

Analysis of the nature and contributory factors of medication safety incidents following hospital discharge using National Reporting and Learning System (NRLS) data from England and Wales: a multi-method study

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Abstract

Introduction: Improving medication safety during transition of care is an international healthcare priority. While existing research reveals that medication-related incidents and associated harms may be common following hospital discharge, there is limited information about their nature and contributory factors at a national level which is crucial to inform improvement strategy.

Aim: To characterise the nature and contributory factors of medication-related incidents during transition of care from secondary to primary care.

Method: A retrospective analysis of medication incidents reported to the National Reporting and Learning System (NRLS) in England and Wales between 2015 and 2019. Descriptive analysis identified the frequency and nature of incidents and content analysis of free text data, coded using the Patient Safety Research Group (PISA) classification, examined the contributory factors and outcome of incidents.

Results: A total of 1121 medication-related incident reports underwent analysis. Most incidents involved patients over 65 years old (55%, $n = 626/1121$). More than one in 10 (12.6%, $n = 142/1121$) incidents were associated with patient harm. The drug monitoring (17%) and administration stages (15%) were associated with a higher proportion of harmful incidents than any other drug use stages. Common medication classes associated with incidents were the cardiovascular ($n = 734$) and central nervous ($n = 273$) systems. Among 408 incidents reporting 467 contributory factors, the most common contributory factors were organisation factors (82%, $n = 383/467$) (mostly related to continuity of care which is the delivery of a seamless service through integration, co-ordination, and the sharing of information between different providers), followed by staff factors (16%, $n = 75/467$).

Conclusion: Medication incidents after hospital discharge are associated with patient harm. Several targets were identified for future research that could support the development of remedial interventions, including commonly observed medication classes, older adults, increase patient engagement, and improve shared care agreement for medication monitoring post hospital discharge.

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Plain language summary

Study using reports about unsafe or substandard care mainly written by healthcare professionals to better understand the type and causes of medication safety problems following hospital discharge

Why was the study done? The safe use of medicines after hospital discharge has been highlighted by the World Health Organization as an important target for improvement in patient care. Yet, the type of medication problems which occur, and their causes are poorly understood across England and Wales, which may hamper our efforts to create ways to improve care as they may not be based on what we know causes the problem in the first place.

What did the researchers do? The research team studied medication safety incident reports collected across England and Wales over a 5-year period to better understand what kind of medication safety problems occur after hospital discharge and why they happen, so we can find ways to prevent them from happening in future.

What did the researchers find? The total number of incident reports studied was 1121, and the majority ($n = 626$) involved older people. More than one in ten of these incidents caused harm to patients. The most common medications involved in the medication safety incidents were for cardiovascular diseases such as high blood pressure, conditions such as mental illness, pain and neurological conditions (e.g., epilepsy) and other illnesses such as diabetes. The most common causes of these incidents were because of the organisation rules, such as information sharing, followed by staff issues, such as not following protocols, individual mistakes and not having the right skills for the task.

What do the findings mean? This study has identified some important targets that can be a focus of future efforts to improve the safe use of medicines after hospital discharge. These include concentrating attention on medication for the cardiovascular and central nervous systems (e.g., via incorporating them in prescribing safety indicators and pharmaceutical prioritisation tools), staff skill mix (e.g., embedding clinical pharmacist roles at key parts of the care pathway where greatest risk is suspected), and implementation of electronic interventions to improve timely communication of medication and other information between healthcare providers.

Keywords: adverse drug event, continuity of patient care, hospital discharge, incident report, medication errors, medication safety

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Introduction

The transition of care from hospital to community settings has been identified as an area of high risk for medication-related safety incidents, due to change in care location and movement between services, and is currently the focus of international improvement efforts.¹ In March 2017, medication safety at the transfer of care was brought to global attention with the publication of the World Health Organization's (WHO) Global Patient Safety Challenge: Medication Without Harm, as one of three priorities for action.¹ A systematic review of 54 studies in this

field reported that one in two, and one in five (adult and elderly) patients after hospital discharge were affected by medication errors (MEs) and adverse drug events (ADEs), respectively.² This confirms the role of MEs and ADEs as a frequent and serious threat to patient safety; however, less is known about their nature and contributory factors.

Recently published studies and reviews have reported initiatives to improve medication safety and reduce ADEs during the transition of care, including pre and post discharge services, such as

medication reconciliation, the use of multidisciplinary teams, deprescribing strategies and information technology-based interventions.^{3–10} However, these studies do not report a consistent impact of these interventions in reducing medication safety challenges post hospital discharge,^{11,12} which may be attributed to a need for greater theoretical understanding of the contributory factors related to such incidents thereby limiting the design of robust interventional studies. It is therefore crucial to explore in depth the cause of MEs that occurs post hospital discharge to inform the design of robust theory-driven interventions.¹³

Previously, the nature and origins of patient safety incidents following hospital discharge have been explored at a national level using incident report reviews,¹⁴ a technique that yields sensitive data to understand causes of incidents and guide improvement.¹⁵ However, available evidence using patient safety incidents post hospital discharge was either not focused on medication safety (such as their severity and contributory factors), or was not conducted at a national level which may support greater generalisability.^{14,16–18} This study was designed to address these limitations and inform improvement strategies by aiming to present up-to-date and in-depth insights into the nature and contributory factors of medication incidents occurring following hospital discharge and reported to the National Reporting and Learning System (NRLS) across England and Wales.^{19,20}

Methods

The reporting of this study follows the criteria specified in The Reporting of Studies Conducted using Observational Routinely Collected Health Data (RECORD) Statement.²¹ The study design was a retrospective multi-methods study, where quantitative descriptive analysis of all incidents was followed by a content analysis of incident report free text narratives to identify contributory factors.

