Routinely recorded patient safety events in primary care: a literature review

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Background. Existing patient-level data can be used to measure and monitor patient safety. Data from sources including electronic patient records are routinely collected in primary care and may be suitable for adverse event screening, such as patient safety indicators. To inform the feasibility of developing primary care measures of patient harm, information about routinely collected data is needed.

Objective. A literature review was conducted to determine the types of adverse events that are routinely recorded in primary care.

Methods. We searched ASSIA, Cochrane Library, Embase, HMIC, ISI Web of Science, Medline and PsycInfo databases, grey literature and websites. We included only original research studies in English where routinely collected patient data were used to identify adverse events occurring in primary or ambulatory care settings. Adverse events were defined as unexpected and undesirable patient outcomes arising from health care contact.

Results. Of 5029 citations identified, 15 were reviewed. Twelve studies used multiple data sources. Approximately 6.5% of adult emergency admissions were due to drug-related events \((n=1225)\). Between 0.7% and 2.3% of deaths following adverse events were attributed to treatment in primary care. A large proportion of adverse events resulting in the most severe harm may be preventable. For example, one study estimated that 42% of serious adverse drug events were avoidable.

Conclusions. There is limited use of routinely collected data to measure adverse events in primary care despite large volumes of data generated. The potential for using readily available data recorded in primary care for active patient safety surveillance needs further exploration.

Keywords. Computerized, general practice, iatrogenic disease, medical records systems.

Introduction

Most consultations in health care take place in primary care,\textsuperscript{1} and on an average weekday in England, there are >1 million GP consultations.\textsuperscript{2} Limited availability of data on errors and patient harm in primary care hinders the formation of strategies to improve patient safety within the new National Health Service (NHS) Outcomes Framework, as proposed in the recent NHS White Paper.\textsuperscript{3} It also makes estimating the costs of adverse events in this care setting difficult.\textsuperscript{4} Financial costs of safety incidents are likely to be considerable. For example, adverse drug reactions (ADRs) resulting in hospital admissions in England are estimated to cost \(\sim £466\) million/\textsuperscript{5} year.\textsuperscript{5} In addition, the mechanisms of care that lead to patient injuries are poorly understood, as is the extent to which adverse events are preventable.\textsuperscript{6} Although used widely, and now mandatory for all NHS Trusts,\textsuperscript{7} incident reporting does not capture all the adverse events that occur in primary care or other care settings.

The World Health Organization’s (WHO) World Alliance on Patient Safety has identified the continued development of patient safety indicators as a priority in developed countries.\textsuperscript{8} Adverse event screens based on routinely collected data, including electronic patient records, have already been successfully implemented in secondary care.\textsuperscript{9,10} The Organisation for Economic Co-operation and Development (OECD) has also made recommendations for the use of existing data to build quality and safety tools in primary care.\textsuperscript{11,12} Large volumes of both clinical and non-clinical data are collected in primary care but are currently under-utilized for improving service quality. There is
Methods

Data sources
We searched a number of electronic databases for literature on the application of administrative data for measuring and monitoring patient safety in primary care. The initial search took place between August 2008 and March 2009 and was updated in August 2009. The following databases were searched: Applied Social Sciences Index and Abstracts (ASSIA), Cochrane Library, Excerpta Medica (Embase), Health Management Information Consortium (HMIC), Institute of Scientific Information (ISI) Web of Science, Medical Literature Analysis and Retrieval System Online (Medline) and PsycInfo.

We also searched ‘grey literature’, including the reference lists of key publications, technical and working documents, book chapters, conference proceedings, websites and consulted experts in patient safety and/or primary care.

These sources of data were identified from searching the websites of governments, organizations associated with health care quality and work and academic institutions (See online supplementary Table S1). The sources were also generated from a previous literature review on adverse event measurement using routinely collected data. Our search strategy incorporated both Medical Subject Headings (MeSH) and non-MeSH terms and was based on methods used in previous reviews of medical errors and patient harm (See online supplementary Figure S2).

Definitions
We defined routinely collected data as clinical or non-clinical patient data recorded during patient contact with health care services and that may be used for monitoring and management purposes by health care organizations. Adverse events were defined as unexpected patient outcomes arising from health care contact and not due to existing patient conditions nor be expected outcomes of treatment. Studies conducted in ambulatory care were included in the review as considerable overlap exists between the services offered in this setting and primary care.

