Nature of Blame in Patient Safety Incident Reports: Mixed Methods Analysis of a National Database

Jennifer Cooper, MBBCh[1]

Adrian Edwards, PhD, MRCGP[2]

Huw Williams, MCRGP[1]

Aziz Sheikh, MD, FRCGP[3,4]

Gareth Parry, PhD[4,5]

Peter Hibbert, BAppSc (Physio)[6]

Amy Butlin, MBBCh[1]

Liam Donaldson, MD, MBChB[7]

Andrew Carson-Stevens, PhD, MBBCh[1,6,8]

[1]Primary Care Patient Safety (PISA) Research Group, Division of Population Medicine, School of Medicine, Cardiff University, Cardiff, Wales

[2]Division of Population Medicine, School of Medicine, Cardiff University, Cardiff, Wales

[3]Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, United Kingdom

[4]Harvard Medical School, Boston, Mass.

[5]Institute for Healthcare Improvement, Cambridge, Massachusetts

[6]Australian Institute of Health Innovation, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia

[7]London School of Hygiene and Tropical Medicine Group, London, United Kingdom

[8]Department of Family Practice, University of British Columbia, Vancouver, British Columbia, Canada

CORRESPONDING AUTHOR

Andrew Carson-Stevens, PhD, MBBCh
Primary Care Patient Safety (PISA) Research Group
Division of Population Medicine
School of Medicine, Cardiff University
Cardiff, Wales CF14 4YS
carson-stevensap@cardiff.ac.uk

ABSTRACT

PURPOSE A culture of blame and fear of retribution are recognized barriers to reporting patient safety incidents. The extent of blame attribution in safety incident reports, which may reflect the underlying safety culture of health care systems, is unknown. This study set out to explore the nature of blame in family practice safety incident reports.

METHODS We characterized a random sample of family practice patient safety incident reports from the England and Wales National Reporting and Learning System. Reports were analyzed according to prespecified classification systems to describe the incident type, contributory factors, outcomes, and severity of harm. We developed a taxonomy of blame attribution, and we then used descriptive statistical analyses to identify the proportions of blame types and to explore associations between incident characteristics and one type of blame.

RESULTS Health care professionals making family practice incident reports attributed blame to a person in 45% of cases (n = 975 of 2,148; 95% CI, 43%-47%). In 36% of cases, those who reported the incidents attributed fault to another person, whereas 2% of those reporting acknowledged personal responsibility. Blame was commonly associated with incidents where a complaint was anticipated.

CONCLUSIONS The high frequency of blame in these safety, incident reports may reflect a health care culture that leads to blame and retribution, rather than to identifying areas for learning and improvement, and a failure to appreciate the contribution of system factors in others' behavior. Successful improvement in patient safety through the analysis of incident reports is unlikely without achieving a blame-free culture.

Ann Fam Med 2017;15:455-461. https://doi.org/10.1370/afm.2123.

INTRODUCTION

In the international agenda for patient safety, incident reporting systems are critical engines for learning.[1,2] For those who report safety incidents, however, fear of blame is a recognized barrier in all safety-critical industries that seek to use the analysis of incidents as a method for improvement.[1-7] The extent of blame attribution within incident reports themselves is unknown. Underreporting is the norm, and it has been estimated that reporting systems detect only 10% of adverse events in hospitals.[8] Such underreporting represents a major missed opportunity to understand errors and prevent harm.

The patient safety movement is based on the premise that patient safety incidents are largely the result of poorly designed systems.[9] Even so, our previous study of primary care incident reports suggests that those who report such incidents focus heavily on describing the shortcomings of the individuals (staff, patients, families, caregivers) involved without considering system failings.[10] In a minority of situations, where there is willful misconduct or negligence, it is appropriate that individual accountability should be enforced.[11] The political and media climates in many countries, however, too often demand that individuals are held responsible

regardless of the reason.[1,12,13] Where there is blame and finger-pointing, the opportunity for shedding light on the real explanation for serious incidents is lost. Fear of blame is a major barrier to both participation in incident reporting and to promoting an underlying safety culture in health systems.[1,6]

Most patient safety studies have been in hospital populations, yet globally, primary care manages up to 90% of all patient contacts.[14] Primary care lags behind secondary care in generating learning from incident reports[15] and has additional challenges when it comes to reporting patient safety concerns. For example, a report on whistle-blowing in a family practice emphasized how difficult it is to report confidentially or anonymously when working in small clinical teams.[16] In addition, a potential immediate employer may be personally involved in the safety incident. Accordingly, we set out to examine a sample of patient safety incidents reported from primary health care settings within a publicly funded health care system. The aim of our study was to identify and classify the types of statements of attributed blame made within the reports and to relate them to the nature of the incidents.