Data source

The research team obtained anonymised medication-related patient safety incident reports pertaining to the transition from secondary to primary care from NHS England/Improvement (NHS E/I). The study was exempt from formal ethical approval due to the anonymised nature of

the data. Following the exploratory stage, a five-year period between 2015 and 2019 was selected to capture sufficient data. The data analytics team at NHS E/I then performed the main extraction of data from the NRLS data set for incident category ‘medication’ and the care setting of occurrence ‘general practice’. To compile the data set, NRLS analytics completed a free text search based on the term ‘discharge’, including misspelling and variations in the free text column fields.

Eligibility criteria

The data consisted of medication-related patient safety incidents pertaining to the transition from secondary care to any settings in primary care, reported to the NRLS in England and Wales between 1 January 2015 and 31 December 2019. The incidents were reviewed to ensure they were related to medication and the post hospital discharge stage. Exclusion criteria included patients discharged from outpatient clinics, hospice care, rehabilitation settings or care/nursing homes.

Variables and definition

The term ‘patient safety incident’ was defined in this study as ‘Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare’.²² Throughout this paper, the terms ‘medication-related patient safety incident’ and ‘incident’ are used interchangeably to mean medication-related patient safety incidents that occurred after hospital discharge. For the contributory factors analysis, the term ‘contributory factor(s)’ was defined as ‘any agent thought to have played a part in the origin or development of an incident, or to increase the risk of an incident’.²³ The term ‘monitoring errors’ was defined as ‘either explicit i.e. the hospital indicated monitoring should be undertaken, or implicit i.e. monitoring would be expected in routine practice based on published guidelines’.²⁴

The NRLS data set consisted of 24 original variables, including descriptive categorical data and unstructured free text data. The variables that were provided as free text data included a description of what happened (IN07), actions preventing reoccurrence (IN10) and apparent cause(s) (IN11). Incident severity data could have been reported as either potential or actual severity by the incident reporter.

Data cleaning and data coding

Initially, incidents not meeting the eligibility criteria were separated in a list which was independently reviewed by two researchers (D.S. and R.N.K.). The research team, including members A.C.S. and R.N.K. experienced in analysing patient safety incident reports, then had frequent concordance meetings to discuss the data and agree on the final list of excluded incidents. Data coding was completed in Microsoft Excel®, 2010 (Microsoft, Redmond, WA, USA). Medication coding was based on medication classifications in the British National Formulary (BNF) chapters.²⁵

Data were further coded without modification of fields based on existing categories from the NRLS. The exception was the severity of harm, which was re-coded where there was explicit evidence to warrant the need to amend the severity using the classification of patient safety incidents in primary care.²⁶ This was undertaken to support the capture of actual (rather than potential/uncertain) healthcare-associated harm events, an approach carried out by other researchers evaluating NRLS data.²⁷ The re-coded severity of harm was used in the results section instead of the severity of harm provided by the incident reporter.

The coding of the descriptive free text data was based on the Patient Safety Research Group (PISA) coding classification.²⁸ The PISA classification has been used to characterise safety incidents from across the healthcare continuum including primary and secondary care.²⁹ It has been empirically developed by analysing national patient safety incidents from the NRLS in England and Wales.²⁸ The PISA classification is inclusive of several coding frameworks aligned to the WHO International Classification of Patient Safety (ICPS) concepts. It has been empirically developed through a constant comparative method from clinician-led analysis of more than 70,000 patient safety incident reports. Previous studies have characterised the nature of patient safety incident data from the NRLS utilising the PISA framework to code the data.^{30–33}

The descriptive free text data were screened and codes were systematically applied from coding frameworks to deconstruct incident report narratives, an approach used by others in the field.^{19,20} The first step of coding included identification of the primary incident type (PIT), followed by tracking events in the incidents chronologically;

backward to identify the contributory factor(s) and forward to identify the outcome(s). The PISA classification includes four main contributory factor codes (including patient factors, staff factors, equipment and organisation factors) and 178 subcodes for the contributory factors, along with five main outcome codes with 153 subcodes. The free text narrative was coded using a two-step process, using main theme codes and sub-theme codes, which served as a quality check of the free text data. The coding was explicitly based on the data in the incident narrative, where no assumption was made regarding the incident's context or patient clinical condition.

Data validation

Twenty per cent of the data ($n = 237/1121$ incidents) was independently coded by two researchers (R.N.K. and D.S.) to confirm the accuracy of coding and validate the coding framework. This coding included the contributory factors and outcome using the PISA classification, and the severity of harm. The team had frequent concordance meetings with A.C.S. to discuss the results of the independent coding validation process and to agree on the strategy for identification of the primary incident type (PIT), and final coding approach.

