Factors related to medication administration incidents in England and Wales: A retrospective trend analysis 2007-2016

Marja Härkänen, Post-doctoral researcher, PhD, RN, Corresponding author
University of Eastern Finland: Department of Nursing Science; Academy of Finland, Yliopistoranta 1c, Kuopio, Finland, marja.harkanen@uef.fi

Katri Vehviläinen-Julkunen, Professor, PhD, RN, RM
University of Eastern Finland: Department of Nursing Science; Kuopio University Hospital, Kuopio, Finland

Bryony Dean Franklin, Professor, PhD, Pharmacist
Centre for Medication Safety and Service Quality, Imperial College Healthcare NHS Trust, Charing Cross Hospital, UCL School of Pharmacy, London, UK

Trevor Murrells, BSc, MSc, Statistician (Nursing & Midwifery)
King's College London: Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, London, UK

Anne Marie Rafferty, Professor, PhD, RN
King's College London: Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, London, UK

Conflicts of Interest and Source of Funding:

Third author of this paper supervises a PhD student part funded by Cerner, a supplier of hospital electronic health record systems, and has received funding from Pfizer for delivering teaching at a one-off symposium on medication safety unrelated to this study.

This work was financially supported by post-doctoral research funding for the first author of this paper by the Academy of Finland. Third author of this paper is supported by the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre, and the NIHR Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance at Imperial College London, in partnership with Public Health England (PHE). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, PHE or the Department of Health and Social Care.

Acknowledgements

We want to thank NHS Improvement Patient safety team for helping the authors through the data acquisition process and refining the data extraction.

ABSTRACT

Objectives To describe medication administration incidents reported in England and Wales between 2007–2016, to identify which factors (reporting year, type of incident, patients' age) are most strongly related to reported severity of medication administration incidents, and to assess the extent to which relevant information was underreported or indeterminate.

Methods Medication administration incidents reported to the National Reporting & Learning System between 1 January 2007 and 31 December 2016 were obtained. Characteristics of the data were described using frequencies, and relationships between variables explored using cross-tabulation.

Results 517,384 incident reports were analysed. Of these, 97.1% (n=502,379) occurred in acute /general hospitals, mostly on wards (69.1%, n=357,463), with medicine the most common specialty area (44.5%, n=230,205). Medication errors were most commonly omitted doses (25.8%, n=133,397). The majority did not cause patient harm (83.5%, n=432,097). When only incidents causing severe harm or death (n=1,116) were analysed, the most common type of error was omitted doses (24.1%). Most incidents causing severe harm or death occurred in patients aged 56 and over. Over the 10-year period, the percentage of incidents with 'no harm' increased (74.1% in 2007 to 86.3% in 2016). For some variables, data was often missing or indeterminate which has implications for data analysis.

Conclusions Medication administration incidents that do not cause harm are increasingly reported whereas incidents reported as severe harm and death have declined. Data quality needs to be improved. Underreporting and indeterminate data, inaccuracies in reporting and coding jeopardize the overall usefulness of these data.

Keywords: medication administration error, medication error, incident reporting, NRLS, patient safety, hospital, England and Wales

INTRODUCTION

Medication errors are a leading cause of avoidable harm in health care systems globally, with an estimated annual cost of 42 billion USD annually[1]. Since the beginning of the third millennium, much effort has focused on patient safety. A major stimulus for this was the US report 'To err is human' published in 1999 by the Institute of Medicine[2]. In the report, one of the key recommendations for learning and decreasing errors was for greater attention to be paid to incident reporting, with a primary purpose of facilitating learning, avoiding the same incidents recurring, and monitoring progress in prevention of errors at the organizational level[3-4]. In addition, increased transparency, together with more thorough reporting and analysis of incidents, provides an opportunity to share experiences[5] and should lead to the development of interventions aimed at mitigating errors[6].

