



The Orthopaedic Error Index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach

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6 **The Orthopaedic Error Index: development and application of a novel**
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9 **national indicator for assessing the relative safety of hospital care using**
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11 **a cross-sectional approach**
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Abstract

Objective: The Orthopaedic Error Index for hospitals aims to provide the first national assessment of the relative safety of provision of orthopaedic surgery.

Design: Cross-sectional study (retrospective analysis of records in a database)

Setting: The National Reporting and Learning System is the largest national repository of patient safety incidents in the world with over 8 million error reports. It offers a unique opportunity to develop novel approaches to enhancing patient safety, including investigating the relative safety of different healthcare providers and specialties.

Participants: We extracted all orthopaedic error reports from the system over one year (2009–2010).

Outcome measures: The Orthopaedic Error Index was calculated as a sum of the error propensity and severity. All relevant hospitals offering orthopaedic surgery in England were then ranked by this metric to identify possible outliers that warrant further attention.

Results: 155 hospitals reported 48,971 orthopaedic-related patient safety incidents. The mean Orthopaedic Error Index was 7.09/year (SD 2.72); five hospitals were identified as outliers. Three of these units were specialist tertiary hospitals carrying out complex surgery; the remaining two outlier hospitals had unusually high Orthopaedic Error Indexes: mean 14.46 (SD 0.29) and 15.29 (SD 0.51), respectively.

Conclusions: The Orthopaedic Error Index has enabled identification of hospitals that may be putting patients at disproportionate risk of orthopaedic-related iatrogenic harm and which therefore warrant further investigation. It provides the prototype of a summary index of harm to enable surveillance of unsafe care over time across institutions. This novel approach has the potential to be extended to other hospital specialties in the UK and also

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3 internationally to other health systems that have comparable national databases of patient
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5 safety incidents.
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11 **Article summary**

12 Article focus:

- 13 • Surveillance of risk through patient safety reporting systems has not been undertaken to
14 date
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- 16 • The Orthopaedic Error Index (OEI) is the first attempt to develop automated
17 procedures to interrogate a national database of patient safety incidents in order to
18 identify hospitals at disproportionate risk of iatrogenic harm
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- 20 • The OEI is the first such metric that is a direct measure of the safety of orthopaedic
21 surgery in a hospital
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38 Key messages:

- 39 • The Orthopaedic Error Index enables identification of hospitals that may be putting
40 patients at disproportionate risk of orthopaedic-related iatrogenic harm
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- 43 • This novel approach has the potential to be extended to other hospital specialties in
44 the UK and also internationally to other health systems that have comparable
45 national databases of patient safety incidents
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Strengths and limitations of this study

- Several notable strengths of the study: a large national dataset was drawn upon; comprising of over 48,000 orthopaedic reports and the data used are specifically for patient safety
- Limitations:
 - There is a trade-off between the depth and breadth of the analysis
 - At present, the learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported
 - Secondary analysis of data, including absence of specific information needed and necessities of using proxies
 - Biases exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. Underlying factors for these biases, such as level of patient safety culture within institutions, were not assessed.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the

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3 submitted work; no financial relationships with any organisations that might have an interest in
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5 the submitted work in the previous three years; no other relationships or activities that could
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7 appear to have influenced the submitted work.
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For peer review only

Introduction

The delivery of safer healthcare remains a challenge globally.[1] Over a decade ago, the Institute of Medicine published the seminal report, *To Err is Human*,[1] which revealed the previously under-recognised high burden of morbidity and mortality associated with iatrogenic harm. This was then followed by the equally influential *Crossing the Quality Chasm*, which highlighted the need to develop and make greater use of error reporting systems to enable learning from patient safety incidents and create opportunities for system-level interventions to reduce future risks of harm.[2] The challenge for healthcare systems globally remains the consistent delivery of safer care and the associated surveillance of safety within an organisation.

Modern day healthcare involves an array of complicated diagnostic and therapeutic decisions affected by the system within which these occur. Poorly functioning systems and teams have the potential to impact on patient safety. Inevitably, there will be unexpected variation in access, outcomes, and quality of care. Whereas some variation is legitimate and indeed desirable (for example, slower surgeons should not be asked to work faster), it is the unwarranted variation that is a major cause of concern to policy-makers and regulators.[3] A much-favoured approach for describing this variability is the use of hospital-wide mortality rates. Proponents have argued that these tools provide useful metrics about problems with the quality of inpatient care; uncover system-wide failures; and can help patients to choose the safest hospital.[4] Patient safety reporting systems are unused sources of data for the surveillance of harm which enable learning from errors, so that the insights create opportunities for system-level interventions to reduce future risks of harm. Some successes have been reported, for example in identifying previously

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3 undetected risks of new drugs or procedures, but there remain doubts about the wider
4 value of investments in developing and maintaining large-scale incident reporting
5 systems.[5]
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11 Databases of error reports now exist in many parts of the world, including the UK and the
12 US.[6-8] The UK's National Reporting and Learning System was launched in 2003 and has
13 since accrued over eight million records, making it the most substantial repository of
14 patient safety incidents in the world. Analyses of this database have revealed risks in a
15 range of clinical areas,[9, 10] but what has been lacking are high-level, valid summary
16 metrics to allow surveillance of harm across a whole healthcare system in a way that
17 allows, for example: comparison between hospitals; monitoring of time trends; and, a
18 baseline for assessing and evaluating interventions. This is necessary because of the large
19 volume of incident reports.
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34 In this paper, we report on the development of one such summary statistic, which aims to
35 (unlike the currently used proxy measures of harm such as hospital standardised mortality
36 ratios) provide a more direct measure of safety.[11] We developed and tested this measure
37 in the field of orthopaedic surgery. This specialty was chosen because it is associated with a
38 relatively high level of harm.[12] For example, from 2000–2006, an equivalent of US\$321
39 million was paid in adult orthopaedic surgery-related negligence settlements in the UK.[13]
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48 Similar figures were reported the Physician Insurers Association of America.[14]
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Methods

Developing a model for an error index

Errors will occur in complex systems like healthcare, and their frequency will relate to the number of procedures undertaken. Such assumptions are made in other fields of risk. In road traffic accidents, for example, predicted crash frequency is a linear function of average daily traffic.[15]

A simple measure of error is the frequency of errors occurring in any hospital. However, since frequency is a function of the number of procedures that have been carried out, we therefore deemed the frequency of errors per unit of procedure as a more appropriate measure.[16] We call this the *error propensity*. In order to calculate this, we extracted data on all orthopaedic reports made by all English hospitals reporting to the UK's National Reporting and Learning System over a 12-month period from April 1, 2009 to March 31, 2010. In parallel, we approximated the total number of orthopaedic procedures carried out in each hospital using data from the national Hospital Episode Statistics (2009–2010) database,[17] which is a mandatory national database of all patient visits to NHS hospitals in England, in order to estimate the error propensity.

A second component of the Orthopaedic Error Index (OEI) reflects the impact the error has on the patients, i.e. how much harm it caused. We call this the *error severity* which is based on categories of harm. Harm was defined by user self-reports; the degree of harm was classified as either: no harm, low harm (minimal harm – patient(s) required extra observation or minor treatment), moderate harm (short-term harm – patient(s) required

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3 further treatment, or procedure), severe harm (permanent or long-term harm), or death.

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5 Further details about the structure of the National Reporting and Learning System are
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7 provided in Appendix 1. We created our summary statistic using principles laid out in the
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9 Standards for Statistical Models used for Public Reporting of Health Outcomes.[18]
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14 The OEI comprised the two main domains of error: the propensity of errors (P) and the
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16 severity of harm (S). The mathematical derivation of the OEI is given in Appendix 2.
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19 20 ***Analyses***

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23 We estimated P, S, and OEI and their standard errors for each hospital using STATA 11
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25 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.).
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28 Since propensity, severity and the OEI deviated from normality, they were first
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30 transformed: OEI using a logarithmic transformation and *severity* and *propensity* by taking
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32 their reciprocal values. We sought to identify outliers by creating control lines at one, two,
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34 and three standard deviations (SD). We plotted OEI (per 1,000 procedures) against number
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36 of procedures and superimposed lines representing the mean and +/- 2SD and 3SD of
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38 predicted OEI values. Funnel plots provided a visual representation of the data and have
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40 been used widely in health services research to compare institutions. We defined outliers
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42 as those with an OEI outside the range of $\mu \pm 3\sigma$, where μ is the mean and σ is the standard
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44 deviation for the whole sample. These hospitals require closer scrutiny.[19]
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Results

OEI for all hospitals in England

In England, 155 NHS hospitals reported 48,971 patient safety incidents with varying degrees of harm: 34530/48971 (70.5%) no harm; 11529/48971 (23.5%) low harm; 2632/48971 (5.4%) moderate harm; 217/48971 (0.4%) severe harm; and 63/48971 (0.1%) deaths in the specialty of trauma and orthopaedic surgery during 2009–2010. The mean hospital OEI was 7.09 (SD 2.72). There was a correlation between the number of procedures and error reports of 0.40; therefore an increase of 1,000 orthopaedic procedures generated approximately 38 additional error reports (Figure 1).

Identifying outlier hospitals

Among the 155 hospitals, five lay outside the pre-specified control limits (Figure 2). These were hospitals which had relatively small numbers of procedures, but high OEI values.

Table 1 identifies the key characteristics of these outliers.

Discussion

The OEI is the first attempt to develop automated procedures to interrogate a national database of patient safety incidents in order to identify hospitals at disproportionate risk of iatrogenic harm. Applying this tool to all hospitals providing orthopaedic care identified five outlying hospitals: three tertiary care providers and two secondary care providers.

Whilst the higher rates may be expected because of case-mix considerations in the tertiary care sites, such deviations are not to be expected in the secondary care providers.

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3 One of these two secondary care providers has subsequently been highlighted nationally as
4 providing sub-standard care due to failures in administration, management, and
5 nursing.[20]
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11 At present, the NHS and other health systems internationally lack direct indicators of
12 safety. Mortality is a proxy measure and cannot be used in isolation to assess the safety of a
13 hospital. Opponents argue that the construction of Hospital Standard Mortality Ratios is
14 flawed as the index is unable to discriminate between inevitable and preventable deaths,
15 and that the huge variability in care suggested by these metrics cannot be accounted for by
16 variable quality of care alone.[21] Nevertheless, one of the hospitals that we identified as
17 an outlier and that has been the subject of national inquiries was also noted to have a high
18 Hospital Standard Mortality Ratio; an excess of up to 1,200 deaths occurred here.[22] We
19 have thus shown that a patient safety reporting system, which until recently has been used
20 as a repository collecting reports of errors, can be used to identify institutions that may
21 pose a disproportionate risk to patient safety.
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39 We have created a novel metric, the OEI, which is a direct marker of patient safety in
40 individual hospitals. The thrust behind this idea has been the occurrence of several high-
41 profile cases of hospitals such as Alder Hey, Mid-Staffordshire and Stockport NHS hospitals,
42 where a catalogue of medical errors occurred that resulted in varying degrees of harm to
43 the patient.[23] Most people would agree that in an era of large datasets, regulators and
44 advisory bodies should have mechanisms to identify hospitals that are struggling to deliver
45 high-quality care at an earlier stage so that corrective responses can be initiated. Despite
46 alarming cases of unsafe care, it appears the NHS is still ill-equipped to identify high-risk
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3 hospitals through early warning systems.[24] More recently, attempts have been made in
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5 the UK to identify failing hospitals by using nationwide surveillance tools which collect data
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7 prospectively: the NHS Safety Thermometer that collects data on four domains – venous
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9 thromboembolism, urinary tract infections, pressure ulcers, and falls;[25] the National
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11 Surgical Quality Improvement Program which collects measures of outcomes to improve
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13 surgical care;[26] and the Global Trigger Tool which measures adverse events.[27]
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17 However, not all hospitals use these tools. Ours is the first tool that uses data from an entire
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19 national healthcare system.
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23 **Strengths and limitations**

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27 Errors can be caused by active failures, for example mistakes and latent conditions, such as
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29 failure of system processes.[28] Usually, primary data from small, in-depth, qualitative
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31 enquiries are used to identify factors that contributed to the errors. The main strength of
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33 this approach is that data are specific for patient safety, but a major limitation is the trade-
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35 off between the depth and breadth of the analysis. We sought to investigate the use of
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37 routinely collected patient safety incident reports to create a numerical index that could
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39 help to provide a complementary perspective by supporting monitoring of the overall
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41 system-wide safety of healthcare provision. Other key strengths of our work include
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43 drawing on a large national dataset, comprising of over 48,000 orthopaedic reports and
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45 utilising the full body of data reporting on patient safety incidents spanning the full
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47 spectrum of severity from no harm to death. At present, the learning from national patient
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49 safety reporting systems is limited; some of the information is lost in translation and it is
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51 unclear whether all patient safety incidents are indeed reported.[29] The sensitivity of the
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NRLS at picking up errors has been questioned in the past;^[30] the low power of the study limits generalizability of results to the entire NRLS. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless this should not deter exploratory work such as ours. Some local systems of risk management at hospitals opt for root cause analyses to develop local solutions to mitigate against harm to patients, but these are not shared nationally, and limited information may be provided to national reporting systems. These systems rely on patient safety experts methodically trawling through patient safety incidents by severity and frequency, thereby leading to the production of quarterly reports, alerts, and rapid response solutions.^[31] Such analyses are time-consuming and, as the number of reports rapidly increases, may in the future be unsustainable. There is also a non-cohesive approach globally to identifying unsafe hospitals. The multitude of quality indicators which are proxy measures of unsafe care is overwhelming. The OEI is a surveillance tool that can enable direct evaluation of safer care in hospitals. It is, we believe, a novel benchmarking tool to assess patient safety across hospitals using a large patient safety reporting system.

The main limitations are those inherent to any secondary analysis of data, including absence of specific information needed and necessities of using proxies. However, these are, we believe, largely mitigated in the present analysis by the fact that the data were collected to study error and we refer to our analyses as secondary only because the analysis approach we employed was unanticipated when the study was designed. However, the OEI has several potential limitations. Reporting of patient safety incidents is a subjective exercise and variation in the dataset is bound to exist. Biases also exist at several levels: reporting of harmful versus non-harmful events and correct classification of

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3 categories of harm. Underlying factors for these biases, such as level of patient safety
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5 culture within institutions, were not assessed. Further work on measuring the extent and
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7 likely impact of such biases is therefore now needed.
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10 11 **Conclusions**

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15 With the proliferation of patient safety reporting systems around the world and an ever-
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17 increasing number of patient safety incidents reported to them, sophisticated analytical
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19 techniques are required to identify hospitals that need to strengthen their emphasis on
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21 patient safety. This is the first time, to our knowledge, that a surveillance mechanism for
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23 safety has been proposed using a reporting system.
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Appendix 1: The National Reporting and Learning System

The National Reporting and Learning System, housed at the National Patient Safety Agency, is a voluntary, national reporting system set up in 2003 for the NHS in England and Wales. To date, it is one of the largest patient safety reporting systems in the world and contains over eight million records of patient safety incidents.[31] Incidents are reported by staff at a local level and corrective measures taken where appropriate. Subsequently, these reports are anonymised for personal identifiers and uploaded to the National Reporting and Learning System. An alternative route by which information is uploaded to the National Reporting and Learning System is through an online reporting form available on the National Patient Safety Agency website, which is also open to members of the public. Each National Reporting and Learning System report refers to an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care. It includes the reporting of those incidents which did not lead to harm despite an error taking place, and those which did not lead to harm because the incident was prevented from reaching the patient. These incidents are further stratified into different levels of harm.[32] The database has 75 data fields, including patient demographics, specialty, location of incident, category of incident and a free-text description of the incident.[33] Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff and a range of outputs is produced to provide solutions to patient safety problems. These include one-page reports called *Rapid Response Reports*, quarterly data summaries and topic-specific information such as preventing inpatient falls in hospitals. There is constant consultation with subject-matter experts including

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3 professional organisations. NHS organisations also have deadlines imposed on them by
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5 which time they should have implemented any findings from these reports.[31]
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10 11 **Appendix 2: Creation of the OEI**

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13 The OEI is the sum of the number of errors (propensity, P) and the degree of harm
14 (severity, S). This should enable us to identify hospitals with large numbers of errors and
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16 similarly those units with the greatest degree of harm. It is reasonable to assume as more
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18 number of procedures are carried out, a larger number of errors will be reported, although
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20 we are also cognizant that there is potentially a high risk of errors in units undertaking
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22 relatively fewer procedures.
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28 29 ***Calculating the error propensity***

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31 For each hospital, P was calculated as:
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$$34 \quad P = 100 \frac{n}{N},$$

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36 where n was the number of procedures where any error had occurred and N was the total
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38 number of procedures; P had a range of 100, with 0 representing the lowest error
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40 propensity and 100 representing the largest error propensity.
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46 The standard error of P (P_{SE}) was calculated as:
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$$50 \quad P_{SE} = \sqrt{\frac{P(100 - P)}{N}}$$

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3 The consequences of a medical error can vary from negligible to fatal. The error propensity
4 index treats all reported errors equally. However, there is a qualitative difference between
5 hospitals which have the same E_p , but in one the proportion of death harm is nearly double
6 the other. Therefore, it is important to capture the severity of the error. Each error report
7 in the database contains a NPSA code for severity which is ordinal in character. We propose
8 a severity index based on proportion of each harm category weighed for its severity.
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19 For each hospital, the Severity (S) was calculated as a weighted sum: $S = \sum w_i n_i / n$, where
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21 w_i is the weight for the i^{th} error severity category; n_i is the number of procedures where i^{th}
22 error severity category occurred; and n is the number of procedures where any error
23 occurred.
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29 30 ***Method of determining weights***

