Supplementary materials

Incidence, nature and causes of avoidable significant harm in primary care in England: retrospective case note review

Details of methods used in the study

Our study protocol describes the methods we employed in detail.[1] Box 1 in the main manuscript provides the definitions used in the study.The study had NHS research ethics committee approval (15/EM/0411), Confidentiality Advisory Group (CAG) support under section 251 to process patient identifiable information without consent (15/CAG/0182) and Research and Development (R&D) approvals.

Participants

We undertook a retrospective case note review of an open cohort of all primary care patients registered with participating general practices (between 1 April 2015 and 31 March 2016) to identify cases of avoidable significant harm. The study took place in 12 general practices from three different areas of England: East Midlands (n=7), Greater London (n=2) and Greater Manchester (n=3). The East Midlands and Greater Manchester were chosen for convenience as this is where most of the English members of our team are based. London was selected to provide geographical and demographic balance.

General practices were eligible to participate if they provided written informed consent, delivered NHS services, had electronic health records and used one of the three main computer systems in England (i.e. EMIS Web, TPP SystmOne, or INPS Vision). General practices were excluded from the study if they were involved in a major reorganisation (such as a merger with another practice) between 1 April 2015 and 31 March 2016 since this would have made it difficult to identify the practice list size for the retrospective case note review.

We aimed to sample general practices with characteristics representative of English practices as a whole, with a total population of up to 100,000. This figure was based on a pilot study, which demonstrated that this was the largest sample we could manage within the substantial available funding, whilst also conducting the study to a high standard. We estimated the precision of our study based on different possible rates of avoidable significant harm. For example, for a rate of avoidable significant harm of 40 per 100,000 patients per

year, the precision (based on 95% confidence intervals) was estimated to be between 28 and 52 per 100,000 patients per year.

From the three regions, we identified a total of 757 practices: East Midlands (n=266), Greater London (n=366) and Greater Manchester (n=125). We used stratified random sampling to identify the general practices to approach. Firstly, the practices from each area were stratified by list size into quartiles, with list sizes taken from the NHS Digital website.[2] Secondly, the practices from each area and each quartile were listed in computer-generated random order. We then selected the 80 practices appearing at the top of the stratified random lists, consisting of 40 practices from the East Midlands (10 practices in each quartile) and 20 practices from each of Greater London and Greater Manchester (five practices in each quartile). Practices were over-recruited from the East Midlands given most of the GPs recruited for data collection were based in this region.

We emailed and/or wrote to general practices (via the practice manager and general practitioners within the practices) inviting participation. We used a range of approaches to encourage participation, including prior publicity about the study, engaging local opinion leaders and providing reassurance about data confidentiality. Of the 80 practices approached, 12 were included in the study (see Figure 1).

Patients in the practices were excluded if they had a computer code in their clinical records indicating that they did not wish to be included in research studies. Patients were also excluded if they completed an opt-out form.

Recruitment and training of data collectors

General practitioners with at least five years' experience in general practice were recruited to collect data from the participating practices. These GPs were recruited from the East Midlands, Greater Manchester and Greater London via the Royal College of General Practitioners and existing contacts. Thirteen general practitioners were recruited and trained to ensure a consistent approach to identifying and classifying patients with avoidable significant harm. Further details are provided in our protocol paper.[1]

Sampling of patient records

We sampled patient records in three stages. In Stage 1, we identified the total patient population of the practices at the start of the retrospective cohort. In Stage 2, we identified patients at increased risk of avoidable significant harm (the 'enhanced sample'), and in

Stage 3, we identified those from Stage 2 who had experienced a significant new health problem during the 12-month retrospective review period.

The population for Stage 1 comprised those patients registered with the 12 general practices at the start of the retrospective cohort (1 April 2015). To identify patients at increased risk of avoidable significant harm (Stage 2), we drew upon suggestions made by the research commissioners, (the National Institute for Health Research (NIHR) Policy Research Programme), the literature on avoidable harm in primary care[3] and our own experience of inductively analysing reports of harm associated with primary care in the National Reporting and Learning System (NRLS).[4] We included patients with characteristics considered to be associated with significant health problems and/or increased risk of patient safety incidents. The identification of patients with a higher likelihood of significant health problems allowed us to focus on those cases where any avoidable harm was likely to be significant too. We included those who had: died[5] or had been admitted to hospital or a mental health facility[6] as these were likely to have experienced a significant health problem; those that were resident in a care home as they were likely to have significant health problems and increased risk of medication errors;[7] those that had 10 or more repeat medications,[8,9] as they were at greatest risk of harm from medication error; those with four or more major morbidities as our previous study had shown multi-morbidity to be associated with avoidable harm;[5] those that had undergone an invasive procedure in general practice, such as a minor operation as safety concerns have been raised about this[10] and those that had been certified unfit for work long-term, as this was suggested by our funder, as it might have resulted from an avoidable harm.