Data analysis

Data analysis was completed in Stata® version 14.0 software (StataCorp, College Station, TX, USA). Once coded, quantitative data analysis involved exploratory analysis of all medication-related incidents to find emerging patterns and trends. Descriptive analyses of all reported incidents was applied to describe the nature (and patterns over time) of medication safety incidents. Cross tabulation was completed to compare variables to determine any patterns. If more than one medication was associated with an incident, then each medication was counted in the analysis. Thus, the total number of medications involved was more than the number of incidents.

Analysis of free text incident descriptions was performed to examine the contributory factors for incidents. This free text analysis involved content analysis, where free text was screened to identify data that aligned to PISA coding categories as described earlier. These data were grouped into emerging categories, an approach used by others in the field.^{19,20}

Table 1. Summary statistics of categorical variables from $N = 1121$ incident reports.

Patient age range	<i>n</i> (%)	Error category	<i>n</i> (%)
<18 years	44 (4%)	Wrong/unclear dose or strength	212 (19%)
18–65 years	218 (19%)	Omitted medicine/ingredient	148 (13%)
>65 years	626 (56%)	Wrong drug/medicine	118 (10%)
Missing data	233 (21%)	Wrong quantity	68 (6%)
Level of harm*	<i>n</i> (%)	Wrong frequency	60 (5%)
No harm	108 (9.6%)	Contra-indication to the use of the medicine in relation to drugs or conditions	58 (5%)
Low harm	58 (5.1%)	Mismatching between patient and medicine	45 (4%)
Moderate harm	69 (6.1%)	Wrong formulation	21 (1.8%)
Severe harm	8 (0.7%)	Wrong/omitted verbal patient directions	18 (1.6%)
Death	7 (0.6%)	Wrong method of preparation/supply	16 (1.4%)
Unclear	871 (77.6%)	Adverse drug reaction (when used as intended)	10 (0.9%)
Medication process	<i>n</i> (%)	Wrong/omitted/passed expiry date	8 (0.7%)
Prescribing	479 (42%)	Patient allergic to treatment	6 (0.5%)
Administration/supply of a medicine from a clinical area	253 (22.5%)	Wrong/transposed/omitted medicine label	5 (0.4%)
Monitoring/follow-up of medicine use	140 (12.5%)	Wrong storage	2 (0.1%)
Preparation of medicines in all locations/dispensing in a pharmacy	64 (5.7%)	Wrong route	2 (0.1%)
Advice	42 (3.7%)	Wrong/omitted patient information leaflet	1 (0.1%)
Supply or use of over-the-counter (OTC)	3 (0.2%)	Other	303 (27%)
Other	140 (12.5%)	Unknown	20 (1.8%)

*Re-coded severity of harm.

Results

Overview of data set

Of 1324 medication-related incident reports, 203 were subsequently excluded. Reasons for exclusion were incident not hospital discharge-related ($n = 131$), discharge from clinic ($n = 33$), repeated incidents ($n = 28$), discharge from rehabilitation settings ($n = 4$), discharge from prison ($n = 3$), discharge from hospice care ($n = 3$) and discharge from a care/nursing home ($n = 1$). The final data set included 1121 medication-related incidents. Patient age was inconsistently provided and present in 79% ($n = 888/1121$) of reports.

Descriptive data

Summary statistics. The majority of reported incidents which included patient age involved patients aged above 65 years (70.4%, $n = 626/888$). A total of 77.6% of the incidents did not contain sufficient information to code a harm outcome. Following recoding, it was found that almost one-eighth (12.6%, $n = 142/1121$) of incidents with a reported harm outcome were associated with actual patient harm [low harm (5.1%, $n = 58/1121$), moderate harm (6.1%, $n = 69/1121$), severe harm (0.7%, $n = 8/1121$) and death (0.6%, $n = 7/1121$)]. Table 1 presents summary statistics for the categorical variables.

Medication incidents occurred most frequently in the prescribing (42%, $n = 479/1121$) followed by the administration stage (22.5%, $n = 253/1121$) and then the monitoring stage (12%, $n = 140/n = 1121$). The most reported MEs categories were wrong or unclear dose or strength (19%, $n = 212/1121$), followed by omitted medicine (13%, $n = 148/1121$) and then wrong drug/medicine (10%, $n = 118/1121$). Incidents involving patients aged less than 18 years were associated with the highest proportion of incidents occurring at the administration stage compared with other age groups (34%, $n = 15/44$), whereas incidents involving patients aged between 18 and 65 were associated with the highest proportion occurring at the prescribing stage (49%, $n = 107/218$). Incidents involving patients aged more than 65 years were associated with the highest proportion of incidents occurring at the monitoring stage (14%, $n = 89/626$). Incidents affecting patients aged more than 65 years had the highest proportion of incidents occurring due medication omission (15%, $n = 93/626$).