METHODS

Data Source

We analyzed data taken from the National Reporting and Learning System, a database of 14 million patient safety incident reports from England and Wales. A patient safety incident was defined as "any unintended or unexpected incident that could have harmed or did harm a patient during healthcare delivery."[17] Reporting incidents started on a voluntary basis in 2003, but since 2010, reporting has been mandatory for incidents resulting in severe harm or death. Reports contained structured categorical information about care setting, patient demographics, and the perception of severity of harm, as well as free-text descriptions of the incident, apparent causes, and planned actions to prevent recurrence. The database is described in more detail in a study of patient safety-related hospital deaths in England.[13]

Study Population

We included reports if they related to the provision of primary health care in England and Wales and were not duplicates. In accordance with the National Academy of Medicine definition of primary care, we also included community health care reports, including those from community-based nursing and mental health care services.[18] Our study period, which was April 2005 to September 2013 (42,729 reports submitted during this period), was dictated by data avail-

ability at the study outset. We combined all reports of severe harm and death (1,199 reports) with a weighted random sample of incident reports of lower harm severity (12,500) to create a sampling frame of 13,699 reports. The weighting gave greater priority to more recent reports. We described the sampling frame in more detail elsewhere.[19]

Sample Size

In a pilot study of 857 patient safety incident reports, we found blame descriptions in 47% (401). To estimate the true proportion of blame descriptions within these primary care data, with a 95% confidence interval of no greater than 2%, we calculated that a sample size of at least 2,043 incident reports was required. From the sampling frame of 13,699 reports, we drew a randomly selected sample of 2,679 (to accommodate for the frequency of duplicates and reports with insufficient detail to interpret) using a random number generator.

Study Design

We took a sequential exploratory approach[20] based on first a qualitative analysis and then a quantitative analysis. We conducted a content analysis[21] of incident reports, coding the incident characteristics and type of blame attributions, after which we conducted a descriptive statistical analysis of the frequency of blame categories.

Data Coding

Using the Recursive Model of Incident Analysis,[22] we coded the free-text descriptions of the incidents using the Primary Care Patient Safety (PISA) Classification System,[10] which is aligned with the World Health Organization (WHO) International Classification for Patient Safety (ICPS).[23] We coded the primary incident type (eg, administration or discharge planning), primary contributory factor (eg, staffing levels or patient vulnerability), and the severity of the outcome (no, low, moderate, or severe harm or death). This method has been described in more detail elsewhere.[10] At the analysis stage, we excluded reports that did not describe a patient safety incident (for example, a patient falling in the clinic parking lot). Reports describing pressure ulcers have been excluded in previous work because they typically describe an outcome rather than an incident type. Pressure ulcers, however, accounted for more than 1 in 8 reports in the database, so we included these as an incident type to ensure the sample reflected the way incident reporting is used.[10]

We coded for blame according to a framework derived empirically by our team of primary care patient safety experts in conjunction with our lay patient and public involvement team. This framework

was tested on a pilot sample of reports and amended as necessary. One of the study team (J.C.) coded the categories, and a random sample of 268 (10%) reports was double-coded. We discussed discordance, rectified discrepancies, and calculated a κ coefficient to determine inter-rater reliability of coding.

Statistical Analysis

We calculated odds ratios and 95% confidence intervals of the odds of blame attribution (vs no blame attribution) and performed χ^2 tests to assess the associations between attribution of blame and the following prespecified variables: incident type, the number and nature of contributory factors reported, and severity of harm.[10] We integrated the quantitative findings with the emerging insights generated from the coding process.