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32 We can give greater weight to less common events by using the inverse probability weight.
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34 The relative frequency of each harm category was calculated using the inverse probability
35 weights (IPW = 1/ relative frequency) and IPW relative to the no harm category. There are
36 two drawbacks to this way of assigning weights: one, it is data specific so that another
37 dataset with a different distribution will yield different weights; and two, it gives, perhaps
38 correctly but inconveniently, high values to severe harm and death, in which case error
39 severity may be measured just by counting these events. Although this proposition is
40 attractive in its simplicity, it is not useful in terms of error monitoring and developing
41 policies. Our finding that greater harm categories are less frequent is a confirmation of the
42 famous Heinrich ratio, which states that for every major injury, there are 29 minor injuries
43 and 300 near misses.[34] Referring to the ratio, an expert group on learning from adverse
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3 events in the NHS argued for the importance of reporting near misses: “Not all unsafe
4 systems produce bad outcomes all the time. The potential for disasters may exist, but for
5 any number of reasons those disasters might not occur at all, or occur very rarely – what
6 has been termed ‘a dynamic non-event’. If there are no bad outcomes to monitor, safety
7 information systems need to collect, analyse, and disseminate information from incidents
8 and near misses, as well as from regular proactive checks on the system’s ‘vital signs.’”[35]
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11 We therefore chose a weighing system computed as 2^i where i is the ordinal number of
12 error severity category, from 0 for no harm to 4 for death. The error severity was also
13 rescaled to a range of 0 to 100 as done with S .
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17 For this purpose, the harm categories were assigned numerical values from 0 to 4 (no harm
18 = 0, low harm = 1, moderate harm = 2, high harm = 3, and death = 4) to reflect their natural
19 order of severity. The weight assigned to the i^{th} harm category was 2^i .
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$$22 \quad S = \frac{100}{16} \left(\frac{\sum_{i=0}^4 2^i n_i}{n} \right)$$

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24 where, n_i is number of procedures where i^{th} harm category occurred and n is the number of
25 procedures where any error occurred. The constant term $100/16$, 16 or 2^4 , being the
26 maximum value possible (when all reported errors were deaths) for the variable part of the
27 formula, was used to adjust the scale of the index so that 100 was the maximum value,
28 representing a situation where all errors reported resulted in deaths. The minimum value
29 would be 6.67, representing the case where all reported errors produced no harm. We
30 intentionally avoided rescaling S , 0 to 100, to differentiate between the situation where no
31 errors were reported and some errors were reported but they were all in the no harm
32 category.
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The standard error of S was computed as:

$$S_{SE} = \frac{100}{16} \left(\sqrt{\sum_{i=0}^4 2^{2i} \left(\frac{p_i - p_i^2}{n} \right)} \right)$$

Orthopaedic Error Index, OEI

We defined the OEI, E , as the weighted sum of error propensity and error severity.

$$E = 0.5P + 0.5S$$

This index gives equal weights for propensity, which captures the overall number of errors and severity of errors, because both aspects are considered important in dealing with errors. **Error! Bookmark not defined.** The weights were chosen so that E has a range of 0 to 100. The standard error of E was computed as:

$$E_{SE} = \sqrt{\frac{P_{SE}^2 + S_{SE}^2}{4}}$$

To identify reporting bias, we used the relationship between number of procedures and OEI. For this purpose we first meta-regressed OEI on number of procedures and saved the predicted values of OEI.

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Figure legends

Figure 1: Relationship between number of error reports and volume of procedures

Figure 2: The Orthopaedic Error Index for all hospitals in England

Table

Table 1: Hospitals identified as outliers that warrant attention (outside 3 standard deviations from the mean Orthopaedic Error Index)

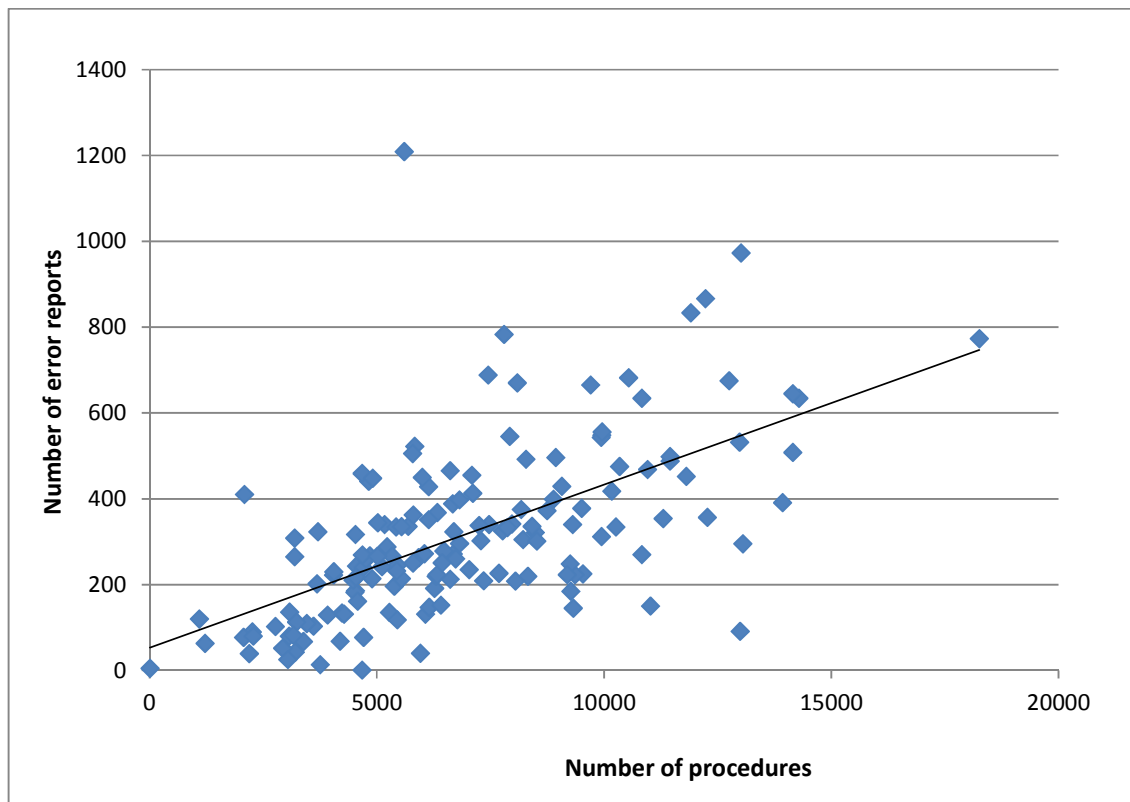
	Cluster	No. orthopaedic procedures	No. incidents reported	Orthopaedic Error Index (OEI)	Standard Error (SE) of OEI
1	Acute specialist hospital (including acute specialist children)	1093	120	9.89	0.72
2	Medium acute hospital	5601	1209	14.46	0.28
3	Small acute hospital	2085	410	15.29	0.51
4	Acute specialist hospital (including acute specialist children)	1222	63	6.04	0.42

5	Acute specialist hospital (including acute specialist children)	2277	80	7.10	0.63
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Authors' contributions

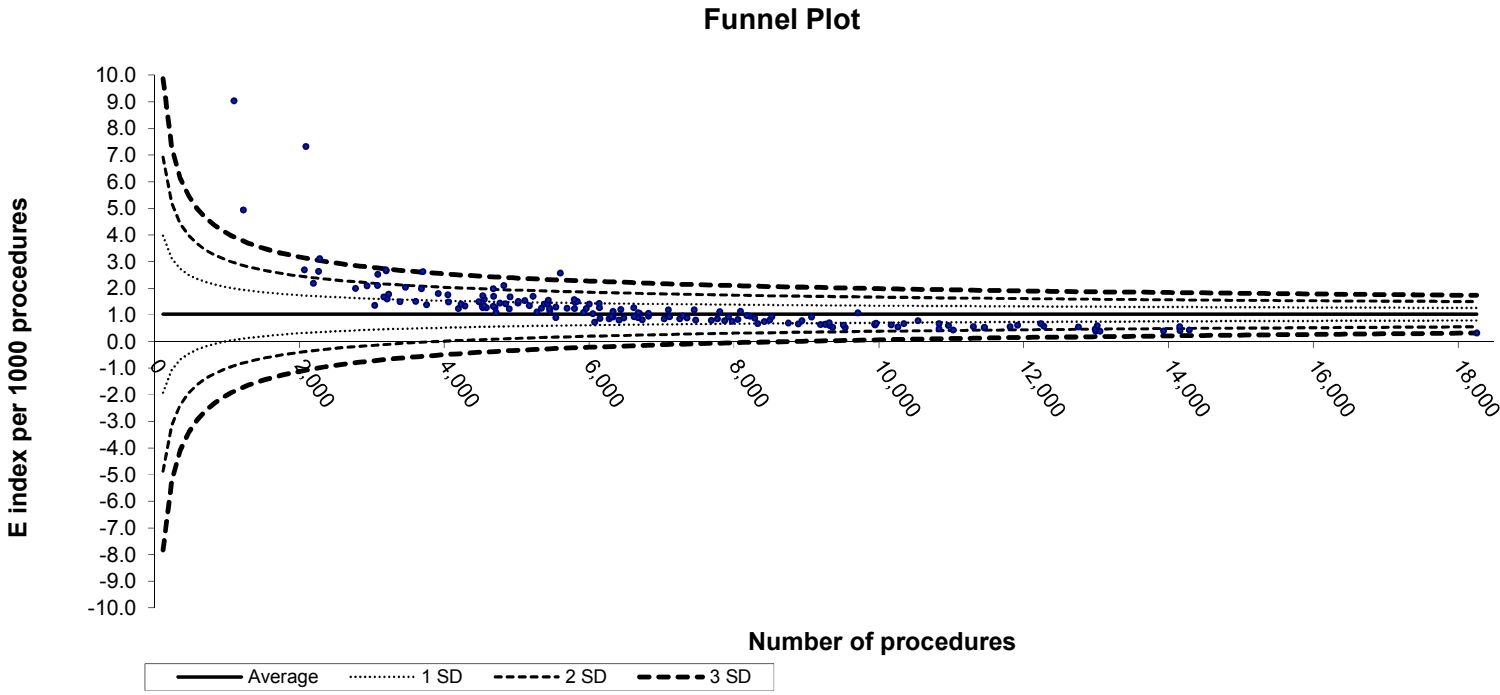
SSP and GN conceived the study design, analysed and interpreted the data. They drafted earlier versions of the article. AC-S, SJ, BP analysed and interpreted the data and helped to draft subsequent versions of the article. GP, LD and AS analysed and interpreted the data and revised it critically for important intellectual content. All authors approved the final version to be published.

Figure 1: Relationship between number of error reports and volume of procedures



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Figure 2: The Orthopaedic Error Index for all hospitals in England



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page number
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2 - 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	7 – 8
Objectives	3	State specific objectives, including any prespecified hypotheses	8
Methods			
Study design	4	Present key elements of study design early in the paper	9 – 10, 16
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9 -10
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	9 -10
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10, 16-17
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	16-17
Bias	9	Describe any efforts to address potential sources of bias	18-19
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	16-19
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	9-10, 16-19
		(b) Describe any methods used to examine subgroups and interactions	16-19
		(c) Explain how missing data were addressed	13
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods	

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taking account of sampling strategy	N/A
(e) Describe any sensitivity analyses	11

Continued on next page

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Results		Page number	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	N/A – all included
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	16 - 20
		(b) Indicate number of participants with missing data for each variable of interest	N/A – all included
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11
		(b) Report category boundaries when continuous variables were categorized	11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11, 16-20
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	5

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely

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available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The Orthopaedic Error Index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003448.R1
Article Type:	Research
Date Submitted by the Author:	17-Sep-2013
Complete List of Authors:	Panesar, Sukhmeet; The University of Edinburgh, Centre for Population Health Sciences Netuveli, Gopalakrishnan; Imperial College London, Carson-Stevens, Andrew; University of Cardiff, Institute of Primary Care and Public Health Javad, Sundas; Imperial College London, Department of Primary Care and Population Health Patel, Bhavesh; National Patient Safety Agency, Analysis Parry, Gareth; Harvard Medical School, Donaldson, Liam; Imperial College London, Institute of Global Health Innovation Sheikh, Aziz; University of Edinburgh, Division of Community Health Sciences
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research
Keywords:	ORTHOPAEDIC & TRAUMA SURGERY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH

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Manuscripts

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6 **The Orthopaedic Error Index: development and application of a novel**
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8 **national indicator for assessing the relative safety of hospital care using**
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10 **a cross-sectional approach**
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Abstract

Objective: The Orthopaedic Error Index for hospitals aims to provide the first national assessment of the relative safety of provision of orthopaedic surgery.

Design: Cross-sectional study (retrospective analysis of records in a database)

Setting: The National Reporting and Learning System is the largest national repository of patient safety incidents in the world with over eight million error reports. It offers a unique opportunity to develop novel approaches to enhancing patient safety, including investigating the relative safety of different healthcare providers and specialties.

Participants: We extracted all orthopaedic error reports from the system over one year (2009–2010).

Outcome measures: The Orthopaedic Error Index was calculated as a sum of the error propensity and severity. All relevant hospitals offering orthopaedic surgery in England were then ranked by this metric to identify possible outliers that warrant further attention.

Results: 155 hospitals reported 48,971 orthopaedic-related patient safety incidents. The mean Orthopaedic Error Index was 7.09/year (SD 2.72); five hospitals were identified as outliers. Three of these units were specialist tertiary hospitals carrying out complex surgery; the remaining two outlier hospitals had unusually high Orthopaedic Error Indexes: mean 14.46 (SD 0.29) and 15.29 (SD 0.51), respectively.

Conclusions: The Orthopaedic Error Index has enabled identification of hospitals that may be putting patients at disproportionate risk of orthopaedic-related iatrogenic harm and which therefore warrant further investigation. It provides the prototype of a summary index of harm to enable surveillance of unsafe care over time across institutions. Further validation and scrutiny of the method will be required to assess its potential to be extended

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10 11 **Article summary**

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20 national patient safety reporting systems has been undertaken in limited situations.
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24 • The Orthopaedic Error Index (OEI) is the first attempt to develop automated
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26 procedures to interrogate a national database of patient safety incidents in order to
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28 identify hospitals at disproportionate risk of iatrogenic harm.
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31 • The OEI is the first such metric that is a direct measure of the safety of orthopaedic
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33 surgery in a hospital.
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37 Key messages:

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42 disproportionate risk of orthopaedic-related iatrogenic harm.
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46 • This novel approach has the potential to be extended to other hospital specialties in
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48 the UK and also internationally to other health systems that have comparable
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Strengths and limitations of this study:

- Several notable strengths of the study: a large national dataset was drawn upon; comprising of over 48,000 orthopaedic reports and the data used are specifically for patient safety.
- Limitations:
 - There is a trade-off between the depth and breadth of the analysis
 - Existing learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported
 - Secondary analysis of data, including absence of specific information needed and necessities of using proxies
 - Biases exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. Underlying factors for these biases, such as level of patient safety culture within institutions, were not assessed.

Funding

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the

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3 submitted work; no financial relationships with any organisations that might have an
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5 interest in the submitted work in the previous three years; no other relationships or
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Introduction

The delivery of safer healthcare remains a challenge globally.[1] Over a decade ago, the Institute of Medicine published the seminal report, *To Err is Human*,[1] which revealed the previously under-recognised high burden of morbidity and mortality associated with iatrogenic harm. This was then followed by the equally influential *Crossing the Quality Chasm*, which highlighted the need to develop and make greater use of error reporting systems to enable the generation of learning from patient safety incidents and inform opportunities for system-level interventions to reduce future risks of harm.[2] The challenge for healthcare systems globally remains the consistent delivery of safer care and the associated surveillance of safety within an organisation.

Modern day healthcare involves an array of complicated diagnostic and therapeutic decisions affected by the system within which these occur. Poorly functioning systems and teams have the potential to impact on patient safety. Inevitably, there will be unexpected variation in access, outcomes and quality of care. Whereas some variation is legitimate and indeed desirable (for example, slower surgeons should not be asked to work faster), it is the unwarranted variation that is a major cause of concern to policy-makers and regulators.[3] A much-favoured approach for describing this variability is the use of hospital-wide mortality rates. Proponents have argued that these tools provide useful metrics about problems with the quality of inpatient care; uncover system-wide failures; and can help patients to choose the safest hospital.[4]

Patient safety reporting systems are unused sources of data for the surveillance of harm which enable learning from errors, so that the insights create opportunities for system-

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3 level interventions to reduce future risks of harm. Some successes have been reported, for
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5 example in identifying previously undetected risks of new drugs or procedures, but there
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7 remain doubts about the wider value of investments in developing and maintaining large-
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9 scale incident reporting systems.[5] Databases of error reports now exist in many parts of
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11 the world, including the UK and the US.[6-8] The UK's National Reporting and Learning
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13 System (NRLS) was launched in 2003 and has since accrued over eight million records,
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15 making it the most substantial repository of patient safety incidents in the world. Analyses
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17 of this database have revealed risks in a range of clinical areas,[9, 10] but what has been
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19 lacking are high-level, valid summary metrics to allow surveillance of harm across a whole
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21 healthcare system in a way that allows, for example: comparison between hospitals;
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23 monitoring of time trends; and a baseline for assessing and evaluating interventions. Some
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25 doubts exist about the wider value of investments in developing and maintaining large-
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27 scale incident reporting systems.[5]
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36 In this paper, we report on the development of one such summary statistic, which aims to
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38 (unlike the currently used proxy measures of harm such as Hospital Standardised Mortality
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40 Ratios) provide a more direct measure of safety.[11] We developed and tested this measure
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42 in the field of orthopaedic surgery. This specialty was chosen because it is associated with a
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44 relatively high level of harm.[12] For example, from 2000 to 2006, an equivalent of US\$321
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46 million was paid in adult orthopaedic surgery-related negligence settlements in the UK.[13]
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48 Similar figures were reported the Physician Insurers Association of America.[14]
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Methods

Developing a model for an error index

Errors will occur in complex systems such as healthcare, and their frequency will relate to the number of procedures undertaken. Such assumptions are made in other fields of risk. In road traffic accidents, for example, predicted crash frequency is a linear function of average daily traffic.[15]

A simple measure of error is the frequency of errors occurring in any hospital. However, since frequency is a function of the number of procedures that have been carried out, we therefore deemed the frequency of errors per unit of procedure as a more appropriate measure.[16] We call this the *error propensity*. In order to calculate this, we extracted data on all orthopaedic reports made by all English hospitals reporting to the UK's NRLS over a 12-month period from April 1, 2009 to March 31, 2010. In parallel, we approximated the total number of orthopaedic procedures carried out in each hospital using data from the national Hospital Episode Statistics (HES; 2009–2010) database,[17] which is a mandatory national database of all patient visits to NHS hospitals in England, in order to estimate the error propensity.