Reporting medication safety incidents

In England and Wales, the National Reporting & Learning System (NRLS) is a national database on patient safety incidents that are voluntarily and anonymously reported electronically by the National Health Services (NHS) and other health care organisations or using a specific on-line form. The NRLS was established by the National Patient Safety Agency (NPSA) in 2003. By June 2017[5] the NRLS database had captured over 16 million reports and is the largest patient safety reporting system in the world[6-7]. Data reported for each incident include both categorical data (e.g. type, severity of incident) and a free text description of what happened.

Medication administration is one part of the medication process with approximately 5-20% of nurses' time allocated to this activity[8-9]. The medication administration process is complex and demanding[10], and medication administration errors (MAEs) are common[11-12], with as many as one in five medications administered to patients associated with an error[13-14]. Fifty to sixty percent of all medication errors reported to the NRLS occur are categorised as 'medication administration' [15-16], potentially representing the most error-prone stage of the medication process.

According to the WHO[17], there is no standard definition of a medication error. One commonly and globally used definition is that proposed by the United States National Coordinating Council for Medication Error Reporting and Prevention [18], which defines a

medication error as 'any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer'. A MAE can be defined as 'any deviation from procedures, policies, and/ or best practices for medication administration'[10]. It includes, for example, a failure to administer medication, giving an incorrect dose or drug, a dose given to the wrong patient, administration via the incorrect route or technique, at an inappropriate rate, or with incorrect timing.

Despite growing empirical evidence, policy, and professional attention to MAEs, so far there is no sign of MAEs diminishing[19]. Incident reporting has become a widely used method for studying medication errors, mainly because these data are relatively easy to obtain and relatively low cost[20].

Quality of reporting

When the quality of incident data in general is discussed, it is mostly in terms of under-reporting[21], which remains a significant problem[22]. Only a fraction of incidents are reported. It has been estimated that self-reporting systems such as the NRLS, detect only 7-15% of all medication incidents[23], but the actual percentage may be even lower. Under-reporting may be either intentional or unintentional. Some unintentional reasons are the healthcare professional failing to recognize the error, or forgetting or not knowing how to report it. There may also be misunderstanding of incidents that should be reported, such as near misses or omissions of medications.[22] Intentional reasons and barriers to reporting include time pressures and fear of the consequences[20-22,24], poor institutional support or processing of incident reports[21,25], lack of awareness of how the reported incidents will be analysed, not knowing how the reports will ultimately lead to changes that improve patient safety[22], lack of feedback[21-22,26-27], blame culture, inadequate training, and poor coordination of reporting[24]. Incidents that are immediate and witnessed are often better reported[22]. Under-reporting limits detection of rare incidents and presents an epidemiological bias; gaining accurate estimates of error rates becomes difficult and prone to bias[28].

Incident reporting has also received criticism in relation to selective and incomplete reporting[29]. There may be differences in how health professional groups rate incidents[30], and significant variations in the quality of free-text descriptions in terms of length, detail, and potential inaccuracies[31]. Reporting of complex multifaceted events may reduce the incident to a simple descriptor such as 'medication error' and the cause into an equally simplistic category such as 'communication failure' or 'staffing'[32]. Thus, important information and understanding will be lost. As the number of reported incidents continues to increase[33], it is vital to be able to analyse those effectively, which requires well-documented information.

The quality of NRLS medication incident data has been highlighted, with the Patient Safety Alert 'Improving medication error incident reporting and learning' published in 2014. This alert calls further improvements to increase the number of incident reports, improve the data quality and maximise what can be learned from medication errors. A previous study reviewed NRLS medication error reports over a 6-year period (2005-2010)[16]. In contrast to this previous analysis, our study will focus specifically on medication administration incidents and will a 10-year period of data to allow for trend analysis of reporting practices, describing missing and other invalid data, and thus offering more detailed information on the changes in data quality over this period. As far as we are aware this is the first study to focus on a longitudinal analysis of reporting practices of medication administration incidents over a 10-year period. Our specific objectives are to describe MAEs reported in England and Wales between 2007–2016, to identify which factors are most strongly related to severity of reported MAEs (reporting year, type of incident, patients' age), and to assess how much information collected on MAEs is underreported or indeterminate.

