Informatics in Primary Care 2010;18:117–24

© 2010 PHCSG, British Computer Society

Refereed paper

Recording of adverse events in English general practice: analysis of data from electronic patient records

Carmen Tsang BSc MSc Research Assistant, Dr Foster Unit at Imperial College

Azeem Majeed MB ChB FRCGP Professor of Primary Care and Head of Department of Primary Care and Public Health

Ricky Banarsee BSc MSc Director of West London Research Network

Shamini Gnani MB ChB MRCGP FFPH Senior Clinical Adviser

Paul Aylin MB ChB FFPH Clinical Reader in Epidemiology and Public Health at Imperial College London and Assistant Director of the Dr Foster Unit at Imperial College

Department of Primary Care and Public Health, Imperial College London, London, UK

WHAT THIS PAPER ADDS

- Potential adverse events are recorded in administrative data from general practice.
- Patients aged 65 years and over experience more adverse drug reactions.
- The number of patients of different ethnicities who experience adverse events appears to be proportional to the size of the ethnic groups within the study population.
- The validity of Read coding for potential adverse events needs to be explored, as does the use of data collected in primary care electronic patient records.

ABSTRACT

Background Although the majority of patient contact within the UK's National Health Service (NHS) occurs in primary care, relatively little is known about the safety of care in this setting compared to the safety of hospital care. Measurement methods to detect iatrogenic diseases in primary care require extensive development. Routinely collected data have been successfully applied to develop patient safety indicators in secondary care. Given the availability of electronic health data in primary care, we explored the potential to build adverse event screening tools using computerised medical record systems. **Objective** To identify the rate and types of adverse events that might be recorded in primary care through routinely collected data. The findings will inform the development of administrative databased indicators to screen for patient harm arising from primary care contact.

Method Descriptive analyses were performed on data extracted from the clinical information management systems (CIMS) at NHS Brent. The data were explored according to age, sex and ethnicity of patients. Potential or actual adverse events were identified by mapping to three Read code chapters. **Results** Records from the calendar year 2007 were available for 69 682 registered patients from 25 practices, consisting of 680 866 consultations. A number of adverse events could be detected through terms contained in certain chapters of the Read code system. These events include injuries due to surgical and medical care (0.72 cases of per 1000 consultations) and adverse drug reactions (1.26 reactions per 1000 consultations). Patterns in the rate of harm among patients from different ethnic groups tended to reflect the proportion of the respective groups in

Introduction

Approximately 90% of patient contact in the UK NHS occurs entirely within primary care, with over 300 million general practice consultations taking place each year.¹ With increasing attention being given to improving patient safety, there has also been a drive to develop taxonomies of key concepts, including the World Health Organization's international classification system.² Adverse events can be deemed as injuries caused by medical management and not due to an underlying disease, that may increase the length of treatment and may also result in temporary or permanent disability.³⁻⁵ Relatively little is known about the nature and frequency of medical errors and patient injuries in primary care. Estimated rates of safety incidents vary considerably, with comparisons between studies hampered by inconsistently applied definitions and methodological differences.⁶ Of all adverse events that are known to occur in this healthcare setting in the UK, between 1.1% and 1.7% of nationally reported incidents are associated with severe harm or death.⁷

An imperative for both the NHS and healthcare systems in other developed countries is to create longterm strategies that will sustain healthcare quality and safety improvements. For this to be achieved, effective and reliable information systems need to be designed to inform clinical decision making and to facilitate the monitoring of progress. Routinely collected data from primary care can be analysed to provide useful safety assessments, yet such data are not commonly used for this purpose.^{8,9} Research specific to the UK primary care structure is required in order to validate models and initiatives that have been developed in countries with different organisational models, as well as frameworks that have been developed for application in secondary care. This pilot study aimed to assess the types of adverse events that can be identified and recorded in electronic patient record data at the individual general practice level.

the overall Brent population, with more injuries occurring among patients of white and Asian ethnicities.

Conclusion These findings suggest that there is scope to develop more accurate and reliable means of safety surveillance in general practice using data obtained from electronic patient records.