A second component of the Orthopaedic Error Index (OEI) reflects the impact the error has on the patients, i.e. how much harm it caused. We call this the *error severity*, which is based on categories of harm. Harm was defined by user self-reports; the degree of harm was classified as either: no harm, low harm (minimal harm – patient(s) required extra observation or minor treatment), moderate harm (short-term harm – patient(s) required

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3 further treatment, or procedure), severe harm (permanent or long-term harm), or death.

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5 Further details about the structure of the NRLS are provided in Appendix 1. We created our
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8 summary statistic using principles laid out in the Standards for Statistical Models used for
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11 Public Reporting of Health Outcomes.[18]

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14 The OEI comprised the two main domains of error: the propensity of errors (P) and the
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16 severity of harm (S). The mathematical derivation of the OEI is given in Appendix 2.
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19 ***Analyses***

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22 We estimated P, S and OEI and their standard errors for each hospital using STATA 11
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24 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.).
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28 Since P, S and the OEI deviated from normality, they were first transformed: OEI using a
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30 logarithmic transformation and *propensity* and *severity* by taking their reciprocal values.
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33 We sought to identify outliers by creating control lines at one, two and three standard
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35 deviations (SD). We plotted OEI (per 1,000 procedures) against number of procedures and
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37 superimposed lines representing the mean and +/- 2SD and 3SD of predicted OEI values.
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40 Funnel plots provided a visual representation of the data and have been used widely in
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42 health services research to compare institutions. We defined outliers as those with an OEI
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44 outside the range of $\mu \pm 3\sigma$, where μ is the mean and σ is the standard deviation for the
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46 whole sample. These hospitals require closer scrutiny.[19]
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Results

OEI for all hospitals in England

In England, 155 NHS hospitals reported 48,971 patient safety incidents with varying degrees of harm: 34,530/48,971 (70.5%) no harm; 11,529/48,971 (23.5%) low harm; 2,632/48,971 (5.4%) moderate harm; 217/48,971 (0.4%) severe harm; and 63/48,971 (0.1%) deaths in the specialty of trauma and orthopaedic surgery during 2009–2010. The mean hospital OEI was 7.09 (SD 2.72). There was a correlation between the number of procedures and error reports of 0.40; therefore an increase of 1,000 orthopaedic procedures generated approximately 38 additional error reports (Figure 1).

Identifying outlier hospitals

Among the 155 hospitals, five lay outside the pre-specified control limits (Figure 2). These were hospitals which had relatively small numbers of procedures, but high OEI values. Of note, there is an almost linear association with larger hospitals having fewer errors.

Discussion

The OEI is the first attempt to develop automated procedures to interrogate a national database of patient safety incidents in order to identify hospitals at disproportionate risk of iatrogenic harm. Applying this tool to all hospitals providing orthopaedic care identified five outlying hospitals: three tertiary care providers and two secondary care providers. Whilst the higher rates may be expected because of case-mix considerations in the tertiary care sites, such deviations are not to be expected in the secondary care providers.

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3 One of these two secondary care providers has subsequently been highlighted nationally as
4 providing sub-standard care due to failures in administration, management and
5 nursing.[20]
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11 At present, the NHS and other health systems internationally lack direct indicators of
12 safety. Mortality is a proxy measure and cannot be used in isolation to assess the safety of a
13 hospital. Opponents argue that the construction of Hospital Standardised Mortality Ratios
14 is flawed as the index is unable to discriminate between inevitable and preventable deaths,
15 and that the huge variability in care suggested by these metrics cannot be accounted for by
16 variable quality of care alone.[11] Although we did not distinguish between avoidable and
17 non-avoidable incidents in our analysis, previous work by the group has shown that most
18 orthopaedic incidents that result in harm could have been prevented if safety measures had
19 been implemented.[21]
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34 The process of identifying outliers could be associated with stigma and extensive resource
35 allocation, both financial and reputational.[11] Nevertheless, in organisations that foster a
36 culture of reporting and learning, this method should be viewed as one of the many tools
37 that need to be used in parallel to understand how unsafe the care is in that particular
38 organisation. Use of outlier analysis in singularity does not ensure safe care; it merely acts
39 as a trigger for further checks. One of the hospitals that we identified as an outlier, and that
40 had been the subject of national inquiries, was also noted to have a high Hospital
41 Standardised Mortality Ratio; an excess of up to 1,200 deaths occurred here.[22] We have
42 thus shown that a patient safety reporting system, which until recently has been used as a
43 repository collecting reports of errors, can be used to identify institutions that may pose a
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3 disproportionate risk to patient safety. However, the work requires greater scrutiny and
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5 validation; the purpose of this undertaking was to see if national patient safety reporting
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7 systems can be used for surveillance of unsafe care. As such, we have created a novel
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9 metric, the OEI, which is a direct marker of patient safety in individual hospitals. The thrust
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11 behind this idea has been the occurrence of several high-profile cases of hospitals such as
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13 Alder Hey, Mid-Staffordshire and Stockport NHS hospitals, where unacceptably high levels
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15 of preventable harm occurred.[23] Most people would agree that in an era of large
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17 datasets, regulators and advisory bodies should have mechanisms to identify hospitals that
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19 are struggling to deliver high-quality care at an earlier stage so that corrective responses
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21 can be initiated. Monitoring trends in unsafe care over time would be invaluable. These
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23 would help, in addition to identifying outliers, in evaluating the effect of safety initiatives
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25 and case-mix of patients during different periods of the year. Despite alarming cases of
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27 unsafe care, it appears the NHS is still ill-equipped to identify high-risk hospitals through
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29 early warning systems.[24] More recently, attempts have been made to identify failing
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31 hospitals by using nationwide surveillance tools which collect data prospectively: the NHS
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33 Safety Thermometer that collects data on four domains – venous thromboembolism,
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35 urinary tract infections, pressure ulcers and falls;[25] the National Surgical Quality
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37 Improvement Program which collects measures of outcomes to improve surgical care;[26]
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39 and the Global Trigger Tool which measures adverse events.[27] However, not all hospitals
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41 use these tools. Ours is the first tool that uses data from an entire national healthcare
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43 system.
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Strengths and limitations

Errors can be caused by active failures, for example mistakes and latent conditions, such as failure of system processes.[28] Usually, primary data from small, in-depth, qualitative inquiries are used to identify factors that contributed to the errors. The main strength of this approach is that data are specific for patient safety, but a major limitation is the trade-off between the depth and breadth of the analysis. We sought to investigate the use of routinely collected patient safety incident reports to create a numerical index that could help to provide a complementary perspective by supporting monitoring of the overall system-wide safety of healthcare provision. Other key strengths of our work include drawing on a large national dataset, comprising of over 48,000 orthopaedic reports, and utilising the full body of data reporting on patient safety incidents spanning the full spectrum of severity from no harm to death. At present, the learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported.[29] The sensitivity of the NRLS at picking up errors has been questioned in the past;[30] the low power of the study limits generalizability of results to the entire NRLS. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless this should not deter exploratory work such as ours. We are also cognizant of the fact that there is likely to be a variation in reporting according to the patient safety culture within hospitals; so a hospital with a high OEI may be one that has an open culture and encourages staff to report patient safety incidents.[31] Of equal importance is the fact that the NRLS was a voluntary reporting system until April 2010, when mandatory reporting was introduced for serious untoward incidents.[32] In Figure 2,

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3 we showed that large hospitals (number of orthopaedic procedures) are associated with
4 reporting fewer errors. This must be interpreted with caution as we have not been able to
5 adjust for patient or procedure case-mix due to paucity and anonymity of the data. Based
6 on work elsewhere, it has been stipulated that specialised surgical services should be
7 provided in tertiary hospitals, although geographical or logistical impediments may
8 occur.[33] We cannot make this claim based on our findings. Some local systems of risk
9 management in hospitals opt for root cause analyses to develop local solutions to mitigate
10 against harm to patients, but these are not shared nationally, and limited information may
11 be provided to national reporting systems. These systems rely on patient safety experts
12 methodically trawling through patient safety incidents by severity and frequency, thereby
13 leading to the production of quarterly reports, alerts, and rapid response solutions.[34]
14 Such analyses are time-consuming and, as the number of reports rapidly increases, may in
15 the future be unsustainable. There is also a non-cohesive approach globally to identifying
16 unsafe hospitals. The multitude of quality indicators which are proxy measures of unsafe
17 care is overwhelming. The OEI is a surveillance tool that can enable direct evaluation of
18 safer care in hospitals. It is, we believe, a novel benchmarking tool to assess patient safety
19 across hospitals using a large patient safety reporting system.

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The main limitations are those inherent to any secondary analysis of data, including
absence of specific information needed and necessities of using proxies. Ideally, we would
have preferred to link HES data to corresponding NRLS incidents. At present, this is not
possible, as the latter does not allow for patient identification via NHS identification
numbers. HES data will also give an approximation of orthopaedic and trauma procedures
due to coding inaccuracies. However, these are, we believe, largely mitigated in the present

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3 analysis by the fact that the data were collected to study error and we refer to our analyses
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5 as secondary only because the analysis approach we employed was unanticipated when the
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7 study was designed. However, the OEI has several potential limitations. Reporting of
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9 patient safety incidents is a subjective exercise and variation in the dataset is bound to
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11 exist. Biases also exist at several levels: reporting of harmful versus non-harmful events
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13 and correct classification of categories of harm. Underlying factors for these biases, such as
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15 level of patient safety culture within institutions, were not assessed. Further work on
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17 measuring the extent and likely impact of such biases is therefore now needed.
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Conclusions

With the proliferation of patient safety reporting systems around the world and an ever-increasing number of patient safety incidents reported to them, sophisticated analytical techniques are required to identify hospitals that need to strengthen their emphasis on patient safety. This is the first time, to our knowledge, that a surveillance mechanism for safety has been proposed using a reporting system.

Appendix 1: The National Reporting and Learning System

The NRLS, housed at the National Patient Safety Agency (NPSA), is a voluntary, national reporting system set up in 2003 for the NHS in England and Wales. To date, it is one of the largest patient safety reporting systems in the world and contains over eight million records of patient safety incidents.[34] Incidents are reported by staff at a local level and corrective measures taken where appropriate. Subsequently, these reports are anonymised for personal identifiers and uploaded to the NRLS. An alternative route by which information is uploaded to the NRLS is through an online reporting form available on the NPSA website, which is also open to members of the public. Each NRLS report refers to an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care. It includes the reporting of those incidents which did not lead to harm despite an error taking place, and those which did not lead to harm because the incident was prevented from reaching the patient. These incidents are further stratified into different levels of harm.[35] The database has 75 data fields, including patient demographics, specialty, location of incident, category of incident and a free-text description of the incident.[36] Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff and a range of outputs is produced to provide solutions to patient safety problems. These include one-page reports called *Rapid Response Reports*, quarterly data summaries and topic-specific information such as preventing inpatient falls in hospitals. There is constant consultation with subject-matter experts including professional organisations. NHS organisations also have deadlines imposed on them by which time they should have implemented any findings from these reports.[34]

Appendix 2: Creation of the OEI

The OEI is the sum of the number of errors (propensity, P) and the degree of harm (severity, S). This should enable us to identify hospitals with large numbers of errors and similarly those units with the greatest degree of harm. It is reasonable to assume as more procedures are carried out, a larger number of errors will be reported, although we are also cognizant that there is potentially a high risk of errors in units undertaking relatively fewer procedures.

Calculating the error propensity

For each hospital, P was calculated as:

$$P = 100 \frac{n}{N},$$

where n was the number of procedures where any error had occurred and N was the total number of procedures; P had a range of 100, with 0 representing the lowest error propensity and 100 representing the largest error propensity.

The standard error of P (P_{SE}) was calculated as:

$$P_{SE} = \sqrt{\frac{P(100 - P)}{N}}$$

The consequences of a medical error can vary from negligible to fatal. The error propensity index treats all reported errors equally. However, there is a qualitative difference between hospitals which have the same E_p , but in one the proportion of death harm is nearly double the other. Therefore, it is important to capture the severity of the error. Each error report

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3 in the database contains a NPSA code for severity which is ordinal in character. We propose
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5 a severity index based on proportion of each harm category weighed for its severity.
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9 For each hospital, the severity (S) was calculated as a weighted sum: $S = \sum w_i n_i / n$, where
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11 w_i is the weight for the i^{th} error severity category; n_i is the number of procedures where i^{th}
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13 error severity category occurred; and n is the number of procedures where any error
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15 occurred.
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18 19 20 ***Method of determining weights*** 21

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23 We can give greater weight to less common events by using the inverse probability weight.
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25 The relative frequency of each harm category was calculated using the inverse probability
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27 weights (IPW = 1/ relative frequency) and IPW relative to the no harm category. There are
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29 two drawbacks to this way of assigning weights: one, it is data specific so that another
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31 dataset with a different distribution will yield different weights; and two, it gives, perhaps
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33 correctly but inconveniently, high values to severe harm and death, in which case error
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35 severity may be measured just by counting these events. Although this proposition is
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37 attractive in its simplicity, it is not useful in terms of error monitoring and developing
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39 policies. Our finding that greater harm categories are less frequent is a confirmation of the
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41 famous Heinrich ratio, which states that for every major injury, there are 29 minor injuries
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43 and 300 near misses.[37] Referring to the ratio, an expert group on learning from adverse
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45 events in the NHS argued for the importance of reporting near misses: “Not all unsafe
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47 systems produce bad outcomes all the time. The potential for disasters may exist, but for
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49 any number of reasons those disasters might not occur at all, or occur very rarely – what
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51 has been termed ‘a dynamic non-event’. If there are no bad outcomes to monitor, safety
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3 information systems need to collect, analyse, and disseminate information from incidents
4 and near misses, as well as from regular proactive checks on the system's 'vital signs'." [38]
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9 We therefore chose a weighing system computed as 2^i where i is the ordinal number of
10 error severity category, from 0 for no harm to 4 for death. The error severity was also
11 rescaled to a range of 0 to 100 as done with S .
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17 For this purpose, the harm categories were assigned numerical values from 0 to 4 (no harm
18 = 0, low harm = 1, moderate harm = 2, severe harm = 3, and death = 4) to reflect their
19 natural order of severity. The weight assigned to the i^{th} harm category was 2^i .
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$$S = \frac{100}{16} \left(\frac{\sum_{i=0}^4 2^i n_i}{n} \right)$$

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25 where, n_i is number of procedures where i^{th} harm category occurred and n is the number of
26 procedures where any error occurred. The constant term 100/16, 16 or 2^4 , being the
27 maximum value possible (when all reported errors were deaths) for the variable part of the
28 formula, was used to adjust the scale of the index so that 100 was the maximum value,
29 representing a situation where all errors reported resulted in deaths. The minimum value
30 would be 6.67, representing the case where all reported errors produced no harm. We
31 intentionally avoided rescaling S , 0 to 100, to differentiate between the situation where no
32 errors were reported and some errors were reported but they were all in the no harm
33 category.
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50 The standard error of S was computed as:
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$$S_{SE} = \frac{100}{16} \left(\sqrt{\sum_{i=0}^4 2^{2i} \left(\frac{p_i - p_i^2}{n} \right)} \right)$$

Orthopaedic Error Index, OEI

We defined the OEI, E , as the weighted sum of error propensity and error severity.

$$E = 0.5P + 0.5S$$

This index gives equal weights for propensity, which captures the overall number of errors and severity of errors, because both aspects are considered important in dealing with errors. The weights were chosen so that E has a range of 0 to 100. The standard error of E was computed as:

$$E_{SE} = \sqrt{\frac{P_{SE}^2 + S_{SE}^2}{4}}$$

To identify reporting bias, we used the relationship between number of procedures and OEI. For this purpose we first meta-regressed OEI on number of procedures and saved the predicted values of OEI.

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Figure legends

Figure 1: Relationship between number of error reports and volume of procedures

Figure 2: The Orthopaedic Error Index for all hospitals in England

Authors' contributions

SSP and GN conceived the study design, and analysed and interpreted the data. They drafted earlier versions of the article. AC-S, SJ, BP analysed and interpreted the data and helped to draft subsequent versions of the article. GP, LD and AS analysed and interpreted the data and revised it critically for important intellectual content. All authors approved the final version to be published.

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Research article

The Orthopaedic Error Index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach

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Abstract

Objective: The Orthopaedic Error Index for hospitals aims to provide the first national assessment of the relative safety of provision of orthopaedic surgery.