METHOD

Design and setting

This is a retrospective trend analysis of anonymous self-reported MAEs.

The NRLS collects reports of patient safety incidents from NHS organisations and other healthcare providers in England and Wales. Incidents can also be reported directly to the NRLS. Data in the national system is designed not to retain any patient or staff personal identifiable information. If such information is submitted in error, NRLS anonymise the data. The data cleaning process also includes the removal of duplicates reports. Based on the NRLS

reporting e-form[34], mandatory fields of reporting are: when (date, time) and where (service, location, country, specialty area) an incident occurred, description of what happened, whether the patient was actually harmed and degree of such harm (if the answer was no harm, then they were asked to provide an evaluation of potential harm), and patient characteristics such as age, gender and ethnic background. In addition, it is mandatory to report contributing factors, as well as details related to the drugs involved such as stage of the medication process, type of error, and approved drug name. Mandatory staff details are staff type, status, and the role of the reporting staff member in the incident. Although these fields are stated as being mandatory, most allow answers such as 'unknown', 'other', or 'not applicable'.

Data source

The data comprised MAEs reported to the NRLS as having occurred between 1 January 2007 and 31 December 2016. We used only data from the closed questions, which are based on what has been reported to the NRLS: incident category (type), degree of harm, incident location, care setting of occurrence, specialty area where the incident occurred, age, and gender of patient and date and time of incident, as well as factors contributing to the incident. These data are mainly captured using drop-down menus during entry. Incident severity was designated by reporters as no harm, low harm (patient(s) required extra observation or minor treatment), moderate harm (short term harm - patient(s) required further treatment, or procedure), severe harm (permanent or long term harm) or death (caused by the Patient Safety Incident).

Data acquisition

A data sharing agreement was signed after applying and receiving acceptance from NRLS for data access. NRLS extracted the data in December 2017 using following inclusion filters: 1) Incidents between 1st January 2007 and 31st December 2016 (based on the date the incident was reported to have occurred), 2) Medication incident, 3) Administration / supply of a medicine from a clinical area, and 4) Acute NHS trust (either specialist or non-specialist).

Data analysis

Incidents were enumerated by year (2007-2016), month of occurrence, time of day, care setting, location, specialty, patients' age, gender, error category, degree of harm, administration route, and contributing factors. Patients' ethnicity was not analysed as it was reported for only 24.7% of reports. Unreported and indeterminate information (classified into unknown, other, not stated, not applicable) was enumerated for those variables where this was an issue (location, hour of occurrence, patients' gender and age, error category, and administration route).

The severity of incidents was further disaggregated by reporting year, error category, and patients' age to explore whether the severity of reported incidents has changed over the period concerned, and whether the severity of incidents varies in different error categories or patient age groups. The incident report severity classifications were used in their original form when the data were described, but due to small numbers in certain categories were re-classified into three groups, for cross-tabulation purposes: 1) No harm, 2) Low and moderate harm, and 3) Severe harm and death. For similar reasons, patients' age bands used within the NRLS were amalgamated into six groups: 1) under 12 years, 2) 12-17 years, 3) 18-25 years, 4) 26-55 years, 5) 56-75 years, and 6) over 75 years.

Descriptive statistical analysis was conducted using IBM SPSS version 23.0. Characteristics of the data were described using frequencies and percentages, and relationships among factors explored via cross-tabulation.

Ethics

The research ethics office of King's College London gave an ethical approval for this study (LRS-17/18-5150) in October 2017. The data did not include any personal or organisational identifiers, thus anonymity of the reporters, patients, other involved persons, and organisations could be guaranteed.