Medication. The total number of medications involved in the incidents was 1504, with some incidents involving more than one medication. In addition, 53 incident reports had no information about the name of medication(s) involved. Table 2 reports the three most common medication classes associated with medication incidents which were the cardiovascular system (48.8%, $n = 734/1504$), central nervous system (18%, $n = 273/1504$) and endocrine system (12%, $n = 183/1504$). Table 2 also provides the most common specific medications within these common medication classes associated with incidents – antiplatelets ($n = 126$) followed by factor Xa inhibitors ($n = 124$), opioids ($n = 79$), insulin ($n = 76$), beta-adrenoceptor blockers ($n = 76$), heparins ($n = 71$), vitamin K antagonists ($n = 67$) and diuretics ($n = 66$). The most common medication classes associated with incidents in the monitoring stages were antithrombotic medications namely warfarin ($n = 34$), antiplatelets ($n = 21$) and factor Xa inhibitors ($n = 19$). Incidents involving heparin (46% $n = 32/70$) followed by insulin (33%, $n = 25/76$) were associated with a higher proportion related to the administration stage than other stages (see Table 1 in Supplementary File). The most frequently observed medication classes associated with incidents in patients aged less than 18 years were

anti-infective medications (36%, $n = 17/47$), for patients aged 18–65 years these were cardiovascular medications (40.2%, $n = 126/313$) and for patients aged more than 65 years, were also cardiovascular medications (53.9%, $n = 458/849$), respectively.

Outcome data 'harm severity'. Table 2 in Supplementary File represents the observed differences between the harm severity originally provided in the incident report data and the severity of 'actual' harm following recoding. To assess the effect of different variables on harm severity, contingency tables were used. Table 3 in Supplementary File compares the re-coded harm severity stratified by patient age and origin of incidents. In addition, a higher proportion of 'any harm' incidents involved patients older than 65 years compared with other age groups.

Table 4 in Supplementary File shows the distribution of re-coded actual harm incident severity according to medication use process stage, and ME categories. The table shows the monitoring (17%) and administration (15%) stages were associated with a higher proportion of harmful incidents compared with the prescribing stage (12%). The table also highlights that for ME types reported at least 60 times, medication omission was associated the greatest proportion of 'harmful' incidents (19%, $n = 28/148$) followed by 'wrong drug/medicine' (16%, $n = 19/118$).

The most common medication group associated with a higher proportion of 'any harm' incidents among the top three most-frequent implicated medication classes were medications for the central nervous system (15.3%, $n = 42/273$), compared with medication for the cardiovascular (13.2%, $n = 97/734$), and endocrine system (12%, $n = 22/183$). The medication classes that were associated with patient death were cardiovascular medication ($n = 5$), nervous system medication ($n = 1$) and medication for the endocrine system ($n = 1$).

Incident outcomes. The reported outcome of all included medication safety incidents is presented in Table 3. This includes a total of 1660 with some incidents containing several reported outcomes. From the cohort of identified and reported outcomes, 34% ($n = 564/1660$) were organisation inconvenience, 27% ($n = 455/1660$) were an

Table 2. Medication associated with medication incidents based on BNF chapter.

BNF chapter	Frequency (%)	Frequency (%)
Cardiovascular system	734 (48.8%)	
Nervous system	273 (18.15%)	
Endocrine system	183 (12.16%)	
Gastro-intestinal system	81 (5.38%)	
Anti-infective	61 (4.05%)	
Respiratory system	51 (3.39%)	
Nutrition and metabolic disorders	45 (2.99%)	
Blood and blood-forming organs	19 (1.26%)	
Genito-urinary system	15 (0.99%)	
Malignant disease	15 (0.99%)	
Eye	9 (0.59%)	
Musculoskeletal system	7 (0.46%)	
Immune system	3 (0.19%)	
Skin	3 (0.19%)	
Poisoning	2 (0.13%)	
Medical emergencies	1 (0.06%)	
Nose	1 (0.06%)	
Vaccines	1 (0.06%)	
Total	1504 (100%)	
Missing data field or unknown	53	
Most frequently observed medications from the three most common chapters		
Endocrine (<i>n</i> = 183)	Insulin	76
	Blood glucose lowering drugs	40
	Corticosteroids	23
	Thyroid disorders	19
	Bisphosphonates	14
	Female sex hormone responsive conditions	7
Central nervous system (<i>n</i> = 273)	Analgesics, opioids	79
	Antiepileptics	54
	Antipsychotics	40
	Antidepressants	35
	Hypnotics, sedatives and anxiolytics	21
	Parkinson's disease, dopaminergic drugs	14
Cardiovascular (<i>n</i> = 734)	Antithrombotic drugs, antiplatelet drugs	126
	Antithrombotic drugs, factor Xa inhibitors	124
	Beta-adrenoceptor blockers	76
	Antithrombotic drugs, heparins	71
	Antithrombotic drugs, vitamin K antagonists	67
	Diuretics	66

BNF, British National Formulary.

Table 3. Frequency of most common medication-related incident outcomes.