Design: Cross-sectional study (retrospective analysis of records in a database)

Setting: The National Reporting and Learning System is the largest national repository of patient safety incidents in the world with over 8.8 million error reports. It offers a unique opportunity to develop novel approaches to enhancing patient safety, including investigating the relative safety of different healthcare providers and specialties.

Participants: We extracted all orthopaedic error reports from the system over one year (2009–2010).

Outcome measures: The Orthopaedic Error Index was calculated as a sum of the error propensity and severity. All relevant hospitals offering orthopaedic surgery in England were then ranked by this metric to identify possible outliers that warrant further attention.

Results: 155 hospitals reported 48,971 orthopaedic-related patient safety incidents. The mean Orthopaedic Error Index was 7.09/year (SD 2.72); five hospitals were identified as outliers. Three of these units were specialist tertiary hospitals carrying out complex surgery; the remaining two outlier hospitals had unusually high Orthopaedic Error Indexes: mean 14.46 (SD 0.29) and 15.29 (SD 0.51), respectively.

Conclusions: The Orthopaedic Error Index has enabled identification of hospitals that may be putting patients at disproportionate risk of orthopaedic-related iatrogenic harm and which therefore warrant further investigation. It provides the prototype of a summary index of harm to enable surveillance of unsafe care over time across institutions. [Further validation and scrutiny of the method will be required to assess its utility.](#) ~~This novel approach has~~

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9 | ~~the~~ potential to be extended to other hospital specialties in the UK and also internationally
10 to other health systems that have comparable national databases of patient safety
11 incidents.
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14 15 16 17 18 **Article summary**

19 20 Article focus:

- 21 • Surveillance of risk through [routinely collected patient safety incidents reported to](#)
22 [national](#) patient safety reporting systems has ~~not been undertaken to date~~
23 [been undertaken in limited situations](#).
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- 26 • The Orthopaedic Error Index (OEI) is the first attempt to develop automated
27 procedures to interrogate a national database of patient safety incidents in order to
28 identify hospitals at disproportionate risk of iatrogenic harm.
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- 30 • The OEI is the first such metric that is a direct measure of the safety of orthopaedic
31 surgery in a hospital.
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38 39 Key messages:

- 40 • The ~~Orthopaedic Error Index~~ OEI enables identification of hospitals that may be
41 putting patients at disproportionate risk of orthopaedic-related iatrogenic harm.
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- 44 • This novel approach has the potential to be extended to other hospital specialties in
45 the UK and also internationally to other health systems that have comparable
46 national databases of patient safety incidents.
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Strengths and limitations of this study:

- Several notable strengths of the study: a large national dataset was drawn upon; comprising of over 48,000 orthopaedic reports and the data used are specifically for patient safety.
- Limitations:
 - There is a trade-off between the depth and breadth of the analysis
 - ~~At present, the~~Existing learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported
 - Secondary analysis of data, including absence of specific information needed and necessities of using proxies
 - Biases exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. Underlying factors for these biases, such as level of patient safety culture within institutions, were not assessed.

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Competing interests

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All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Introduction

The delivery of safer healthcare remains a challenge globally.[1] Over a decade ago, the Institute of Medicine published the seminal report, *To Err is Human*,[1] which revealed the previously under-recognised high burden of morbidity and mortality associated with iatrogenic harm. This was then followed by the equally influential *Crossing the Quality Chasm*, which highlighted the need to develop and make greater use of error reporting systems to enable [the generation of](#) learning from patient safety incidents and [create](#) [inform](#) opportunities for system-level interventions to reduce future risks of harm.[2] The challenge for healthcare systems globally remains the consistent delivery of safer care and the associated surveillance of safety within an organisation.

Modern day healthcare involves an array of complicated diagnostic and therapeutic decisions affected by the system within which these occur. Poorly functioning systems and teams have the potential to impact on patient safety. Inevitably, there will be unexpected variation in access, outcomes, and quality of care. Whereas some variation is legitimate and indeed desirable (for example, slower surgeons should not be asked to work faster), it is the unwarranted variation that is a major cause of concern to policy-makers and regulators.[3] A much-favoured approach for describing this variability is the use of hospital-wide mortality rates. Proponents have argued that these tools provide useful metrics about problems with the quality of inpatient care; uncover system-wide failures; and can help patients to choose the safest hospital.[4]

Patient safety reporting systems are unused sources of data for the surveillance of harm which enable learning from errors, so that the insights create opportunities for system-

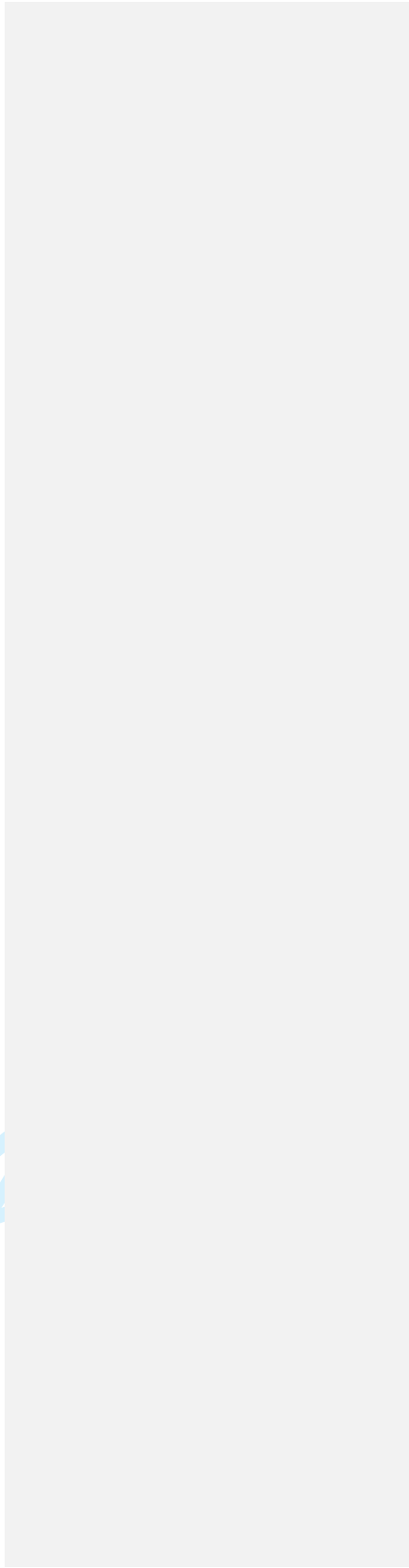
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9 level interventions to reduce future risks of harm. Some successes have been reported, for
10 example in identifying previously undetected risks of new drugs or procedures, but there
11 remain doubts about the wider value of investments in developing and maintaining large-
12 scale incident reporting systems.[5]
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17 Databases of error reports now exist in many parts of the world, including the UK and the
18 US.[6-8] The UK's National Reporting and Learning System (NRLS) was launched in 2003
19 and has since accrued over eight million records, making it the most substantial repository
20 of patient safety incidents in the world. Analyses of this database have revealed risks in a
21 range of clinical areas,[9, 10] but what has been lacking are high-level, valid summary
22 metrics to allow surveillance of harm across a whole healthcare system in a way that
23 allows, for example: comparison between hospitals; monitoring of time trends; and, a
24 baseline for assessing and evaluating interventions. Some doubts exist about the wider
25 value of investments in developing and maintaining large-scale incident reporting
26 systems.[5] This is necessary because of the large volume of incident reports.
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37 In this paper, we report on the development of one such summary statistic, which aims to
38 (unlike the currently used proxy measures of harm such as Hospital Standardised
39 Mmortality Ratios) provide a more direct measure of safety.[11] We developed and tested
40 this measure in the field of orthopaedic surgery. This specialty was chosen because it is
41 associated with a relatively high level of harm.[12] For example, from 2000 to–2006, an
42 equivalent of US\$321 million was paid in adult orthopaedic surgery-related negligence
43 settlements in the UK.[13] Similar figures were reported the Physician Insurers Association
44 of America.[14]
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Methods

Developing a model for an error index

Errors will occur in complex systems ~~like such as~~ healthcare, and their frequency will relate to the number of procedures undertaken. Such assumptions are made in other fields of risk.

In road traffic accidents, for example, predicted crash frequency is a linear function of average daily traffic.[15]

A simple measure of error is the frequency of errors occurring in any hospital. However, since frequency is a function of the number of procedures that have been carried out, we therefore deemed the frequency of errors per unit of procedure as a more appropriate measure.[16] We call this the *error propensity*. In order to calculate this, we extracted data on all orthopaedic reports made by all English hospitals reporting to the UK's ~~National Reporting and Learning System~~ ~~NRLS~~ over a 12-month period from April 1, 2009 to March 31, 2010. In parallel, we approximated the total number of orthopaedic procedures carried out in each hospital using data from the national Hospital Episode Statistics (~~HES~~; 2009–2010) database,[17] which is a mandatory national database of all patient visits to NHS hospitals in England, in order to estimate the error propensity.

A second component of the Orthopaedic Error Index (OEI) reflects the impact the error has on the patients, i.e. how much harm it caused. We call this the *error severity*, which is based on categories of harm. Harm was defined by user self-reports; the degree of harm was classified as either: no harm, low harm (minimal harm – patient(s) required extra observation or minor treatment), moderate harm (short-term harm – patient(s) required

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further treatment, or procedure), severe harm (permanent or long-term harm), or death.

Further details about the structure of the [National Reporting and Learning System/NRLS](#) are provided in Appendix 1. We created our summary statistic using principles laid out in the Standards for Statistical Models used for Public Reporting of Health Outcomes.[18]

The OEI comprised the two main domains of error: the propensity of errors (P) and the severity of harm (S). The mathematical derivation of the OEI is given in Appendix 2.

Analyses

We estimated P, S, and OEI and their standard errors for each hospital using STATA 11 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.).

Since ~~propensity~~P, ~~severity~~S and the OEI deviated from normality, they were first transformed: OEI using a logarithmic transformation and ~~propensity severity~~ and ~~severity propensity~~ by taking their reciprocal values. We sought to identify outliers by creating control lines at one, two, and three standard deviations (SD). We plotted OEI (per 1,000 procedures) against number of procedures and superimposed lines representing the mean and +/- 2SD and 3SD of predicted OEI values. Funnel plots provided a visual representation of the data and have been used widely in health services research to compare institutions. We defined outliers as those with an OEI outside the range of $\mu \pm 3\sigma$, where μ is the mean and σ is the standard deviation for the whole sample. These hospitals require closer scrutiny.[19]

Results

OEI for all hospitals in England

In England, 155 NHS hospitals reported 48,971 patient safety incidents with varying degrees of harm: 34,530/48,971 (70.5%) no harm; 11,529/48,971 (23.5%) low harm; 2,632/48,971 (5.4%) moderate harm; 217/48,971 (0.4%) severe harm; and 63/48,971 (0.1%) deaths in the specialty of trauma and orthopaedic surgery during 2009–2010. The mean hospital OEI was 7.09 (SD 2.72). There was a correlation between the number of procedures and error reports of 0.40; therefore an increase of 1,000 orthopaedic procedures generated approximately 38 additional error reports (Figure 1).

Identifying outlier hospitals

Among the 155 hospitals, five lay outside the pre-specified control limits (Figure 2). These were hospitals which had relatively small numbers of procedures, but high OEI values. [Of note, there is an almost linear association with larger hospitals having fewer errors. Table 1 identifies the key characteristics of these outliers.](#)

Discussion

The OEI is the first attempt to develop automated procedures to interrogate a national database of patient safety incidents in order to identify hospitals at disproportionate risk of iatrogenic harm. Applying this tool to all hospitals providing orthopaedic care identified five outlying hospitals: three tertiary care providers and two secondary care providers.

Whilst the higher rates may be expected because of case-mix considerations in the tertiary care sites, such deviations are not to be expected in the secondary care providers.

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One of these two secondary care providers has subsequently been highlighted nationally as providing sub-standard care due to failures in administration, management, and nursing.[20]

At present, the NHS and other health systems internationally lack direct indicators of safety. Mortality is a proxy measure and cannot be used in isolation to assess the safety of a hospital. Opponents argue that the construction of ~~HH~~hospital ~~SS~~standardised ~~MM~~mortality ~~RR~~ratios is flawed as the index is unable to discriminate between inevitable and preventable deaths, and that the huge variability in care suggested by these metrics cannot be accounted for by variable quality of care alone.~~[21 should be 11]~~ [Although we did not](#)

[distinguish between avoidable and non-avoidable incidents in our analysis, previous work by the group has shown that most orthopaedic incidents that result in harm could have been prevented if safety measures ~~were~~had been implemented.](#) ~~[ref21]~~

[The process of identifying outliers ~~is undeniably~~could be associated with stigma and extensive resource allocation, both financial and reputational.](#) ~~[11]~~ [Nevertheless, in organisations that foster a culture of reporting and learning, this method, should be viewed as one of the many tools that need to be used in parallel to understand how unsafe the care is in that particular organisation. Use of outlier analysis in singularity does not ensure safe care; it merely acts as a trigger for further checks. ~~Nevertheless, one~~One of the hospitals](#)

that we identified as an outlier, and that had ~~ds~~ been the subject of national inquiries, was also noted to have a high ~~HH~~hospital ~~SS~~standardised ~~MM~~mortality ~~RR~~ratio; an excess of up to 1,200 deaths occurred here.[22] We have thus shown that a patient safety reporting system, which until recently has been used as a repository collecting reports of errors, can

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9 be used to identify institutions that may pose a disproportionate risk to patient safety.

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11 [However, the work requires greater scrutiny and validation; the purpose of this](#)
12 [undertaking was to see if national patient safety reporting systems can be used for](#)
13 [surveillance of unsafe care.](#)

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17 [As such, we](#) have created a novel metric, the OEI, which is a direct marker of patient
18 safety in individual hospitals. The thrust behind this idea has been the occurrence of
19 several high-profile cases of hospitals such as Alder Hey, Mid-Staffordshire and Stockport
20 NHS hospitals, where [a catalogue of medical errors occurred that resulted in varying](#)
21 [degrees of harm to the patients; unacceptably high levels of preventable harm occurred.](#) [23]

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27 Most people would agree that in an era of large datasets, regulators and advisory bodies
28 should have mechanisms to identify hospitals that are struggling to deliver high-quality
29 care at an earlier stage so that corrective responses can be initiated. [Monitoring trends in](#)
30 [unsafe care over time would be invaluable. These would help, in addition to](#)
31 [assessing identifying outliers, in evaluating the effect of safety initiatives and case-mix of](#)
32 [patients during different periods of the year.](#) Despite alarming cases of unsafe care, it
33 appears the NHS is still ill-equipped to identify high-risk hospitals through early warning
34 systems.[24] More recently, attempts have been made [in the UK](#) to identify failing hospitals
35 by using nationwide surveillance tools which collect data prospectively: the NHS Safety
36 Thermometer that collects data on four domains – venous thromboembolism, urinary tract
37 infections, pressure ulcers, and falls; [25] the National Surgical Quality Improvement
38 Program which collects measures of outcomes to improve surgical care; [26] and the Global
39 Trigger Tool which measures adverse events. [27] However, not all hospitals use these
40 tools. Ours is the first tool that uses data from an entire national healthcare system.

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Strengths and limitations

Errors can be caused by active failures, for example mistakes and latent conditions, such as failure of system processes.[28] Usually, primary data from small, in-depth, qualitative enquiries are used to identify factors that contributed to the errors. The main strength of this approach is that data are specific for patient safety, but a major limitation is the trade-off between the depth and breadth of the analysis. We sought to investigate the use of routinely collected patient safety incident reports to create a numerical index that could help to provide a complementary perspective by supporting monitoring of the overall system-wide safety of healthcare provision. Other key strengths of our work include drawing on a large national dataset, comprising of over 48,000 orthopaedic reports, and utilising the full body of data reporting on patient safety incidents spanning the full spectrum of severity from no harm to death. At present, the learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported.[29] The sensitivity of the NRLS at picking up errors has been questioned in the past;[30] the low power of the study limits generalizability of results to the entire NRLS. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless this should not deter exploratory work such as ours. [We are also cognizant of the fact that there is likely to be a variation in reporting according to the patient safety culture within hospitals; so a hospital with a high OEI may be one that has an open culture and encourages staff to report patient safety incidents.](#) ~~[Ref31]~~ Of equal

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9 importance is the fact that the NRLS was a voluntary reporting system until April 2010,
10 when mandatory reporting was introduced for serious untoward incidents. [Ref32] In
11 Figure 2, we showed that large hospitals (number of orthopaedic procedures) are
12 associated with reporting fewer errors. This must be interpreted with caution as we have
13 not been able to adjust for patient or procedure case-mix due to paucity and anonymity of
14 the data. Based on work elsewhere, it has been stipulated that specialised surgical services
15 should be provided in tertiary hospitals, although geographical or logistical impediments
16 may occur. [Ref33] We cannot make this claim based on our findings.

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<http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/about-reporting-patient-safety-incidents/>

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Comment [SP4]: Reference: Shervin N, Rubash HE, Katz JN. Orthopaedic procedure volume and patient outcomes: a systematic literature review. Clin Orthop Relat Res. 2007 Apr;457:35-41

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31 Some local systems of risk management ~~at in~~ hospitals opt for root cause analyses to
32 develop local solutions to mitigate against harm to patients, but these are not shared
33 nationally, and limited information may be provided to national reporting systems. These
34 systems rely on patient safety experts methodically trawling through patient safety
35 incidents by severity and frequency, thereby leading to the production of quarterly reports,
36 alerts, and rapid response solutions. [34] Such analyses are time-consuming and, as the
37 number of reports rapidly increases, may in the future be unsustainable. There is also a
38 non-cohesive approach globally to identifying unsafe hospitals. The multitude of quality
39 indicators which are proxy measures of unsafe care is overwhelming. The OEI is a
40 surveillance tool that can enable direct evaluation of safer care in hospitals. It is, we
41 believe, a novel benchmarking tool to assess patient safety across hospitals using a large
42 patient safety reporting system.