Electronic registry queries at each practice (for 12 months from the start of the retrospective cohort) identified these patients who formed the 'enhanced sample'. Search strategies were developed and tested for the medical record systems of participating practices. This was an iterative process aimed at identifying 10-15% of the population for the enhanced sample and influenced the choice of four or more comorbidities and 10 or more repeat medications (smaller numbers of each would have resulted in an enhanced sample that was too large for the resources available for detailed records review).

The approach we used was different to that used in trigger tool methods[11] as were trying to identify a sample for detailed case note review, whereas trigger tool methods are applied to a patient sample that has already been selected. There was overlap in the criterion of

hospital admissions, for example,[11] but other 'triggers' (such as repeat medication discontinued) would have identified too many patients.

We also asked the participating general practices to identify any patients they knew who had experienced avoidable harm, e.g. based on significant event analyses;[12] this did not identify any additional patients but some practices did not engage in providing this information to reviewers.

The next stage of sampling (Stage 3) identified patients with significant health problems (irrespective of whether these were avoidable or not). It involved one of the GP data collectors screening the electronic health record of each patient in the 'enhanced sample' to identify any new significant health problems experienced by patients over the 12 months of the study (1 April 2015 – 31 March 2016); this included all deaths. The research team provided the GP data collectors with detailed guidance on the significant health problems we wanted to screen for; this included all new major physical and psychiatric morbidities, and accidents (with examples including acute kidney injury, asthma requiring hospital admission, cancer, diabetes mellitus (including serious complications), deep vein thrombosis, heart failure, myocardial infarction, pulmonary embolism, and stroke). The GPs then undertook detailed retrospective reviews of the records of this final sample of patients to identify the extent to which errors of omission (e.g. failures of prevention) or commission in primary healthcare provision contributed to any of these significant health problems.

For the purposes of sensitivity analysis (recognising that cases might have been missed by our sampling approach), the GP data collectors also undertook a detailed records review for the following:

- 2.5% random sample of the Stage 1 population, but not including patients identified for the Stage 2 enhanced sample; each record was examined by a single GP reviewer.
- 10% random sample of the Stage 2 enhanced sample; each record was examined by a second GP reviewer.

Variables

For participating general practices we obtained data on the following variables: list size (number of patients); age distribution (particularly highlighting the number and percentage of patients aged 65 years and older); number and percentage of males and females; ethnicity (number and percentage of non-White patients); Index of Multiple Deprivation (IMD), the official measure of deprivation in England; whether practices were rural or urban; Care

Quality Commission (CQC) overall rating for the practices, and CQC safety rating for the practices. The CQC is an independent regulator health and adult social care service providers in England and responsible for checking through inspection and ongoing monitoring that care quality and safety standards are being met.[13] In addition, for each practice we calculated the number of patient-years of data available for the period 1 April 2015 to 31 March 2016 using registration data.

Identification of avoidable significant harm, and factors associated with this

For those patients with significant health problems, the GP data collectors reviewed the patient records and recorded whether they considered that the patient had received an adequate standard of care for these problems, or whether there was any evidence of avoidable harm. For the latter cases, the GPs provided a detailed written account of the principal problem in the patient's primary care that led to the significant health problem, a narrative describing the manner in which the significant health problem could have potentially been prevented within primary care, and a judgement on the avoidability of the significant health problem using a validated six-point scale (see Box 2 of the main manuscript).[14,15] The GP data collectors searched back in patients' records as far as was needed to establish whether the significant health problem was avoidable or not. The evidence recorded by the GP data collectors was typically descriptions of salient signs or symptoms, pertinent past or concurrent medical or psychosocial history detail, and/or the actions or plans recorded by GPs in entries for each clinical encounter. Such descriptions were essentially 'signals' in the case note entries identified by the reviewers informing judgements about avoidability.

All cases were considered in detail by the study team, and the GP data collectors were asked to provide additional information if any clarification were needed. Each case was discussed by the study team and we considered what additional evidence (or signals) we would be seeking in the case notes in order to justify the avoidability score awarded, or to upgrade or downgrade the score. During those discussions, a member of the study team had online access to published guidelines to ensure our study team judgements were compliant with best practice guidelines. If relevant guidelines had been published since the observed study period, we considered the evidence available at that time. Where there was an absence of published guidelines, we considered trial data or systematic reviews (particularly Cochrane reviews). If necessary, we asked the GP data collector to return to the relevant general practice to examine the clinical records again to confirm the presence or absence of the evidence the study team deemed relevant to inform final judgements about avoidability. GPs only recorded what was explicitly stated in the records, or described what

was evidently absent in relation to what would be expected based on relevant guidelines for the condition. To ensure consistency the study team made the final judgement, through consensus, in terms of the classification of avoidable significant harm.

