the West Midlands. There are insufficient data to ascertain trends in reporting rates at regional level.

Table 5b.b Patient safety incidents involving severe harm or death reported to the NRLS by provider organisations by SHA per 100,000 population

| | 2010/11 | 2011/12 |
|--------------------------|---------|---------|
| North East | 22.8 | 23.1 |
| North West | 16.4 | 14.8 |
| Yorkshire and The Humber | 15.8 | 15.9 |
| East Midlands | 12.3 | 12.5 |
| West Midlands | 26.1 | 30.1 |
| East of England | 11.2 | 15.2 |
| London | 20.1 | 17.9 |
| South East | 10.9 | 10.7 |
| South West | 24.1 | 26 |
| South Central | 20.9 | 24.2 |

Source: NRLS

Figure 5b.b Patient safety incidents involving severe harm or death reported to the NRLS by provider organisations by SHA per 100,000 population



International position

7.54 There are no international patient safety indicators that are directly comparable to those in the NHS Outcomes Framework. However, the Office for Economic Co-operation and Development (OECD) and the Agency for Healthcare Research and Quality (AHRQ) have published patient safety indicators to provide an international focus on measuring a range of potentially avoidable adverse events, for instance, covering obstetric trauma and postoperative complications.

Notes:

- Why is the reporting of incidents involving severe harm or death declining relative to overall incident reporting (indicator 5a)?
- Why are reporting levels diverging across regions?

Drivers of this indicator

7.55 The table below describes two types of drivers for indicator 5b. The first type relates to drivers of reporting PSIs, the second relates to drivers of the ‘true’ incident rate, relating to influences on the overall burden of harm associated with PSIs.

| KEY DRIVERS OF REPORTING PSIs | |
|---|---|
| Healthcare need/activity | There is no direct evidence about the effect of healthcare need/activity on reporting, however, an increase in activity associated with an increasing population may have some effect on the overall reporting rate |
| Automating reporting systems | As more medical records become electronic, there will soon be an ability to detect medical errors referred to in clinical notes and e-prescribing systems for example. |
| OTHER DRIVERS (RELATING TO THE ‘TRUE’ INCIDENT RATE) | |
| Chronic Kidney Disease (CKD) | There is evidence that the presence of severe CKD increases the likelihood of adverse patient safety incidents (Seliger et al, 2008). Among a sample of older people, the greatest additional risk was from infection among a group that would otherwise have low mortality rates (Manley et al, 2005) Medication problems can arise in haemodialysis patients particularly those requiring several drugs to treat co-morbidities (Manley et al, 2003; Corsonello et al, 2005). Older hospitalized patients can have impaired renal function despite normal serum creatinine levels and are exposed to an increased risk of adverse drug reactions to water-soluble drugs (Chapin et al, 2010; Hassan et al, 2009). |
| Average age or frailty of population treated | There is a strong correlation between age and adverse patient safety incidents (Ellis et al, 2011). This reflects increasing frailty with age. The transfer of patients from secondary care to home/long term care is an area that can lead to patient safety incidents, especially in the absence of a comprehensive geriatric assessment on admission (Laugaland et al, 2012; Boockvar et al, 2004). The majority of errors seem to be related to medication or adverse drug events, diagnostic test errors, nosocomial infections and falls whilst waiting for transfer (Healey et al, 2008; Schwendimann et al, 2008). |
| Prevalence of comorbidities | There is weak evidence in the literature to relate number of co-morbidities to adverse patient safety incidents, and is linked with the age/frailty driver (Naessens et al, 2012). Adverse safety incidents come in the form of falls, transfer to long term care, poor communication, poly-pharmacy and so on. |

(b) Indicator 5b: Current Practice Projections

7.56 The projections arrived at in Table 5b.c and Figure 5b.c are arrived at via the following methodology:

- A default position that the indicator will remain “flat”.

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- The annual rates are averaged by exponential smoothing (using a damping factor of 0.3), therefore giving greater weight to more recent observations and this exponentially smoothed average is used as the “flat” projection.

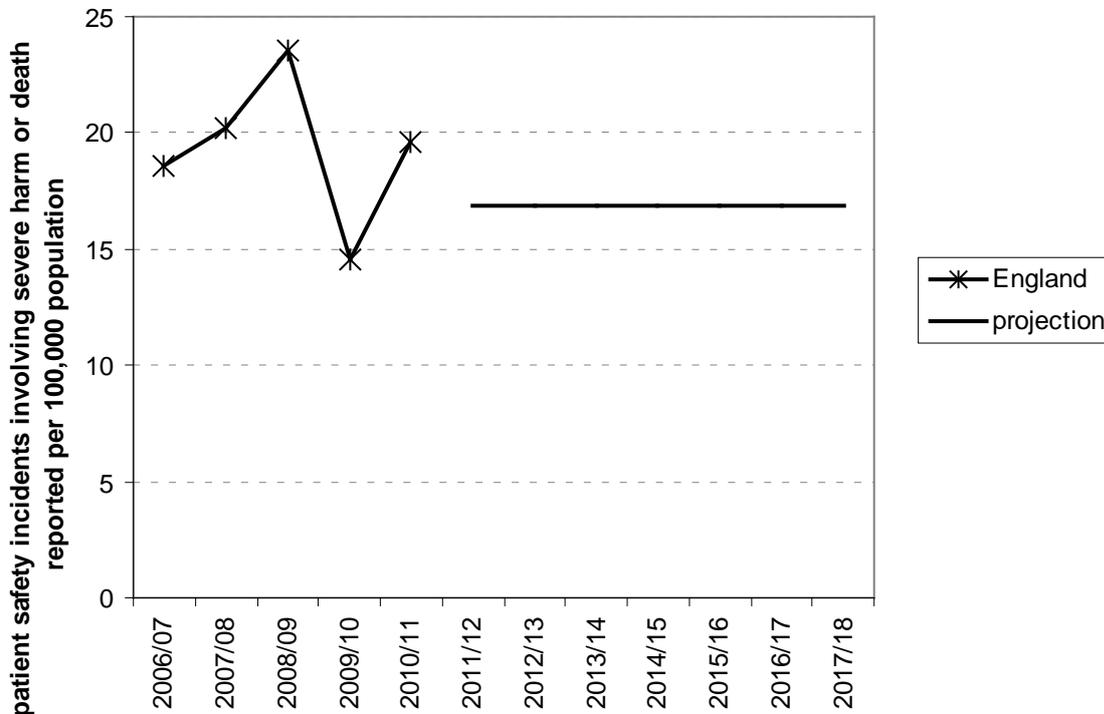
Results

Table 5b.c – Current Practice Projection for: rate of patient safety incidents reported, involving severe harm or death per 100,000 population

| | England | Projection |
|---------|---------|------------|
| 2006/07 | 18.6 | |
| 2007/08 | 20.2 | |
| 2008/09 | 23.5 | |
| 2009/10 | 14.6 | |
| 2010/11 | 19.6 | |
| 2011/12 | | 16.9 |
| 2012/13 | | 16.9 |
| 2013/14 | | 16.9 |
| 2014/15 | | 16.9 |
| 2015/16 | | 16.9 |
| 2016/17 | | 16.9 |
| 2017/18 | | 16.9 |

Source, NRLS, ONS, NHS Information Centre

Figure 5b.c – Current Practice Projection for: rate of patient safety incidents reported, involving severe harm or death per 100,000 population



Source: NRLS, ONS, NHS Information Centre

(c) Indicator 5b: Scope for Improvement

7.57 The scope for improvement in this indicator relates in the first instance to the establishment of a reliable data source for the prevalence of serious safety incidents occurring in all NHS settings.

- CQC registration requirements state that all serious incidents should be reported to them via the NRLS. This has been in place since 2010.
- The Serious Incident Reporting and Learning Framework (SIRL) was introduced in 2010. The framework needs review and updating but also encourages the reporting of serious incidents to the NRLS by providing a nationally consistent definition of a serious incident that requires investigation, setting out roles, responsibilities and drawing together the legal/regulatory framework for managing such incidents.
- It may not be appropriate to use the NRLS, which is designed to encourage reporting and learning, as the metric of accountability for safety, lest ambitions for safety perversely deter reporting. Alternative assessments of safety should be investigated.

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- 7.58 In the absence of reliable estimates of safety incidents, it is not possible to quantify scope for improvement for safety overall. Scope for improvement relates to individual areas of service for which estimates are available – see indicators 5.1-5.3.
- 7.59 Given the evidence presented here, there is a strong argument for developing new ways of measuring the safety of health services. Unsurprisingly, given the fact that the National Reporting and Learning System was not designed to provide an accurate picture of the true number of patient safety incidents, it does not do so. However, data relating to incident reporting to the NRLS does provide an indicator of the development of an improving patient safety culture, particularly if increases in the number of incident reports reflect increasing reporting and disclosure of incidents.
- 7.60 The following is a specific suggestion of an area in which there is scope for improvement in safety. Over time, as reporting and learning increases, it should be possible to build a larger menu of areas in which action can cost-effectively be taken to reduce harm.
- 7.61 Over time, as reporting and learning increases, it should be possible to quantify scope for improvement by building a menu of specific areas of care in which action can cost-effectively be taken to reduce harm

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5.1 – Incidence of healthcare related venous thromboembolism

| | |
|-----------------------|--|
| Outcome sought | Reduced harm from failure to prevent venous thromboembolism (VTE) in a healthcare setting |
| Indicator definition | Incidence of healthcare related VTE |

Background to measuring incidence of VTE

7.62 There are no definitive estimates for the incidence of healthcare related VTE. Options for routinely measuring this indicator include use of Hospital Episode Statistics (HES) and the NHS Safety Thermometer.