Selection criteria
We only reviewed original research studies (observational or experimental) where routinely collected data from any health care setting were used to measure potential or actual adverse patient outcomes that were explicitly associated with primary or ambulatory care contact. Studies also had to provide numerical data for the measured adverse patient outcomes. For example, to be eligible for review, studies where patient injuries, hospital admissions or mortality were described had to also include rates of occurrence.

Exclusion criteria
We excluded all non-original research studies where administrative data were not applied, where numerical results were not provided for adverse events measured and where the focus of the research was either related to the diagnosis or treatment of specific diseases or associated with teaching or research tools. Pharmaco-epidemiological studies investigating ADRs from a single drug or drug group (e.g. gastrointestinal bleeding following use of non-steroidal anti-inflammatory drugs) were excluded as drug reactions are not always due to inappropriate medical care or non-standard drug administration and data on patient endpoints are unavailable in many instances. We did however retain studies that examined the impact of ADRs on health care utilization, such as hospitalizations following drug reactions. We also excluded studies on medical errors where defined adverse outcomes were not reported. Although errors are an integral part of safety research, they are extremely difficult to pick out from routinely collected data, which lack clinical detail. Publications not in English were also excluded.

Data extraction and review
One of the authors (CT) initially screened all publications by title and abstract. Following screening, full versions of the publications that were eligible for further assessment were obtained. We also examined the full versions of publications with ambiguous titles or abstracts or where abstracts were not available for initial screening. The Strengthening The Reporting of Observational Studies in Epidemiology (STROBE) structured checklist and Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement were used to guide the review process and presentation of data. Following the removal of all ineligible studies, data for each study were extracted...
for a predetermined list of data fields within the categories of study type, participants, variables, data sources/measurement, statistical methods and results (Table 1).

As well as patient outcomes, risk factors and assessments of adverse event severity and preventability were also extracted from articles where available. Studies on drug-related incidents were only included in the review if patient outcomes were described and measured, and measurements of the severity or preventability of the adverse drug events were also made.

Results

A search of electronic databases identified 4771 publications for further assessment (Fig. 1). An additional 258 publications were retrieved from grey literature and hand searching of publication reference lists. After a review of titles, 237 publications were retrieved for data extraction and 15 were included in the review. Studies were frequently excluded for lacking documented measurement of patient harm, with many ineligible studies describing measures of medical errors. Other excluded studies failed to provide adequate details about adverse patient outcomes or used simulated datasets instead of real patient data. Due to the heterogeneity in adverse events measured in the included studies, only a narrative synthesis was possible. The studies reported uses of routinely collected data for measuring patient harm that ranged from estimates of adverse events and their burden on health services, to the examination of risk factors, assessments of injury severity and the amenability of adverse events to organizational change.

Study characteristics

Of the 15 reviewed studies, 9 were cross-sectional in design, with the remainder of studies using cohort or case control methods (Table 1). Many of the studies took place in the USA (n = 9/15); the remaining studies were conducted in England (n = 4) and Canada (n = 2). Study periods spanned from 1990 to 2008. All but one study investigated adverse events in patients aged ≥16 years.

The types of data used in the studies were medical records/administrative data, surveys (staff or patient), incident reports and population-based data (including census). Approximately half of the studies used multiple data sources (n = 7/15). In each of two related studies by the same authors, data were obtained from six sources: health provider reports, hospital discharge summaries, emergency department notes, computer-generated signals, electronic clinic notes and administrative incident reports.18,19 Seven studies used primary or ambulatory care data only, while the other eight studies drew from secondary care

<table>
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<tr>
<th>Table 1</th>
<th>Types of data extracted</th>
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<tr>
<td><strong>Section</strong></td>
<td><strong>Data field</strong></td>
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<tr>
<td>Design</td>
<td>Study type</td>
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<td>Participants</td>
<td>Participants</td>
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<td>Recruitment/sampling method</td>
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<td>Response rate</td>
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<td>Inclusion criteria</td>
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<td>Variables</td>
<td>Adverse event type/exposure</td>
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<td>Predictor variable(s)</td>
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<td>Confounding variable(s)</td>
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<td>Outcome(s)</td>
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<td>Bias(es) accounted for</td>
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<td>Participants</td>
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<td>Outcome(s)</td>
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<td>Study limitation(s)</td>
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<td>Interpretation</td>
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FIGURE 1 Flow chart of study selection process
### Table 2  Characteristics of reviewed studies