RESULTS

Demographics

During 2007-2016, there were a total of 517,384 MAEs reporting as occurring. The number of incidents increased every year. In 2007, there were 29,455 and in 2016 72,390 MAEs reported (Figure 1). Fewer incidents were reported as occurring in February (7.6%, n=39,517) and most in October (9.0%, n=46,601) (Figure 2). Most MAEs were reported to have occurred between 10 a.m. – 1 p.m. (16.0 %, n=82,997), 7 – 10 a.m. (14.4%) or 4 – 7 p.m. (14.4%), and fewer between 4 – 7 a.m. (3.6%). Most MAEs occurred in acute or general hospitals (97.1%, n=502,379), on wards (69.1%, n=357,463), in intensive care unit / high dependency units (8%, n=41,149), or in operating theatres (2.3%, n=11,867). The most common specialty areas were medical (44.5%, n=230,205) and surgical (20.0%, n=103,686). (online only supplementary material.)

Mean reported patient age was 53.9 years and over 40% were aged 75 and over (43.1% n= 222,775). Children aged 12-17 (2.2%) and young adults aged 18-25 (3.0%) had fewest reports. About one third of the patients were reported as being female (35.3%, n= 182,451), 30.2% (n=156,419) as males, n=78 gender indeterminate and for 34.5% (n=178,436) gender was not reported. (online only supplementary material.)

MAEs were mostly attributed to omitted medicines or ingredients (25.8%, n=133,397), wrong frequency (9.9%, n=51,003), or wrong / unclear dose or strength (9.0%, n=46,389). The majority of the MAEs caused ‘no harm’ (83.5%, n=432,097). The administration route was not reported for 73.0% of incidents, but of those for which this was reported, intravenous (9.1%, n=46,837) and oral (9.0%, n=46,728) administration was most common. The majority (92.3% / n=477,728) of incident reports included no description of perceived contributing factors. (online only supplementary material.) Of the n=39,656 incidents that did include contributing factors, the most common were “medication factors” (33.6 %, n=13,306), and “task factors” (13.0 %, n=5,136) (Table 1).

Factors related to severity of incidents

Over the 10-year period, the percentage of MAEs reported as resulting in ‘No harm’ increased (2007: 74.1% - 2016: 86.3%). At the same time, percentage of incident with ‘Low and moderate harm’ (2007: 25.2% - 2016: 13.6%) and ‘Severe harm and death’ (2007: 0.7% - 2016:

0.1%) decreased. When severity of each error type were compared, it was found that the most common incident types associated with 'No harm' or 'Low and moderate harm' were omitted medicine/ingredient, wrong frequency, or wrong or unclear dose or strength. For 'Severe harm and death' omitted medicine/ingredient (24.1%) was mentioned most often followed by wrong/unclear dose or strength (13.4%), or wrong drug/medicine (9.0%). A higher percentage of people with reports of 'Severe harm and death' were aged 56 and over (51.8%), than for 'Low and moderate harm' (46.9%) or 'no harm' (42.3%). Conversely a lower percentage of people with reports of 'Severe harm and death' were under 12 (7.4%), than for 'Low and moderate harm' (9.8%) or 'no harm' (10.7%). (Table 2.)

Unreported and indeterminate information in incident reports

When the proportion of missing and indeterminate information (classified as 'unknown' / 'other' / 'not stated' / 'not applicable' factors) in incident reports was studied, it was found that valid information decreased over the 10-year period for some factors. For example, information on 'Location of incident' decreased each year (2007: 89.9% - 2016: 79.6%). In contrast, completeness increased for other factors, such as for 'Patient age' which increased each year (2007: 65.6% - 2016: 80.8%). However, for 122 patients, ages were recorded as being between 110 and 120 years suggesting a data entry error (e.g. an extra zero). The completeness of reporting increased for some factors: for example reporting 'Administration route of drug' increased between 2007 (15.2%) to 2015 (30.4%). For other factors, such as in 'Patient gender' or 'Medication error category', completeness of reporting fluctuated over time. (Table 3.)