Keywords: computerised, iatrogenic disease, medical errors, medical records systems, primary health care, safety management

Methods

Design

We analysed data for a cohort of patients who were registered with general practices in NHS Brent (formerly Brent Teaching Primary Care Trust) during 2007. The occurrence of adverse events, as measured by Read codes recorded in the electronic patient records,¹⁰ was explored to determine patterns in patient injuries.

Participants

The Applied Research Unit at NHS Brent is affiliated with the Department of Primary Care and Public Health at Imperial College London. Through this association we gained access to anonymised, electronically recorded patient data from the primary care trust (PCT). There are 97 primary care practice sites in NHS Brent, including 79 general practices and services such as the Accident and Emergency Primary Medical Service and Community Dermatology.¹¹

Data set

Of the 79 GP practices in NHS Brent, 26 were voluntary users of CIMS. This software collected clinical, administrative and demographic data about patients, including details of treatment and prescribing, coded using the Read classification system. The information extracted from the electronic records allowed for patient level analyses to be performed by age, sex and ethnicity. Data were extracted from the CIMS for the 2007 calendar year. The dataset consisted of data files for each of the Read code 5-byte (version 2) chapters from A to Z, with additional data files for ethnicity coding and general practice details. The data fields were arranged by patient observation. Each consultation record contained details of the practice

118

number, local patient identification number and Read code, a 30-character description of the consultation, the date of consultation and age and sex of patient.

Data extraction

Adverse events that might be attributable to medical care can be identified through the clinical terms stored in the electronic CIMS. These adverse event types were mapped to the Read code chapters 'Injury and poisoning' (Chapter S), 'Causes of injury and poisoning' (Chapter T) and 'External causes of morbidity and mortality' (Chapter U).¹² A list of the Read codes used in the analyses is available from the authors. The NHS Information Authority Clinical Terminology Browser Version 1.04 was used to identify the appropriate codes to be applied during the data extraction and analysis.

Statistical methods

The Brent dataset was imported and analysed using SAS version 9.2 for Windows. Patients were grouped into ethnicity categories as used in the 2001 Census.¹³ Descriptive analyses for the three Read code chapters were performed by age, sex and ethnicity. The rate of adverse events was calculated for each of the three Read code chapters of interest.

Ethical considerations

The Department of Primary Care and Public Health received approval to use Brent CIMS data from the Brent Local Research Ethics Committee. The data was received in a pseudo-anonymised format and stored within a secure, private network at Imperial College.

Results

CIMS data were available for 25 out of the 26 participating general practices, providing records for 69 682 out of the 105 877 registered patients in the CIMS. After data cleaning to remove duplicate and otherwise erroneous records, data were available for 680 866 out of 808 127 consultations. Among the 68 567 patients with a recorded age, the average age was 37.7 years, ranging between 0 and 104 years. The representativeness of CIMS data was assessed by comparing age, sex and ethnicity data with 2001 Census information for the borough. Brent has a relatively young population compared with the rest of the country, with 33.3% of the population being aged 24 years or under $(n=87\ 749)$.¹⁴ In the study sample, 27.8% of patients were in the same age group $(n=19\ 037)$. In the 25 to 64 years age group, 59.5% $(n=40\ 731)$ of the sample fell into this category compared with 55.2% $(n=145\ 478)$ of Brent's population.¹⁴ A smaller difference between the datasets was found in the proportion of people aged 65 years or older $(n=30\ 237,\ 11.5\%$ compared with n=8799, 12.8%).¹⁴

Valid ethnicity codes were recorded for 30115 patients (n=382 846 consultations). Patients with ethnicity recorded as white tended to be older than patients of other ethnicities, with an average age of 44 years (ranging from 0 to 104 years, n=8489) compared with 38 years for patients of Asian ethnicity (ranging from 0 to 102 years, n=14 927) and 31 years among patients where the 'Not stated' ethnicity coding was indicated (ranging from 0 to 91 years, n=255). The distribution of males and females was similar among patients of different ethnic groups, with a slightly greater proportion of male patients. However, the proportions of male and female patients of Asian ethnicity were approximately equal (49.4% male compared to 50.1% female).