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The main limitations are those inherent to any secondary analysis of data, including absence of specific information needed and necessities of using proxies. [Ideally, we would have preferred to link HES data to corresponding NRLS incidents. At present, this is not possible, as the latter does not allow for patient identification via ~~and~~ NHS identification numbers.](#) [-HES data will also give an approximation of orthopaedic and trauma procedures due to coding inaccuracies.](#) However, these are, we believe, largely mitigated in the present analysis by the fact that the data were collected to study error and we refer to our analyses as secondary only because the analysis approach we employed was unanticipated when the study was designed. However, the OEI has several potential limitations. Reporting of patient safety incidents is a subjective exercise and variation in the dataset is bound to exist. Biases also exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. Underlying factors for these biases, such as level of patient safety culture within institutions, were not assessed. Further work on measuring the extent and likely impact of such biases is therefore now needed.

Conclusions

With the proliferation of patient safety reporting systems around the world and an ever-increasing number of patient safety incidents reported to them, sophisticated analytical techniques are required to identify hospitals that need to strengthen their emphasis on patient safety. This is the first time, to our knowledge, that a surveillance mechanism for safety has been proposed using a reporting system.

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Appendix 1: The National Reporting and Learning System

The [National Reporting and Learning System \(NRLS\)](#), housed at the National Patient Safety Agency ([NPSA](#)), is a voluntary, national reporting system set up in 2003 for the NHS in England and Wales. To date, it is one of the largest patient safety reporting systems in the world and contains over eight million records of patient safety incidents.^[344] Incidents are reported by staff at a local level and corrective measures taken where appropriate. Subsequently, these reports are anonymised for personal identifiers and uploaded to the [National Reporting and Learning System \(NRLS\)](#). An alternative route by which information is uploaded to the [National Reporting and Learning System \(NRLS\)](#) is through an online reporting form available on the [National Patient Safety Agency \(NPSA\)](#) website, which is also open to members of the public. Each [National Reporting and Learning System \(NRLS\)](#) report refers to an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care. It includes the reporting of those incidents which did not lead to harm despite an error taking place, and those which did not lead to harm because the incident was prevented from reaching the patient. These incidents are further stratified into different levels of harm.^[352] The database has 75 data fields, including patient demographics, specialty, location of incident, category of incident and a free-text description of the incident.^[363] Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff and a range of outputs is produced to provide solutions to patient safety problems. These include one-page reports called *Rapid Response Reports*, quarterly data summaries and topic-specific information such as preventing inpatient falls in hospitals. There is constant consultation with subject-matter experts including professional organisations. NHS organisations also have deadlines

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9 imposed on them by which time they should have implemented any findings from these
10 reports.^[341]

11 12 13 14 15 **Appendix 2: Creation of the OEI**

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17 The OEI is the sum of the number of errors (propensity, P) and the degree of harm
18 (severity, S). This should enable us to identify hospitals with large numbers of errors and
19 similarly those units with the greatest degree of harm. It is reasonable to assume as more
20 number of procedures are carried out, a larger number of errors will be reported, although
21 we are also cognizant that there is potentially a high risk of errors in units undertaking
22 relatively fewer procedures.
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28 29 ***Calculating the error propensity***

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31 For each hospital, P was calculated as:

$$32 \quad P = 100 \frac{n}{N},$$

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34 where n was the number of procedures where any error had occurred and N was the total
35 number of procedures; P had a range of 100, with 0 representing the lowest error
36 propensity and 100 representing the largest error propensity.
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43 The standard error of P (P_{SE}) was calculated as:

$$44 \quad P_{SE} = \sqrt{\frac{P(100 - P)}{N}}$$

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The consequences of a medical error can vary from negligible to fatal. The error propensity index treats all reported errors equally. However, there is a qualitative difference between hospitals which have the same E_p , but in one the proportion of death harm is nearly double the other. Therefore, it is important to capture the severity of the error. Each error report in the database contains a NPSA code for severity which is ordinal in character. We propose a severity index based on proportion of each harm category weighed for its severity.

For each hospital, the **s**Severity (S) was calculated as a weighted sum: $S = \sum w_i n_i / n$, where w_i is the weight for the i^{th} error severity category; n_i is the number of procedures where i^{th} error severity category occurred; and n is the number of procedures where any error occurred.

Method of determining weights

We can give greater weight to less common events by using the inverse probability weight. The relative frequency of each harm category was calculated using the inverse probability weights (IPW = 1/ relative frequency) and IPW relative to the no harm category. There are two drawbacks to this way of assigning weights: one, it is data specific so that another dataset with a different distribution will yield different weights; and two, it gives, perhaps correctly but inconveniently, high values to severe harm and death, in which case error severity may be measured just by counting these events. Although this proposition is attractive in its simplicity, it is not useful in terms of error monitoring and developing policies. Our finding that greater harm categories are less frequent is a confirmation of the famous Heinrich ratio, which states that for every major injury, there are 29 minor injuries and 300 near misses.^[374] Referring to the ratio, an expert group on learning from adverse

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9 events in the NHS argued for the importance of reporting near misses: “Not all unsafe
10 systems produce bad outcomes all the time. The potential for disasters may exist, but for
11 any number of reasons those disasters might not occur at all, or occur very rarely – what
12 has been termed ‘a dynamic non-event’. If there are no bad outcomes to monitor, safety
13 information systems need to collect, analyse, and disseminate information from incidents
14 and near misses, as well as from regular proactive checks on the system’s ‘vital
15 signs’.”[385]

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23 We therefore chose a weighing system computed as 2^i where i is the ordinal number of
24 error severity category, from 0 for no harm to 4 for death. The error severity was also
25 rescaled to a range of 0 to 100 as done with S .
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30 For this purpose, the harm categories were assigned numerical values from 0 to 4 (no harm
31 = 0, low harm = 1, moderate harm = 2, ~~severe~~high harm = 3, and death = 4) to reflect their
32 natural order of severity. The weight assigned to the i^{th} harm category was 2^i .
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$$S = \frac{100}{16} \left(\frac{\sum_{i=0}^4 2^i \frac{n_i}{n}}{16} \right)$$

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39 where, n_i is number of procedures where i^{th} harm category occurred and n is the number of
40 procedures where any error occurred. The constant term $100/16$, 16 or 2^4 , being the
41 maximum value possible (when all reported errors were deaths) for the variable part of the
42 formula, was used to adjust the scale of the index so that 100 was the maximum value,
43 representing a situation where all errors reported resulted in deaths. The minimum value
44 would be 6.25 , representing the case where all reported errors produced no harm. We
45 intentionally avoided rescaling S , 0 to 100, to differentiate between the situation where no
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errors were reported and some errors were reported but they were all in the no harm category.

The standard error of S was computed as:

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$$S_{SE} = \frac{100}{16} \left(\sqrt{\sum_{i=0}^4 2^{2i} \left(\frac{p_i - p_i^2}{n} \right)} \right)$$

Orthopaedic Error Index, OEI

We defined the OEI, E , as the weighted sum of error propensity and error severity.

$$E = 0.5P + 0.5S$$

This index gives equal weights for propensity, which captures the overall number of errors and severity of errors, because both aspects are considered important in dealing with errors.³⁴ The weights were chosen so that E has a range of 0 to 100. The standard error of E was computed as:

$$E_{SE} = \sqrt{\frac{P_{SE}^2 + S_{SE}^2}{4}}$$

To identify reporting bias, we used the relationship between number of procedures and OEI. For this purpose we first meta-regressed OEI on number of procedures and saved the predicted values of OEI.

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Figure legends

Figure 1: Relationship between number of error reports and volume of procedures

Figure 2: The Orthopaedic Error Index for all hospitals in England

Table

Comment [SSP5]: Suggest delete table

Table 1: Hospitals identified as outliers that warrant attention (outside 3 standard deviations from the mean Orthopaedic Error Index)

	Cluster	No. orthopaedic procedures	No. incidents reported	Orthopaedic Error Index (OEI)	Standard Error (SE) of OEI
1	Acute specialist hospital (including acute specialist children)	1093	120	9.89	0.72
2	Medium acute hospital	5601	1209	14.46	0.28
3	Small acute hospital	2085	410	15.29	0.51
4	Acute specialist hospital (including acute specialist children)	1222	63	6.04	0.42
5	Acute specialist hospital (including acute specialist children)	2277	80	7.10	0.63

Authors' contributions

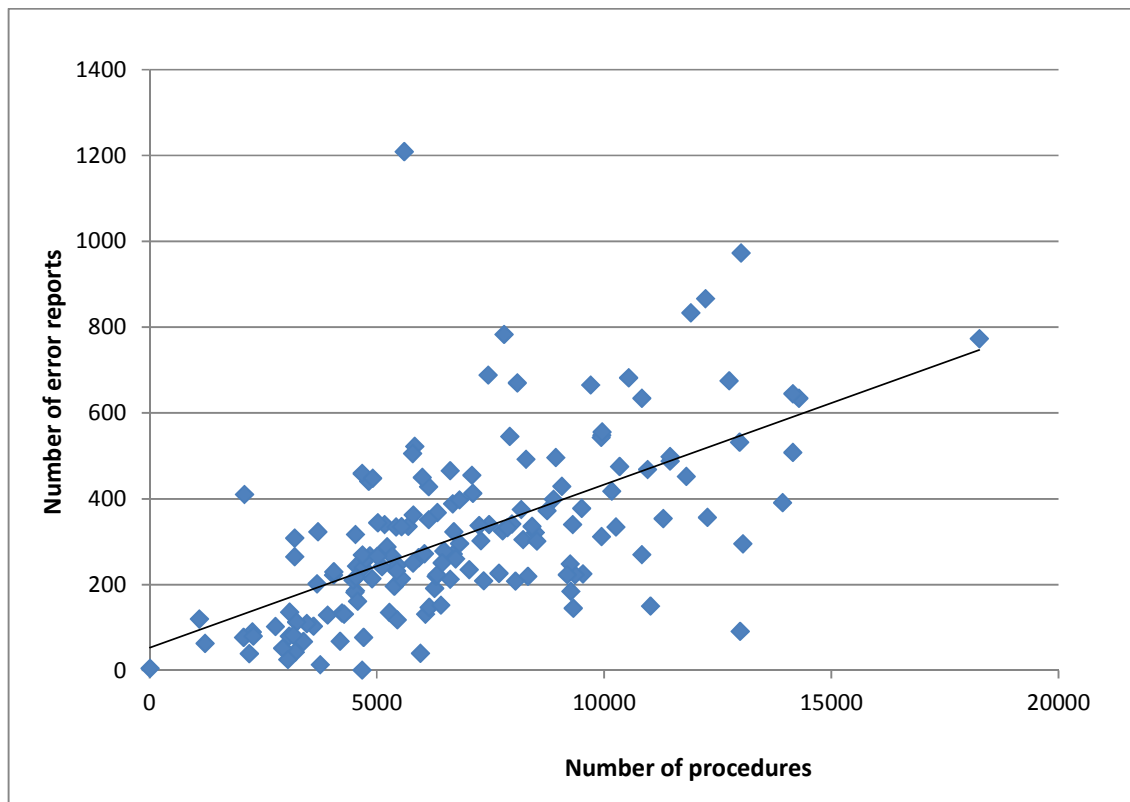
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SSP and GN conceived the study design, and analysed and interpreted the data. They drafted earlier versions of the article. AC-S, SJ, BP analysed and interpreted the data and helped to draft subsequent versions of the article. GP, LD and AS analysed and interpreted the data and revised it critically for important intellectual content. All authors approved the final version to be published.

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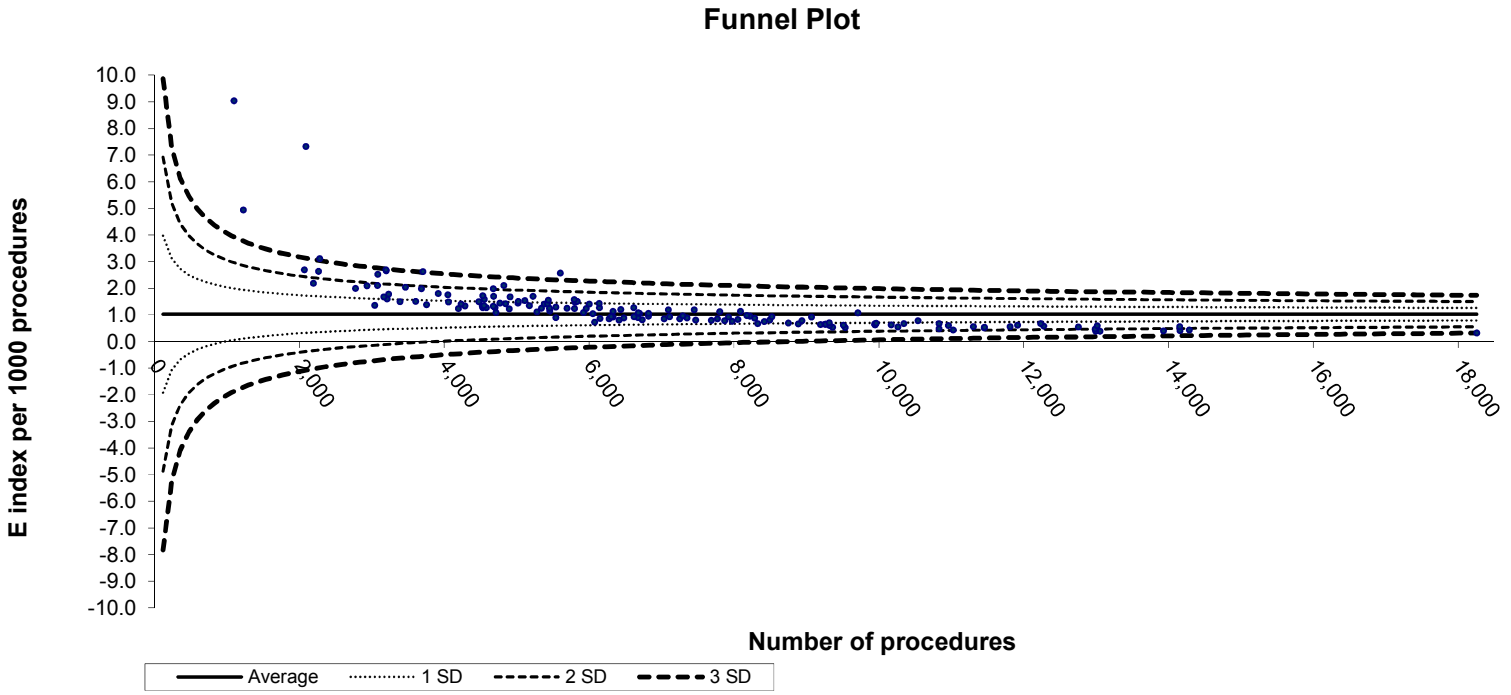
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Figure 1: Relationship between number of error reports and volume of procedures



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Figure 2: The Orthopaedic Error Index for all hospitals in England



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page number
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	7 – 8
Objectives	3	State specific objectives, including any pre-specified hypotheses	8
Methods			
Study design	4	Present key elements of study design early in the paper	9 – 10, 18 - 22
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9 -10
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	9 -10
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10, 18 - 22
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	18 - 22
Bias	9	Describe any efforts to address potential sources of bias	18-22
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	18-22
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	9-10, 18 - 22
		(b) Describe any methods used to examine subgroups and interactions	18 - 22
		(c) Explain how missing data were addressed	13
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods	

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taking account of sampling strategy

N/A

(e) Describe any sensitivity analyses

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Results		Page number	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11 - 13
		(b) Give reasons for non-participation at each stage	N/A – all included
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	18 - 22
		(b) Indicate number of participants with missing data for each variable of interest	N/A – all included
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11
		(b) Report category boundaries when continuous variables were categorized	11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11, 18 - 22
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	5

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely

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available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The Orthopaedic Error Index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003448.R2
Article Type:	Research
Date Submitted by the Author:	11-Oct-2013
Complete List of Authors:	Panesar, Sukhmeet; The University of Edinburgh, Centre for Population Health Sciences Netuveli, Gopalakrishnan; Imperial College London, Carson-Stevens, Andrew; University of Cardiff, Institute of Primary Care and Public Health Javad, Sundas; Imperial College London, Department of Primary Care and Population Health Patel, Bhavesh; National Patient Safety Agency, Analysis Parry, Gareth; Harvard Medical School, Donaldson, Liam; Imperial College London, Institute of Global Health Innovation Sheikh, Aziz; University of Edinburgh, Division of Community Health Sciences
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research
Keywords:	ORTHOPAEDIC & TRAUMA SURGERY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH

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Manuscripts

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6 **The Orthopaedic Error Index: development and application of a novel**
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9 **national indicator for assessing the relative safety of hospital care using**
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11 **a cross-sectional approach**
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Abstract

Objective: The Orthopaedic Error Index for hospitals aims to provide the first national assessment of the relative safety of provision of orthopaedic surgery.

Design: Cross-sectional study (retrospective analysis of records in a database)

Setting: The National Reporting and Learning System is the largest national repository of patient safety incidents in the world with over eight million error reports. It offers a unique opportunity to develop novel approaches to enhancing patient safety, including investigating the relative safety of different healthcare providers and specialties.

Participants: We extracted all orthopaedic error reports from the system over one year (2009–2010).

Outcome measures: The Orthopaedic Error Index was calculated as a sum of the error propensity and severity. All relevant hospitals offering orthopaedic surgery in England were then ranked by this metric to identify possible outliers that warrant further attention.

