Title: Medication safety in mental health hospitals: A mixed-methods analysis of incidents reported to the National Reporting and Learning System

Short title: Medication safety in mental health hospitals

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Abstract

Background

Medication safety incidents commonly occur in mental health hospitals. There is a need to improve understanding of the circumstances which are thought to have played a part in the origin of these incidents to design safer systems to improve patient safety.

Aim

To undertake a mixed-methods analysis of medication safety incidents reported to the National Reporting and Learning System (NRLS) in England and Wales during 2010-2017.

Method

Quantitative analyses were undertaken of anonymised medication safety incidents occurring in mental health hospitals that were reported to the NRLS over an eight-year period to characterise their type, severity, and the medication(s) involved. Secondly, a content analysis of the free-text reports associated with all incidents of at least moderate harm severity was undertaken to identify the underlying contributory factors.

Results

Overall, 94,134 medication incident reports were examined, of which 10.4% (n=9,811) were reported to have resulted in harm. The three most frequent types of reported medication incidents involved omission of medication (17,302; 18.3%), wrong frequency (11,882; 12.6%) and wrong/unclear dose of medication (10,272; 10.9%). Medicines from the central nervous system (42,609; 71.0%), cardiovascular (4,537; 7.6%) and endocrine (3,669; 6.1%) medication classes were the most frequently involved with incidents. Failure to follow protocols (n=93), lack of continuity of care (n=92), patient behaviours (n=62) and lack of stock (n=51) were frequently reported as contributory factors.

Conclusion

Medication incidents pose an enduring threat to patient safety in mental health hospitals. This study has identified important targets that can guide the tailored development of remedial interventions.

Background

Mental health illness is one of the most important contributors to overall disease burden worldwide.[1] During 2018-2019 in England alone, more than two million people were in contact with secondary mental health services, 4.1% of whom were hospitalised.[2] Patients with mental health illnesses are recognised as a vulnerable population within health care systems worldwide due to their unique safety issues that are distinct from patients in other health care settings.[3,4] These issues may be related to the nature of their illnesses which can be manifested in aggression, suicide [5] and a lack of treatment adherence due to poor insight.[6] Other risks may be associated with their medical treatment such as adverse drug events and medication errors attributed to psychotropic medications,[7-9] problems associated with antipsychotic high-dose prescribing,[10] antipsychotic polypharmacy,[11] and the use of high-risk medications with a narrow therapeutic index such as clozapine and lithium.[12] Other unique risks are related to the legal frameworks that inform the management of mental illness along with the settings and context within which treatment takes place.[13] For example, mental health care in the UK has experienced a shortage of inpatient beds[14] and qualified staff, and has faced financial pressures for a long period of time.[15]

In mental health hospitals, medication errors are common,[7] and the frequency of their occurrence was reported to range from 5.7 to 88.8 per 100 admissions.[16-19] Whilst we now have greater awareness of the frequency of medication errors in mental health settings, a more in-depth understanding of their underlying contributory factors is yet to be adequately addressed. Patient safety incident reporting systems such as the National Reporting and Learning System (NRLS) in England and Wales constitute an important source of information on medication safety incidents by providing details of what happened along with the perceived contributory factors which make up an essential prerequisite for designing remedial interventions to mitigate future incidents.[20]

The NRLS is one of the largest safety incident reporting systems in the world. It is managed by the National Patient Safety Team (previously called the National Patient Safety Agency) which is a part of the Medical Directorate of National Health Service (NHS) England and NHS Improvement organisation.[21] The NRLS receives over two million patient safety incident reports per year from NHS healthcare organisations in England and Wales.[22] National Patient Safety Team uses these incident reports to monitor trends and develop patient safety learning outputs including patient safety alerts,[23] NRLS Official Statistics [24]

and review and response alerts.[25] For example, patient safety alerts are designed to warn health care providers about any new or under-recognised patient safety incidents that have the potential to cause harmful consequences.[23] In the mental health context, two patient safety alerts have been published to target incidents related to lithium prescribing and monitoring [26] as well as incidents that occur at hospital discharge.[27]

In 2006, the first analysis of medication safety incidents reported within mental health settings was extracted and presented from the NRLS between November 2004 and August 2005.[28] Whilst this report provided an early snapshot for understanding the burden of medication incidents in this health context, it included a limited time window and does not provide any up-to-date insights following more recent changes to patient safety reporting in the NHS, including mandatory reporting of all incidents resulting in death since 2010.[23] Crucially, it also did not provide data regarding the contributory factors that lead to medication incidents in order to direct improvement efforts. Earlier evidence concerning medication incidents' causation in mental health settings were used either in a purely quantitative [29-31] or qualitative analysis of the data,[32,33] whereas other studies that used a mixed-method approach to analyse medication incidents from individual mental health organisations may not reflect the patterns of events in more generalisable samples at a national scale.[34,35] The aim of this study, therefore, is to use a large national database to characterise medication safety incidents reported to the NRLS in England and Wales from mental health hospitals and to examine their reported contributory factors in order to highlight potential targets for improvement.