Outcome	Outcome subcategory	Total	Total
Organisational inconvenience	Phone calls/follow-up	412	564 (33.9%)
	Treating patient without sufficient information	110	
	Destruction of medication	19	
	Increased documentation	10	
	Other	13	
Inconvenience to patient (nonclinical)	Missed dose(s) of medication*	107	455 (27.4%)
	Unnecessary treatment**	90	
	Repeated visits to/from healthcare providers	76	
	Hospital admission	55	
	Other	127	
Patient clinical harm (pathophysiological/ disease-related pain)	Changes in physiological parameters	41	216 (13%)
	Discomfort/pain	22	
	Missed dose***	22	
	General deterioration/progression of condition	21	
	Other	110	
Staff outcomes	Psychological harm	1	1 (0.06%)
No outcome (or error identified, and harm prevented)	No outcome described	247	424 (25.5%)
	Unclear outcome/insufficient information to ascertain outcome	105	
	Patient identified error and harm prevented	27	
	Relatives identified error and harm prevented	29	
	Carer (not a healthcare worker) identified error and harm prevented	9	
	Patient identified error and further harm prevented	1	
	Relatives identified error and further harm prevented	6	
Total		1660	1660 (100%)

*The first missed dose outcome refers to when the outcome caused inconvenience to the patient without reported patient harm.

**If the patient had a medication with a wrong frequency (more than what is intended), or in the patient had been given a medication that was used before but is no longer needed.

***The second missed dose outcome refers to when the patient had a clinical harm as a result.

inconvenience to the patient, and 13% inconvenience were phone calls/follow-up (73%,
($n = 216/1660$) were patient clinical harm. The ($n = 412/564$), and the most common outcome
most common outcomes related to organisation related to patient inconvenience was missed

Table 4. Frequency of incidents' contributory factors.

Contributory factors category	Contributory factors (subcategories)	Total	Total	
Organisation	<i>Continuity of care – the delivery of a seamless service through integration, co-ordination and the sharing of information between different providers</i> Between Secondary and Primary Care	308	383	
	Between healthcare and pharmacy	35		
	Unknown to staff have not been made aware of a patient by colleagues	13		
	Within Primary Care, for example, when a patient is seen by multiple GPs within the same practice and there is therefore a resulting failure to a pattern or increasing severity of patient symptoms	13		
	Out-of-hours service	1		
	Registering with a GP	2		
	Locum/agency staff	5		
	<i>Working conditions</i> Staff behaviour	2		
	Busy/overloaded by work	3		
	<i>Protocols/Policies/Standards/Guidelines inadequate, inefficient absent or not available</i> Poor design of prescription	1		
	Staff	<i>Cognitive: includes abilities such as perception, learning, memory, language, concept formation, problem-solving and thinking.</i> Mistake	7	75
		Misread/Did not read	9	
		Distraction/Inattention/Oversight/Forgot	6	
		Similar patient names	4	
	Similar medication names/appearances confused	2		
	Haste/Poor time management	1		
	Hand writing	5		
	Did not consider all clinical possibilities	1		
	<i>Task-a piece of work to be done or undertaken.</i> Failure to follow protocol – failure to adhere to procedures or regulation.	14		
	New protocol	3		
	Inadequate skill set/knowledge	2		
	Wrong professional carries out task. For example, admin clerk filling out prescriptions	14		
	<i>Junior staff</i>	3		
	<i>Verbal reporting used</i>	3		
	<i>Physical and mental well-being</i> Fatigue – extreme tiredness resulting from mental or physical exertion or illness	1		

(Continued)

Table 4. (Continued)

Contributory factors category	Contributory factors (subcategories)	Total	Total
Patient	<i>Behaviour: the way in which patients/family act or conduct themselves</i> Noncompliance: patient does not follow advice or instructions	2	5
	Fraudulent behaviour	1	
	<i>Knowledge: patient or parent of child has poor understanding</i>	1	
	<i>Language: patient unable to communicate in English</i>	1	
Equipment	<i>Use of fax machine</i>	3	4
	<i>Poor equipment designs: the design of equipment is impractical, faulty or in some way inadequate</i>	1	
Total			467

GP, General Practitioner.

dose(s) of medication (23%, $n = 107/455$). Table 3 presents the breakdown of the top four most-common outcomes in each main category (see Table 5 in Supplementary File for full list).

Inconvenience to patients due to unnecessary treatment was highlighted. These included short medication regimens that were continued for the long term ($n = 12$), with the most common medications involved being antiplatelets ($n = 8$), and anticoagulants ($n = 3$). One incident stated ‘Patient attended for medication review May 2016 – noted been on clopidogrel since ACS in December 2010. Discharge letter recorded to continue clopidogrel for 9 months only. Discussed with patient and medication stopped following review medical records’. Another inconvenience to patients was repeated visits to/from healthcare providers, which was observed in three incidents in which the quantity of liquid antibiotic medication dispensed for the paediatric patients was insufficient at discharge prompting further supplies. One incident stated, ‘This child was discharged from hospital; according to discharge he should be on antibiotics for 2 weeks but was given only one bottle and was advised to ask GP for another’.

Contributory factors. A total of 36% ($n = 408/1121$) of the reported incidents contained at least one contributory factor explicitly mentioned in the incident free text narrative. Among the incidents with known contributory factors ($n = 408$)

the majority (87%, $n = 357/408$) had one contributory factor, 10.7% ($n = 44$) of the incidents reported two factors, 1.4% ($n = 6$) of incidents contained three factors, and 0.2% ($n = 1$) incidents had four reported contributory factors. The total number of identified contributory factors were therefore 467 from 408 incidents. The most common types of factors involved in the 51 incidents with multiple contributory factors were organisation factors (65%, $n = 72/110$), followed by staff factors (30%, $n = 33/110$). The most common combination of factors in incidents with multiple contributory factors was continuity of care issues between secondary and primary care, and between healthcare and pharmacy (20%, $n = 10/51$).