Ethical Approval

The Aneurin Bevan University Health Board (Wales, United Kingdom) research risk review committee was consulted for ethical approval. As all identifiable details were removed before the submission of reports to the National Reporting and Learning System, ethical approval was waived for analysis of this anonymized data set. To further protect confidentiality, we made minor editorial adjustments to any examples provided, for example, removal of dates, location, and in 1 case, a rare diagnosis.

RESULTS

The 2,679 patient safety incident reports were reviewed against the criteria for inclusion. We excluded reports that did not describe a patient safety incident (n = 134) or did not involve primary health care (n = 397), leaving 2,148 incident reports for analysis. Reports came from a range of primary care settings: 1,405 from family practice, 644 from community nursing services, and the remainder from dentistry, mental health, and pharmacy services.

We defined blame as evidence in the free-text of a judgement about a deficiency or fault by a person or people. Described failure of aspects of the system rather than a person was coded as no blame. The remaining incidents described human errors leading to patient safety incidents. We found 5 key categories of blame (Figure 1 and Table 1). Blames self and blamed by another described

reports in which the person reporting the incident found fault in his own actions and acknowledged personal responsibility. Blames another and others blaming others, on the other hand, reflect reports that were used to identify others considered worthy of censure: we call this directed blame (Figure 1).

We found an attribution of blame statement in 45% (975) of patient safety incident reports (95% CI, 43%-47%). Cohen's κ for inter-rater reliability for coding of blame was calculated at κ = 0.81 (95% CI, 0.74-0.88), indicating strong agreement.[24] Table 2 shows that where blame was attributed, 92% (894) were cases of directed blame, whereas only 2% (41) acknowledged personal responsibility.

We found many cases of directed blame, both from the person reporting the incident and from other reports generated in response to or in anticipation of a complaint (Table 2, example 3: blames another).

Table 3 shows that the 3 types of incidents most likely to be associated with directed blame were those involving discharge planning, communication problems, and referrals. Incident reports involving record keeping and documentation, pressure ulcers, and investigations were significantly less likely to contain directed blame than other incidents.

Where incident reports described 1 or more contributory factors, 50% (433 of 865) attributed directed blame compared with 36% (461 of 1,283) of reports without contributory factors. Table 4 shows the ratios for the odds of blame for each type of primary contributory factor against the odds of blame in the other 3 categories.

Severity of harm to the patient, ranging from no harm to death, was described in 1,475 incident reports, with 44% (653) of these attributing directed blame (Table 5).
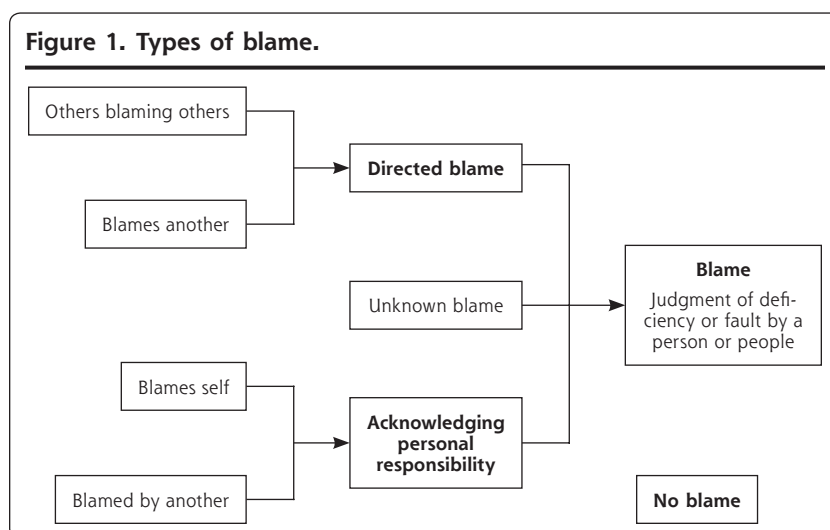

Figure 1. Types of blame.