7.63 Estimating incidence based on HES data requires an agreed definition of the appropriate clinical coding for VTE. The All-Party Parliamentary Thrombosis Group suggested that the appropriate codes could be agreed by the Academy of Medical Royal Colleges (AoMRC). Although the AoMRC has proposed clinical definitions for VTE, relating to Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT), further work undertaken by NHS South of England for the National VTE Prevention Programme to reconcile these definitions with the codes available within the ICD-10 clinical classification scheme suggests using the following set of codes.

| ICD10 Code | Name |
|------------|---|
| I260 | Pulmonary embolism with mention of acute cor pulmonale |
| I269 | Pulmonary embolism without mention of acute cor pulmonale |
| I800 | Phlebitis/thrombophlebitis superfic vessels low extremities |
| I801 | Phlebitis and thrombophlebitis of femoral vein |
| I802 | Phlebitis/thrombophlebitis oth deep vessels low extremities |
| I803 | Phlebitis and thrombophlebitis of lower extremities, unspec |
| I808 | Phlebitis and thrombophlebitis of other sites |
| I809 | Phlebitis and thrombophlebitis of unspecified site |
| I821 | Thrombophlebitis migrans |
| I822 | Embolism and thrombosis of vena cava |
| I823 | Embolism and thrombosis of renal vein |
| I828 | Embolism and thrombosis of other specified veins |
| I829 | Embolism and thrombosis of unspecified vein |
| O223 | Deep phlebothrombosis in pregnancy |
| O229 | Venous complication in pregnancy, unspecified |
| O871 | Deep phlebothrombosis in the puerperium |
| O87.0 | Superficial thrombophlebitis in the puerperium |
| O87.9 | Venous complication in the puerperium, unspecified |

- 7.64 The NHS Safety Thermometer (NHS ST) is a local improvement tool for measuring, monitoring and analysing patient harms and 'harm free' care. Harm free in this context relates to incidence of four specific harms, including VTE (the remaining three being pressure ulcers, falls and catheter-associated urinary tract infections).
- 7.65 Data are collected via a snapshot audit on one day in each month in a sample of wards within participating healthcare providers. Within this audit, data are collected on 'new VTE' patients. These are patients receiving anticoagulation treatment for treatment of a new clinically documented VTE.
- 7.66 The NHS ST is relatively new. Pilot data were collected through 2011, and these data are based on a skewed sample of participating hospitals that may be those more vigilant in avoidance of VTE than non-participating hospitals. The first set of monthly data for April 2012 was published by the NHS Information Centre in May 2012. Around half of the 323 organisations registered to use the NHS Safety Thermometer submitted data for the April 2012 return. As coverage increases month by month, the reliability of national estimates should improve.
- 7.67 In the interim, extrapolating national incidence figures in this way is likely to be unreliable and the figures should be treated with caution.
- 7.68 The NHS Information Centre plans to publish NHS ST data as 'experimental official statistics' towards the end of 2012.

(a) Indicator 5.1: Recent Trends and Explanations

- 7.69 Data from the NHS Safety Thermometer were published for the first time in May 2012, covering data for April 2012. Around 70,500 patients were surveyed in April 2012, of which around 1.2% were identified as 'new VTE' cases. This is the proportion of patients receiving anticoagulation treatment for treatment of a new clinically documented VTE
- 7.70 A crude estimate of around 98,000 VTE cases per annum nationally would be derived by extrapolating this percentage on the basis of total NHS annual hospital bed days given average length of stay for Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT).
- 7.71 The proportion of beds occupied by VTE sufferers on any day will on average reflect the proportion of total bed days through the year taken by VTE sufferers, and the latter is estimated as incidence times average length of stay divided by total NHS bed days.
- 7.72 However as set out above, extrapolating national incidence figures in this way is likely to be unreliable until coverage improves and the estimate presented here should be treated with caution.

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7.73 On the basis of the VTE-related codes set out above and data recorded for primary and secondary diagnosis in Hospital Episode Statistics, there were around 110,000 cases of VTE in 2010/11.

7.74 Both HES and NHS Safety Thermometer estimates are likely to be under-estimates of the true extent of VTE incidence in hospitals. Stein et al reported an incidence of PE and DVT alone at 1.7% of admissions equivalent to around 253,000 admissions annually if extrapolated from the total of 14.89 million admissions reported annually in HES data for 2010/11.

7.75 Evidence presented to the Health Select Committee included estimates that around 10 – 30% of Medical and General Surgery cases result in DVT (House of Commons Health Committee, 2005). Extrapolating again from HES data on admissions for those estimates alone, suggests between around 360,000 to 1.1 million potential cases.

7.76 These estimates illustrate the degree of uncertainty in ascertaining the ‘true’ incidence of VTE in hospitals

International position

7.77 There are no available international indicators for direct comparison.

Drivers of this indicator

| KEY DRIVERS | |
|-----------------------------|---|
| Obesity | There is considerable evidence of increased risk of VTE in the general population and post-surgery associated with obesity. |
| Diabetes | There is weak evidence of increased risk of VTE associated with those with diabetes aged under 50. |
| Prevalence of comorbidities | There is strong evidence of increased risk of VTE associated with co-morbidities based on studies of people with a range of conditions including cancer and thrombophilias. |

Healthcare contribution

7.78 Contributors include care in prescribing, improving the culture of development and spread of learning from reported incidents, risk assessment on admission, and focused prophylactic care.

(b) Indicator 5.1: Current Practice Projections

7.79 No reliable trend data on hospital-related VTE incidence data is currently available on which to make a projection.

Results

7.80 As a quality improvement tool, the NHS Safety Thermometer may help to embed VTE risk assessment as a core element of care, but is likely to secure progress already made as at national level, providers of NHS acute funded care have reached the 90% goal for risk assessments being carried out.

7.81 The next step is to embed appropriate prophylaxis, which is still thought to be inconsistently applied. The national VTE Programme is planned to continue for at least another year, with strong engagement from key stakeholders including the '4 professions' group of Royal Colleges.

7.82 This will provide drive and leadership to support institutions not yet fully implementing the risk assessment requirements and ensure VTE prevention remains firmly embedded as a core patient safety requirement, building updated requirements in to the system levers such as standard contracts and CQUIN.

7.83 In time, it will be possible to understand and evaluate the emerging data from the first two years of the programme, to get a more accurate national picture of the incidence of avoidable VTE, and the impact of the prevention programme on it.

7.84 The national data collection gives us robust data about risk assessments for VTE, but we do not have similarly robust national data about the incidence of VTE, which would enable more meaningful comparisons between regions or individual trusts to be made.

7.85 Individual trusts have their own data, and the VTE Programme Team are considering how this data can be used reliably to give a national picture. Once we have that we will be able to make an assessment of regional variation and scope for improvement.

7.86 A reduction in the percentage of trusts reaching the 90% risk assessment goal would indicate that basic patient safety checks are being reduced, which may be an early warning of a more general drop in the standard of care.

(c) Indicator 5.1: Scope for Improvement

7.87 Preventing VTE among the inpatient population relies on following the appropriate VTE prevention pathway. Two key elements of this are the risk assessment of all adult inpatients on admission followed by appropriate prophylaxis when increased risk of VTE is indicated by the assessment. This involves assessing against several risk factors including age, obesity, major surgery and significantly reduced mobility for at least three days.

Setting Levels of Ambition for the NHS Outcomes Framework

- 7.88 A national mandatory data collection was introduced in 2010 in support of the national CQUIN goal that 90% of adult inpatients should be risk assessed on admission.
- 7.89 Data for Q3 2011-12 showed that for the first time, at national level, over 90% of adult inpatients were reported to have been risk assessed on admission (90.7%). The national CQUIN goal was confirmed to continue in the 2012-13 NHS Operating Framework, so that incentives remain to at least maintain the 90% risk assessment goal until April 2013.
- 7.90 There is still scope for improvement. For instance, In Q3 2011-12, just under a fifth of providers did not reach the 90% goal. If they had achieved this, an extra 70,000 assessment would have been carried out in that quarter, and the proportion risk assessed would have been 92.9%.
- 7.91 There is also a shortfall in appropriate prophylaxis given to patients identified at increased risk of VTE. NICE guidance on reducing the risk of venous thromboembolism published in 2010 reported research that over 70% of patients at increased risk of VTE did not receive any form of VTE prophylaxis.
- 7.92 A 1992 study of acute care patients indicated that around half of patients had multiple risk factors for VTE – and a fifth had at least three risk factors. Given that 12.6 million adults inpatients were risk assessed in 2011, that would suggest that as many as 2.4 million inpatients annually have at least three risk factors for VTE. If these are considered to be cases of increased risk from VTE, then as many as 1.7 million patients annually may not be receiving appropriate prophylaxis. However, it is not clear how many of these cases are likely to become subsequent VTE cases that can be identified as associated with being in hospital. Further analysis would be required to establish such a baseline.
- 7.93 Reducing the harm associated with VTE is also one of the harms identified within the QIPP Safe Care ‘harmfree’ care campaign. The aim of this campaign is to deliver harm free care as defined by the absence of pressure ulcers, falls, VTE and Catheter Associated –Urinary Tract Infections by December 2012 – expressed as an ambition to eliminate harm from these conditions in 95% of patients. It should be noted that this 95% ‘harm free’ goal is considered to be a stretch ambition rather than being necessarily achievable nationwide.
- 7.94 The scope for improvement in this indicator is based on DH estimates made of the potential level of reduction that could be achieved in VTEs to contribute to the elimination of harm from 95% of patients. The ambition is that a 50% reduction in VTE could be achieved and maintained within two years – ie from 2014/15 onwards. However, this will require further analysis to understand the proportion of VTE incidents and deaths which are actually preventable and therefore what proportion of cases provide realistic scope for successful healthcare intervention. The stretching nature of the 95% goal should also be acknowledged.

7.95 As such there is an expectation that this initiative will lead to improvements in this indicator within current resources.