The rate of medical or surgical complications in the Brent population was 0.72 cases per 1000 consultations (n=492; 95% confidence interval (CI), 0.66–0.79). Approximately 42% of complications recorded were in adult female patients aged between 16 and 64 years (n=208/491), while gender was unknown in one case. Postoperative infections were the most frequently reported surgical complication (n=268/492). Where ethnicity was known, complications were most often recorded for consultations by patients of Asian (n=107/262) and white (n=99/262) ethnicities.

Few medical accidents that occurred during medical or surgical care were recorded by designated Read codes, with a rate of 0.08 medical accidents per 1000 consultations (n=56; 95% CI, 0.06–0.1). The majority of cases of medical accidents were in patients aged between 16 and 64 years (n=31/55). The numbers of cases among children aged under 16 years (n=10) and older adults aged over 64 years (n=14) were similar. The most common cause of medical accidents was accidental cut, puncture, perforation or haemorrhage during medical care (n=50/56). This type of incident accounted for all medical accidents recorded during consultations by patients of Asian (n=17/28), white (n=8/28) and mixed ethnicities (n=1/28).

The rate of adverse drug events was 1.94 per 1000 consultations (n=1321; 95% CI, 1.84–2.04). By mapping to codes from Read Chapter T, we found 1.26 adverse drug reactions per 1000 consultations (n=855; 95% CI, 1.17–1.34). Over 57% of recorded adverse drug reactions occurred in female patients (n=487/855; Table 1). As individual patients may have experienced

more than one adverse drug reaction, it was not possible to determine the true rate of such reactions in the Brent population. However, there appeared to be a trend in adverse drug reactions being recorded more frequently among residents aged over 64 years than among younger residents (Table 1). Out of all adverse drug reactions, 41.5% were recorded in consultations by patients of white ethnicity (n=225/542). Adverse drug effects were also frequently detected among patients of Asian ethnicity, comprising of 38.9% of cases (n=211/542).

Systemic antibiotics, drugs primarily affecting the autonomic nervous system and those that affect the cardiovascular system were among the medications most commonly associated with adverse reactions (n=855; see Figure 1). Penicillins accounted for 14.3% of recorded adverse drug reactions (n=122/

855). In 106 cases, no further information about the drug that had caused the reaction was provided in the Read code field of the dataset. Similar categories of drugs were recorded as causing adverse reactions among patients of different ages. For patients aged under 16 years, the five drugs most frequently associated with adverse reactions were responsible for 42 (71.2%) of the recorded adverse drug reactions in this age group (Figure 1). In adults aged between 16 and 64 years, the five drugs most commonly associated with adverse reactions were responsible for 45.2% of adverse reactions (n=201), and the same drugs were responsible for 48.1% of adverse reactions in adults over 64 years (n=169).

Amoxicillin was the most commonly recorded drug to cause adverse effects in patients under 16 years (n=18/59). In patients aged 16–64 years, atenolol was

	Read chapters				Brent
	Causes of injury and poisoning (Chapter T)		External causes of morbidity and mortality (Chapter U)		population size ^{14,15}
	n	%	п	%	-
Sex*					
Female	487	57.23	223	47.85	135 659
Male	364	42.77	243	52.15	127 804
Age group*					
Under 16	55	6.46	12	2.58	10 516
16–64	445	52.29	219	47.00	49 252
65 and over	351	41.25	235	50.43	8800

Table 1 Age and sex of cases of adverse drug events, n=1321

* Data were unavailable for four cases



Drug type

Figure 1 Drugs most frequently causing adverse drug reactions by age group, n=855

the drug that was most frequently associated with adverse reactions (n=82/445). In older adults (aged over 64 years), 41 adverse reactions were attributed to drug reactions not otherwise specified (n=351), with simvastatin being a named drug that was often associated with adverse effects (n=38/351).