Table 1. Categories of Blame by Persons Reporting Safety Incidents

Blame Focus and Definition	Example
Acknowledging personal responsibility	
Blames self Blames himself/herself for the incident	"Seen as temporary resident for an inguinal hernia awaiting operation. Was incarcerated (probably) and I acted on his history of this being reducible. I should have admitted him there and then and didn't. No complaint by patient."
Blamed by another Describes a third party blaming him/her for the incident	"The patient was diagnosed as having a [rare type of cancer]. He had attended the surgery on and off since [date] with urinary symptoms which seemed to respond to antibiotics. He saw every clinical member of the practice and was examined but a thorough examination was impossible. He was referred for a possible hernia on [date] and to the urology department on [date]. He was seen by both specialties within a week and diagnosis was confirmed. There has been a comment made to the family by a consultant that we should have spotted it sooner."
Directed blame	
Blames another Blames another individual for the incident	Example 1: "A terminally ill patient attended A&E in possible retention of urine. This patient has a syringe driver in situ with morphine and metoclopramide. The syringe driver was clearly labelled as per policy but despite this the doctor who saw the patient in A&E took the syringe driver down and left the patient without any analgesia or anti-sickness medication. As a result, the patient was in a lot of pain and was only given a small amount of oral analgesia after being in A&E for some hours. TOTALLY UNACCEPTABLE. Medication error/critical incident. Complete lack of knowledge demonstrated by the doctor. Inadequate assessment and lack of knowledge on behalf of the doctor, and failure to listen to the patient, as he did question why they were taking the syringe driver down."
	Example 2: "Patient brought to locum GP by mother with 3 / 52 history of symptoms of diabetes. After blood tests, she was diagnosed and started on oral hypoglycemic drug. She took one dose only and then was admitted to hospital with blurred vision. Patient was inappropriately treated by GP and not referred promptly."
	Example 3: "Patient's INR was 8.00 on [date]. Her warfarin was stopped on [date] and nobody has been to check her since urgent referral made to primary care trust. Patient left without warfarin cover for 10 days. There is a chance that the patient may have had a stroke with an INR of 8. This is a dangerous reading and the patient should have been seen earlier. Patient's daughter is making a formal complaint against the doctors. The paperwork received is inadequate with no target, no drugs listed, no information on present state.
Others blaming others Describes another individual being blamed for the incident	"Patient had an appointment with the doctor. Patient was in discomfort with problems swallowing and indigestion. This lady has complex co-morbidities. After a few days she felt very ill and thought it was the medication that had been prescribed on the day of her appointment. The patient contacted the practice but the practice would/could not provide an appointment that day or indeed the next day. The doctor eventually agreed to do another prescription without seeing her again (stemetil). When the patient went to collect the medication the pharmacist would not dispense the medication as it was not suitable for people with under active thyroid and it was for vertigo/nausea/vomiting. The patient could not raise this issue since the practice was then closed. The patient added that this is not the first time that something has happened like this."
Unknown blame Blame identified but source unclear	"Patient with rheumatoid arthritis on steroids was taken off bone protection medication for 1 year giving a 'drug free holiday' to reduce the incidence of atypical fracture (without a review date to re-start). She had been on this medication for 7 years. Stopping this medication was inappropriate."
No blame No attribution of blame to a person	"Computer system misinterpreted the directions for the dose of amiodarone and printed out 1/2 tablet daily instead of 1 1/2 stated on the prescription even though the patient's computer record showed 1 1/2 daily as issued."

A&E = accident and emergency; GP = general practitioner; INR = international normalized ratio.

DISCUSSION

In almost one-half of incident reports, reports containing a judgment featured fault by a person (975 of 2,148), and 42% of reports featured directed blame (894 of 2,148). The proportion showing directed blame varied depending on the incident type, contributory factors involved, and the severity of harm to the patient. Directed blame was less likely in incidents where the patient was harmed (except for the small category of reports about death).

Fear of being held personally accountable is thought to explain much of the reluctance of frontline health care staff to use incident reporting systems to communicate patient safety concerns.[2,5,7, 25-27] Although blame is acknowledged to hinder reporting,[6] ours is the first study to identify and characterize its use within incident reports themselves.