Data collection and coding

Each of the participating general practices was visited by an informatician from the study team who collected baseline data on the practice population and ran a computer search to identify patients for the enhanced sample and for the sensitivity analyses. Using encrypted tablet computers and a Virtual Private Network (VPN) connection, the GP data collectors entered anonymised data directly into a database on a secure server at Cardiff University. The nature of the avoidable harm was recorded by the GP data collectors using the comprehensive patient safety classification system developed in the Primary Care Patient Safety Classification (PISA) study.[16] The classification system has been empirically derived and aligned to the WHO International Classification for Patient Safety using a constant comparative approach.[17] The system has been used for analysis of over 72,000 patient safety incident reports from NHS organisations in England and Wales for 26 major studies of patient safety predominantly in primary care.[18-33]

Case narratives were deconstructed using codes from the classification system to describe: incident types (primary and contributory); potential contributory factors which are circumstances, actions of influences that played a part in the origin or development of the incident; incident outcomes; and harm severity. Primary incidents included those proximal (chronologically) to the patient outcome, whereas contributory incidents included those that contributed to the occurrence of another incident. Multiple codes for incident type (e.g. administration, medication), contributory factor (e.g. patient co-morbidity, staff workload), and incident outcome were applied to each case where necessary. The codes were applied systematically and chronologically [16,34].

Analysis

We estimated the incidence of significant harm that was considered at least probably avoidable (our primary outcome – avoidability score 4 or more) and at least possibly avoidable (avoidability score 3 or more) and expressed these as 'per 100,000 patient-years' accompanied by 95% confidence intervals (95% CI).[1] We assessed inter-rater reliability of judgements made by paired GP data collectors using the Cohen's Kappa statistic (with 95% CI).

Members of the study team then undertook a detailed analysis of the information provided on each case of potentially avoidable significant harm and included cases with at least 'slight to modest' (score 2 or more) evidence of avoidability, as we judged that even in these cases there were important insights. This included in-depth case analysis meetings, also involving team members with patient and public involvement background (ACh and AD). We reviewed and discussed the cases with the purpose of identifying commonalities and differences between them. We analysed the data recorded on the cases and examined the relationships between different types of incident and the factors that contributed to these incidents. As a result, we identified the most important factors contributing to avoidable significant harm.

References

1. Bell BG, Campbell S, Carson-Stevens A. et al. Understanding the epidemiology of avoidable significant harm in primary care: Protocol for a retrospective cross-sectional study. BMJ Open. 2017;7(2):e013786.
2. NHS Digital. Number of Patient Registered at a GP Practice-April 2015. Published on 16 April 2015. https://digital.nhs.uk/data-and-information/publications/statistical/patients-registered-at-a-gp-practice/april-2015. Accessed 19 August 2020.
3. Panesar SS, deSilva D, Carson-Stevens A et al. How safe is primary care? A systematic review. BMJ Quality and Safety. 2015; doi: 10.1136/bmjqs-2015-004178.
4. Carson-Stevens A, Hibbert P, Williams H, et al. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and learning system: A mixed-methods agenda-setting study for general practice. NIHR Journals Library: Southampton; 2016; 4(27):1-76.
5. Hogan H, Healey F, Neale G et al. Preventable deaths due to problems in care in English acute hospitals: A retrospective case record review study. BMJ Quality & Safety. 2012;21(9):737-745.
6. Avery AJ, Savelyich SP, Sheikh A. et al. Identifying and establishing consensus on the most important safety features of GP computer systems: E-Delphi study. Informatics in Primary Care. 2005;13:3-11.
7. Barber ND, Alldred DP, Raynor DK. et al. Care homes' use of medicines study: Prevalence, causes and potential harm of medication errors in care homes for older people. Quality and Safety in Health Care. 2009;18:341-346.
8. King's Fund. PARR Combined Predictive Model Final Report. December 2006. Available online at: http://www.kingsfund.org.uk/sites/files/kf/field/field_document/PARR-combined-predictive-model-final-report-dec06.pdf Accessed 19 August 2020.