Chapter U was introduced into the 5-byte (version 2) Read codes to reflect terms mirrored in the 'Chapter XX External causes of morbidity' of the ICD-10.^{16,17} This new chapter is an updated version of Chapter T 'Causes of injury and poisoning'.¹⁷ Of the 467 drug or associated substance-related complications of care recorded by codes from Chapter U, one adverse event was associated with ophthalmic diagnostic and monitoring devices. The majority of complications were reported in adults aged over 64 years (n=236/467). A greater proportion of males compared to females aged 15 years or under and aged 65 years and over experienced complications (Table 1). A similar proportion of consultations by patients of white and black ethnicities contained records of potential and actual adverse events identified from codes in this chapter (n=88/367 and n=79/367, respectively). Cases of drug-related injuries were greatest among patients of Asian ethnicity (n=165/367).

Cardiovascular agents, angiotensin converting enzyme inhibitors (ACE inhibitors) and angiotensin II receptor antagonists (ARBs) account for the majority of drug complications recorded using this newer Read code chapter (n=348/467). We estimated a rate of 0.35 per 1000 consultations (n=238; 95% CI, 0.31-0.39) complications of care due to ACE inhibitors, with adverse effects due this type of drug accounting for 61% of consultations for drug-related complications among patients of Asian ethnicity (n=100/165). There was an estimated rate of 0.16 complications per 1000 consultations associated with ARBs (n=110; 95% CI, 0.13-0.19). Between 28% and 30% of consultations for ill effects of drugs among patients of white and black ethnicities were due to ARBs (n=26/88 and n=22/79, respectively). A lower rate of between 0.02 and 0.03 complications per 1000 consultations was associated with statins (n=19), penicillins (n=17) and calcium-channel blockers (n=16).

There were 0.58 incidents of suicide or self harm per 1000 consultations (n=396, 95% CI, 0.52–0.64). More females consulted for suicide and self injury (n=243/394, gender was not recorded in two cases). Nearly half of consultations related to suicide and self harm were made by patients of white ethnicity (48%, n=119/246), followed by patients of Asian ethnicity (34%, n=83) and patients of black ethnicity (9%, n=21). In nine cases, MRI contrast media were associated with the injuries recorded.

Discussion

Principal findings

Undesirable patient outcomes were recorded in electronic patient records in primary care, but at a relatively low rate. Effects of drug-related treatment were the most common type of recorded adverse event detectable using Read codes. The high number of drug-related events occurring in patients of 65 years and over which were found in the Brent dataset is comparable to findings from studies looking at adverse drug events leading to emergency department visits and hospital admissions in the UK and the USA.^{18,19} Other types of potential adverse events were also detectable through routine primary care data, such as medical and surgical complications and suicide and acts of suicidal intent. Some of these types of events are likely to indicate safety incidents occurring in secondary care but potentially not detected in that care setting due to their occurrence after hospital discharge.²⁰

Comparison with the literature

As noted in other research,^{19,21} the types of drugs that were identified from the Brent data as commonly causing adverse reactions and other drug-related events were often drugs that have been in clinical use for many years. Unfortunately details about the specific drugs responsible for adverse reactions not otherwise specified were not readily available in the limited dataset extracted from the PCT. These drugs accounted for 9.8% of all adverse drug reactions recorded among the study sample.

Strengths and limitations of the study

This study explored Read coding to identify potential adverse events that are electronically recorded in English general practice. Unlike previous studies that have looked only at drug-related morbidity and mortality, we have tried to capture adverse events across the spectrum of care. Our analyses used data from over 65% of patients who were registered for the electronic system. The results will facilitate future validation efforts for measuring patient harm using electronic patient records in general practice.

Given the simple analyses performed using only three chapters of the Read coding system, other types of adverse events that might be identified using this data source will not have been detected. More extensive analyses of the data in the Brent dataset were not possible without the necessary clinical data. As with all research that uses routinely collected data, there are

121

limitations given the nature of the data collected. A lack of treatment and patient detail in the dataset prevented adjustments being applied for potential confounders such as comorbidities, disease severity and polypharmacy. Similarly, information about the characteristics particular to individual general practices, such as the number of general practitioners and general practitioners' duration of clinical practice, were not available for analysis in this study but may be related to the occurrence of adverse events in this setting.