DISCUSSION

This study focused specifically on a retrospective trend analysis of anonymous self-reported MAEs over a 10-year period using NRLS national level data for England and Wales. We analysed over 500,000 MAEs and found that the number of reported MAEs increased year on year. Cousins et al.[16] found that the increasing number of medication reports each year is significantly higher than increases in the total number of patient safety incidents reported to the NRLS. Many possible reasons for this exist. First, staff are being encouraged to increase

their reporting to promote a more open culture in healthcare services. It is anticipated that the volume of reporting will continue to increase as this culture spreads more widely [33]. An increase in the number of incidents reported should not be taken as a marker of deterioration in patient safety but rather an indication of rising levels of safety awareness among healthcare professionals. However, the increase in medication incidents may also be partly linked also to increased use of drugs[16]. In addition, the number of total reported incidents (not only medication related) has increased over the years. Incidents have been reported to the NRLS since October 2003, with all NHS organisations being able to access the system from 2005. There were 153 incidents reported from October to December 2003 and 135,356 in October to December 2005, in contrast 508,409 incidents were reported from October to December 2017. [35]

Findings related to severity of incidents

The majority of MAEs did not cause harm to patients either in this study or an earlier study of medication errors in NRLS[15]. Over the years, the number of 'No harm' incidents has increased (2007-2016: 21,817 to 62,461) in this dataset and 'Severe harm and death' incidents decreased (2007-2016: 202 to 74). This is an interesting finding because from 2010 it became mandatory for NHS trusts in England to report all serious patient safety incidents to the Care Quality Commission. To avoid duplication of reporting, all incidents resulting in death or severe harm should therefore be reported to the NRLS which are then passed onto the Care Quality Commission.[36] Despite this mandatory requirement there has been a clear decrease in the percentage of serious reports. Most incidents occurred amongst patients aged 56 and over. Over 50% of 'Serious harm' incidents occurred in this age-group. Howell et al.[7] also found that patients most vulnerable to reported harm were elderly medical inpatients.

It should be noted that the reported severity is only indicative evaluation. Possible inconsistencies in severity ratings may be caused by a lack of understanding of how to report the 'degree of harm'. This should relate to the actual harm resulting directly from the incident itself rather than perceived potential harm. For example, sometimes the degree of harm is coded as 'severe harm' in near-miss cases, where no harm resulted because the impact of the incident was prevented [37].

Findings related to data quality

We found many issues related to the quality of the data. Some of the fields had comparatively high levels of missing or indeterminate information: in one third of the incidents, patients' gender was not reported, administration route was not reported in 73%, and contributing factors not reported for 93%. Similarly Panesar et al.[6] found that gender was completed for approximately 70% of entries, age for 66% and ethnicity for only 20%. For some variables, improvement in completeness of reporting could be seen over time (e.g. age). For other variables the volume of indeterminate information increased each year, for example 'Location of incidents'. Even though most of the fields are stated as being mandatory, it was common to use categories such as other, unknown, or not applicable.

Low data quality and under-reporting jeopardize the aims of incident reporting. Thus, individuals should therefore be encouraged to report incidents as accurately and completely as possible[38]. The reasons for reporting invalid information requires further investigation. In some cases this could be due to lack of available details, lack of time, or a willingness to prioritise. Time pressure is one particular issue and choosing 'other' or 'unknown' is likely to speed up data entry and allow the person to return to more immediate activities. First and foremost, awareness of the problem should be raised, because missing and indeterminate information affect the reliability of the findings. In particular, Panesar et al.[6] state that it should not be assumed that missing or other invalid data are evenly distributed which has analysis implications. Analysis is straightforward if data are missing randomly but becomes more taxing if they are not. It is important for researchers in this field to assess missing data and report this in the findings. In addition, a lack of a true denominator limits what can be inferred from epidemiological analysis, but it is important to remember that the purpose of the NRLS is to enable learning and not carry out epidemiological analysis. Studies that reveal the potential usefulness of incident data may help to increase the frequency and quality of reporting.[28] Some of the NRLS questions may require further development to help minimize the amount of unknown and invalid data, for example incident type where one fifth of incidents are coded to 'Other'.