Results: 155 hospitals reported 48,971 orthopaedic-related patient safety incidents. The mean Orthopaedic Error Index was 7.09/year (SD 2.72); five hospitals were identified as outliers. Three of these units were specialist tertiary hospitals carrying out complex surgery; the remaining two outlier hospitals had unusually high Orthopaedic Error Indexes: mean 14.46 (SD 0.29) and 15.29 (SD 0.51), respectively.

Conclusions: The Orthopaedic Error Index has enabled identification of hospitals that may be putting patients at disproportionate risk of orthopaedic-related iatrogenic harm and which therefore warrant further investigation. It provides the prototype of a summary index of harm to enable surveillance of unsafe care over time across institutions. Further validation and scrutiny of the method will be required to assess its potential to be extended

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3 to other hospital specialties in the UK and also internationally to other health systems that
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5 have comparable national databases of patient safety incidents.
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11 **Article summary**

12 Article focus:

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18 • Surveillance of risk through routinely collected patient safety incidents reported to
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20 national patient safety reporting systems has been undertaken in limited situations.
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24 • The Orthopaedic Error Index (OEI) is the first attempt to develop automated
25
26 procedures to interrogate a national database of patient safety incidents in order to
27
28 identify hospitals at disproportionate risk of iatrogenic harm.
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31 • The OEI is the first such metric that is a direct measure of the safety of orthopaedic
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33 surgery in a hospital.
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38 Key messages:

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40 • The OEI enables identification of hospitals that may be putting patients at
41
42 disproportionate risk of orthopaedic-related iatrogenic harm.
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- 45
46 • This novel approach has the potential to be extended to other hospital specialties in
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48 the UK and also internationally to other health systems that have comparable
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50 national databases of patient safety incidents.
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3 Strengths and limitations of this study:
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- 5
- 6 • Several notable strengths of the study: a large national dataset was drawn upon;
7
8 comprising of over 48,000 orthopaedic reports and the data used are specifically for
9
10 patient safety.
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 - 12 • Limitations:
13
 - 14 ○ There is a trade-off between the depth and breadth of the analysis
 - 15
 - 16 ○ Existing learning from national patient safety reporting systems is limited;
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18 some of the information is lost in translation and it is unclear whether all
19
20 patient safety incidents are indeed reported
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 - 23 ○ Secondary analysis of data, including absence of specific information needed
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25 and necessities of using proxies
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 - 28 ○ Biases exist at several levels: reporting of harmful versus non-harmful events
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30 and correct classification of categories of harm. Underlying factors for these
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32 biases, such as level of patient safety culture within institutions, were not
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34 assessed.
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Introduction

The delivery of safer healthcare remains a challenge globally.[1] Over a decade ago, the Institute of Medicine published the seminal report, *To Err is Human*,[1] which revealed the previously under-recognised high burden of morbidity and mortality associated with iatrogenic harm. This was then followed by the equally influential *Crossing the Quality Chasm*, which highlighted the need to develop and make greater use of error reporting systems to enable the generation of learning from patient safety incidents and inform opportunities for system-level interventions to reduce future risks of harm.[2] The challenge for healthcare systems globally remains the consistent delivery of safer care and the associated surveillance of safety within an organisation.

Modern day healthcare involves an array of complicated diagnostic and therapeutic decisions affected by the system within which these occur. Poorly functioning systems and teams have the potential to impact on patient safety. Inevitably, there will be unexpected variation in access, outcomes and quality of care. Whereas some variation is legitimate and indeed desirable (for example, slower surgeons should not be asked to work faster), it is the unwarranted variation that is a major cause of concern to policy-makers and regulators.[3] A much-favoured approach for describing this variability is the use of hospital-wide mortality rates. Proponents have argued that these tools provide useful metrics about problems with the quality of inpatient care; uncover system-wide failures; and can help patients to choose the safest hospital.[4]

Patient safety reporting systems are unused sources of data for the surveillance of harm which enable learning from errors, so that the insights create opportunities for system-

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3 level interventions to reduce future risks of harm. Some successes have been reported, for
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5 example in identifying previously undetected risks of new drugs or procedures, but there
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7 remain doubts about the wider value of investments in developing and maintaining large-
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9 scale incident reporting systems.[5] Databases of error reports now exist in many parts of
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11 the world, including the UK and the US.[6-8] The UK's National Reporting and Learning
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13 System (NRLS) was launched in 2003 and has since accrued over eight million records,
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15 making it the most substantial repository of patient safety incidents in the world. Analyses
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17 of this database have revealed risks in a range of clinical areas,[9, 10] but what has been
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19 lacking are high-level, valid summary metrics to allow surveillance of harm across a whole
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21 healthcare system in a way that allows, for example: comparison between hospitals;
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23 monitoring of time trends; and a baseline for assessing and evaluating interventions. Some
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25 doubts exist about the wider value of investments in developing and maintaining large-
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27 scale incident reporting systems.[5]
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36 In this paper, we report on the development of one such summary statistic, which aims to
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38 (unlike the currently used proxy measures of harm such as Hospital Standardised Mortality
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40 Ratios) provide a more direct measure of safety.[11] We developed and tested this measure
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42 in the field of orthopaedic surgery. This specialty was chosen because it is associated with a
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44 relatively high level of harm.[12] For example, from 2000 to 2006, an equivalent of US\$321
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46 million was paid in adult orthopaedic surgery-related negligence settlements in the UK.[13]
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48 Similar figures were reported the Physician Insurers Association of America.[14]
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Methods

Developing a model for an error index

Errors will occur in complex systems such as healthcare, and their frequency will relate to the number of procedures undertaken. Such assumptions are made in other fields of risk. In road traffic accidents, for example, predicted crash frequency is a linear function of average daily traffic.[15]

A simple measure of error is the frequency of errors occurring in any hospital. However, since frequency is a function of the number of procedures that have been carried out, we therefore deemed the frequency of errors per unit of procedure as a more appropriate measure.[16] We call this the *error propensity*. In order to calculate this, we extracted data on all orthopaedic reports made by all English hospitals reporting to the UK's NRLS over a 12-month period from April 1, 2009 to March 31, 2010. In parallel, we approximated the total number of orthopaedic procedures carried out in each hospital using data from the national Hospital Episode Statistics (HES; 2009–2010) database,[17] which is a mandatory national database of all patient visits to NHS hospitals in England, in order to estimate the error propensity. We defined an orthopaedic procedure as any patient entry that involves an OPCS (Office of Population Censuses and Surveys Classification of Interventions and Procedures) code in the OP1 field of HES with a treatment speciality code of 110.

A second component of the Orthopaedic Error Index (OEI) reflects the impact the error has on the patients, i.e. how much harm it caused. We call this the *error severity*, which is based on categories of harm. Harm was defined by user self-reports; the degree of harm was

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3 classified as either: no harm, low harm (minimal harm – patient(s) required extra
4 observation or minor treatment), moderate harm (short-term harm – patient(s) required
5 further treatment, or procedure), severe harm (permanent or long-term harm), or death.
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10 Further details about the structure of the NRLS are provided in Appendix 1. We created our
11 summary statistic using principles laid out in the Standards for Statistical Models used for
12 Public Reporting of Health Outcomes.[18]
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19 The OEI comprised the two main domains of error: the propensity of errors (P) and the
20 severity of harm (S). The mathematical derivation of the OEI is given in Appendix 2.
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24 ***Analyses***

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28 We estimated P, S and OEI and their standard errors for each hospital using STATA 11
29 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.).
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31 Since P, S and the OEI deviated from normality, they were first transformed: OEI using a
32 logarithmic transformation and *propensity* and *severity* by taking their reciprocal values.
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35 We sought to identify outliers by creating control lines at one, two and three standard
36 deviations (SD). We plotted OEI (per 1,000 procedures) against number of procedures and
37 superimposed lines representing the mean and +/- 2SD and 3SD of predicted OEI values.
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Results

OEI for all hospitals in England

In England, 155 NHS hospitals reported 48,971 patient safety incidents with varying degrees of harm: 34,530/48,971 (70.5%) no harm; 11,529/48,971 (23.5%) low harm; 2,632/48,971 (5.4%) moderate harm; 217/48,971 (0.4%) severe harm; and 63/48,971 (0.1%) deaths in the specialty of trauma and orthopaedic surgery during 2009–2010. The mean hospital OEI was 7.09 (SD 2.72). There was a correlation between the number of procedures and error reports of 0.40; therefore an increase of 1,000 orthopaedic procedures generated approximately 38 additional error reports (Figure 1).

Identifying outlier hospitals

Among the 155 hospitals, five lay outside the pre-specified control limits (Figure 2). These were hospitals which had relatively small numbers of procedures, but high OEI values. Of note, there is an almost linear association with larger hospitals having fewer errors.

Discussion

The OEI is the first attempt to develop automated procedures to interrogate a national database of patient safety incidents in order to identify hospitals at disproportionate risk of iatrogenic harm. Applying this tool to all hospitals providing orthopaedic care identified five outlying hospitals: three tertiary care providers and two secondary care providers.

Whilst the higher rates may be expected because of case-mix considerations in the tertiary care sites, such deviations are not to be expected in the secondary care providers.

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3 One of these two secondary care providers has subsequently been highlighted nationally as
4 providing sub-standard care due to failures in administration, management and
5 nursing.[20]
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11 At present, the NHS and other health systems internationally lack direct indicators of
12 safety. Mortality is a proxy measure and cannot be used in isolation to assess the safety of a
13 hospital. Opponents argue that the construction of Hospital Standardised Mortality Ratios
14 is flawed as the index is unable to discriminate between inevitable and preventable deaths,
15 and that the huge variability in care suggested by these metrics cannot be accounted for by
16 variable quality of care alone.[11] Although we did not distinguish between avoidable and
17 non-avoidable incidents in our analysis, previous work by the group has shown that most
18 orthopaedic incidents that result in harm could have been prevented if safety measures had
19 been implemented.[21]
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34 The process of identifying outliers could be associated with stigma and extensive resource
35 allocation, both financial and reputational.[11] Nevertheless, in organisations that foster a
36 culture of reporting and learning, this method should be viewed as one of the many tools
37 that need to be used in parallel to understand how unsafe the care is in that particular
38 organisation. Use of outlier analysis in singularity does not ensure safe care; it merely acts
39 as a trigger for further checks. One of the hospitals that we identified as an outlier, and that
40 had been the subject of national inquiries, was also noted to have a high Hospital
41 Standardised Mortality Ratio; an excess of up to 1,200 deaths occurred here.[22] We have
42 thus shown that a patient safety reporting system, which until recently has been used as a
43 repository collecting reports of errors, can be used to identify institutions that may pose a
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3 disproportionate risk to patient safety. However, the work requires greater scrutiny and
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5 validation; the purpose of this undertaking was to see if national patient safety reporting
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7 systems can be used for surveillance of unsafe care. As such, we have created a novel
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9 metric, the OEI, which is a direct marker of patient safety in individual hospitals. The thrust
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11 behind this idea has been the occurrence of several high-profile cases of hospitals such as
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13 Alder Hey, Mid-Staffordshire and Stockport NHS hospitals, where a catalogue of medical
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15 errors occurred that resulted in varying degrees of harm to the patients.[23] Most people
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17 would agree that in an era of large datasets, regulators and advisory bodies should have
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19 mechanisms to identify hospitals that are struggling to deliver high-quality care at an
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21 earlier stage so that corrective responses can be initiated. Monitoring trends in unsafe care
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23 over time would be invaluable. They would help, in addition to identifying outliers, in
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25 evaluating the effect of safety initiatives and case-mix of patients during different periods
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27 of the year. Despite alarming cases of unsafe care, it appears the NHS is still ill-equipped to
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29 identify high-risk hospitals through early warning systems.[24] More recently, attempts
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31 have been made in the UK to identify failing hospitals by using nationwide surveillance
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33 tools which collect data prospectively: the NHS Safety Thermometer that collects data on
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35 four domains – venous thromboembolism, urinary tract infections, pressure ulcers and
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37 falls;[25] the National Surgical Quality Improvement Program which collects measures of
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39 outcomes to improve surgical care;[26] and the Global Trigger Tool which measures
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41 adverse events.[27] However, not all hospitals use these tools. Ours is the first tool that
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43 uses data from an entire national healthcare system.
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Strengths and limitations

Errors can be caused by active failures, for example mistakes and latent conditions, such as failure of system processes.[28] Usually, primary data from small, in-depth, qualitative inquiries are used to identify factors that contributed to the errors. The main strength of this approach is that data are specific for patient safety, but a major limitation is the trade-off between the depth and breadth of the analysis. We sought to investigate the use of routinely collected patient safety incident reports to create a numerical index that could help to provide a complementary perspective by supporting monitoring of the overall system-wide safety of healthcare provision. Other key strengths of our work include drawing on a large national dataset, comprising of over 48,000 orthopaedic reports, and utilising the full body of data reporting on patient safety incidents spanning the full spectrum of severity from no harm to death. At present, the learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported.[29] The sensitivity of the NRLS at picking up errors has been questioned in the past;[30] the low power of the study limits generalizability of results to the entire NRLS. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless this should not deter exploratory work such as ours. We are also cognizant of the fact that there is likely to be a variation in reporting according to the patient safety culture within hospitals; so a hospital with a high OEI may be one that has an open culture and encourages staff to report patient safety incidents.[31] Of equal importance is the fact that the NRLS was a voluntary reporting system until April 2010, when mandatory reporting was introduced for serious untoward incidents.[32] In Figure 2,

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3 we showed that large hospitals (number of orthopaedic procedures) are associated with
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5 fewer errors. This must be interpreted with caution as we have not been able to adjust for
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7 patient or procedure case-mix due to paucity and anonymity of the data. Based on work
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9 elsewhere, it has been stipulated that specialised surgical services should be provided in
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11 tertiary hospitals, although geographical or logistical impediments may occur.[33] We
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13 cannot make this claim based on our findings. Some local systems of risk management in
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15 hospitals opt for root cause analyses to develop local solutions to mitigate against harm to
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17 patients, but these are not shared nationally, and limited information may be provided to
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19 national reporting systems. These systems rely on patient safety experts methodically
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21 trawling through patient safety incidents by severity and frequency, thereby leading to the
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23 production of quarterly reports, alerts, and rapid response solutions.[34] Such analyses are
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25 time-consuming and, as the number of reports rapidly increases, may in the future be
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27 unsustainable. There is also a non-cohesive approach globally to identifying unsafe
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29 hospitals. The multitude of quality indicators which are proxy measures of unsafe care is
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31 overwhelming. The OEI is a surveillance tool that can enable direct evaluation of safer care
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33 in hospitals. It is, we believe, a novel benchmarking tool to assess patient safety across
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35 hospitals using a large patient safety reporting system.
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45 The main limitations are those inherent to any secondary analysis of data, including
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47 absence of specific information needed and necessities of using proxies. Ideally, we would
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49 have preferred to link HES data to corresponding NRLS incidents. At present, this is not
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51 possible, as the latter does not allow for patient identification via NHS identification
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53 numbers. HES data will also give an approximation of orthopaedic and trauma procedures
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55 due to coding inaccuracies. However, these are, we believe, largely mitigated in the present
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3 analysis by the fact that the data were collected to study error and we refer to our analyses
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5 as secondary only because the analysis approach we employed was unanticipated when the
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7 study was designed. However, the OEI has several potential limitations. Reporting of
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9 patient safety incidents is a subjective exercise and variation in the dataset is bound to
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11 exist. Biases also exist at several levels: reporting of harmful versus non-harmful events
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13 and correct classification of categories of harm. Underlying factors for these biases, such as
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15 level of patient safety culture within institutions, were not assessed. Further work on
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17 measuring the extent and likely impact of such biases is therefore now needed.
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Conclusions

With the proliferation of patient safety reporting systems around the world and an ever-increasing number of patient safety incidents reported to them, sophisticated analytical techniques are required to identify hospitals that need to strengthen their emphasis on patient safety. This is the first time, to our knowledge, that a surveillance mechanism for safety has been proposed using a reporting system.

Appendix 1: The National Reporting and Learning System

The NRLS, housed at the National Patient Safety Agency (NPSA), is a voluntary, national reporting system set up in 2003 for the NHS in England and Wales. To date, it is one of the largest patient safety reporting systems in the world and contains over eight million records of patient safety incidents.[34] Incidents are reported by staff at a local level and corrective measures taken where appropriate. Subsequently, these reports are anonymised for personal identifiers and uploaded to the NRLS. An alternative route by which information is uploaded to the NRLS is through an online reporting form available on the NPSA website, which is also open to members of the public. Each NRLS report refers to an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care. It includes the reporting of those incidents which did not lead to harm despite an error taking place, and those which did not lead to harm because the incident was prevented from reaching the patient. These incidents are further stratified into different levels of harm.[35] The database has 75 data fields, including patient demographics, specialty, location of incident, category of incident and a free-text description of the incident.[36] Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff and a range of outputs is produced to provide solutions to patient safety problems. These include one-page reports called *Rapid Response Reports*, quarterly data summaries and topic-specific information such as preventing inpatient falls in hospitals. There is constant consultation with subject-matter experts including professional organisations. NHS organisations also have deadlines imposed on them by which time they should have implemented any findings from these reports.[34]

Appendix 2: Creation of the OEI

The OEI is the sum of the number of errors (propensity, P) and the degree of harm (severity, S). This should enable us to identify hospitals with large numbers of errors and similarly those units with the greatest degree of harm. It is reasonable to assume as more procedures are carried out, a larger number of errors will be reported, although we are also cognizant that there is potentially a high risk of errors in units undertaking relatively fewer procedures.