While the Read system provides an extensive range of terms for many aspects of clinical practice, the structure of the coding hierarchy and limited clinical detail contained in each patient record may restrict the detection of adverse events and evaluations of preventability. Examination of the free text fields in primary care clinical databases may improve the richness of information relating to adverse events and patient care in general. However, the data quality of these fields may be variable and successful interpretation of free text will demand a different set of analytical skills from those applied to quantitative data.

Implication of the findings

More complex statistical analyses with linking of consultation records by patients might have allowed for crude estimations of adverse reactions from prescriptions made during prior consultations. However, this type of analysis would only capture treatments received within primary care. Data linkage across datasets in other care settings, such as hospital episode statistics and disease registries, may improve the validity of estimation efforts. The quality of databases will also affect the effectiveness of active surveillance methods that have been predominantly implemented in pharmaco-epidemiology to date. Recently adapted data mining techniques apply statistical algorithms to large datasets for identifying unexpected patterns in adverse reactions and other drug-related adverse events.²² This signal detection tool shows promise in supporting existing mechanisms (e.g. reporting systems) for detecting drug-related adverse events, especially given international collaborations such as the EU-ADR project.²³ Screens developed from administrative data may complement data mining tools and improve the precision of adverse event detection, especially medication-related incidents.

Adverse drug reactions are currently underdetected in administrative data from secondary care.^{18,24} By linking with data from primary care, more accurate detection of these drug events may be achieved. Reports from the National Patient Safety Agency's National Reporting and Learning System (NRLS) show that 725 of the 3417 safety incidents reported between July 2008 and June 2009 were related to medication errors, accounting for the most commonly occurring type of mistake or failure resulting in patient injury.⁷ With indications of under-reporting through the NRLS and especially in primary care,²⁵ more accurate detection methods for adverse events need to be developed in this care setting. Patients from ethnic minority groups might commonly experience potential adverse events. In this study, the proportion of potential safety incidents documented among the different ethnic groups was comparable with the ethnic representation within the overall population of the borough.

Conclusions

It is possible to identify potential adverse events in general practice from routinely collected electronic data. Injuries following surgery, medical accidents and adverse drug reactions are most frequently recorded. Early detection systems can only provide an indication of potential errors and adverse events. More detailed investigations using other data sources, such as medical record review and patient surveys, will be required to accurately determine the presence and extent of patient harm.

Greater use of routinely available data may also help overcome the considerable under-reporting of adverse events found in voluntary reporting systems in primary care in the UK.²⁶ Currently, less than 0.5% of safety incidents reported in the NHS in England come from general practice and this is unlikely to reflect actual practice.⁷ Improved coding by primary care clinicians of adverse events and healthcare complications in primary care information systems, supplemented by greater routine analysis of these data, could help identify potential threats to patient safety in community settings and improve reporting of safety incidents.

ACKNOWLEDGEMENTS

We thank the 26 general practices that participated in the study, and Mike Sievwright and the NHS Brent CIMS team for their help.

FUNDING

This study was supported by the National Institute for Health Research and the Department of Primary Care and Public Health at Imperial College. The Applied Research Unit is an integral part of the Public Health Department within NHS Brent which also funds the Brent Clinical Information Management. The Imperial Centre for Patient Safety and Service Quality at Imperial College Healthcare NHS Trust is funded by the National Institute of Health Research. The Dr Foster Unit at Imperial College London is funded by a grant from Dr Foster Intelligence (an independent health service research organisation). The Department of Primary Care and Public Health at Imperial College is grateful for support from the National Institute for Health Research Centre for Patient Safety and Service Quality; the National Institute for Health Research Biomedical Research Centre scheme; and the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care scheme. We are also grateful for past support from the Medical Research Council and the Engineering and Physical Sciences Research Council. The views expressed in this article are those of the authors.