9. Duerden M, Avery T, Payne R. Polypharmacy and Medicines Optimisation: Making it Safe and Sound. London: The King's Fund, 2013.
10. Gaal S, Verstappen W, Wolters R et al. Prevalence and consequences of patient safety incidents in general practice in the Netherlands: A retrospective medical record review study. Implementation Science. 2011;6(1):37.
11. de Wet C, Black C, Luty S et al. Implementation of the trigger review method in Scottish general practices: Patient safety outcomes and potential for quality improvement. BMJ Quality and Safety. 2017;26(4):335-342.
12. McKay J, Bradley N, Lough M et al. A review of significant events analysed in general practice: Implications for the quality and safety of patient care. BMC Family Practice. 2009;10(1):61.
13. Care Quality Commission. How We Monitor GP Practices. Last Updated on 25th February 2019. https://www.cqc.org.uk/guidance-providers/gps/how-we-monitor-gp-practices.. Accessed 19 August 2020.
14. Hogan H, Healey F, Neale G et al. Preventable deaths due to problems in care in English acute hospitals: A retrospective case record review study. BMJ Quality & Safety. 2012;21(9):737-745.
15. APEAS Study. Patient Safety in Primary Health Care. Madrid: Ministry of Health and Consumer Affairs, 2008.
16. Carson-Stevens A, Hibbert P, Avery A. A cross-sectional mixed methods study protocol to generate learning from patient safety incidents reported from general practice. BMJ Open. 2015; 5(12):e009079.
17. Glaser BG, Strauss AL. Discovery of grounded theory: Strategies for qualitative research. London Routledge. 2017.
18. Young, RS, Deslandes P, Cooper J et al. A mixed methods analysis of lithium-related patient safety incidents in primary care. Therapeutic Advances in Drug Safety. 2020; 11; 1-8.
19. Gibson R, Macleod N, Donaldson LJ et al. A mixed-methods analysis of patient safety incidents involving opioid substitution treatment with methadone or buprenorphine in community-based care in England and Wales. Addiction. 2020; doi:10.1111/add.15039.
20. Omar A, Rees P, Cooper A et al. Health and social care-associated harm amongst vulnerable children in primary care: Mixed methods analysis of national safety reports. Archives of Disease in Childhood. 2020; doi: 10.1136/archdischild-2020-320094.
21. Hussain F, Cooper A, Carson-Stevens A et al. Diagnostic error in the emergency department: Learning from national patient safety incident report analysis. BMC Emergency Medicine. 2019;19(1):77.
22. Williams H, Donaldson SL, Noble S et al. Quality improvement priorities for safer out-of-

hours palliative care: Lessons from a mixed-methods analysis of a national incident-reporting database. Palliative Medicine. 2019; 33(3):346-356.

23. Dinnen T, Williams H, Yardley S et al. Patient safety incidents in advance care planning for serious illness: A mixed-methods analysis. BMJ Supportive & Palliative Care. 2019; doi:10.1136/ bmjspcare-2019-001824.
24. Evans HP, Anastasiou A, Edwards A et al. Automated classification of primary care patient safety incident report content and severity using supervised machine learning (ML) approaches. Health Informatics Journal. 2019; doi:10.1177/1460458219833102.
25. Ensaldo-Carrasco E, Sheikh A, Cresswell K et al. Patient safety incidents in primary care dentistry in England and Wales: A mixed-methods study. Journal of Patient Safety. 2019; doi: 10.1097/PTS.0000000000000530.
26. Yardley I, Yardley S, Williams H et al. Patient safety in palliative care: A mixed methods study of reports to a national database of serious incidents. Palliative Medicine. 2018; 32(8):1353-1362.
27. Yardley IE, Carson-Stevens A, Donaldson L. Serious incidents after death: Content analysis of incidents reported to a national database. Journal of the Royal Society of Medicine. 2018; 111(2): 57-64
28. Cooper J, Edwards A, Williams H et al. Nature of blame in patient safety incident reports: Mixed methods analysis of a national database. Annals of Family Medicine. 2017; 15(5): 455-461.
29. Cooper A, Edwards A, Williams H et al. Sources of unsafe primary care for older adults: A mixed-methods analysis of patient safety incident reports. Age and Ageing. 2017; 46(5): 833-839.
30. Rees P, Edwards A, Powell C et al. Patient safety incidents involving sick children in primary care in England and Wales: A mixed methods analysis. PLoS Medicine. 2017; 14(1); e1002217.
31. Williams H, Edwards A, Hibbert P et al. Harms from discharge to primary care - Mixed methods analysis of patient safety incident reports. British Journal of General Practice. 2015; 65(641):e829-837.
32. Rees P, Edwards A, Powell C et al. Safety incidents in the primary care office practice setting. Pediatrics. 2015; 135(6):1027-1035.
33. Rees P, Edwards A, Powell C et al. Pediatric immunization-related safety incidents in primary care: A mixed methods analysis of a national database. Vaccine. 2015; 33(32):3873-3880.
34. Hibbert P, Runciman W, Deakin A. A recursive model of incident analysis. Adelaide: Australian Patient Safety Foundation. 2007.