<table>
<thead>
<tr>
<th>Study, Country</th>
<th>Study period (months)</th>
<th>Study design</th>
<th>Methods</th>
<th>Sample (N) (n = cases)</th>
<th>Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budnitz et al., 22 USA</td>
<td>2004–05 (24)</td>
<td>Cross-sectional</td>
<td>Medical records, surveillance data</td>
<td>n = 21 298</td>
<td>Admissions, Emergency department visits</td>
<td>3487 patients admitted. 2.4 ADEs per 1000 population, 95% CI 1.7–3.0.</td>
</tr>
<tr>
<td>Field et al., 19 USA</td>
<td>1999–2000 (12)</td>
<td>Cohort (nested)</td>
<td>Administrative data, reports and medical records</td>
<td>n = 1523, &gt;65 years</td>
<td>Admissions, ADEs</td>
<td>421 preventable ADEs. 5% ADEs identified through more than one source.</td>
</tr>
<tr>
<td>Gandhi et al., 24 USA</td>
<td>1999–2000 (9)</td>
<td>Cohort</td>
<td>Patient survey and medical records</td>
<td>N = 1879, n = 143, &gt;18 years</td>
<td>ADEs, prescribing errors</td>
<td>62 potential ADEs and 3 preventable ADEs.</td>
</tr>
<tr>
<td>Gurwitz et al., 18 USA</td>
<td>1999–2000 (12)</td>
<td>Cross-sectional</td>
<td>Administrative data, reports and medical records</td>
<td>N = 27 617, n = 1523, &gt;65 years</td>
<td>ADEs, death and disability</td>
<td>50.1 ADEs per 1000 person-years. 421 (27.6%) preventable, 13.8 per 1000 person-years.</td>
</tr>
<tr>
<td>Korst et al., 25 USA</td>
<td>1997 (12)</td>
<td>Cohort (population based)</td>
<td>Administrative data</td>
<td>N = 507, 592, n = 1853, &gt;67 years</td>
<td>ADEs</td>
<td>MediCal patients (odds ratio 1.60, 95% CI 1.46–1.80) and patients of African American ethnicity (odds ratio 1.24, 95% CI 1.10–1.41) at greater risk of admission.</td>
</tr>
<tr>
<td>Menec et al., 26 Canada</td>
<td>1990 and 1996 (24)</td>
<td>Cross-sectional</td>
<td>Administrative data and medical records</td>
<td>N = 1863, &gt;67 years</td>
<td>ADEs</td>
<td>High continuity of care associated with reduced odds of ACS admission (adjusted odds ratio 0.67, CI 0.51–0.90). 1% incidence. Approximatley 60% of events due to four indicators.</td>
</tr>
<tr>
<td>Pirmohamed et al., 2 England</td>
<td>2001–02 (5)</td>
<td>Cross-sectional</td>
<td>Administrative data and medical records</td>
<td>N = 18 820, n = 1225, &gt;16 years</td>
<td>ADEs and death</td>
<td>Most common error was failure to investigate possible UTIs (n = 7).</td>
</tr>
<tr>
<td>Singh et al., 27 USA</td>
<td>2004–05 (12)</td>
<td>Case–control</td>
<td>Administrative data and medical records</td>
<td>N = 25 594, n = 652, adults only</td>
<td>ADEs and service use</td>
<td>27% patients urgently readmitted within 3 months. Patients seen by physicians who received discharge summary had decreased adjusted risk of readmission (relative risk 0.74, 95% CI 0.50–1.11).</td>
</tr>
<tr>
<td>South Bedfordshire Practitioners’ Group, England</td>
<td>Unknown</td>
<td>Cross-sectional</td>
<td>Medical records and reports</td>
<td>N = 23, n = 7, children only</td>
<td>ADEs and poor treatment for UTI</td>
<td>Prescription filling identified as problematic by 48% of patients. Approximately 81% of ADEs were reported electronically (n = 17). 3481 consecutive alerts assessed and 91 were overrode. ADEs in written prescriptions for alerted medication in 122 patients. 70 AEs in ambulatory care, of which 31 were preventable.</td>
</tr>
<tr>
<td>van Walraven et al., 28 Canada</td>
<td>1996–97 (9)</td>
<td>Cross-sectional</td>
<td>Medical records and administrative data</td>
<td>N = 1402, n = 240</td>
<td>ADE, adverse drug event; AE, adverse event; CUSUM, cumulative sum; Disability, physical or mental, temporary or permanent; PDRM, preventable drug-related morbidity; UTI, urinary tract infection.</td>
<td></td>
</tr>
<tr>
<td>Weingart et al., 29 USA</td>
<td>2001–02 (10)</td>
<td>Cohort</td>
<td>Computerized physician order entry data and medical records</td>
<td>N = 267, n = 21, adults only</td>
<td>ADEs and communication</td>
<td>3481 consecutive alerts assessed and 91 were overrode. ADEs in written prescriptions for alerted medication in 122 patients.</td>
</tr>
<tr>
<td>Weingart et al., 30 USA</td>
<td>2000 (3)</td>
<td>Cohort</td>
<td>Electronic portal data and medical records</td>
<td>N = 24 034, n = 3, adults only</td>
<td>ADEs and physician decision to override alert</td>
<td>70 AEs in ambulatory care, of which 31 were preventable.</td>
</tr>
<tr>
<td>Woods et al., 31 USA</td>
<td>1992 (12)</td>
<td>Cohort (population based)</td>
<td>Administrative data</td>
<td>N = 14 700, n = 587</td>
<td>ADEs, adverse events, death and disability</td>
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</tr>
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sources (including administrative data, electronic patient records and prescription charts). The studies’ sample sizes ranged from 24 patients from 12 general practices over 3 months to 88,822,005 hospital episodes over 7 years.\textsuperscript{20,21}