Calculating the error propensity

For each hospital, P was calculated as:

$$P = 100 \frac{n}{N},$$

where n was the number of procedures where any error had occurred and N was the total number of procedures; P had a range of 100, with 0 representing the lowest error propensity and 100 representing the largest error propensity.

The standard error of P (P_{SE}) was calculated as:

$$P_{SE} = \sqrt{\frac{P(100 - P)}{N}}$$

The consequences of a medical error can vary from negligible to fatal. The error propensity index treats all reported errors equally. However, there is a qualitative difference between hospitals which have the same E_p , but in one the proportion of death harm is nearly double the other. Therefore, it is important to capture the severity of the error. Each error report

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3 in the database contains a NPSA code for severity which is ordinal in character. We propose
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5 a severity index based on proportion of each harm category weighed for its severity.
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9 For each hospital, the severity (S) was calculated as a weighted sum: $S = \sum w_i n_i / n$, where
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11 w_i is the weight for the i^{th} error severity category; n_i is the number of procedures where i^{th}
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13 error severity category occurred; and n is the number of procedures where any error
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15 occurred.
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18 19 20 ***Method of determining weights***

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22 We can give greater weight to less common events by using the inverse probability weight.
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24 The relative frequency of each harm category was calculated using the inverse probability
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26 weights (IPW = 1/ relative frequency) and IPW relative to the no harm category. There are
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28 two drawbacks to this way of assigning weights: one, it is data specific so that another
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30 dataset with a different distribution will yield different weights; and two, it gives, perhaps
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32 correctly but inconveniently, high values to severe harm and death, in which case error
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34 severity may be measured just by counting these events. Although this proposition is
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36 attractive in its simplicity, it is not useful in terms of error monitoring and developing
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38 policies. Our finding that greater harm categories are less frequent is a confirmation of the
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40 famous Heinrich ratio, which states that for every major injury, there are 29 minor injuries
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42 and 300 near misses.[37] Referring to the ratio, an expert group on learning from adverse
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44 events in the NHS argued for the importance of reporting near misses: "Not all unsafe
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46 systems produce bad outcomes all the time. The potential for disasters may exist, but for
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48 any number of reasons those disasters might not occur at all, or occur very rarely – what
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50 has been termed 'a dynamic non-event'. If there are no bad outcomes to monitor, safety
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3 information systems need to collect, analyse, and disseminate information from incidents
4 and near misses, as well as from regular proactive checks on the system's 'vital signs.' [38]
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9 We therefore chose a weighing system computed as 2^i where i is the ordinal number of
10 error severity category, from 0 for no harm to 4 for death. The error severity was also
11 rescaled to a range of 0 to 100 as done with S .
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17 For this purpose, the harm categories were assigned numerical values from 0 to 4 (no harm
18 = 0, low harm = 1, moderate harm = 2, high harm = 3, and death = 4) to reflect their natural
19 order of severity. The weight assigned to the i^{th} harm category was 2^i .
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$$S = \frac{100}{16} \left(\frac{\sum_{i=0}^4 2^i n_i}{n} \right)$$

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28 where, n_i is number of procedures where i^{th} harm category occurred and n is the number of
29 procedures where any error occurred. The constant term 100/16, 16 or 2^4 , being the
30 maximum value possible (when all reported errors were deaths) for the variable part of the
31 formula, was used to adjust the scale of the index so that 100 was the maximum value,
32 representing a situation where all errors reported resulted in deaths. The minimum value
33 would be 6.67, representing the case where all reported errors produced no harm. We
34 intentionally avoided rescaling S , 0 to 100, to differentiate between the situation where no
35 errors were reported and some errors were reported but they were all in the no harm
36 category.
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50 The standard error of S was computed as:
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$$S_{SE} = \frac{100}{16} \left(\sqrt{\sum_{i=0}^4 2^{2i} \left(\frac{p_i - p_i^2}{n} \right)} \right)$$

Orthopaedic Error Index, OEI

We defined the OEI, E , as the weighted sum of error propensity and error severity.

$$E = 0.5P + 0.5S$$

This index gives equal weights for propensity, which captures the overall number of errors and severity of errors, because both aspects are considered important in dealing with errors. **Error! Bookmark not defined.** The weights were chosen so that E has a range of 0 to 100. The standard error of E was computed as:

$$E_{SE} = \sqrt{\frac{P_{SE}^2 + S_{SE}^2}{4}}$$

To identify reporting bias, we used the relationship between number of procedures and OEI. For this purpose we first meta-regressed OEI on number of procedures and saved the predicted values of OEI.

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Figure legends

Figure 1: Relationship between number of error reports and volume of procedures

Figure 2: The Orthopaedic Error Index for all hospitals in England

Authors' contributions

SSP and GN conceived the study design, and analysed and interpreted the data. They drafted earlier versions of the article. AC-S, SJ, BP analysed and interpreted the data and helped to draft subsequent versions of the article. GP, LD and AS analysed and interpreted the data and revised it critically for important intellectual content. All authors approved the final version to be published.

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Data sharing

The data used for this study can be requested from NHS England by interested researchers and a case by case evaluation is made. No additional unpublished data rests with the authors.

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Research article

The Orthopaedic Error Index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach

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Abstract

Objective: The Orthopaedic Error Index for hospitals aims to provide the first national assessment of the relative safety of provision of orthopaedic surgery.

Design: Cross-sectional study (retrospective analysis of records in a database)

Setting: The National Reporting and Learning System is the largest national repository of patient safety incidents in the world with over eight million error reports. It offers a unique opportunity to develop novel approaches to enhancing patient safety, including investigating the relative safety of different healthcare providers and specialties.

Participants: We extracted all orthopaedic error reports from the system over one year (2009–2010).

Outcome measures: The Orthopaedic Error Index was calculated as a sum of the error propensity and severity. All relevant hospitals offering orthopaedic surgery in England were then ranked by this metric to identify possible outliers that warrant further attention.

Results: 155 hospitals reported 48,971 orthopaedic-related patient safety incidents. The mean Orthopaedic Error Index was 7.09/year (SD 2.72); five hospitals were identified as outliers. Three of these units were specialist tertiary hospitals carrying out complex surgery; the remaining two outlier hospitals had unusually high Orthopaedic Error Indexes: mean 14.46 (SD 0.29) and 15.29 (SD 0.51), respectively.

Conclusions: The Orthopaedic Error Index has enabled identification of hospitals that may be putting patients at disproportionate risk of orthopaedic-related iatrogenic harm and which therefore warrant further investigation. It provides the prototype of a summary index of harm to enable surveillance of unsafe care over time across institutions. Further validation and scrutiny of the method will be required to assess its potential to be extended

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9 to other hospital specialties in the UK and also internationally to other health systems that
10 have comparable national databases of patient safety incidents.
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14 15 16 **Article summary**

17 18 Article focus:

- 19
20 • Surveillance of risk through routinely collected patient safety incidents reported to
21 national patient safety reporting systems has been undertaken in limited situations.
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- 24 • The Orthopaedic Error Index (OEI) is the first attempt to develop automated
25 procedures to interrogate a national database of patient safety incidents in order to
26 identify hospitals at disproportionate risk of iatrogenic harm.
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- 29 • The OEI is the first such metric that is a direct measure of the safety of orthopaedic
30 surgery in a hospital.
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36 Key messages:

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38 • The OEI enables identification of hospitals that may be putting patients at
39 disproportionate risk of orthopaedic-related iatrogenic harm.
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- 42 • This novel approach has the potential to be extended to other hospital specialties in
43 the UK and also internationally to other health systems that have comparable
44 national databases of patient safety incidents.
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9 Strengths and limitations of this study:

- Several notable strengths of the study: a large national dataset was drawn upon; comprising of over 48,000 orthopaedic reports and the data used are specifically for patient safety.
- Limitations:
 - There is a trade-off between the depth and breadth of the analysis
 - Existing learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported
 - Secondary analysis of data, including absence of specific information needed and necessities of using proxies
 - Biases exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. Underlying factors for these biases, such as level of patient safety culture within institutions, were not assessed.

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48 **Competing interests**

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50 All authors have completed the ICMJE uniform disclosure form at
51 www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the
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9 submitted work; no financial relationships with any organisations that might have an
10 interest in the submitted work in the previous three years; no other relationships or
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Introduction

The delivery of safer healthcare remains a challenge globally.[1] Over a decade ago, the Institute of Medicine published the seminal report, *To Err is Human*,[1] which revealed the previously under-recognised high burden of morbidity and mortality associated with iatrogenic harm. This was then followed by the equally influential *Crossing the Quality Chasm*, which highlighted the need to develop and make greater use of error reporting systems to enable the generation of learning from patient safety incidents and inform opportunities for system-level interventions to reduce future risks of harm.[2] The challenge for healthcare systems globally remains the consistent delivery of safer care and the associated surveillance of safety within an organisation.

Modern day healthcare involves an array of complicated diagnostic and therapeutic decisions affected by the system within which these occur. Poorly functioning systems and teams have the potential to impact on patient safety. Inevitably, there will be unexpected variation in access, outcomes and quality of care. Whereas some variation is legitimate and indeed desirable (for example, slower surgeons should not be asked to work faster), it is the unwarranted variation that is a major cause of concern to policy-makers and regulators.[3] A much-favoured approach for describing this variability is the use of hospital-wide mortality rates. Proponents have argued that these tools provide useful metrics about problems with the quality of inpatient care; uncover system-wide failures; and can help patients to choose the safest hospital.[4]

Patient safety reporting systems are unused sources of data for the surveillance of harm which enable learning from errors, so that the insights create opportunities for system-

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9 level interventions to reduce future risks of harm. Some successes have been reported, for
10 example in identifying previously undetected risks of new drugs or procedures, but there
11 remain doubts about the wider value of investments in developing and maintaining large-
12 scale incident reporting systems.[5] Databases of error reports now exist in many parts of
13 the world, including the UK and the US.[6-8] The UK's National Reporting and Learning
14 System (NRLS) was launched in 2003 and has since accrued over eight million records,
15 making it the most substantial repository of patient safety incidents in the world. Analyses
16 of this database have revealed risks in a range of clinical areas,[9, 10] but what has been
17 lacking are high-level, valid summary metrics to allow surveillance of harm across a whole
18 healthcare system in a way that allows, for example: comparison between hospitals;
19 monitoring of time trends; and a baseline for assessing and evaluating interventions. Some
20 doubts exist about the wider value of investments in developing and maintaining large-
21 scale incident reporting systems.[5]

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35 In this paper, we report on the development of one such summary statistic, which aims to
36 (unlike the currently used proxy measures of harm such as Hospital Standardised Mortality
37 Ratios) provide a more direct measure of safety.[11] We developed and tested this measure
38 in the field of orthopaedic surgery. This specialty was chosen because it is associated with a
39 relatively high level of harm.[12] For example, from 2000 to 2006, an equivalent of US\$321
40 million was paid in adult orthopaedic surgery-related negligence settlements in the UK.[13]
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46 Similar figures were reported the Physician Insurers Association of America.[14]
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Methods

Developing a model for an error index

Errors will occur in complex systems such as healthcare, and their frequency will relate to the number of procedures undertaken. Such assumptions are made in other fields of risk. In road traffic accidents, for example, predicted crash frequency is a linear function of average daily traffic.[15]

A simple measure of error is the frequency of errors occurring in any hospital. However, since frequency is a function of the number of procedures that have been carried out, we therefore deemed the frequency of errors per unit of procedure as a more appropriate measure.[16] We call this the *error propensity*. In order to calculate this, we extracted data on all orthopaedic reports made by all English hospitals reporting to the UK's NRLS over a 12-month period from April 1, 2009 to March 31, 2010. In parallel, we approximated the total number of orthopaedic procedures carried out in each hospital using data from the national Hospital Episode Statistics (HES; 2009–2010) database,[17] which is a mandatory national database of all patient visits to NHS hospitals in England, in order to estimate the error propensity. According to HES, an orthopaedic procedure is described as any patient entry that involves an OPCS (Office of Population Censuses and Surveys Classification of Interventions and Procedures) code in the OP1 field of HES with a treatment speciality code of 110.

A second component of the Orthopaedic Error Index (OEI) reflects the impact the error has on the patients, i.e. how much harm it caused. We call this the *error severity*, which is based

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9 on categories of harm. Harm was defined by user self-reports; the degree of harm was
10 classified as either: no harm, low harm (minimal harm – patient(s) required extra
11 observation or minor treatment), moderate harm (short-term harm – patient(s) required
12 further treatment, or procedure), severe harm (permanent or long-term harm), or death.
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14 Further details about the structure of the NRLS are provided in Appendix 1. We created our
15 summary statistic using principles laid out in the Standards for Statistical Models used for
16 Public Reporting of Health Outcomes.[18]
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23 The OEI comprised the two main domains of error: the propensity of errors (P) and the
24 severity of harm (S). The mathematical derivation of the OEI is given in Appendix 2.
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27 **Analyses**

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30 We estimated P, S and OEI and their standard errors for each hospital using STATA 11
31 (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.).
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33 Since P, S and the OEI deviated from normality, they were first transformed: OEI using a
34 logarithmic transformation and *propensity* and *severity* by taking their reciprocal values.
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37 We sought to identify outliers by creating control lines at one, two and three standard
38 deviations (SD). We plotted OEI (per 1,000 procedures) against number of procedures and
39 superimposed lines representing the mean and +/- 2SD and 3SD of predicted OEI values.
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42 Funnel plots provided a visual representation of the data and have been used widely in
43 health services research to compare institutions. We defined outliers as those with an OEI
44 outside the range of $\mu \pm 3\sigma$, where μ is the mean and σ is the standard deviation for the
45 whole sample. These hospitals require closer scrutiny.[19]
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Results

OEI for all hospitals in England

In England, 155 NHS hospitals reported 48,971 patient safety incidents with varying degrees of harm: 34,530/48,971 (70.5%) no harm; 11,529/48,971 (23.5%) low harm; 2,632/48,971 (5.4%) moderate harm; 217/48,971 (0.4%) severe harm; and 63/48,971 (0.1%) deaths in the specialty of trauma and orthopaedic surgery during 2009–2010. The mean hospital OEI was 7.09 (SD 2.72). There was a correlation between the number of procedures and error reports of 0.40; therefore an increase of 1,000 orthopaedic procedures generated approximately 38 additional error reports (Figure 1).

Identifying outlier hospitals

Among the 155 hospitals, five lay outside the pre-specified control limits (Figure 2). These were hospitals which had relatively small numbers of procedures, but high OEI values. Of note, there is an almost linear association with larger hospitals having fewer errors.

Discussion

The OEI is the first attempt to develop automated procedures to interrogate a national database of patient safety incidents in order to identify hospitals at disproportionate risk of iatrogenic harm. Applying this tool to all hospitals providing orthopaedic care identified five outlying hospitals: three tertiary care providers and two secondary care providers.

Whilst the higher rates may be expected because of case-mix considerations in the tertiary care sites, such deviations are not to be expected in the secondary care providers.

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9 One of these two secondary care providers has subsequently been highlighted nationally as
10 providing sub-standard care due to failures in administration, management and
11 nursing.[20]
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15 At present, the NHS and other health systems internationally lack direct indicators of
16 safety. Mortality is a proxy measure and cannot be used in isolation to assess the safety of a
17 hospital. Opponents argue that the construction of Hospital Standardised Mortality Ratios
18 is flawed as the index is unable to discriminate between inevitable and preventable deaths,
19 and that the huge variability in care suggested by these metrics cannot be accounted for by
20 variable quality of care alone.[11] Although we did not distinguish between avoidable and
21 non-avoidable incidents in our analysis, previous work by the group has shown that most
22 orthopaedic incidents that result in harm could have been prevented if safety measures had
23 been implemented.[21]
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33 The process of identifying outliers could be associated with stigma and extensive resource
34 allocation, both financial and reputational.[11] Nevertheless, in organisations that foster a
35 culture of reporting and learning, this method should be viewed as one of the many tools
36 that need to be used in parallel to understand how unsafe the care is in that particular
37 organisation. Use of outlier analysis in singularity does not ensure safe care; it merely acts
38 as a trigger for further checks. One of the hospitals that we identified as an outlier, and that
39 had been the subject of national inquiries, was also noted to have a high Hospital
40 Standardised Mortality Ratio; an excess of up to 1,200 deaths occurred here.[22] We have
41 thus shown that a patient safety reporting system, which until recently has been used as a
42 repository collecting reports of errors, can be used to identify institutions that may pose a
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9 disproportionate risk to patient safety. However, the work requires greater scrutiny and
10 validation; the purpose of this undertaking was to see if national patient safety reporting
11 systems can be used for surveillance of unsafe care. As such, we have created a novel
12 metric, the OEI, which is a direct marker of patient safety in individual hospitals. The thrust
13 behind this idea has been the occurrence of several high-profile cases of hospitals such as
14 Alder Hey, Mid-Staffordshire and Stockport NHS hospitals, where a catalogue of medical
15 errors occurred that resulted in varying degrees of harm to the patients.[23] Most people
16 would agree that in an era of large datasets, regulators and advisory bodies should have
17 mechanisms to identify hospitals that are struggling to deliver high-quality care at an
18 earlier stage so that corrective responses can be initiated. Monitoring trends in unsafe care
19 over time would be invaluable. They would help, in addition to identifying outliers, in
20 evaluating the effect of safety initiatives and case-mix of patients during different periods
21 of the year. Despite alarming cases of unsafe care, it appears the NHS is still ill-equipped to
22 identify high-risk hospitals through early warning systems.[24] More recently, attempts
23 have been made in the UK to identify failing hospitals by using nationwide surveillance
24 tools which collect data prospectively: the NHS Safety Thermometer that collects data on
25 four domains - venous thromboembolism, urinary tract infections, pressure ulcers and
26 falls;[25] the National Surgical Quality Improvement Program which collects measures of
27 outcomes to improve surgical care;[26] and the Global Trigger Tool which measures
28 adverse events.[27] However, not all hospitals use these tools. Ours is the first tool that
29 uses data from an entire national healthcare system.
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Strengths and limitations