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5.2.i – Incidence of healthcare associated infection: MRSA bloodstream infections

| | |
|-----------------------|--|
| Outcome sought | Reducing the incidence of avoidable healthcare associated infections (HCAI) |
| Indicator definition | Overall number of cases of MRSA bloodstream infections |

(a) Indicator 5.2.i: Recent Trends and Explanations

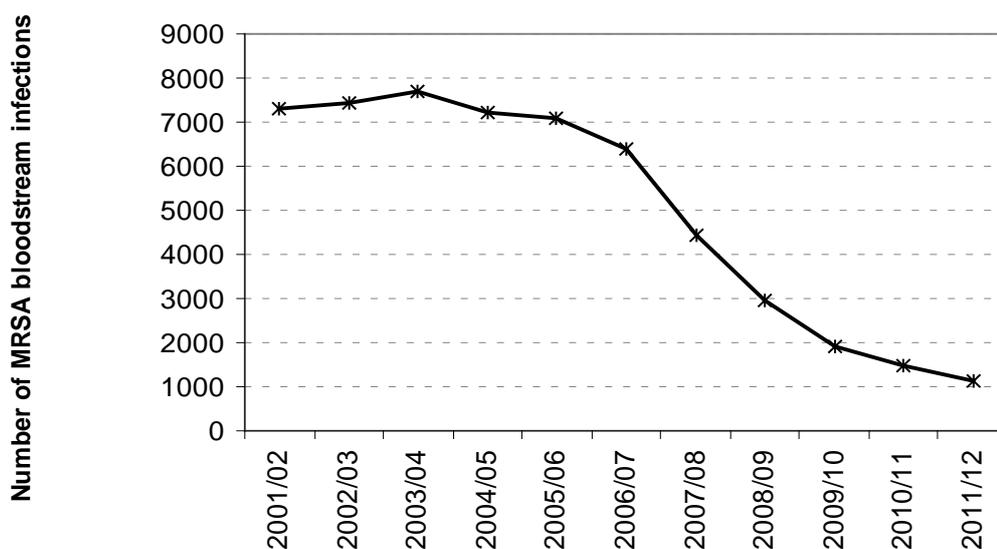
7.96 The overall annual number of cases of MRSA bloodstream infections based on mandatory surveillance data captured by the Health Protection Agency, decreased by around 25% between 2010/11 and 2011/12 from 1,481 to 1,114.

Table 5.2.i.a – Number of MRSA bloodstream infections

| | England |
|---------|---------|
| 2001/02 | 7,291 |
| 2002/03 | 7,426 |
| 2003/04 | 7,700 |
| 2004/05 | 7,233 |
| 2005/06 | 7,096 |
| 2006/07 | 6,383 |
| 2007/08 | 4,451 |
| 2008/09 | 2,935 |
| 2009/10 | 1,898 |
| 2010/11 | 1,481 |
| 2011/12 | 1,114 |

Source: Health Protection Agency

Figure 5.2.i.a – Number of MRSA bloodstream infections



Source: Health Protection Agency

International position

7.97 The NHS in England is now significantly ahead of the rest of the UK, with rates of MRSA bloodstream infections in England less than half those of Scotland, Wales and Northern Ireland.

7.98 Due to different methods of surveillance operated in other countries, it is not possible to make direct comparisons on HCAI performance between England and other overseas countries, apart from Germany which undertakes similar mandatory surveillance for MRSA bloodstream infections as England. The rate in Germany for 2009/10, the latest year for which data is available was 4.2 per 100,000 inhabitants. In the same year, the figure for England was 3.7 per 100,000.

Drivers of this indicator

| KEY DRIVERS | |
|--|---|
| The consistent implementation of evidence based effective infection prevention and control practices | Actions to reduce levels of healthcare associated infections include reducing the risk of infection from medical devices, better antibiotic prescribing, isolating infected patients, environmental cleaning and disinfection and improved hand hygiene |
| Community onset infections | <p>There is moderate evidence that numbers of MRSA bloodstream infections in healthcare settings are influenced by general colonisation rates and the occurrence of community onset infections, but some of these may be linked to previous healthcare</p> <p>Up to 3% of the general population is colonised with MRSA (Office for National Statistics, 2011) and these are asymptomatic carriers of the bacterium in places like anterior nares and armpits.</p> <p>MRSA colonization of nares, either present at admission to the hospital or acquired during hospitalization, increases the risk for MRSA infection. Identifying MRSA colonization at admission could target a high-risk population that may benefit from interventions to decrease the risk for subsequent MRSA infection.</p> |
| Screening of patients on admission to hospital | There is also growing evidence that screening of patients being admitted into hospital for MRSA has helped in reducing the incidences of MRSA bacteraemia and therefore resulted in cost benefits to the hospital. There is a recent study proving the same point (Guleri et al, 2011) |

(b) Indicator 5.2.i: Current Practice Projections Methodology

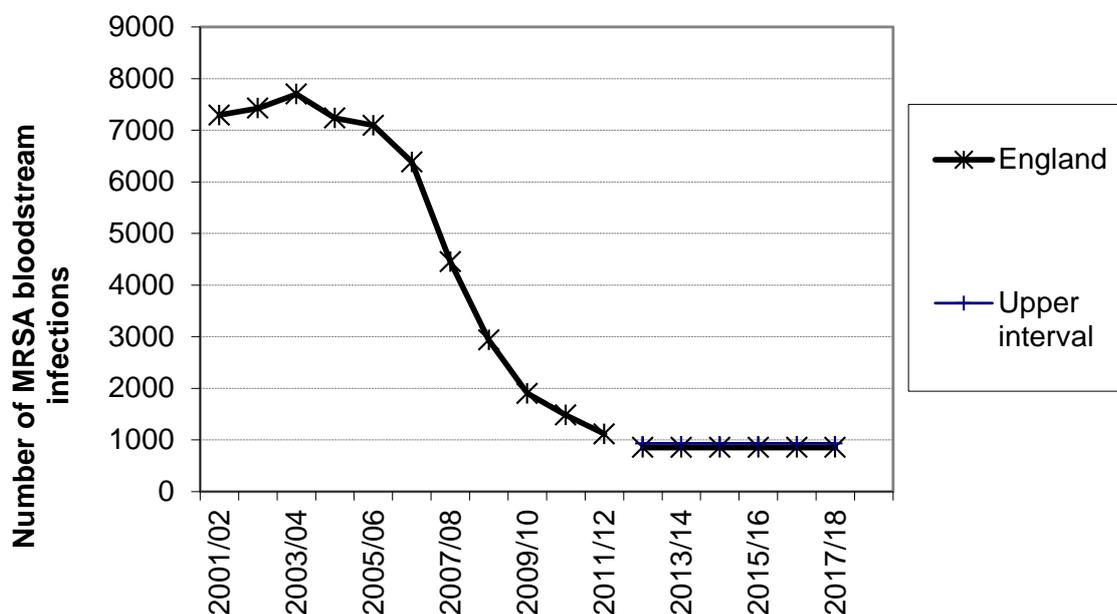
- We assume that the indicator will have maintained recent average annual decreases of 23.4% through 2012/13, calculated as the average percentage change between 2009/10 and the latest data available for 2011/12. Beyond that, we project what would occur if no further action were taken after the current year to reduce healthcare associated infections, ie a flat projection from 2012/13 onwards.
- A Prediction Interval is calculated by assuming in steady state that individual trusts will show variability around a fixed mean approximating a Poisson process and assuming that trusts are independent, as a first approximation that the annual total is itself Poisson.
- The interval is two times the square root of the latest available figure for 2010/11, on the basis of the standard deviation being the square root of the 'mean' for a Poisson process. The upper interval is shown as a potential 'worst case scenario'.

Results

Table 5.2.i.b – Current Practice Projection for: number of MRSA bloodstream infections

| | England | Projection | Upper Interval |
|---------|---------|------------|----------------|
| 2001/02 | 7,291 | | |
| 2002/03 | 7,426 | | |
| 2003/04 | 7,700 | | |
| 2004/05 | 7,233 | | |
| 2005/06 | 7,096 | | |
| 2006/07 | 6,383 | | |
| 2007/08 | 4,451 | | |
| 2008/09 | 2,935 | | |
| 2009/10 | 1,898 | | |
| 2010/11 | 1,481 | | |
| 2011/12 | 1,114 | | |
| 2012/13 | | 853 | 930 |
| 2013/14 | | 853 | 930 |
| 2014/15 | | 853 | 930 |
| 2015/16 | | 853 | 930 |
| 2016/17 | | 853 | 930 |
| 2017/18 | | 853 | 930 |

Figure 5.2.i.b – Current Practice Projection for: number of MRSA bloodstream infections



(c) Indicator 5.2.i: Scope for Improvement

7.99 The MRSA Objective¹ for 2012-13 sets this year’s ambition for the NHS to reduce MRSA bloodstream infections. In 2012-13, the NHS is being asked collectively to reduce the number of MRSA bloodstream infections by 29%. A number of organisations have already achieved many months of zero MRSA bloodstream infections by ensuring they have robust “board to ward” systems in place to implement best practice.

7.100 To deliver the Government’s aspiration for a zero tolerance approach to all avoidable healthcare associated infections, the Department is developing a new approach for the MRSA Objective based on avoidable bloodstream infections across healthcare settings from April 2013. Options are under development and still to be finalised.

7.101 The Department has funded an MRSA screening audit due to report in the summer. The output from this should enable DH to issue updated guidance on MRSA screening which will enable organisations to better target those patients most at risk of MRSA bloodstream infections. We anticipate this more targeted approach will lead to fewer patients being tested and fewer patients with MRSA bloodstream infections.

7.102 There are no substantiated costs associated with achieving the Objective figure. Implementation requires adherence to evidence based good practice.

¹ The Objectives for 2012/13 can be found in the NHS Operating Framework at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132045.pdf

7.103 The Impact Assessment for the NHS Outcomes Framework for 2011-12 (based on the Objective methodology used for that year) produced the following estimated benefits when compared to the baseline 'do nothing' trend:

- Benefit to NHS of avoided treatment cost: £13.8m NPV (Net present value) over 4 years
- Benefit to patients of avoided deaths: £187.3m NPV over 4 years

7.104 If adoption of good practice is costless, the overall net benefit of this ambition is: £201.2m NPV over 5 years (year 0 to year 4)

7.105 The approach taken by the Objective² already seeks to reduce regional variation by setting the greatest level of ambition to those with the highest numbers of MRSA bloodstream infections. The Code of Practice on the prevention and control of infections and related guidance and best practice guidance has been published on by the Department of Health to raise standards across the board and reduce regional variation.

7.106 Improved focus on reducing these infections will lead to savings for the NHS. Improvements to this Indicator should have minimal cost implications. Based on this zero tolerance approach initial quantitative estimates of the scope for improvement are presented in Section 3.