Table 4 presents summary statistics for the contributory factors identified from the free text descriptions across all incidents. The most common contributory factors reported were organisation factors (82%, $n = 383/467$) followed by staff factors (16%, $n = 75/467$). Almost all organisation factors (98%, $n = 377/383$) were related to continuity of care (the delivery of a seamless service through integration, co-ordination and the sharing of information between different providers), followed by working conditions (1%, $n = 5/383$), and protocols/policies/standards/guidelines inadequate, inefficient absent or not available ($n = 1/383$). The most common continuity of care-related organisation factor was ‘continuity of care between secondary and primary

care' ($n = 308$) and included issues in the discharge letters such as hard to read discharge letters, contradicting information in discharge letters, delay in sending discharge letters and no discharge letter communication being sent. This was followed by 'continuity of care issues between wider healthcare and pharmacy services' ($n = 35$). A total of 47% ($n = 35/75$) of staff-related contributory factors were cognitive issues, such as mistakes, followed by task-related issues (44%, $n = 33/75$). Other staff-related factors included 'failure to follow protocol' ($n = 14$) and 'wrong professional carrying out the task' ($n = 14$). Table 5 provides examples of incident report extracts describing these factors. A total of 13.5% ($n = 52/383$) incidents involving organisation factors and 16% ($n = 12/75$) involving staff factors resulted in 'any harm' to patients.

Organisation factors were the major factor affecting the monitoring stage (36%, $n = 56/153$) (e.g. referrals to the anticoagulation clinic), administration stage (32.8%, $n = 87/265$) (e.g. medication administration by district nurse), and prescribing stage incidents (28%, $n = 142/505$) [e.g. prescribing of medication in Monitored Dosage Systems (MDS); blister packs] (see Table 6 in Supplementary File). Examples of 'continuity of care between secondary and primary care' incidents includes issues with referrals to anticoagulation clinic after hospital discharge ($n = 12$). Incident narratives mentioned that local anticoagulation services were not being made aware of patient's warfarin status (whether to start/stop warfarin) post discharge; other incidents stated there was an absence of arrangement for INR testing and follow-up with the anticoagulation clinic. One incident stated, 'Patient discharged after DVT on warfarin but no referral to anticoagulation clinic done, only given 3 days warfarin and clexane and told to go to GP for INR testing and onward management'. Other incidents in this category involving community ($n = 9$) or district nurses ($n = 27$). Incident narratives reported that nurses were not being made aware that the patient was discharged, and no administration sheet/prescription was sent to the nurse. Insulin administration was the most common medication implicated with these incidents, with one incident stating 'District nurses stated that they were not aware of the discharge and that they should give the patient this daily injection'. Organisational factors including those relating to both 'continuity of care between secondary and primary care'

($n = 24$) and 'between healthcare and pharmacy' ($n = 19$) were seen to be associated with patients using MDS (otherwise known as compliance aids). Incidents stated that MDS was involved in incidents in a variety of ways, including confusion and errors due to sending a faxed discharge letters to the community pharmacy but not to the general practitioner, and the community pharmacy supplying the patient with 'old' medication in an MDS before receiving the updated medication list in a discharge letter, which then resulted in medication getting mixed up as the new medication was dispensed.

Incidents involving central nervous system medication were associated with the highest proportion of those occurring due to staff contributory factors (25%, $n = 29/117$). These included examples of opioid prescribing based on clinical notes being inappropriately handled by administrative staff, failure to follow relevant safety alert when prescribing metoclopramide and issues with prescriptions related to mental healthcare. Incidents involving cardiovascular and endocrine systems were associated with higher proportion of those occurring due to organisation contributory factors [86% ($n = 274/318$) and 84% ($n = 69/82$), respectively].

Discussion

Key results

The results of this study highlight that the time-period following hospital discharge is a high-risk phase of care associated with ME, associated harm and inconvenience to patients and health providers, and reflects the problems catalysing the need for current international and national safety improvement priorities. The findings help characterise the breadth of problems the WHO and NHS safety agendas seek to address by elucidating important contributory factors to these incidents relating mainly to organisational and patient issues, and in doing so identify emerging targets to support the development of remedial interventions. These targets include the older adult population, medication monitoring stage, specific medication classes and the importance of cross-interface working.^{1,34}

We have observed that medications commonly implicated in reported incidents were cardiovascular, endocrine and central nervous systems,

Table 5. Incident extracts of the most common contributory factors in each category.