REFERENCES

- 1 Department of Health. Department of Health: Departmental Report 2008. *The Health and Personal Social Services Programmes.* London: The Stationery Office, 2008.
- 2 World Health Organization. Project to Develop International Patient Safety. Report of the WHO World Alliance for Patient Safety Drafting Group, 24–25 October 2005, Vancouver. Final report. Geneva: WHO, 2005.
- 3 Ely J, Levinson W, Elder N, Mainous A and Vinson D. Perceived causes of family physicians' errors. *Journal of Family Practice* 1995;40:337–44.
- 4 Elder NC and Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. *Journal of Family Practice* 2002; 51:927–32.
- 5 Brennan TA, Leape LL, Laird NM *et al.* Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New England Journal of Medicine* 1991;324:370–6.
- 6 Makeham M, Dovey S, Runciman W and Larizgoitia I (on behalf of the Methods and Measures Working Group of the WHO World Alliance for Patient Safety). *Methods and Measures Used in Primary Care Patient Safety Research. Results of a literature review.* WHO, 2009.
- 7 National Patient Safety Agency. Patient Safety Incident Reports in the NHS: reporting and learning system quarterly data summary. Issue 14: November 2009 – England. www.nrls.npsa.nhs.uk/
- 8 Singh R, Servoss T, Kalsman M, Fox C and Singh G. Estimating impacts on safety caused by the introduction of electronic medical records in primary care. *Informatics in Primary Care* 2004;12:235–42.
- 9 Avery AJ, Savelyich BSP and Teasdale S. Improving the safety features of general practice computer systems. *Informatics in Primary Care* 2003;11:203–6.

10 NHS Connecting for Health. Systems and Services: data services – Read codes. www.connectingforhealth.nhs.uk/ systemsandservices/data/readcodes

123

- 11 Brent Teaching Primary Care Trust. *Patient Guide 2008–2009.* London: Magnet Harlequin, 2008.
- 12 NHS Information Authority. *Clinical Terminology Browser* v1.04. 2009.
- 13 Office of National Statistics. *Ethnicity*. www.ons.gov.uk/ about-statistics/classifications/archived/ethnic-interim/ index.html
- 14 Office of National Statistics. 2001 Census: key statistics area: Brent (Local Authority). neighbourhood.statistics. gov.uk/dissemination/
- 15 Brent Council. *The 2001 Census: a profile of Brent*. London: Brent Council, 2004. www.brent.gov.uk
- 16 Graham L, Ward A and Mulvenna G. Read Code User Guide. www.isdscotland.org/
- 17 Leeds North West PCT. Leeds Health Informatics Service. Clinical Coding: a basic guide for GPs and practice staff. www.leeds.nhs.uk/
- 18 Patel H, Bell D, Molokhia M *et al.* Trends in hospital admissions for adverse drug reactions in England: analysis of national hospital episode statistics 1998–2005. *BMC Clinical Pharmacology* 2007;7:9.
- 19 Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ and Annest JL. National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events. *Journal of the American Medical Association* 2006;296:1858–66.
- 20 Drosler SE, Klazinga NS, Romano PS *et al.* Application of patient safety indicators internationally: a pilot study among seven countries. *International Journal for Quality in Health Care* 2009;21:272–8.
- 21 Pirmohamed M, James S, Meakin S *et al*. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ* 2004;329:15–19.
- 22 Wilson A, Thabane L and Holbrook A. Application of data mining techniques in pharmacovigilance. *British Journal of Clinical Pharmacology* 2004;57:127.
- 23 EU-ADR project. Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge. www.alert-project.org/
- 24 Waller P. Hospital admissions for 'drug-induced' disorders in England: a study using the Hospital Episodes Statistics (HES) database. BMC Clinical Pharmacology 2005;59:213.
- 25 House of Commons Health Committee. *Patient Safety: sixth report of session 2008–2009. Volume 1.* London: The Stationery Office, 2009.
- 26 Wise J. Less than 0.5% of safety incidents reported in 2008–2009 came from general practice. *BMJ* 2010;340: c885.

CONFLICTS OF INTEREST

None.

124

C Tsang, A Majeed, R Banarsee et al

ADDRESS FOR CORRESPONDENCE

Carmen Tsang Dr Foster Unit at Imperial College Department of Primary Care and Public Health Imperial College London St Dunstan's Rd London W6 8RP UK Tel: +44 (0) 207 332 8809 Email: c.tsang@imperial.ac.uk

Accepted August 2010