References

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Department of Health (2010). Impact Assessment: NHS Outcomes Framework 2011-12

² Ibid

5.2.ii – Incidence of healthcare associated infection: *C.difficile*

| | |
|-----------------------|--|
| Outcome sought | Reducing the incidence of avoidable healthcare associated infections (HCAI) |
| Indicator definition | Overall number of cases of <i>C.difficile</i> infections |

(a) Indicator 5.2.ii: Recent Trends and Explanations

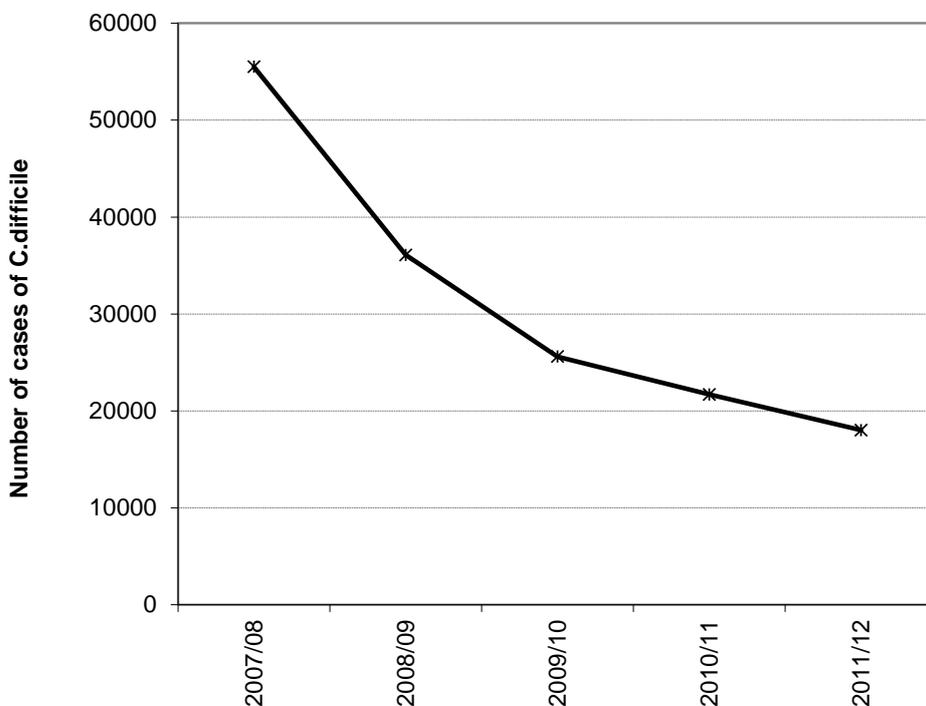
7.107 The overall annual number of cases of *C. difficile* infections (four-quarter rolling totals) based on mandatory surveillance data captured by the Health Protection Agency, decreased by 17% between 2010/11 and 2011/12 from around 21,695 to 18,005.

Table 5.2.ii.a – Number of cases of *C.difficile*

| | England |
|---------|----------------|
| 2007/08 | 55,498 |
| 2008/09 | 36,095 |
| 2009/10 | 25,604 |
| 2010/11 | 21,695 |
| 2011/12 | 18,005 |

Source: Health Protection Agency

Figure 5.2.ii.a – Number of cases of *C.difficile*



Source: Health Protection Agency

International position

7.108 Due to different methods of surveillance operated in other countries, it is not possible to make meaningful comparisons on *C.difficile* performance between England and other countries.

Drivers of this indicator

| KEY DRIVERS | |
|--|---|
| The consistent implementation of evidence based effective infection prevention and control practices | Actions to reduce levels of healthcare associated infections include reducing the risk of infection from medical devices, better antibiotic prescribing, isolating infected patients, environmental cleaning and disinfection and improved hand hygiene |
| Community onset infections | <p>There is moderate evidence that numbers of MRSA bloodstream infections in healthcare settings are influenced by general colonisation rates and the occurrence of community onset infections, but some of these may be linked to previous healthcare</p> <p>Up to 3% of the general population is colonised with MRSA (Office for National Statistics, 2011) and these are asymptomatic carriers of the bacterium in places like anterior nares and armpits.</p> <p>MRSA colonization of nares, either present at admission to the hospital or acquired during hospitalization, increases the risk for MRSA infection. Identifying MRSA colonization at admission could target a high-risk population that may benefit from interventions to decrease the risk for subsequent MRSA infection.</p> |
| Screening of patients on admission to hospital | There is also growing evidence that screening of patients being admitted into hospital for MRSA has helped in reducing the incidences of MRSA bacteraemia and therefore resulted in cost benefits to the hospital. There is a recent study proving the same point (Guleri et al, 2011) |

(b) Indicator 5.2.ii: Current Practice Projections Methodology

7.109 The projections were obtained by employing the following methodology:

- We assume that the indicator will have maintained recent decreases of 16.1% through 2012/13, calculated as the average annual percentage change between 2009/10 and the latest available data for 2011/12. Beyond that it is thought that the indicator will have maintained recent average annual decreases of 15% (calculated on annual figures from 2007/08 onwards) at least through 2012/13. Beyond that, we project what would occur if no further action were taken to reduce healthcare associated infections, ie a flat projection from 2012/13 onwards.
- A Prediction Interval is calculated by assuming in steady state that individual trusts will have show variability around a fixed mean approximating a Poisson process and assuming that trusts are independent, as a first approximation that annual total is itself Poisson.
- The interval is two times the square root of the latest available figure for 2010/11, on the basis of the standard deviation being the square root of the 'mean' for a Poisson process. The upper interval is shown as a potential 'worst case scenario'.

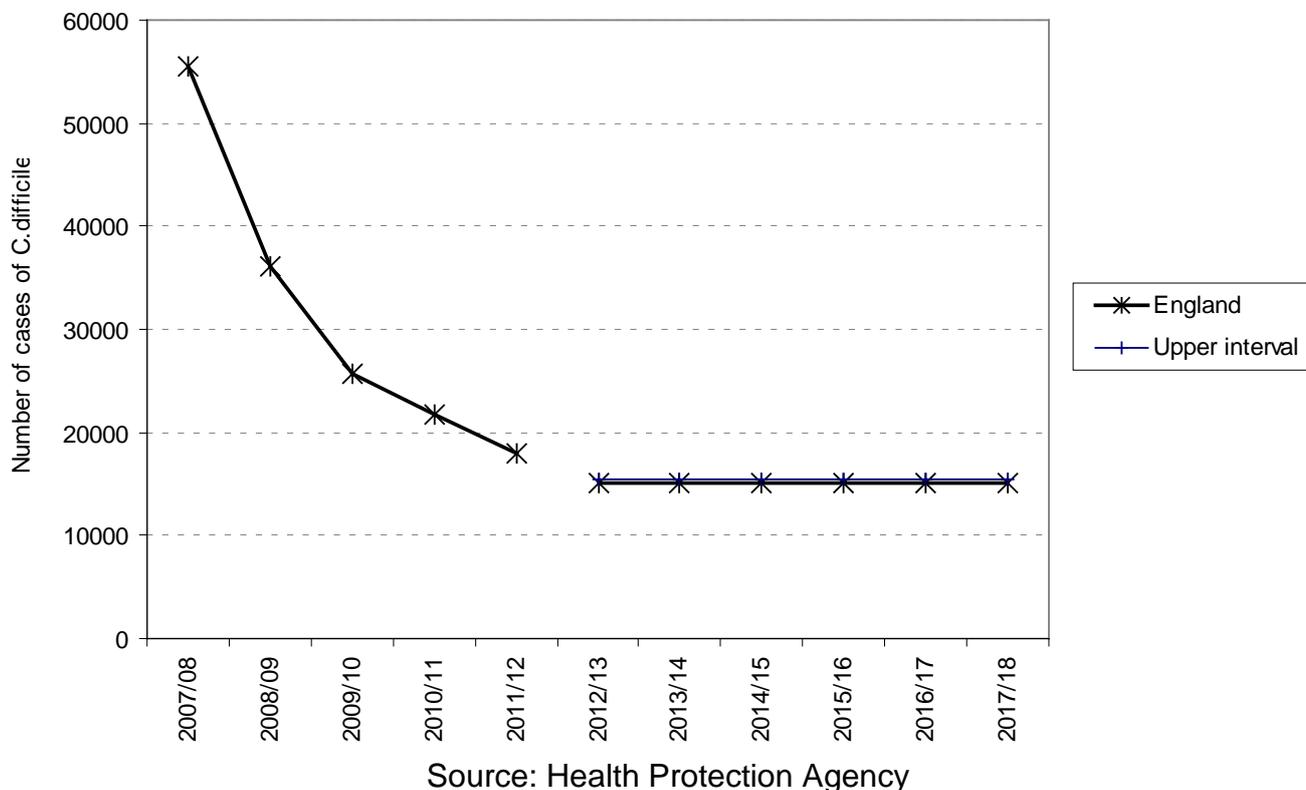
Results

Table 5.2.ii.b – Current Practice Projection for: number of cases of C.difficile

| | England | Projection | Upper interval |
|---------|---------|------------|----------------|
| 2007/08 | 55,498 | | |
| 2008/09 | 36,095 | | |
| 2009/10 | 25,604 | | |
| 2010/11 | 21,695 | | |
| 2011/12 | 18,005 | | |
| 2012/13 | | 15,106 | 15,401 |
| 2013/14 | | 15,106 | 15,401 |
| 2014/15 | | 15,106 | 15,401 |
| 2015/16 | | 15,106 | 15,401 |
| 2016/17 | | 15,106 | 15,401 |
| 2017/18 | | 15,106 | 15,401 |

Source: Health Protection Agency

Figure 5.2.ii.b – Current Practice Projection for: number of cases of C.difficile



(c) Indicator 5.2.ii: Scope for Improvement

7.110 The *C. difficile* Objective for 2012-13 sets out this year’s ambition for the NHS to reduce *C. difficile* infections. In 2012-13, the NHS is being asked collectively to reduce the number of *C. difficile* infections by 17% (over the baseline period).

7.111 In April 2012, updated guidance on the testing for *C. difficile* infections was introduced to increase accuracy of reporting cases and reduce the number of patients without the disease being diagnosed as having the infection (false positives) and isolation bed space (previously taken up unnecessarily) will be freed up. This will result in savings to the NHS and clinicians will be able to treat those with *C. difficile* infection better.

7.112 Trusts are expected to be more effective in the work they already do and to prioritise resources appropriately and the continued downward trend in *C. difficile* infections indicates the NHS is getting progressively better. There is, therefore, no need for substantial additional activity that would require an increase in staffing levels.

7.113 The Impact Assessment for the NHS Outcomes Framework for 2011-12 estimated that an additional 168 additional staff would be required at a cost of £7.5 million per annum,

but these costs would be far exceeded by the savings to the NHS of avoided treatment costs and benefits to patients of avoided deaths.