**Common adverse events**

Where a single administrative data source was used, derived estimates of patient injuries in primary or ambulatory care included 2.4 adverse drug events per 1000 population treated in emergency departments in the USA [95\% confidence interval (CI) 1.7–3.0%].\textsuperscript{22} 1\% incidence of preventable drug-related events (n = 507)\textsuperscript{23} and 6.5\% of acute hospitalizations in England resulting from ADRs (n = 1225) (Table 2).\textsuperscript{5} The undesirable patient outcomes that were most frequently measured in the studies were additional health care contact, hospital admissions and death. A list of adverse events identified from the review is available online (See online supplementary Table S3).

A number of studies were focused on adverse drug events (n = 8) and they produced the majority of indicators identified. In patients aged ≥65 years, the occurrence of adverse drug events was estimated at 4.9 per 1000 population.\textsuperscript{22} Commonly prescribed drugs, including non-steroidal anti-inflammatory drugs (NSAIDs) (n = 363), diuretics (n = 334) and anticoagulants (n = 129), were associated with hospital admissions in a study of 18,820 patients.\textsuperscript{5} Complications arising from drug treatment included gastrointestinal (n = 336/1523), electrolyte or renal (n = 255/1523) and haemorrhagic events (n = 194/1523).\textsuperscript{19}

**Hospital admissions and mortality**

Other complications associated with adverse drug events were hospital admissions, readmissions and emergency department visits (n = 8) (Table 2). A study conducted in the USA found that 16.7\% of patients who were treated in emergency departments for drug-related adverse events were subsequently admitted to hospital (n = 3487/21,298, 95\% CI 13.1–20.3\%).\textsuperscript{22} Female patients were admitted to hospital for ADRs more frequently than male patients (59\% compared to 52\%; 95\% CI 4–10\%, P < 0.0001).\textsuperscript{5} As well as being more likely to experience adverse drug events, patients admitted to hospital for adverse reactions caused by drugs were more likely to be older than patients admitted to hospital with other diagnoses (median 66 years, interquartile range 46–79 years, 95\% CI for difference of 8–10 years, P < 0.0001).\textsuperscript{5} Reductions in admissions and re-admissions were associated with higher levels of continuity of care.\textsuperscript{26,28} For example, the odds of admissions for ambulatory care sensitive conditions were reduced among patients who received high continuity of care (adjusted odds ratio 0.67, 95\% CI 0.51–0.90\%).\textsuperscript{5}