Health service managers have a responsibility, to motivate reporting within a blame-free culture[28,29]; further it is difficult to generate learning from reports unless health care is free from an atmosphere of

Table 2. Numbers and Proportions of Blame Attribution (N = 2,148 Reports)

Focus of Blame	Reports[a] No. (%)
Acknowledges personal responsibility	
Blames self	28 (1)
Blamed by another	13 (1)
Directed blame	
Blames another	766 (36)
Others blaming others	128 (6)
Unknown blame	40 (2)
No blame	1,173 (55)

[a] Rounded to the nearest integer.

Table 3. Likelihood of Directed Blame Attribution With Different Types of Safety Incidents Reported

Incident Type	Reports No.	Reports Containing Directed Blame No. (%)	OR (95% CI)[a]
Discharge planning	33	27 (82)	6.5 (2.7-15.8)
Communication	36	25 (69)	3.3 (1.6-6.6)
Referral	170	106 (62)	2.5 (1.8-3.5)
Diagnosis and assessment	62	37 (60)	2.1 (1.3-3.6)
Medication	417	228 (54)	1.9 (1.6-2.4)
Administration	379	181 (48)	1.4 (1.1-1.7)
Treatment	77	37 (48)	1.3 (0.8-2.1)
Equipment provision	94	40 (43)	1.0 (0.7-1.6)
Other	68	27 (40)	0.9 (0.6-1.5)
Investigations	251	76 (30)	0.6 (0.4-0.8)
Record keeping and documentation	80	19 (24)	0.5 (0.3-0.7)
Vaccination	100	21 (21)	0.4 (0.2-0.6)
Pressure ulcer	381	70 (18)	0.3 (0.2-0.3)

OR = odds ratio.

[a] ORs for odds of directed blame when incident type is present vs incident type absent.

Table 4. Directed Blame and Contributory Factors in Safety Incident Reports

Contributory Factor	Reports No.	Directed Blame No. (%)	OR (95% CI)[a]
Staff factors (eg, staff knowledge, failure to follow protocols)	351	203 (58)	1.7 (1.3-2.3)
Organizational factors (eg, staffing level, continuity of care)	216	122 (56)	1.4 (1.0-1.9)
Patient factors (eg, frailty, language barrier)	263	100 (38)	0.5 (0.4-0.7)
Equipment factors (eg, faulty or missing equipment)	35	8 (29)	0.3 (0.1-0.6)
No contributory factors reported	1,283	461 (36)	...
All reports	2,148	894 (42)	...

OR = odds ratio.

[a] Comparing odds of directed blame where contributory factor is present vs odds of blame where an alternative contributory factor is present.

placed ahead of identifying the scope for learning.[6,11] Coles et al[30] found that hospital clinicians had little confidence managers would deal with reports in a blame-free way. Hospital managers also perceived that incident reports were being used by those making the report to "cover one's own back" in the event of an incident. Indeed, many directed blame reports were generated in response to or anticipation of a complaint (Table 1, Blames another, example 3).

Second, as Reason explains, humans are susceptible to the fundamental attribution error in that they tend to appreciate systems factors in understanding one's own actions but tend focus on others' personal behaviors rather than the wider context influencing them.[9] The blames-another example of directed blame (Table 1, Blames another, example 1) lists numerous failures of the physician involved but provides no insights into whether the department was busy or the physician had the appropriate training or supervision.

Those reporting incidents acknowledged personal responsibility for their actions in only 2% of their reports, compared with the 42% of reports directing blame at others. Although the exact proportions may not be generalizable for all incidents or routine practice (because of selection biases in the reporting system), this difference is substantial and suggests key differences and missed learning. We may be missing key insights and soft intelligence that individuals closest to these incidents might have offered.[31,32] Soft intelligence is insight from experiences of frontline staff about the reality of the system, which can thrive only where staff feel valued and respected.[31,32] Historically, despite its potential, analyses of incident reporting have failed to provide this soft intelligence or support this ethic.

It is unsurprising that persons reporting incidents who identified staff factors contributing to the incident were more likely to apportion directed blame than where equipment or patient factors were considered to be causative. Reports describing organizational contributory factors, however, also had higher odds of containing directed blame. It is possible that those reporting incidents may still make fundamental attribution errors despite recognizing system factors.

blame.[2,12,13] That 42% of reports were used to censure others, however, suggests progress toward a blame-free and supportive culture is slow.