- 7.114 The Impact Assessment estimated benefits (based on the level of ambition set for 11-12) when compared to the baseline 'do nothing' trend:
- Benefit to NHS of avoided treatment cost: £142.3m NPV
 - Benefit to patients of avoided deaths: £162.1m NPV
 - Cost of delivering these benefits: £27.5m NPV
 - Net overall benefit (4 years NPV): £276.9m
- 7.115 The approach taken by the Objective already seeks to reduce the regional variation in performance by setting the greatest level of ambition to those with the highest numbers. We have also made available best practice on infection prevention and control through the Code of Practice on the prevention and control of infections and related guidance and best practice guidance on www.hcai.dh.gov.uk.
- 7.116 Although *C. difficile* infections are at their lowest level since mandatory surveillance was introduced in 2004, there is scope to reduce regional variation in performance and to drive further improvements within existing resources. As the cost of treating a patient with *C. difficile* infection is around £10,000, this could lead to savings to the NHS in avoided treatment costs.
- 7.117 It should be noted however, that more than half of the *C. difficile* infections reported by acute trusts are community on-set cases. Work is underway to get a better understanding of the source of these infections and the interventions necessary to reduce the numbers of these cases. The output of this work will inform the proposed approach to setting the ambition for *C. difficile* Objective in 2013-14
- 7.118 Improved focus on reducing these infections will lead to savings for the NHS or be cost neutral.
- 7.119 If reductions in the efficiency of the way the NHS delivers healthcare impact negatively on infection prevention and control practices - this could lead to increases in the numbers of *C. difficile* infections.
- 7.120 While all tiers of the healthcare system are involved to some degree, the extent of their individual roles is unknown and is an area where we need better intelligence. To date the focus has been on reducing cases in hospital settings, without taking account of the reason for admission or who had referred them and from what environment. Going forward it will be important that all sectors of the healthcare system fulfil their role and effectively monitor, report, prevent and manage HCAI.

7.121 The Department of Health's Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infections has been asked to consider and offer advice to the Department on:

- Actions that might be expected to deliver the greatest benefit in terms of reducing *C. difficile* infections; and
- Whether it is possible to determine the irreducible minimum *C. difficile* infection level achievable in the primary and secondary healthcare settings.
- Based on a continued focus on reducing *C-difficile* infections initial quantitative estimates of the scope for improvement are presented in section 3.

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Department of Health (2010). Impact Assessment: NHS Outcomes Framework 2011-12

5.3 – Incidence of newly acquired category 2,3 and 4 pressure ulcers

| | |
|-----------------------|--|
| Outcome sought | Reduced harm associated with newly acquired pressure ulcers |
| Indicator definition | Incidence newly acquired category 2,3 and 4 pressure ulcers |

(a) Indicator 5.3: Recent Trends and Explanations

- 7.122 Options for routinely measuring this indicator include the potential use of the NHS Safety Thermometer and Hospital Episode Statistics.
- 7.123 Data from the NHS Safety Thermometer were published for the first time in May 2012, covering data for April 2012. Around 70,500 patients were surveyed in April 2012, of which around 1.8% were identified as ‘new pressure ulcer’ cases. This is the proportion of patients with a new pressure ulcer not present on admission or developed within 72 hours, of category 2, 3 or 4, on the day of the survey.
- 7.124 Based on total bed days reported in Hospital Episode Statistics and average length of stay of around 4.3 days (as a minimum figure based on excess length of stay (Graves et al, 2005), this would result in a crude estimated incidence of around 216,000 category 2, 3 or 4 pressure ulcers annually.
- 7.125 However, these data are based on a skewed sample of participating hospitals that may be those more vigilant in avoidance and reporting of pressure ulcers than non-participating hospitals. Around half of the 323 organisations registered to use the NHS Safety Thermometer submitted data for the April 2012 return. As coverage increases month by month, the reliability of national estimates should improve.
- 7.126 In the interim, extrapolating national incidence figures in this way is likely to be unreliable and these figures should be treated with caution.
- 7.127 Evidence from the NHS Institute for Innovation and Improvement suggests that new pressure ulcers are estimated to occur in 4 – 10% of patients admitted to hospitals in the UK, with one study putting the figure at around 20% (Clark et al, 2004).
- 7.128 By extrapolating the lower range based on Hospital Episode Statistics, this results in an estimate of around 600,000 to 1.5 million new pressure ulcers in hospitals annually – up to 10 times higher than the estimate based on NHS Safety Thermometer data.
- 7.129 These figures will include category 1 pressure ulcers, which are not included in this indicator.

International position

- 7.130 There are no available international indicators for direct comparison.

Drivers of this indicator

| KEY DRIVERS | |
|-----------------------------|--|
| Diabetes | There is debate as to whether diabetic foot ulcers and pressure ulcers are the same entity (Ousey, Chadwick and Cook, 2011). Diabetic ulcers may involve pressure and shearing in their pathogenesis. NICE (2005) does not specifically mention diabetes as a risk factor for developing pressure ulcers. Diabetes is a risk factor for development of peripheral vascular disease (NICE, 2004), which is a recognised risk factor for pressure ulcers (NICE, 2005). Diabetes can also cause peripheral neuropathy, which can lead to ulceration (NICE, 2004; Nonnemacher et al, 2009). |
| Prevalence of comorbidities | Acute and chronic illness are both identified as linked to incidence of pressure ulcers by NICE (2005) A cohort study by Margolis, Knauss, Bilker and Baumgarten (2003) identified a large number of medical co-morbidities as being associated with development of pressure ulcers in outpatients. This is also supported by other studies (Pieper and Weiland, 1997). Olsen et al (1996) identify anaemia as being associated with pressure ulcers, which can be a component of many co-morbid illnesses. Decreased mental awareness, identified by NICE (2005) as a risk factor, could be considered under this category, as co-morbidities such as dementia and delirium will contribute to a reduced awareness. |
| Vascular disease | This is identified by NICE (2005) as being a major risk factor for the development of pressure ulcers. |
| Nursing care | This includes a number of specific interventions, such as use of surface supports, repositioning, incontinence exercises and treatment, interventions targeting impaired nutrition and interventions targeting impaired skin health. A Cochrane review of an original systemic review concluded at best weak evidence for each of these (Reddy, Gill and Rochon, 2006). Systemic review by Soban et al (2011) suggests that quality improvements in nursing care can positively impact on development of pressure ulcers. Incontinence of faeces and urine is specifically identified as being associated with incidence of pressure ulcers (NICE, 2005). Malnutrition and dehydration are identified by NICE (2005) and Nonnemacher et al (2009) as being a risk factor for developing pressure ulcers. This could most effectively be modified by improved nursing care. |

| | |
|----------------------|---|
| Mobility | Reduced mobility or immobility is identified as a risk in both the NICE (2005) guidelines. There may be some overlap with nursing care, as nurses play a key role in mobilising the patient groups who are susceptible to pressure ulcers (Amidei, 2012). |
| Sensory deficits | Sensory deficits are identified in the NICE (2005) guidelines as having an association with the development of pressure ulcers. |
| OTHER DRIVERS | |
| Obesity | Prospective cohort study by Compher (2007) suggests that obesity reduces risk of developing pressure sores. |

(b) Indicator 5.3: Current Practice Projections

7.131 No reliable trend data on pressure ulcer incidence data is currently available on which to make a projection.

(c) Indicator 5.3: Scope for Improvement

7.132 Reducing the harm associated with pressure ulcers is one of the harms identified within the QIPP Safe Care 'harmfree' care campaign. The 'harmfree' care aim is to deliver harm free care as defined by the absence of pressure ulcers, falls, VTE and CA-UTI by December 2012 – expressed as an ambition to eliminate harm from these conditions in 95% of patients.

7.133 The scope for improvement in this indicator builds on DH assumptions made as part of analytical work to support the QIPP Safe Care workstream that an 80% reduction in hospital-associated pressure ulcers could be achieved and maintained within two years – ie from 2014/15 onwards. This is a stretch ambition for those organisations signed up to the 'harmfree' care campaign.

7.134 As such there is an expectation that this initiative will lead to improvements in this indicator within current resources.

7.135 'High Impact Actions' and 'Energising for Excellence,' two quality improvement campaigns which will be led by the Patient Safety Function of the NHS Commissioning Board Authority and have a centre and sector focus, also include actions to improve pressure ulcer incidence.

7.136 There is scope for improving NHS efficiency at zero cost in relation to pressure ulcer prevention and there are examples of best practice already existing.

7.137 In Wales some areas have achieved hundreds of pressure ulcer free days through the use of patient safety crosses, turning patients and intentional rounding. Some hospitals

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in England have applied the same methods with success and South Central's No Needless Skin Damage workstream have applied these methods across the region, again with some examples of success and suggests some reductions can be achieved with no cost in terms of new equipment or system change.

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5.4 – Incidence of medication errors causing serious harm

| | |
|-----------------------|--|
| Outcome sought | Reducing serious harm caused by medication errors |
| Indicator definition | Patient safety incidents reported to the National Reporting and Learning Service (NRLS), where degree of harm is recorded as severe harm or death, and incident type is 'medication' by provider organisations in England, per 10,000 population |

(a) Indicator 5.4: Recent Trends and Explanations

7.138 This indicator is a sub-indicator of 5b – ie those PSIs reported under 5b for which the incident type is 'medication'.

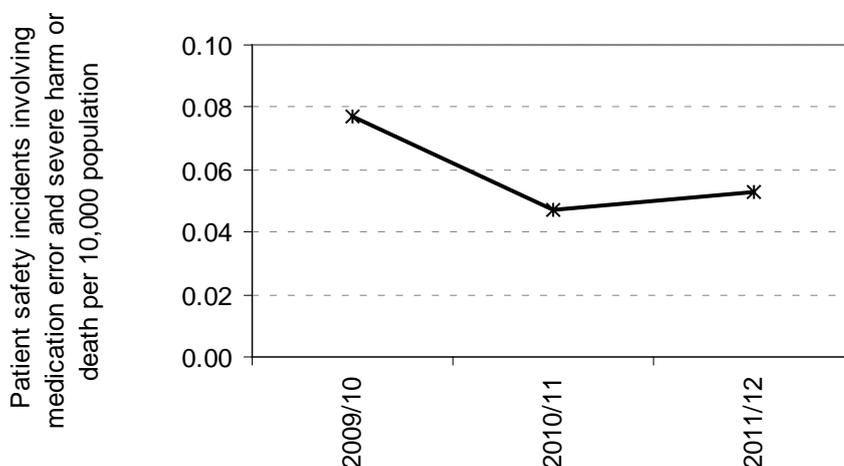
7.139 The reported rate of patient safety incidents (PSIs) involving medication error resulting in severe harm or death remained unchanged at 0.05 per 10,000 population, between 2009/10 and 2010/11, having decreased from 0.08 in 2008/09. The rate is based on a relatively small proportion of the overall number of reported PSIs - 261 such incidents were reported in 2010/11 out of the total of 1.15 million reported PSIs.