Errors can be caused by active failures, for example mistakes and latent conditions, such as failure of system processes.[28] Usually, primary data from small, in-depth, qualitative inquiries are used to identify factors that contributed to the errors. The main strength of this approach is that data are specific for patient safety, but a major limitation is the trade-off between the depth and breadth of the analysis. We sought to investigate the use of routinely collected patient safety incident reports to create a numerical index that could help to provide a complementary perspective by supporting monitoring of the overall system-wide safety of healthcare provision. Other key strengths of our work include drawing on a large national dataset, comprising of over 48,000 orthopaedic reports, and utilising the full body of data reporting on patient safety incidents spanning the full spectrum of severity from no harm to death. At present, the learning from national patient safety reporting systems is limited; some of the information is lost in translation and it is unclear whether all patient safety incidents are indeed reported.[29] The sensitivity of the NRLS at picking up errors has been questioned in the past;[30] the low power of the study limits generalizability of results to the entire NRLS. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless this should not deter exploratory work such as ours. We are also cognizant of the fact that there is likely to be a variation in reporting according to the patient safety culture within hospitals; so a hospital with a high OEI may be one that has an open culture and encourages staff to report patient safety incidents.[31] Of equal importance is the fact that the NRLS was a voluntary reporting system until April 2010, when mandatory reporting was introduced for serious untoward incidents.[32] In Figure 2,

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9 we showed that large hospitals (number of orthopaedic procedures) are associated with
10 fewer errors. This must be interpreted with caution as we have not been able to adjust for
11 patient or procedure case-mix due to paucity and anonymity of the data. Based on work
12 elsewhere, it has been stipulated that specialised surgical services should be provided in
13 tertiary hospitals, although geographical or logistical impediments may occur.[33] We
14 cannot make this claim based on our findings. Some local systems of risk management in
15 hospitals opt for root cause analyses to develop local solutions to mitigate against harm to
16 patients, but these are not shared nationally, and limited information may be provided to
17 national reporting systems. These systems rely on patient safety experts methodically
18 trawling through patient safety incidents by severity and frequency, thereby leading to the
19 production of quarterly reports, alerts, and rapid response solutions.[34] Such analyses are
20 time-consuming and, as the number of reports rapidly increases, may in the future be
21 unsustainable. There is also a non-cohesive approach globally to identifying unsafe
22 hospitals. The multitude of quality indicators which are proxy measures of unsafe care is
23 overwhelming. The OEI is a surveillance tool that can enable direct evaluation of safer care
24 in hospitals. It is, we believe, a novel benchmarking tool to assess patient safety across
25 hospitals using a large patient safety reporting system.

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42 The main limitations are those inherent to any secondary analysis of data, including
43 absence of specific information needed and necessities of using proxies. Ideally, we would
44 have preferred to link HES data to corresponding NRLS incidents. At present, this is not
45 possible, as the latter does not allow for patient identification via NHS identification
46 numbers. HES data will also give an approximation of orthopaedic and trauma procedures
47 due to coding inaccuracies. However, these are, we believe, largely mitigated in the present
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9 analysis by the fact that the data were collected to study error and we refer to our analyses
10 as secondary only because the analysis approach we employed was unanticipated when the
11 study was designed. However, the OEI has several potential limitations. Reporting of
12 patient safety incidents is a subjective exercise and variation in the dataset is bound to
13 exist. Biases also exist at several levels: reporting of harmful versus non-harmful events
14 and correct classification of categories of harm. Underlying factors for these biases, such as
15 level of patient safety culture within institutions, were not assessed. Further work on
16 measuring the extent and likely impact of such biases is therefore now needed.
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Conclusions

With the proliferation of patient safety reporting systems around the world and an ever-increasing number of patient safety incidents reported to them, sophisticated analytical techniques are required to identify hospitals that need to strengthen their emphasis on patient safety. This is the first time, to our knowledge, that a surveillance mechanism for safety has been proposed using a reporting system.

Appendix 1: The National Reporting and Learning System

The NRLS, housed at the National Patient Safety Agency (NPSA), is a voluntary, national reporting system set up in 2003 for the NHS in England and Wales. To date, it is one of the largest patient safety reporting systems in the world and contains over eight million records of patient safety incidents.[34] Incidents are reported by staff at a local level and corrective measures taken where appropriate. Subsequently, these reports are anonymised for personal identifiers and uploaded to the NRLS. An alternative route by which information is uploaded to the NRLS is through an online reporting form available on the NPSA website, which is also open to members of the public. Each NRLS report refers to an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care. It includes the reporting of those incidents which did not lead to harm despite an error taking place, and those which did not lead to harm because the incident was prevented from reaching the patient. These incidents are further stratified into different levels of harm.[35] The database has 75 data fields, including patient demographics, specialty, location of incident, category of incident and a free-text description of the incident.[36] Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff and a range of outputs is produced to provide solutions to patient safety problems. These include one-page reports called *Rapid Response Reports*, quarterly data summaries and topic-specific information such as preventing inpatient falls in hospitals. There is constant consultation with subject-matter experts including professional organisations. NHS organisations also have deadlines imposed on them by which time they should have implemented any findings from these reports.[34]

Appendix 2: Creation of the OEI

The OEI is the sum of the number of errors (propensity, P) and the degree of harm (severity, S). This should enable us to identify hospitals with large numbers of errors and similarly those units with the greatest degree of harm. It is reasonable to assume as more procedures are carried out, a larger number of errors will be reported, although we are also cognizant that there is potentially a high risk of errors in units undertaking relatively fewer procedures.

Calculating the error propensity

For each hospital, P was calculated as:

$$P = 100 \frac{n}{N},$$

where n was the number of procedures where any error had occurred and N was the total number of procedures; P had a range of 100, with 0 representing the lowest error propensity and 100 representing the largest error propensity.

The standard error of P (P_{SE}) was calculated as:

$$P_{SE} = \sqrt{\frac{P(100 - P)}{N}}$$

The consequences of a medical error can vary from negligible to fatal. The error propensity index treats all reported errors equally. However, there is a qualitative difference between hospitals which have the same E_p , but in one the proportion of death harm is nearly double the other. Therefore, it is important to capture the severity of the error. Each error report

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9 in the database contains a NPSA code for severity which is ordinal in character. We propose
10 a severity index based on proportion of each harm category weighed for its severity.

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13 For each hospital, the severity (S) was calculated as a weighted sum: $S = \sum w_i n_i / n$, where
14 w_i is the weight for the i^{th} error severity category; n_i is the number of procedures where i^{th}
15 error severity category occurred; and n is the number of procedures where any error
16 occurred.
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21 22 **Method of determining weights**

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24 We can give greater weight to less common events by using the inverse probability weight.
25 The relative frequency of each harm category was calculated using the inverse probability
26 weights (IPW = 1/ relative frequency) and IPW relative to the no harm category. There are
27 two drawbacks to this way of assigning weights: one, it is data specific so that another
28 dataset with a different distribution will yield different weights; and two, it gives, perhaps
29 correctly but inconveniently, high values to severe harm and death, in which case error
30 severity may be measured just by counting these events. Although this proposition is
31 attractive in its simplicity, it is not useful in terms of error monitoring and developing
32 policies. Our finding that greater harm categories are less frequent is a confirmation of the
33 famous Heinrich ratio, which states that for every major injury, there are 29 minor injuries
34 and 300 near misses.[37] Referring to the ratio, an expert group on learning from adverse
35 events in the NHS argued for the importance of reporting near misses: "Not all unsafe
36 systems produce bad outcomes all the time. The potential for disasters may exist, but for
37 any number of reasons those disasters might not occur at all, or occur very rarely – what
38 has been termed 'a dynamic non-event'. If there are no bad outcomes to monitor, safety
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information systems need to collect, analyse, and disseminate information from incidents and near misses, as well as from regular proactive checks on the system's 'vital signs'." [38]

We therefore chose a weighing system computed as 2^i where i is the ordinal number of error severity category, from 0 for no harm to 4 for death. The error severity was also rescaled to a range of 0 to 100 as done with S .

For this purpose, the harm categories were assigned numerical values from 0 to 4 (no harm = 0, low harm = 1, moderate harm = 2, high harm = 3, and death = 4) to reflect their natural order of severity. The weight assigned to the i^{th} harm category was 2^i .

$$S = \frac{100}{16} \left(\frac{\sum_{i=0}^4 2^i \frac{n_i}{n}}{n} \right)$$

where, n_i is number of procedures where i^{th} harm category occurred and n is the number of procedures where any error occurred. The constant term $100/16$, 16 or 2^4 , being the maximum value possible (when all reported errors were deaths) for the variable part of the formula, was used to adjust the scale of the index so that 100 was the maximum value, representing a situation where all errors reported resulted in deaths. The minimum value would be 6.67, representing the case where all reported errors produced no harm. We intentionally avoided rescaling S , 0 to 100, to differentiate between the situation where no errors were reported and some errors were reported but they were all in the no harm category.

The standard error of S was computed as:

$$S_{SE} = \frac{100}{16} \left(\sqrt{\sum_{i=0}^4 2^{2i} \left(\frac{p_i - p_i^2}{n} \right)} \right)$$

Orthopaedic Error Index, OEI

We defined the OEI, E , as the weighted sum of error propensity and error severity.

$$E = 0.5P + 0.5S$$

This index gives equal weights for propensity, which captures the overall number of errors and severity of errors, because both aspects are considered important in dealing with errors. [Error! Bookmark not defined.](#)³⁴ The weights were chosen so that E has a range of 0 to 100. The standard error of E was computed as:

$$E_{SE} = \sqrt{\frac{P_{SE}^2 + S_{SE}^2}{4}}$$

To identify reporting bias, we used the relationship between number of procedures and OEI. For this purpose we first meta-regressed OEI on number of procedures and saved the predicted values of OEI.

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Figure legends

Figure 1: Relationship between number of error reports and volume of procedures

Figure 2: The Orthopaedic Error Index for all hospitals in England

Authors' contributions

SSP and GN conceived the study design, and analysed and interpreted the data. They drafted earlier versions of the article. AC-S, SJ, BP analysed and interpreted the data and helped to draft subsequent versions of the article. GP, LD and AS analysed and interpreted the data and revised it critically for important intellectual content. All authors approved the final version to be published.

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Figure 1: Relationship between number of error reports and volume of procedures

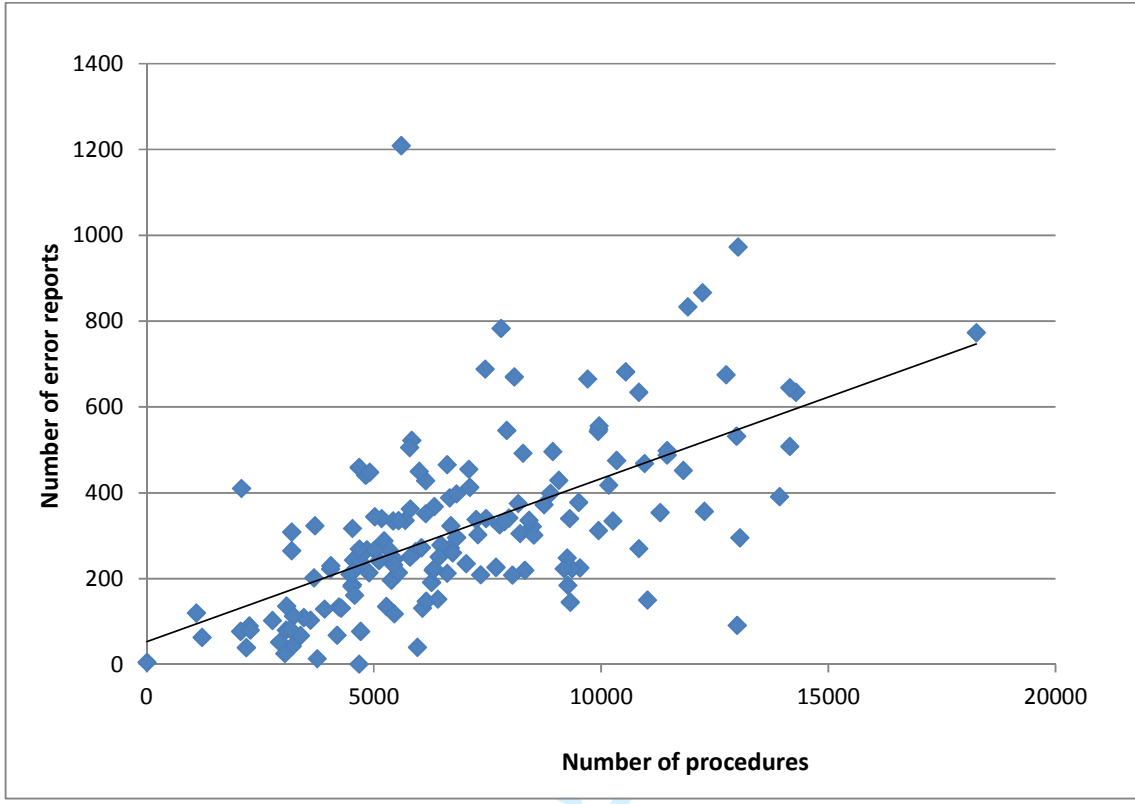
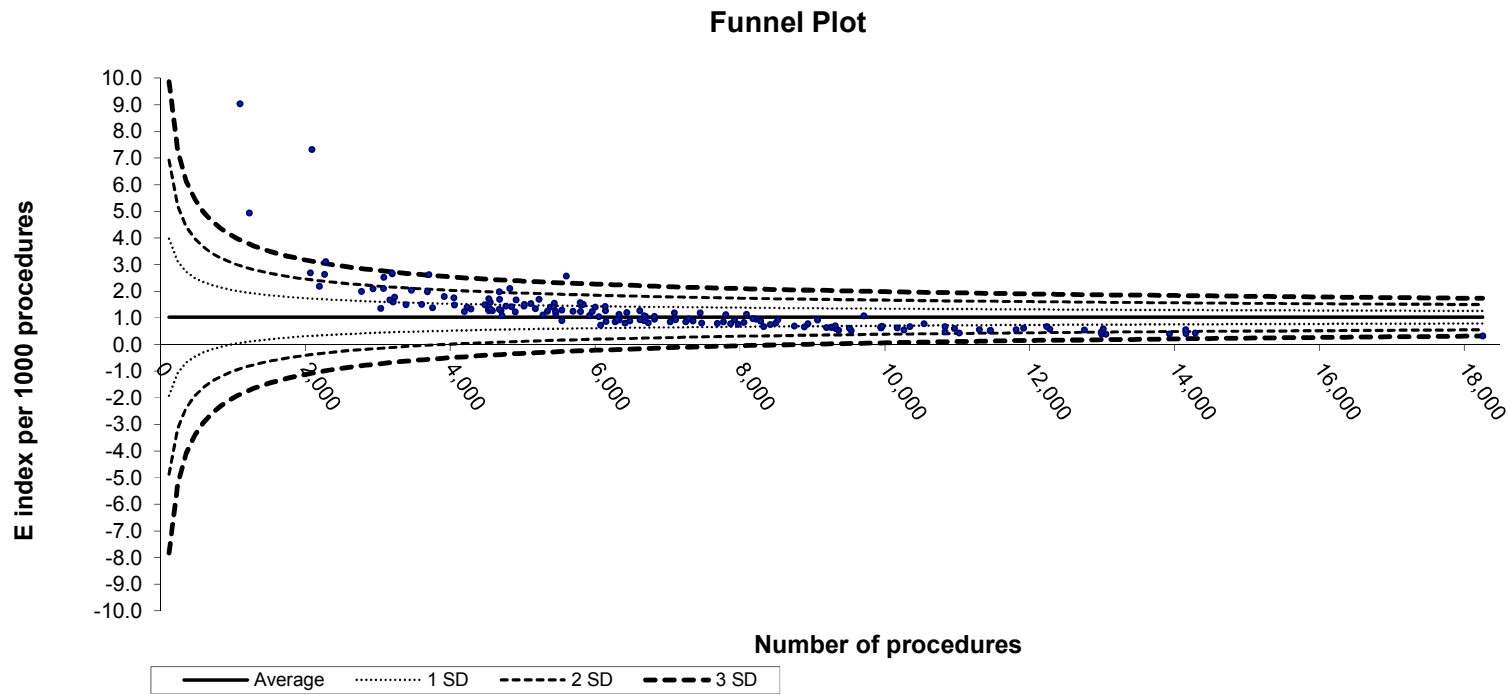


Figure 2: The Orthopaedic Error Index for all hospitals in England



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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page number
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	7 – 8
Objectives	3	State specific objectives, including any pre-specified hypotheses	8
Methods			
Study design	4	Present key elements of study design early in the paper	9 – 10, 18 - 22
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9 -10
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	9 -10
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10, 18 - 22
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	18 - 22
Bias	9	Describe any efforts to address potential sources of bias	18-22
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	18-22
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	9-10, 18 - 22
		(b) Describe any methods used to examine subgroups and interactions	18 - 22
		(c) Explain how missing data were addressed	13
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods	

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taking account of sampling strategy

N/A

(e) Describe any sensitivity analyses

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Continued on next page

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Results		Page number	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11 - 13
		(b) Give reasons for non-participation at each stage	N/A – all included
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	18 - 22
		(b) Indicate number of participants with missing data for each variable of interest	N/A – all included
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11
		(b) Report category boundaries when continuous variables were categorized	11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11, 18 - 22
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	5

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely

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2 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
3 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
4 available at www.strobe-statement.org.
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