Strengths and weaknesses

We studied the characteristics of MAEs over a 10-year period between 2007–2016 including over 500,000 incident reports. The unique strengths of the NRLS are its size, duration and the inclusion of reports of no and low levels of harm as well as adverse outcomes[39]. This kind of national level incident analysis can be valuable and has the advantage of highlighting the areas for improvement that can be disseminated widely for raising awareness, research, audits, training initiatives, curriculum, specific guidelines, and generating a culture of safety [22,40]. Reporting systems overall can provide warnings, point to important problems, and provide some understanding of causes.

The current study has some limitations, primarily around under-reporting and the quality of the data although this appears to be improving overall. Some data entry errors relate to data collection and others to classifying. Reported severity may not relate precisely to actual severity. Typically this will be a subjective assessment and is sometimes mistaken for potential rather than actual degree of harm. In addition, reports will include incidents where the impact on the patient is not yet known. It is now mandatory to report serious incidents in England and Wales to Strategic Executive Information System (STEIS), but not the less-harmful incidents, which rely on voluntary self-reporting. Therefore less-harmful incidents may be more prone to under-representation, which poses problems for analysis, interpretation and generalizability. On a smaller scale, the data may contain duplicates and some minor coding or data entry errors (e.g. age). The way the data are collected anonymously means that it is not possible to verify or clarify incident details afterwards[6].

CONCLUSION

Based on findings over at 10-year period 2007-2016, absolute numbers of ‘No harm’ incidents continued to increase annually. The total number of reported serious harm incidents has declined and fallen below 100. However, it is important not to lose sight of incidents categorised as ‘No harm’ and ‘Mild harm’ which could be precursors or indicators of potential ‘Serious-harm’. The quality of reports should be improved, because under-reporting and indeterminate data, inaccuracies in reporting and coding jeopardize the overall usefulness of the data. Further studies should clarify the reasons for indeterminate reporting and missing

data. As most serious medication administration incidents occurred in elderly patients, additional studies and interventions should focus on safe administration of drugs to these patients.

REFERENCES

1 WHO. Medication Without Harm: WHO's Third Global Patient Safety Challenge. Available at: http://www.who.int/patientsafety/medication-safety/en/. Accessed June 10, 2018

2 Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human: Building a Safer Health System. Institute of Medicine (US) Committee on Quality of Health Care in America;. Washington (DC): National Academies Press (US); 2000.

3 Leape LL. Reporting of adverse events. *N Engl J Med* 2002;14:347(20):1633-8.

4 Savage SW, Schneider PJ, Pederson GA. Utility of an online medication-error-reporting system. *Am J Health Syst Pharm* 2005;62(21):2265-70.

5 NRLS. NaPSIR quarterly data workbook up to June 2017. Data on patient safety incidents reported to the NRLS up to June 2017. Available at: https://improvement.nhs.uk/resources/national-patient-safety-incident-reports-september-2017/. Accessed August 3, 2018.

6 Panesar SS, Warner B, Sheikh A. Incident reporting and feedback approaches. In: Tully MP, Franklin BD. Safety in medication use. CRC press 2016: 157-170.

7 Howell AM, Burns EM, Bouras G, et al. Can Patient Safety Incident Reports Be Used to Compare Hospital Safety? Results from a Quantitative Analysis of the English National Reporting and Learning System Data. *PLoS One* 2015;10(12):e0144107. doi: 10.1371/journal.pone.0144107.