Table 5.4.a – Patient safety incidents, of type 'medication' severe harm or death reported to the NRLS by provider organisations in England (per 10,000 population)

| | England |
|---------|---------|
| 2008/09 | 0.08 |
| 2009/10 | 0.05 |
| 2010/11 | 0.05 |

Source: NRLS, ONS, NHS Information Centre

Figure 5.4.a – Patient safety incidents, of type 'medication' resulting in severe harm or death reported to the NRLS by provider organisations in England (per 10,000 population)



Source: NRLS, ONS, NHS Information Centre

7.140 The trend is difficult to interpret and significant changes may be difficult to detect on the basis of the relatively small numbers involved. Further analysis of the data to understand the trends in reporting medication errors of all degrees of harm (including no harm) is likely to be required to help understand the trends in this indicator.

Completeness of reporting PSIs involving medication error and severe harm or death

7.141 The underlying trend in reporting medication errors varies by degree of harm. There was a substantial increase in reporting of medication errors involving 'no harm' from around 70,000 to 110,000 between 2008/09 and 2010/11. In the same period medication errors involving severe harm or death decreased from 397 to 261.

7.142 In the same period the ratio of reports involving no harm to those with any degree of harm has increased from around 4:1 to 6:1 during that time.

7.143 It is not clear why overall levels of reporting medication errors should have increased so significantly while the proportion (and number) involving severe harm or death have decreased.

7.144 This suggests that as with overall incident reporting, this indicator currently reflects an under-estimate of the actual levels of harm associated with medication errors.

International position

7.145 There are no available international indicators for direct comparison.

Drivers of this indicator

| KEY DRIVERS | |
|---|--|
| Healthcare need/activity | There is no direct evidence about the effect of healthcare need/activity on reporting, an increase in activity associated with an increasing population may have some effect on the overall reporting rate |
| Changes to IT systems supporting automated or easier incident reporting | As more medical records become electronic, there will soon be an ability to detect medical errors referred to in clinical notes and e-prescribing systems for example. |
| OTHER DRIVERS (RELATING TO THE 'TRUE' INCIDENT RATE) | |
| Chronic Kidney Disease (CKD) | Medication problems can arise in haemodialysis patients particularly those requiring several drugs to treat co-morbidities (Manley et al, 2003; Corsonello et al, 2005). Older hospitalized patients can have impaired renal function despite normal serum creatinine levels and are exposed to an increased risk of adverse drug reactions to water-soluble drugs |

| | |
|--|--|
| | (Chapin et al, 2010; Hassan et al, 2009). However, the evidence does not allude to a specific link with serious patient safety incidents, but with patient safety more generally. |
| Average age or frailty of population treated | Various patient safety incidents such as medication or or adverse drug events, diagnostic test errors, nosocomial infections and falls whilst waiting for transfer are associated with increasing risk with increasing age (Healey et al, 2008; Schwendimann et al, 2008). |
| Diabetes | Several studies report medical mishandling of insulin which might be categorised as a “medication error” (Hellman, 2001; Hellman, 2004; Taub et al, 2010; Milligan et al, 2011, Ben-Ami, et al, 1999).The NPSA issued a patient safety alert in March 2011 regarding the safe administration of insulin to patients. |

(b) Indicator 5.4: Current Practice Projections Methodology

7.146 The projection is derived by employing the following methodology:

- A default position that the indicator will remain “flat. There is insufficient data or evidence available to assume any increasing or decreasing trend..
- The annual rates are averaged by exponential smoothing (using a damping factor of 0.3), therefore giving greater weight to more recent observations; this exponentially smoothed average is used as the “flat” projection.

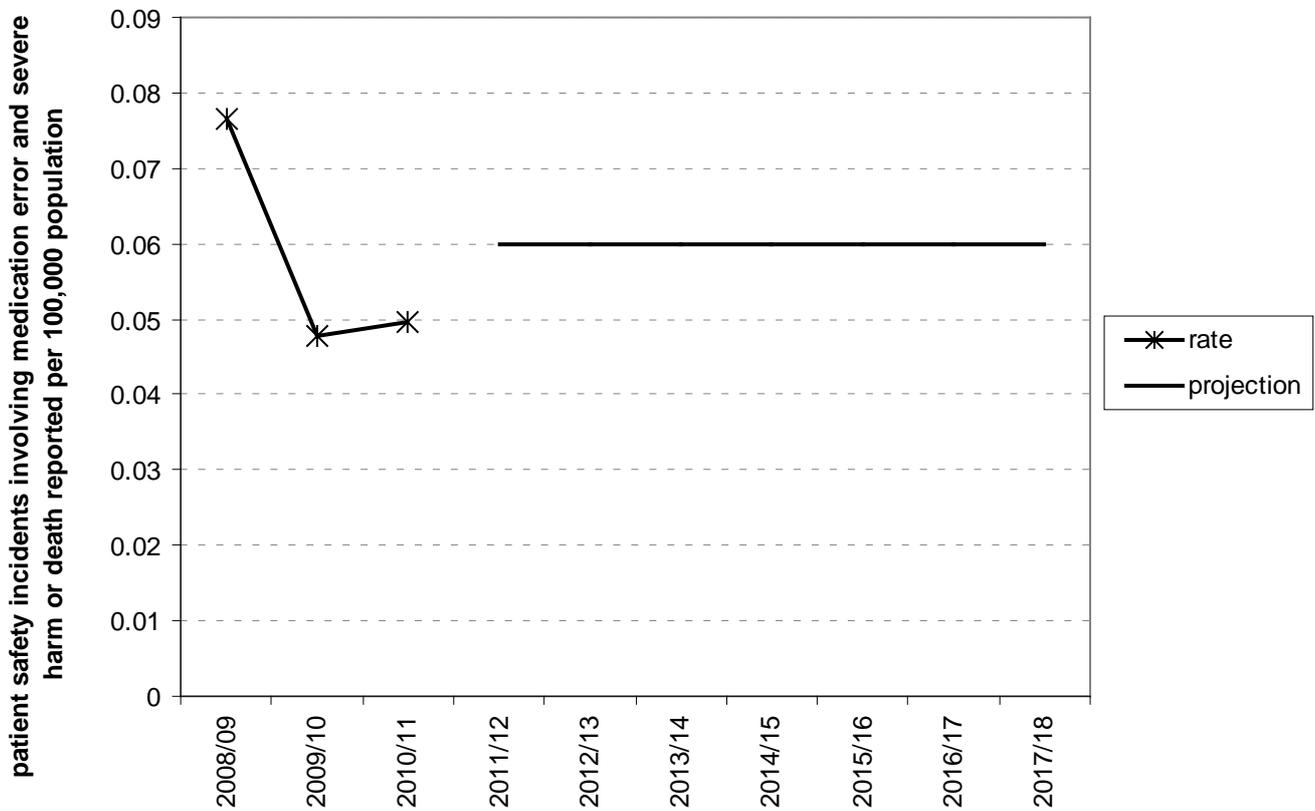
Results

Table 5.4.b – Current Practice Projection for: rate of patient safety incidents reported, of type ‘medication’ resulting in severe harm or death per 10,000 population

| | England | Projection |
|---------|---------|------------|
| 2008/09 | 0.08 | |
| 2009/10 | 0.05 | |
| 2010/11 | 0.05 | |
| 2011/12 | | 0.06 |
| 2012/13 | | 0.06 |
| 2013/14 | | 0.06 |
| 2014/15 | | 0.06 |
| 2015/16 | | 0.06 |
| 2016/17 | | 0.06 |
| 2017/18 | | 0.06 |

Source: NRLS, ONS, NHS Information Centre

Figure 5.4.b – Current Practice Projection for: rate of patient safety incidents reported, of type ‘medication’ resulting in severe harm or death per 10,000 population



Source: NRLS, ONS, NHS Information Centre

(c) Indicator 5.4: Scope for Improvement

7.147 There are a number of initiatives that could affect this indicator:

- Taunton & Somerset NHS Foundation Trust are engaged an initiative to decrease missed doses and improve patient safety and outcomes
- The Royal Pharmaceutical Society initiative. Keeping patients safe when they transfer between care providers – getting the medicines right A guide for all providers and commissioners of NHS services.

7.148 A recent analysis of 526,186 medication incidents reported to the National Reporting and Learning System between January 2005 – December 2010 (Cousins et al, 2011) identified 822 reports of death and serious harm. Many recent incidents could have been prevented if the NPSA guidance had been better implemented. It is recommended that healthcare organisations in all sectors establish an effective infrastructure to

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oversee and promote safe medication practice, including an annual medication safety report.

- 7.149 The new EU Directive on measures to minimise counterfeiting of medicines will require greater use of bar code technology when dispensing medicines. It is important to ensure that full use is made of this of this technology to also minimise dispensing errors and release pharmacists from product checking duties to spend more time on clinical duties ensuring the safety and effectiveness of medicines use.
- 7.150 The new medicines and medicines use review services in the community pharmacy contract will help improve clinical effectiveness and reduce the incidence of preventable harms from medicines.

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5.5 – Admission of full-term babies to neonatal care

| | |
|-----------------------|--|
| Outcome sought | Safe delivery of babies |
| Indicator definition | Proportion of all term babies (≥ 37 weeks gestation) admitted to neonatal care |

(a) Indicator 5.5: Recent trends and explanations

7.151 Data on admissions of babies to neonatal care is not sufficiently robust prior to 2008. The NHS Information Centre is reviewing the quality of the data for the numerator compared to the denominator for this indicator and will shortly re-calculate a figure for this indicator for 2009.

7.152 This will provide the baseline datapoint for this indicator. Data for 2010 are expected to be available later this year.