Most safety incidents are caused by a complex interaction of individual actions and system failures, with greater weight given to system factors.[9] Reason's Swiss cheese model describes how, although human error is inevitable, incidents are frequently the result of multiple smaller errors within a failed system: "The important question is not who blundered, but how and why the defenses failed."[9]

First, we hypothesize that our results may reflect the outlook and behavior of those working in a culture in which seeking personal accountability for errors is

Table 5. Directed Blame and Severity of Harm in Safety Incident Reports

Variable	Reports No.	Directed Blame No. (%)	OR (95% CI)[a]
No harm	271	145 (54)	1.0
Mild	1,028	435 (42)	0.6 (0.6-0.9)
Moderate	149	66 (44)	0.7 (0.7-1.4)
Severe	21	2 (10)	0.1 (0.0-0.5)
Death	6	5 (83)	4.4 (0.6-46.2)
Patient outcome not reported	673	241 (36)	...
Total reports	2,148	894 (42)	...

ICPS = International Classification for Patient Safety; OR = odds ratio; WHO = World Health Organization.

Note: Based on WHO ICPS harm level classification.

[a] Odds of directed blame for each level of harm compared with odds of blame for no harm.

Directed blame was more likely in situations of discharge planning, communication, referrals and diagnosis, and assessment. These types of incidents involved clinical judgment and interactions with patients, their relatives, and other health care professionals. Perhaps the more emotive nature and context of these incidents resulted in more frequent directed blame. Furthermore, recognizing a diagnostic error may require judgment by the person reporting the incident, whereas a pressure ulcer or documentation error is a matter of fact and more easily reported as such. Many decisions and judgments in primary care are made by individual clinicians in practices where there are no checks and balances that a larger team provides, as in hospital care. Primary care professionals may therefore be more individually vulnerable to directed blame than their hospital colleagues when an error is made.[16]

Strengths and Limitations

We used a well-established coding method[10] with a high level of coding agreement (κ = 0.81) to ensure methodological rigor. Our study examined associations with blame attribution, and we offer new insights into the way incident reports are used. Generalizations from our study should be made cautiously: selection bias in reporting is important,[33] rendering this analysis essentially inductive rather than deductive; the quality of incident report analysis relies heavily on the use of subjective interpretation of events during reporting and the depth of information provided by the those reporting the incidents.[34] Also, persons reporting incidents may not necessarily have all the information at the time of writing. Further research should explore how persons reporting incidents are affected by social and cultural influences, as well as by their the

motivations and understanding of the potential impact of blame. Such explorations, as well as a comparative analysis of blame in secondary care incident reporting, would enable the effective targeting of interventions to improve the learning from these reports.

Leaders and managers of health care systems and health organizations are frequently urged to develop and promote a climate of learning from things that go wrong. It seems that their current approach, however, may drive their staff to point the finger at their colleagues. This amplification of the process of seeking someone to blame is neither in the interests of patients, nor staff, nor of making health care safer.

References

1. Berwick D. *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England.* London, England: Crown Publishing; 2013.

2. Donaldson L. *An Organisation With a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer.* London, England: The Stationery Office; 2000.

3. Barach P, Small SD. How the NHS can improve safety and learning. By learning free lessons from near misses. *BMJ.* 2000;320(7251): 1683-1684.

4. Firth-Cozens J. Barriers to incident reporting. *Qual Saf Health Care.* 2002;11(1):7.

5. Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract.* 1999;5(1): 13-21.

6. Waring JJ. Beyond blame: cultural barriers to medical incident reporting. *Soc Sci Med.* 2005;60(9):1927-1935.

7. Iedema R, Allen S, Sorensen R, Gallagher TH. What prevents incident disclosure, and what can be done to promote it? *Jt Comm J Qual Patient Saf.* 2011;37(9):409-417.

8. Sari AB, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ.* 2007;334(7584):79-81.

9. Reason J. Human error: models and management. *BMJ.* 2000; 320(7237):768-770.

10. 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. *Health Services and Delivery Research.* 2016;4(27): 10.3310/hsdr04270.