Mortality among cases of adverse events were reported in three studies and ranged from 0.7\% (n = 28/1225) to 2.3\% (n = 11/1523) of patients (Table 2).\textsuperscript{5,18,31} A small sample study estimated that 10\% of patients who had preventable adverse events experienced serious harm or died (n = 3/31), although the exact number of patients who died was not available.\textsuperscript{31} Common causes of death identified from the literature included drug-related gastrointestinal bleeding (n = 15/28).\textsuperscript{5} Other causes of death, such as renal failure (n = 5/28), were also associated with drug treatment.\textsuperscript{5}

**Quality of studies**

Evidence of quality assessment was not provided by three studies. Multi-reviewer assessments were conducted in approximately half of studies where data were extracted from medical records or incident reports (n = 6/11). All studies with calculations of inter-rater agreement reported good or excellent scores between reviewers except in one study where the level at which good agreement was determined was set at a low kappa statistic of 0.40.\textsuperscript{27} Reporting of methodology varied in quality and complexity. Nine publications contained details of inclusion and/or exclusion criteria used and two-thirds of studies described the statistical methods that were applied. Recruitment methods included voluntary participation by self-selected general practices, sampling from single or multiple hospital sites and evaluations using population-based data collected nationally. The validity of adverse event measures was seldom assessed in the descriptive studies.

**Factors associated with adverse events**

Prescribing errors,\textsuperscript{18} poor communication between clinicians\textsuperscript{28,29} and diagnostic failures\textsuperscript{21,27} were frequently indicated as contributory factors in patient safety incidents. Potential causes of adverse events were examined by 60\% of the reviewed studies (n = 9). In one study, 7.6\% of prescriptions from four primary care practices in Boston, USA, were found to contain errors (n = 143, 95\% CI 6.4–8.8\%).\textsuperscript{24} Errors in diagnosis and treatment, including missed or delayed diagnoses, were repeatedly identified as causing adverse events.\textsuperscript{21,27,31} Some of the diagnostic errors that were attributable to patient harm included poor history taking and investigative failures.\textsuperscript{21,27} These types of errors were estimated to cause between 24.4\% (n = 139) and 36\% (n = 1296, 95\% CI 21.8–50.2\%) of potential and actual adverse events.\textsuperscript{27,31}

Few specific risk factors were measured in the reviewed studies. Older patients who experienced drug-related adverse events were more likely to require hospital admission. Budnitz et al.\textsuperscript{22} found that patients aged ≥65 years treated in emergency departments were more likely to be hospitalized (1.6 compared to 0.23 per 1000 population, 95\% CI 4.3–9.2\%). Poor continuity of care and unavailability of hospital discharge summaries were associated with increased risk of readmissions.\textsuperscript{26,28}
Measuring severity and preventability of harm
A third of the studies assessed the severity of adverse events \( (n = 5) \). Assessments were made using severity scales or patient endpoint markers, such as hospital admission being an indicator of serious patient harm.\(^{18,22,24,29,31}\) Like the evaluations of preventability, assessments of injury severity were often performed by doctors, nurses and pharmacists. Low to moderate levels of patient harm were most commonly experienced by patients.\(^{18,31}\)

Forty per cent of studies explored the preventability of adverse events \( (n = 6) \). It was estimated that between 9% \( (n = 1225) \) and 12% \( (n = 587) \) of hospital admissions were due to preventable adverse events in ambulatory and primary care.\(^{5,31}\) Five of the six studies investigating the preventability of patient harm were studies on drugs and their adverse effects.\(^{5,18,23,24,31}\)

One study estimated a 1% incidence of preventable drug-related morbidity occurring in English primary care \( (n = 49 658)\).\(^{23}\) Across the studies, estimates of preventable adverse events varied considerably as did the nature of the assessments. Gurwitz et al.\(^{18}\) reported that 42.2% of serious adverse drug events were preventable \( (n = 1523) \). They found that events caused by cardiovascular drugs or diuretics accounted for 46.6% of preventable drug-related events \( (n = 421) \).\(^{18}\) In contrast, Pirmohamed et al.\(^{5}\) used existing definitions of avoidability in their measurements and found that 9% of adverse events were avoidable \( (n = 1225, 95\% \text{ CI } 7–10\%) \).