Drivers of this indicator

| KEY DRIVERS | |
|----------------------|---|
| Multiple birth rates | There is clear evidence for increasing risk (Ross et al, 1989; Tracey et al, 2007) with multiple births. Multiple births have increased delivery complication rates. Admissions would drop rapidly if multiple birth rates were to fall (within a year or so). |
| Number older mothers | Advanced maternal age increases the requirement for neonatal intensive care unit admission (NICU) (Yuksel et al, 1996; Battin et al, 2007) (and this effect is enhanced by smoking). Babies of older mothers have increased risk of fetal malformations and syndromes. A reduction in the number of older mothers having children would result in a reduction of admission to NICU. This would probably take 3-5 years to have a noticeable effect as the definition of 'older' is difficult to define and so effects are likely to be spread out. |
| Type of delivery | There is an increased risk of admission following caesarean section (Fallah et al, 2011; Tracey et al, 2007). A reduction in the number of caesarean sections would reduce admission rates in a short time frame (a year or so). As part of a long-term upward trend of caesarean deliveries, the proportion of elective and emergency caesarean deliveries has been relatively stable over the last few years. There were slight increases from 9.5% and 14.6% in 2006 to 9.8% and 14.8% in 2009 for elective and emergency deliveries, respectively, of total deliveries. |
| OTHER DRIVERS | |
| Alcohol | While it is difficult to find evidence directly citing a relationship between |

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| | |
|---------------------------------------|--|
| consumption | alcohol consumption and admissions to neonatal care, there is likely to be an association with increased fetal malformation, but potentially not very strong association. |
| Drug use | Newborns who were exposed to maternal drug use can suffer opiate withdrawal symptoms, for which admission to a NICU is sometimes required. There is evidence of association between drug use and increased NICU admissions (Hayatbakhsh et al, 2012). |
| Ethnicity | Effects are mediated by associations and there is no obvious direct relationship (Neonatal Intensive Care Unit, 2010; Ruan et al, 2011) |
| Health of mother and co-morbidities | There is increased risk for mothers with pre-eclampsia and placenta praevia (Ross et al, 1989) |
| Incidence of congenital abnormalities | There is some evidence for increased risk (Lindower, 1999) |
| Midwife or consultant led care | Although the Dutch system is different from the UK, a large cohort study found NICU admission rates did not differ between pregnancies supervised by a midwife and those supervised by an obstetrician (Evers et al, 2010). Infants of women who were referred by a midwife to an obstetrician during labour had a 3.66 times higher risk of delivery related perinatal death than did infants of women who started labour supervised by an obstetrician (relative risk 3.66, 1.58 to 8.46) and a 2.5-fold higher risk of NICU admission (2.51, 1.87 to 3.37). |
| Number of pregnancies | In one large cohort study, nulliparous women had a significantly higher risk than did multiparous women of their child being admitted to the NICU (8.03 (6.67 to 9.38) v 3.67 (2.85 to 4.49) per 1000 live births; relative risk 2.19, 1.65 to 2.89) (Ever et al, 2010) |
| Number of younger mothers | It is likely the increased neonatal mortality seen in this group translates into increased NICU admission. To what extent this occurs for term infants is not completely clear. |
| Obesity | Obesity is associated with increased delivery complication rates. |
| Smoking | There are mixed reports in this area. Studies exist showing association (Adams et al, 2002) but also (from the same author) no association (Adams et al, 2011), this is replicated by other groups (Donaldson et al 2008). |
| Socio-economic status | It is likely that although low socio-economic status increases admissions to NICU, this is through the other associated effects of prematurity, such as being small for gestational age. Evidence for this being an independent driver was difficult to find (Jenkins et al, 2009) |

Healthcare contribution

7.153 Improvements in the quality and safety of antenatal and intrapartum care.

Sources of bias

7.154 This indicator may be biased as a representation of the outcome sought to the extent that babies brought to term require planned admission to neonatal care. Low birth weight is a key determinant of this outcome for which public health factors such as smoking, alcohol and illicit drug use, nutrition and obesity in the mother are significant risk factors.

7.155 Following a review of the drivers since the publication of the NHS Outcomes Framework 2012/13 – Technical Appendix, the extent to which women choose to terminate pregnancies has been removed as a driver, while alcohol consumption, drug use, ethnicity, health of mother and co-morbidities, midwife or consultant led-care, number of pregnancies, number of younger mothers, obesity, smoking, socio-economic status and type of delivery were added as drivers.

(b) Indicator 5.5: Current Practice Projections

7.156 Current practice projections will be constructed once the baseline 2009 figure for this indicator has been recalculated.

(c) Indicator 5.5: Scope for Improvement

7.157 This section considers the scope for potential improvements attributable to safety aspects of maternity care leading to admission of full-term babies to neonatal care.

7.158 The two key safety issues under consideration are

- the use and interpretation of electronic fetal heart monitoring (CTG), which can result in intrauterine hypoxia and birth asphyxia, and
- failure to investigate, intervene or provide adequate monitoring in labour for intrauterine growth restriction.

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7.159 In relation to hypoxia and asphyxia, the table below indicates the overall number of such cases between 2006/07 and 2010/11:

| | Intrauterine hypoxia (ICD-10 = P20) | Birth asphyxia (ICD-10 = P21) | Intrauterine hypoxia | Birth asphyxia | Number of live births (NHS hospitals) | Percentage of births with hypoxia or asphyxia |
|---------|-------------------------------------|-------------------------------|----------------------|----------------|---------------------------------------|---|
| 2006/07 | 29,355 | 5,191 | 4.7 | 0.8 | 635,930 | 5.4 |
| 2007/08 | 26,356 | 5,085 | 4.1 | 0.8 | 635,370 | 4.9 |
| 2008/09 | 27,966 | 5,162 | 4.3 | 0.8 | 654,936 | 5.1 |
| 2009/10 | 27,713 | 5,757 | 4.2 | 0.9 | 656,406 | 5.1 |
| 2010/11 | 30,104 | 5,713 | 4.4 | 0.8 | 676,854 | 5.3 |

7.160 These data relate to all births, not just those relating to full-term births. Although there is no evidence of an association between hypoxia/asphyxia and gestational age, further analysis would be required to understand this more fully.

7.161 On the basis of this data, the overall trend in the percentage of births with hypoxia or asphyxia is broadly flat between 2006/07 and 2010/11.

7.162 To understand the potential scope for improvement, it is important to recognise that not all of the birth complications for hypoxia and asphyxia will be due to a lack of fetal heart monitoring or inaccurate interpretation of CTG. Research by Draycott et al (2006) suggests that training courses on obstetric emergencies were associated with a significant reduction in neonatal hypoxic-ischaemic encephalopathy (HIE), a condition which hypoxia and asphyxia can lead to.

7.163 These results were based on 1998-2003 data with a relatively small sample size, making national estimation problematic. However, wider implementation of effective training courses, delivered at organisation level, could plausibly lead to small but increasing reductions in hypoxia/asphyxia related cases – with a knock-on effect for reducing unnecessary admissions to neonatal care.

7.164 As maternity service providers may not all roll out such training routinely, a reduction of eg 1% initially, increasing over time provides a conservative estimate of potential reductions.

7.165 In relation to intrauterine growth, further analysis of patient level data on hospital inpatients or neonates would be required to quantify any potential gains from improved antenatal monitoring.

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5.6 – Incidence of harm to children due to ‘failure to monitor’

| Outcome sought | Harm from failing to monitor children properly in an acute setting. |
|----------------------|--|
| Indicator definition | Total number of Patient Safety incidents reported in England to the NPSA via the NRLS where age of the patient at the time of the incident is less than eighteen, and incident categories are associated with ‘failure to monitor’ |

(a) Indicator 5.6: Recent Trends and Explanations

7.166 A proposed definition for this indicator was published in the NHS Outcomes Framework 2012/13. The methodology and data quality issues underpinning this definition as proposed by the NPSA have been tested following development work conducted with the NPSA and the NHS Information Centre.

7.167 This indicator will be derived from the National Reporting and Learning System on the following basis:

Incident categories

7.168 The ‘failure to monitor’ category is a level 2 category under the level1 “Implementation of care and ongoing monitoring / review” category in the NRLS dataset.

7.169 During a meeting between DH and the NPSA in February 2010 concerns around the small number of reports which would fall in this category were raised and it was agreed that the NPSA would review the data and other similar categories to advise.

7.170 Based on the NRLS dataset and previous analysis on deterioration the top four (excluding “other”) incident categories identified are:

| Incident category level 1 | Incident category level 2 |
|--|--|
| Implementation of care and ongoing monitoring / review | Delay or failure to monitor |
| Treatment, procedure | Treatment / procedure - delay / failure |
| Treatment, procedure | Treatment / procedure - inappropriate / wrong |
| Clinical assessment (including diagnosis, scans, tests, assessments) | Assessment - lack of clinical or risk assessment |

Degree of harm

7.171 For the indicator on incident of harm to children due to ‘failure to monitor’ incidents categorised as “No harm” are excluded.

| | |
|--|--|
| <p>Numerator definition</p> | <p>Total number of Patient Safety incidents reported in England to the NPSA via the NRLS where age of the patient at the time of the incident is less than eighteen, and incident categories are associated with ‘failure to monitor’ as follows:</p> <p>(Care Setting = “Acute”)</p> <p>AND</p> <p>(Age at time of the incident < 18)</p> <p>AND</p> <p>(Degree of harm = (“Low” OR “Moderate” OR “Severe” OR “Death”))</p> <p>AND</p> <p>((Incident Category level 1 = “Implementation of care and ongoing monitoring / review”) AND (Incident Category level 2 = “Delay or failure to monitor”))</p> <p>OR</p> <p>((Incident Category level 1 = “Treatment, procedure”) and (Incident Category level 2 = “Treatment / procedure - delay / failure”))</p> <p>OR (Incident Category level 1 = “Treatment, procedure”) and (Incident Category level 2 = “Treatment / procedure - inappropriate / wrong”))</p> <p>OR</p> <p>((Incident Category level 1 = “Clinical assessment (including diagnosis, scans, tests, assessments”) AND (Incident Category level 2 = “Assessment - lack of clinical or risk assessment”))</p> |
| <p>Availability and periodicity</p> | <p>As numbers are likely to be small, this indicator would be reported on an annual basis. Data for 2008/09 to 2011/12 are expected to be published in September 2012. An earlier time series will not be available due to data quality issues relating to recording of age in the NRLS.</p> |

| | |
|-----------------------|---|
| Further issues | The reporting of severe harm or death as result of a Patient Safety incident to the NPSA via the NRLS has become mandatory from April 2010. This may increase the proportion of these reports in 2010/11 compared with previous years. This should be decreasing in the future as fewer serious incidents should occur if a patient safety culture is developing and lessons are being learnt. |
|-----------------------|---|

(3) Domain Levels of Ambition for Domain 5

7.172 This section considers for Domain 5 as a whole:

- a) Aggregated Scope for Improvement
- b) Levels of Ambition
- c) Implications for Inequality

(3)(a) Aggregated Domain 5: Scope for Improvement

7.173 In this section partial analysis of the scope for improvement for Domain 5 is presented. This is based on scope for improvement in VTEs and Pressure Ulcers, MRSA and *C-difficile*, supplemented with additional analysis to convert these improvements into the domain metric. This is subject to change as further analysis is undertaken to replace the assumptions with evidence. This is only a partial assessment of the domain, not least because it only includes four indicators which present a partial picture of patient safety.