11. Aveling EL, Parker M, Dixon-Woods M. What is the role of individual accountability in patient safety? A multi-site ethnographic study. *Sociol Health Illn.* 2016;38(2):216-232.

12. Francis R. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.* London, England: The Stationary Office; 2013.

13. Donaldson LJ, Panesar SS, Darzi A. Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010-2012. *PLoS Med.* 2014;11(6):e1001667.

14. NHS England (London Region)/Primary Care Transformation Programme. Transforming primary care in London: general practice a call to action. NHS England. https://www.england.nhs.uk/london/wp-content/uploads/sites/8/2013/12/london-call-to-action.pdf. Published Nov 28, 2013. Accessed Sep 22, 2016.

15. National Reporting and Learning System. Organisation patient safety incident reports. NHS England. http://www..npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/. Accessed Sep 19, 2016.

16. NHS England. Freedom to speak up in primary care. NHS England. https://www.england.nhs.uk/wp-content/uploads/2016/11/whistleblowing-guidance.pdf. Accessed Sep 12, 2016.

17. National Patient Safety Agency. What is a patient safety incident? http://www.npsa.nhs.uk/nrls/reporting/what-is-a-patient-safety-incident/. Accessed Oct 24, 2016.

18. Institute of Medicine. *Defining Primary Care: An Interim Report.* Washington, DC: National Academy Press; 1994.

19. Carson-Stevens A, Hibbert P, Avery A, et al. A cross-sectional mixed methods study protocol to generate learning from patient safety incidents reported from general practice. *BMJ Open.* 2015;5(12): e009079.

20. Curry LA, Krumholz HM, O'Cathain A, Plano Clark VL, Cherlin E, Bradley EH. Mixed methods in biomedical and health services research. *Circ Cardiovasc Qual Outcomes.* 2013;6(1):119-123.

21. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ.* 2000;320(7227):114-116.

22. Hibbert P, Runciman W, Deakin A. *A Recursive Model of Incident Analysis.* Adelaide, SA: Australian Patient Safety Foundation; 2007.

23. World Health Organization. *The Conceptual Framework for the International Classification for Patient Safety: Final Technical Report.* Geneva, Switzerland: World Health Organization; 2009.

24. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977;33(1):159-174.

25. Vincent C. Incident reporting and patient safety. *BMJ.* 2007; 334(7584):51.

26. Stanhope N, Crowley-Murphy M, Vincent C, O'Connor AM, Taylor-Adams SE. An evaluation of adverse incident reporting. *J Eval Clin Pract.* 1999;5(1):5-12.

27. Lawton R, Parker D. Barriers to incident reporting in a healthcare system. *Qual Saf Health Care.* 2002;11(1):15-18.

28. Patient Safety and Quality of Care Working Group (PSQCWG). Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe. http://ec.europa.eu/health//sites/health/files/patient_safety/docs/guidelines_psqcwg_reporting_learningsystems_en.pdf. Published May 2014.

29. World Health Organization. *The World Health Organisation (WHO) Patient Safety Curriculum Guide: Multi-professional Edition.* Geneva, Switzerland: World Health Organization; 2011.

30. Coles J, Pryce D, Shaw C. *The Reporting of Adverse Clinical Incident – Achieving High Quality Reporting: The Results of a Short Research Study.* London, England: CASPE Research; 2001.

31. Dixon-Woods M, Baker R, Charles K, et al. Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study. *BMJ Qual Saf.* 2014;23(2):106-115

32. Martin GP, McKee L, Dixon-Woods M. Beyond metrics? Utilizing 'soft intelligence' for healthcare quality and safety. *Soc Sci Med.* 2015;142:19-26.

33. Johnson CW. How will we get the data and what will we do with it then? Issues in the reporting of adverse healthcare events. *Qual Saf Health Care.* 2003;12(Suppl 2):ii64-ii67.

34. Russ AL, Fairbanks RJ, Karsh B-T, Militello LG, Saleem JJ, Wears RL. The science of human factors: separating fact from fiction. *BMJ Qual Saf.* 2013;22(10):802-808.