Discussion
Unlike other research in this area, our review included only studies that have measured patient harm due to contact with primary health care services using routinely collected data. We found the research to be descriptive, small scale and drug-orientated, with measurement of patient outcomes focused on hospitalizations. The reviewed studies drew upon multiple sources of data to develop a more comprehensive picture of patient care. To do so, data were collated from both acute and non-acute care settings. Overall, definitions of adverse events and other measured variables were provided clearly in the reviewed studies.

Limitations of the study
The first limitation of the review was associated with the studies’ heterogeneous methods, which did not allow the comparison of results by meta-analysis or other techniques. Future reviews will benefit from the application of more sophisticated and rigorous study selection strategies and so improve the likelihood of collecting data suitable for detailed and statistical analyses. Secondly, accurately attributing the occurrence of adverse events to specific care settings is difficult. Not all of the reviewed studies validated their methods for case identification. Within individual studies, some cases of adverse events may have been missed.

Thirdly, the review may be affected by selection bias due to data extraction and synthesis being conducted by a single reviewer. The occurrence of bias was reduced by the use of a systematic search strategy and the consistent application of a predetermined set of data extraction criteria. Finally, the restrictive selection criteria applied in this review limited the inferences that can be made. For example, many studies on medical errors and adverse drug reactions were excluded yet the extensive literature on adverse drug events remains important in understanding errors and patient harm in primary care.

Value of routinely collected data for patient safety measurement
Existing knowledge about adverse events in non-acute care settings is largely based on research from the USA, comprising 60% of studies in our review. Dissimilarities in health care systems mean that a solid understanding of the safety issues specific to the UK and other developed countries is yet to be attained. For example, ambulatory care in the USA encompasses all outpatient care, including community and day case treatment.\(^{32,33}\) This contrasts with the narrower field of community-based primary care that exists in the UK.\(^{34–36}\)

Development of valid measures using routinely collected data will be challenging, as evident from initiatives to create hospital-based patient safety indicators in the USA, UK and other countries.\(^{10,15,37}\) A wealth of data routinely collected in general practice exists in the UK and other countries with well-developed primary care systems, notably in the Netherlands and across Scandinavia.\(^{38}\) For example, large databases, such as the General Practice Research Database (GPRD), are derived from primary care electronic medical records for secondary research uses and differ from administrative data collected in the USA, which are principally for reimbursement.

Implications for research and clinical practice
The frequency of adverse drug events, high-risk groups and some of the errors associated with these events are well documented.\(^{39,40}\) However, other types of adverse events that can potentially be detected through readily available data have been far less frequently reported, such as diagnostic errors and delays.\(^{41}\) We found that measurement of primary care adverse events was often based on secondary care data in conjunction with other clinical and non-clinical information. This use of multiple data sources will enhance the accuracy of measurements and compensate for weaknesses inherent to individual data types.\(^{42,43}\)
When ready for assimilation, integration of routinely collected data-based measures into existing safety improvement systems may be an effective method of active patient safety surveillance.44

There are considerable flaws in current mechanisms of capturing adverse events in health care.5 Enormous investments have been made in the building of Information Technology (IT) infrastructures for health systems in the UK, USA and elsewhere. Greater attention must now be placed on developing indicators and other measures that take advantage of the available IT resources to improve quality and safety. Assessments of the capacity of coding systems, including Read codes, to document adverse events in primary care should also take place.

Conclusions

There has been limited use of routinely collected data to measure patient safety in primary care. One of the most important questions to be addressed in the next stages of the patient safety movement is how measurement of patient harm translates into changes in the delivery of care and commissioning of services and ultimately into improvements to patient outcomes.

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Declaration

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Conflicts of interest: there are no conflicts of interests to declare.

Supplementary material

Supplementary material is available at Family Practice online.

References

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