8 Westbrook JI, Duffield C, Li L, et al. How much time do nurses have for patients? a longitudinal study quantifying hospital nurses' patterns of task time distribution and interactions with health professionals. *BMC Health Serv Res* 2011;11:319. doi: 10.1186/1472-6963-11-319.

9 Antinaho T, Kivinen T, Turunen H, et al. Nurses' working time use – how value adding it is? *J Nurs Manag* 2015;23(8):1094-105. doi: 10.1111/jonm.12258.

10 Drach-Zahavy A, Somech A, Admi H, et al. (How) do we learn from errors? A prospective study of the link between the ward's learning practices and medication administration errors. *Int J Nurs Stud* 2014;51(3):448-57. doi: 10.1016/j.ijnurstu.2013.06.010

11 McLeod MC, Barber N, Franklin BD. Methodological variations and their effects on reported medication administration error rates. *BMJ Qual Saf* 2013;22(4):278-89. doi: 10.1136/bmjqs-2012-001330.

12 Raban MZ, Westbrook JI. Are interventions to reduce interruptions and errors during medication administration effective?: a systematic review. *BMJ Qual Saf* 2014;23: 414-421. doi: 10.1136/bmjqs-2013-002118.

13 Keers RN, Williams SD, Cooke J. Causes of medication administration errors in hospitals: a systematic review of quantitative and qualitative evidence. *Drug Saf* 2013;36(11):1045-67. doi: 10.1007/s40264-013-0090-2.

14 Härkänen M, Ahonen J, Kervinen M, et al. The factors associated with medication errors in adult medical and surgical inpatients: a direct observation approach with medication record reviews. *Scand J Caring Sci* 2015;29(2):297-306. doi: 10.1111/scs.12163

15 NPSA. 2007. Safety in doses: medication safety incidents in the NHS. 2007. Available at: http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=61392. Accessed June 11, 2018.

16 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005-2010). *Br J Clin Pharmacol* 2012;74:597-604.

17 WHO. Medication Errors. Technical Series on Safer Primary Care. Available at: http://apps.who.int/iris/bitstream/handle/10665/252274/9789241511643-eng.pdf;jsessionid=2C5F14D40CBFE11B2D4CC3A0B130396C?sequence=1. Accessed June 12, 2018.

18 NCCMERP. The National Coordinating Council for Medication Error Reporting and Prevention. Medication errors – Definition. Available at: http://www.nccmerp.org/about-medication-errors. Accessed June 12, 2018.

19 Parry AM, Barriball KL, While AE. Factors contributing to Registered Nurse medication administration error: A narrative review. *Int J Nurs Stud* 2015;52(1):403-20. doi: 10.1016/j.ijnurstu.2014.07.003.

20 Meyer-Massetti C, Cheng CM, Schwappach DL, et al. Systematic review of medication safety assessment methods. *Am J Health Syst Pharm* 2011;68, 227-240.

21 Noble DJ, Pronovost PJ. Underreporting of patient safety incidents reduces health care's ability to quantify and accurately measure harm reduction. *J Patient Saf* 2010; 6:247-250.

22 Mahajan RP. Critical incident reporting and learning. *Br J Anaesth* 2010;105(1):69-75. doi: 10.1093/bja/aeq133.

23 Elliott RA, Camacho E, Campbell F, et al. Prevalence and economic burden of medication errors in the NHS in England. Rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK. Policy Research Unit in Economic Evaluation of Health & Care Interventions (EEPRU). 2018. Available at:

402 http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-
403 feb-2018.pdf. Accessed June 14, 2018.

404 24 Holmström A-R, Airaksinen M, Weiss M, et al. National and Local Medication Error
405 Reporting Systems. A Survey of Practices in 16 Countries. *J Patient Saf* 8, 165-176.