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| Domain 5 - reduction in QALYs lost per annum | | | |
|---|--|--|-----------------------|
| | | | Scope for Improvement |
| 2012/13* | | | 0 |
| 2013/14 | | | 3,000 |
| 2014/15 | | | 5,000 |
| 2015/16 | | | 6,000 |
| 2016/17 | | | 7,000 |
| 2017/18 | | | 8,000 |
| 2018/19 | | | 8,000 |
| 2019/20 | | | 8,000 |
| 2020/21 | | | 8,000 |
| 2021/22 | | | 8,000 |
| 2022/23 | | | 8,000 |
| 2 year | | | 8,000 |
| 5 year | | | 29,000 |
| 10 year | | | 69,000 |
| Level of ambition relates to ambition to reduce safety incidents (applied to VTEs & pressure ulcers) and through a zero-tolerance approach to MRSA and <i>C-difficile</i> | | | |

7.174 *These figures will be updated in the consultation period such that the scope for improvement is calculated from a 2012/2013 base year. As data for 2012/13 will not be available at that time it will be necessary to forecast a 2012/2013 outturn as the basis for such calculation, which will then be subject to review in light of the final figures once available.

7.175 Domain 5 scope for improvement includes health gains in quality-adjusted life-years (QALYs) from:

- Ambitions to improve the safety of care which lead to reductions in the number of safety incidents (VTE and pressure ulcers)
- Ambitions for reductions in Health-Care acquired infections (HCAIs) based on potential reductions in the rate of MRSA and *C-difficile*, through a zero tolerance approach.

Scope for improvement – safety incidents VTEs and Pressure Ulcers

7.176 Potential improvements are described in the scope for improvements sections above. The quantitative estimates of the potential reductions in VTEs and Pressure Ulcers are presented in the tables below. These reductions are percentage reductions against current practice projections.

| | Reduce VTEs by (%) | Pressure Ulcers by (%) |
|--|--------------------|------------------------|
| 2012/13* | 0% | 0% |
| 2013/14 | 25.00% | 40.00% |
| 2014/15 | 50.00% | 80.00% |
| 2015/16 | 50.00% | 80.00% |
| 2016/17 | 50.00% | 80.00% |
| 2017/18 | 50.00% | 80.00% |
| 2018/19 | 50.00% | 80.00% |
| 2019/20 | 50.00% | 80.00% |
| 2020/21 | 50.00% | 80.00% |
| 2021/22 | 50.00% | 80.00% |
| 2022/23 | 50.00% | 80.00% |
| | | |
| Potential reductions in safety incidents which could be achieved through improvements to acute care services | | |

7.177 *These figures will be updated in the consultation period such that the scope for improvement is calculated from a 2012/2013 base year. As data for 2012/13 will not be available at that time it will be necessary to forecast a 2012/2013 outturn as the basis for such calculation, which will then be subject to review in light of the final figures once available.

Scope for improvement – HCAIs – MRSA and C-difficile

7.178 The NHS Operating Framework for 2012-13 sets out a zero tolerance approach to all avoidable healthcare associated infections (HCAIs) the national objective for the reduction in incidence states that if the NHS achieves individual organisational level objectives nationally at a commissioner level, then the number of MRSA infections will reduce by **29%** in 2012/13 and the number of C.Difficile infections will reduce by **18%**, compared to 2011/12 performance.

7.179 Based on analysis in the NHS Outcomes Framework Impact Assessment a zero tolerance approach to MRSA and C-difficile is likely to be cost neutral or cost saving for the NHS as a whole in the short term.

7.180 Modelled estimates of the potential reduction in HCAs through a zero tolerance approach are presented in the table below. This is compared to the current practice projections for MRSA and *C. difficile* to give an estimate of the number of infections avoided.

| | Rate of MRSA under a “zero tolerance approach” | Rate of <i>C-difficile</i> under a zero tolerance approach |
|----------|--|--|
| 2012/13* | 853 | 15106 |
| 2013/14 | 706 | 13098 |
| 2014/15 | 627 | 11903 |
| 2015/16 | 571 | 10973 |
| 2016/17 | 530 | 10249 |
| 2017/18 | 501 | 9685 |
| 2018/19 | 501 | 9685 |
| 2019/20 | 501 | 9685 |
| 2020/21 | 501 | 9685 |
| 2021/22 | 501 | 9685 |
| 2022/23 | 501 | 9685 |

7.181 *These figures will be updated in the consultation period such that the scope for improvement is calculated from a 2012/2013 base year. As data for 2012/13 will not be available at that time it will be necessary to forecast a 2012/2013 outturn as the basis for such calculation, which will then be subject to review in light of the final figures once available.

Conversion to domain metric – VTEs

7.182 Evidence on the impact of VTEs in QALY terms is calculated based on the likely utility associated with a longer stay in hospital. In this case we estimate:

- the stay associated with VTE to be 6.11 days
- the likely reduction Quality-of-Life from 1 to 0.5 (consistent with estimate in domain 3); and
- therefore a QALY loss per VTE of 0.008 is estimated

Conversion to domain metric – Pressure Ulcers

7.183 The QALY loss from pressure ulcers are estimated in a similar way:

- the stay associated with pressure ulcers is estimated to be 5.7 days
- the reduction in QoL is estimated to be 0.1 based on a review of the evidence on the impact of pressure ulcers on patient outcomes .
- therefore a QALY loss per Pressure Ulcer of 0.002 is estimated.

7.184 The QALY loss impacts for VTE and PUs are combined with the estimated reduction in the incidence of these safety incidents to give the QALY loss scores in the table below

| Year | QALY gains from reduced VTEs | QALY gains from reduced PUs |
|----------|------------------------------|-----------------------------|
| 2012/13* | 0 | 0 |
| 2013/14 | 163 | 106 |
| 2014/15 | 329 | 213 |
| 2015/16 | 331 | 215 |
| 2016/17 | 334 | 217 |
| 2017/18 | 337 | 219 |
| 2018/19 | 340 | 220 |
| 2019/20 | 342 | 222 |
| 2020/21 | 345 | 224 |
| 2021/22 | 348 | 226 |
| 2022/23 | 350 | 227 |

7.185 *These figures will be updated in the consultation period such that the scope for improvement is calculated from a 2012/2013 base year. As data for 2012/13 will not be available at that time it will be necessary to forecast a 2012/2013 outturn as the basis for such calculation, which will then be subject to review in light of the final figures once available.

Conversion to domain metric - HCAs and C-difficile

7.186 The initial analysis of the scope for improvement in these indicators is based on combining the estimated reduction in the rate of infections through the scope for improvements projections. This is the difference between the flat current practice projections and the scope for improvement in the sections above. This combined with estimates of QALYs gained based on reduced deaths, in the Impact Assessment for the NHS Outcomes Framework.

7.187 The number of deaths reduced based on the estimated scope for improvement are then converted into QALY gains, using the average age of death from MRSA and *C-difficile*. For the purpose of this analysis the average age of death is estimated to be 75; and the QALY expectancy at those ages (i.e. expected length of life adjusted for quality) based on DH estimates (=9 QALYs for age 75). These estimates and assumptions need to be refined through further analysis and are therefore subject to change.

7.188 The results are presented in the table below:

| Year | QALY gain from MRSA reduction | QALY gain from C-Difficile reductions |
|---------|-------------------------------|---------------------------------------|
| 2012/13 | 0 | 0 |
| 2013/14 | 302 | 2,331 |
| 2014/15 | 464 | 4,798 |
| 2015/16 | 579 | 5,639 |
| 2016/17 | 663 | 6,294 |
| 2017/18 | 723 | 6,294 |
| 2018/19 | 723 | 6,294 |
| 2019/20 | 723 | 6,294 |
| 2020/21 | 723 | 6,294 |
| 2021/22 | 723 | 6,294 |
| 2022/23 | 723 | 6,294 |

Sensitivities and discussion

7.189 Data on pressure ulcers and VTEs is partial and more data points are required to gain a fuller picture of incidence. This may affect the final level of ambition for the domain.

7.190 In planning for improvement the NHS may choose not to reduce pressure ulcers and VTEs as much as the level of ambition implies.

7.191 Estimated age of death for *C-difficile* and MRSA is currently estimated at 75, as explained above.

Domain 5: (3)(b) Levels of Ambition

7.192 This section assesses appropriate Levels of Ambition for Domain 5, adding to the scope for improvement of individual indicators the scope for gains in allocative efficiency, conditioned by a realistic assessment of the challenge presented to the NHS to achieve requisite change.

7.193 A principal ambition for the domain is to achieve robust measures of outcome for more severe patient safety incidents.

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7.194 Only in the presence of such estimates will it be possible to create an adequate understanding of scope for improvement, and thus to assess an appropriate level of ambition.

7.195 In the meantime, the previous section sets out an aggregate measure of potential gains for the areas for which robust measures of outcome are available.

7.196 Levels of ambition will be included in the final mandate.

(3)(c) Domain 5 Implications for Inequality

We will be reviewing this domain to explore relevant considerations for the assessment of inequality.

(4) Considerations for Retrospective Assessment of Domain 5 NHS Performance

7.197 This section draws attention to the factors that should be taken into account when assessing whether overall domain performance by the NHS has met levels of ambition set.

7.198 These factors include obtaining more accurate baseline estimates of harm arising during NHS care, particularly for VTE and pressure ulcers, and the ability to identify and measure those incidents which are preventable.