Contributory factors (subcategories)
<p><i>Organisation</i> Continuity of care—the delivery of a seamless service through integration, co-ordination and the sharing of information between secondary and primary care [n = 308]</p> <p>Patient discharged on 24/X from XX with no discharge information to GP or sent with patient and only enough medication to cover until 26/XX. I was asked to take an urgent phone call from the patient's partner on 25/XX at 6 pm asking me to prescribe further medication. I subsequently phone XX at 6.15 pm but my phone call was not answered.</p>
<p><i>Organisation</i> Continuity of care—the delivery of a seamless service through integration, co-ordination and the sharing of information between healthcare and pharmacy [n = 35]</p> <p>Discharge summary went into F2 inbox. Medicine reconciliation performed but doctor failed to check it went to pharmacy. Patient had memory issues and lived alone. Mr XX emailed me on a bank holiday Monday; concerned that the medicines on discharge had not been supplied to his father. He had taken the 7 days given by the hospital but had no new supplies. The patient's heart failure had worsened as a result which constitutes a major alert. We have added a new stage to the reconciliation process to include pharmacist alerted in a new template.</p>
<p><i>Staff factor</i> Failure to follow protocol—failure to adhere to procedures or regulation [n = 14]</p> <p>An FP10 was issues by a psychiatrist on discharge with 9 items on. The chemist refused to issue as did not comply to national guidance of a max of 4 items per scrips.</p>
<p><i>Staff factor</i> Wrong professional carries out task. For example, admin clerk filling out prescriptions [n = 14]</p> <p>Member of reception staff added incorrect discharge letter to patients notes. Doctor prescribed medication mentioned on letter to incorrect patient. Incorrect patient noticed new medication on repeat slip and contacted the surgery to bring to our attention.</p>
<p><i>Patient factor</i> Behaviour: Noncompliance: patient does not follow advice or instructions [n = 2]</p> <p>Patient admitted on 24/XX with confusion, general malaise, during medicines reconciliation noted patient discharged 19/XX with dosette box containing paracetamol and meptazinol. Discharge letter received by GP on System One. On 23/XX patient requested co-codamol from GP for knee pain, GP prescribed co-codamol 30/500. On 24/XX, home visit doctor noted patient drowsy, stopped co-codamol and supplied codeine 15mg tds prn and paracetamol. Noted: patient has poor compliance with medicines. Codeine and meptazinol stopped on admission due to confusion.</p>
<p><i>Equipment</i> Use of fax machine [n = 3]</p> <p>Patient discharged from 6/XX following episode of meds related orthostatic hypotension. Meds changed significantly on discharge. Went through eDNF and GP records pre (failed) visit today. Some changes had been made but was still on previous dose bumetende and ISMO and prescription had been done on 7/XX for regime that was inconsistent with Ednf. Hospital pharmacy had annotated ednf as faxed to community pharmacy but appeared not to be received by pharmacy. Hospital pharmacy have reviewed process and communicated to team ie to annotate discharge once faxed.</p>
<p>GP, General Practitioner; FP10, prescription paper form.</p>

with the most common specific medications being antithrombotic medications, insulin, beta-blockers, diuretics and opioids. These results further

support the observation raised by others previously that these medication groups are implicated in MEs and related patient harm across multiple

stages of the patient healthcare journey.^{35–41} The medication groups identified from this study may therefore become a focus of attention by researchers and healthcare staff for remedial action.⁴² For example, a system to identify medications/patients at high risk of medication safety incidents for review in primary care may be helpful. Prescribing safety indicators could be used following hospital discharge in a more targeted way to help identify patients at risk, including elderly patients prescribed such medication classes without planned monitoring post hospital discharge. These could be incorporated into prescribing indicator tools/interventions.^{42–45} These indicators/high risk medication data might also be incorporated into pharmaceutical prioritisation tools,⁴⁶ which may be used to target post hospital discharge reviews in general practices. Such tools are already used in acute hospital care to identify high risk medications and patient characteristics (e.g. older age) for intervention and prioritisation of pharmacy service provision.⁴⁷

This study adds important understanding regarding the underlying origins of MEs and related harm incidents arising post hospital discharge. Organisational issues were the most commonly reported contributory factors and frequently involved lack of co-ordination of care between secondary and primary care, and between healthcare and pharmacy services. This involved poor co-ordination in sending discharge-related documentation with general practices and community pharmacies. It has been observed that community pharmacies may be left out of the loop at care transition⁴⁸ despite the valuable role community pharmacies could play in hospital discharge care transitions.^{49,50} These findings support the recent implementation of electronic interventions to improve timely communication of medication and other information between healthcare providers,⁵¹ such as the NHS Discharge Medicine Service (DMS) which involves sending electronic discharge letters to a named community pharmacy in a timely manner.⁵¹ Implementation science approaches may be a useful lens by which to study the introduction of such organisational interventions,^{52,53} as more research is needed to understand the contextual impact of organisational interventions focusing on MEs post hospital discharge. A previous systematic review of evidence of interventions in primary care to reduce MEs concluded that organisational and

professional interventions had little or no impact on reducing preventable MEs that led to hospital admission, emergency department visits or mortality.⁵⁴

The next most commonly identified contributory factor was staff factors ($n = 75$), with cognitive issues (including mistakes and misinterpreting handwriting) being the most common specific factors under this category. Previous studies have demonstrated the importance of adequate space, time and concentration to complete tasks⁵⁵ with our findings highlighting similar issues. While not one of the more commonly reported contributory factors in our study, administrative procedures [such as wrong professional carries out task (e.g. admin staff filling out prescriptions)] have been cited elsewhere as a leading cause of healthcare-associated adverse events in primary care settings.^{56,57} These and wider findings support focusing on skill mix as an improvement target, with one example of integrating clinical pharmacists in general practices to triage discharge letters and complete medication reconciliations.⁵⁸ Yet, the results presented in this study highlighted that in a number of incidents the origins were multifactorial, which highlights the potential need for one or more interventions to address multiple contributory factors.