406 25 Mitchell I, Schuster A, Smith K, et al. Patient safety incident reporting: a qualitative study
407 of thoughts and perceptions of experts 15 years after 'To Err is Human'. *BMJ Qual Saf*
408 2016;25:92–99.

409 26 Stavropoulou C, Doherty C, Tosey P. How Effective Are Incident-Reporting Systems for
410 Improving Patient Safety? A Systematic Literature Review. *Milbank Q* 2015;93(4):826-66.

411 27 Hartnell N, MacKinnon N, Sketris I et al. Identifying, understanding and overcoming
412 barriers to medication error reporting in hospitals: a focus group study. *BMJ Qual Saf*
413 2012;21(5), 361-368.

414 28 Panesar SS, Noble DJ, Mirza SB, et al. Can the surgical checklist reduce the risk of wrong
415 site surgery in orthopaedics? - can the checklist help? Supporting evidence from analysis of a
416 national patient incident reporting system. *J Orthop Surg Res* 2011;6:18.

417 29 Donaldson LJ, Panesar SS, Darzi A. Patient-Safety-Related Hospital Deaths in England:
418 Thematic Analysis of Incidents Reported to a National Database, 2010–2012. *PLoS Med*
419 2014;11(6):e1001667.

420 30 Williams SD, Ashcroft DM. Medication errors: how reliable are the severity ratings reported
421 to the national reporting and learning system? *Int J Qual Health Care* 2009;21(5):316-20. doi:
422 10.1093/intqhc/mzp034.

423 31 Sevdalis N, Jacklin R, Arora S, et al. Diagnostic error in a national incident reporting system
424 in the UK. *J Eval Clin Pract* 2010;16(6):1276-81.

425 32 Renshaw M, Vaughan C, Ottewill M, et al. Clinical incident reporting: wrong time, wrong
426 place. *Int J Health Care Qual Assur* 2008;21(4):380-4.

427 33 NHS Improvement. National patient safety incident reports: September 2017. Available at:
428 https://improvement.nhs.uk/resources/national-patient-safety-incident-reports-september-
429 2017. Accessed June 12, 2018.

430 34 NRLS reporting e-form. Available at:
431 https://www.eforms.nrls.nhs.uk/staffreport/incident_report.jsp. Accessed June 12, 2018.

432 35 NRLS national patient safety incident reports: commentary March 2018. Available at:
433 https://improvement.nhs.uk/documents/2543/NAPSIR_commentary_FINAL_data_to_Dece
434 mber_2017.pdf. Accessed May 28, 2019.

435 36 NRLS 2018b. About reporting patient safety incidents. Available at:
436 http://www.nrls.nhs.uk/report-a-patient-safety-incident/about-reporting-patient-safety-
437 incidents/. Accessed June 12, 2018.

438 37 NHS Improvement. Guidance notes on National Reporting and Learning System quarterly
439 data summary publications. 22 March 2017. Available at:
440 https://improvement.nhs.uk/documents/834/QDS_GUIDE_TO_MAR17.pdf. Accessed May
441 28, 2019.

442 38 NHS England. Patient Safety Alert. Improving medication error incident reporting and
443 learning. 20 March 2014. Available at: https://www.england.nhs.uk/wp-
444 content/uploads/2014/03/psa-sup-info-med-error.pdf. Accessed June 07, 2018.

445 39 Franklin BD, Panesar SS, Vincent C, et al. Identifying systems failures in the pathway to a
446 catastrophic event: an analysis of national incident report data relating to vinca alkaloids. *BMJ*
447 *Qual Saf* 2014;23(9):765-72. doi: 10.1136/bmjqs-2013-002572.

448 40 Vincent C. Incident reporting and patient safety. *BMJ* 2007;13; 334(7584): 51.

449

Figure legends

Figure 1. Number of reported medication administration incidents per year between years 2007-2016, (n=517,384 in total)

Figure 2. Number of reported medication administration incidents / total per month between years 2007-2016, (n=517,384 in total)