This study observed wrong/unclear dose or strength and medication omission as the most commonly reported error categories ($n = 212/1121$), with medication omission also associated with a high proportion of incidents causing actual harm (19%, $n = 28/148$). The results presented in this study reflect those of Riordan *et al.*⁵⁹ and Ashcroft *et al.*,⁶⁰ who also found that medication omission was the most common prescribing error at or post hospital discharge. This study also found that medication incidents were reported most commonly in the prescribing stage (42%, $n = 479/1121$) followed by the administration stage (22.5%, $n = 253/1121$). Medication processes implicated with a high proportion of patient harm were the drug monitoring (17%, $n = 24/140$) and administration stages (15%, $n = 39/253$). This might be due to the context surrounding this stage of the care journey, where an error in conducting medication monitoring might be unnoticed without adequate follow-up and result in patient harm. The latter suggests that real-time surveillance of risk may help and could be a target for additional safeguarding *via*

prescribing safety indicators for medication monitoring.

Additional novel insights to emerge from this analysis is the wider consequences of medication incidents post-discharge beyond patient harm outcomes, including organisational and patient inconvenience. Our analysis revealed that providers and patients often needed to work across care boundaries to resolve medication issues, taking time and resources away from self-care and other interventions. MEs have already shown to have a significant economic burden attached to them,⁶¹ and this study adds to this narrative. For example, this study found that monitoring errors commonly led to extended courses of medication, sometimes lasting years, when they were intended for a specific short course. However, the financial implication of these incidents was not factored in this analysis, and few previous studies have investigated this cost.⁶² In addition, in this study 72 incidents were reported where the patient or relative/carer identified the error, and harm was prevented or mitigated. Comparison of this finding with those of other recent studies confirms that the active involvement of patients and carers can have a positive impact on patient safety.^{18,63–70} These results further support the incorporation of patient and family engagement in patient safety strategies.^{34,71}

The involvement of MDS prescribing and supply errors in medication safety incidents emerged from the incident reports we analysed. These results align with those observed in a recent report of patient harm due to MDS through analysing incident reports submitted to the NRLS in 2018, which found that prescribing errors were the most common error associated with MDS.⁷² These findings suggest that future research is needed to improve medication safety for patients supplied and using MDS post hospital discharge. These findings, while preliminary, suggest that MDS use and the patients whom they are supplied to post discharge might be associated with MEs. Despite their widespread use, there remains a paucity of evidence on the impact of MDS on patient adherence.^{73,74}

Despite the useful data identified from this study, the NRLS data are still under-utilised by health service researchers.²⁷ There may be scope to further enhance use of incident report data in research with the new system [Learn From

Patient Safety Events (LFPSE)], formally launched nationally in August 2022. The LFPSE is expected to be easier to access and report, and collect different types of data than the existing NRLS system.^{75,76}

Strengths and limitations

Key strengths of this study include a systematic approach to coding of the incident reports using a validated framework (PISA classification) that has been used previously by several incident report analysis papers, alongside the use of independent validation of incidents with consensus meetings within the research team. The study also examined incidents over a 5-year period to capture medication-related patient safety incidents after hospital discharge and based our approach on the findings of a preliminary data analysis phase involving 500 incidents to support refinement of our data extraction strategy. However, this study has several limitations. The data lacked complete information on patient age. Inherent limitations associated with incident report research also include a lack of further patient demographic information such as gender and co-morbidities which may enhance the understanding of incident context through other fields such as incident type and incident location were completed in all reports.^{77,78} A limitation of the data may also relate to the quality of the free text information that is being written to describe the incidents as described above, as we identified only 36% ($n = 408/1121$) incidents with sufficient free text data to analyse contributory factors. This is in common with earlier research,^{19,20} and when considered alongside the known under-reporting of incidents might limit learning from their occurrence. Furthermore, there is a risk with studies of this nature that misclassification is possible given the interpretation required to code free text data using coding frameworks.

Conclusion

This is the first study to perform an in-depth analysis of the nature and contributory factors underpinning medication-related incidents occurring after hospital discharge in the United Kingdom. The study found that almost one-eighth of included incidents were associated with patient harm and that incident origins were often multi-factorial and emerging at organisational and staff levels. The study highlights the importance of

adequate skill mix, cross-interface working and accurate and prompt communication of discharge letters post hospital discharge, which highlights and informs the role of interventions in improving communication post hospital discharge, and their impact on medication safety.

Declarations

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Author contributions

Fatema A. Alqenae: Conceptualisation; Data curation; Formal analysis; Methodology; Project administration; Visualisation; Writing – original draft; Writing – review & editing.

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Andrew Carson-Stevens: Conceptualisation; Methodology; Supervision; Validation; Writing – review & editing.

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Competing interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Fatema Alqenae, Dr Douglas Steinke, Professor Andrew Carson-Stevens and Dr Richard Keers have no conflicts of interest to declare. NHS Improvement approved the current version of this manuscript as part of a data sharing agreement.

Availability of data and materials

The data sets generated during and/or analysed during the current study are not publicly available due to the nature of the data, and data sharing agreement with NHS England/ Improvement.

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Supplemental material

Supplemental material for this article is available online.

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