Method

Study design

We undertook a mixed-method exploratory analysis of medication safety incidents reported to the NRLS from inpatient mental health settings across England and Wales between January 1, 2010 and December 31, 2017. This study comprised two distinctive phases:

- Phase 1 aimed to characterise the frequency, type and severity of medication incidents reported over an eight-year period (quantitative analysis),

- Phase 2 sought to identify the underlying contributory factors for medication safety incidents reported to be of at least moderate harm severity using content analysis approach (qualitative analysis).

Data source

The data were extracted from the NRLS database in which the original classification of incidents was used. Patient safety incidents are defined as "any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS-funded healthcare".[23] The NRLS receives data mainly from 'local risk management systems' that are used to record patient safety incidents in NHS organisations where reporters are expected to describe what happened, the reason(s) behind it and how incidents could have been prevented using free text responses. In addition, there are also structured categorical information fields such as the date of the incident, incident specialty and outcome severity. The reports are submitted electronically to the National Patient Safety Team where the reports pass through electronic data cleansing software for data anonymisation before being integrated into the NRLS database.[24]

Sample selection and data cleaning

A complete dataset of 94,571 anonymised medication safety incidents reported between 1 January 2010 and 31 December 2017 within inpatient mental health settings in England and Wales were obtained. Reported incidents related to adverse drug reactions (ADRs), when the medication was used as intended, were excluded as these reports are routinely collected by the Medicines and Healthcare products Regulatory Agency (MHRA) through the 'Yellow Card Scheme'.[36] This dataset was then used for phase 1 of the analysis and included the following information: date of the incident, medication incident category, stage at which the medication safety incident was reported to have occurred (i.e. prescribing, dispensing, administration, or monitoring), specialty of the incident (e.g. acute adult ward, later life ward), class of medication involved in the incident and reported severity of the medication safety incident (which might have been potential or actual harm); the NRLS definition of harm [23] is provided in Box 1. Medication classes were coded according to those used in the British National Formulary (BNF) chapters.[37] In cases where the drug name was not provided, the drug class was coded as unknown. The drug class was further classified based

on whether the medication belonged to the psychotropic (i.e. antipsychotic, antidepressant, anxiolytic/hypnotic, mood stabiliser, central nervous system (CNS) stimulant and drugs used for dementia) or non-psychotropic group of medications. Information regarding the actions to prevent the re-occurrence of medication incidents was not analysed as it was beyond the scope of this study.

Box 1: The NRLS definition of harm

Degree of harm	Definition
No harm	A situation where no harm occurred: either a prevented patient safety incident or a no harm incident.
Low harm	Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons.
Moderate harm	Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm to one or more persons receiving NHS-funded care.
Severe harm	Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.
Death	Any unexpected or unintended incident that directly resulted in the death of one or more persons.

Following the quantitative analysis of all medication safety incidents in phase 1, a sub-sample of all incidents reported to be associated with moderate harm, severe harm and death was identified, and additional free-text data were requested from National Patient Safety Team. Content analysis was then undertaken of this data in phase 2 of the study to identify contributing factors and the contexts within which incidents occurred.[38]

Data analysis

Phase 1 (Quantitative analysis of medication incidents)

Frequency tables using Microsoft Excel® software were used to identify the most commonly reported incidents (including those reported to be associated with moderate, severe and fatal consequences) according to their main characteristics including the stage of medication use process during which medication safety incidents occurred, the specialty in which medication safety incidents took place (e.g. acute adult ward, forensic ward), the classes of medication involved and the reported severity of incidents. Further analysed was undertaken using cross tabulations to explore the relationships between different data variables (e.g. the class of

medication and severity, type of medication incidents involved and their associated reported severity).

Phase 2 (Analysis of contributory factors using content analysis approach)

The narrative descriptions of those medication incidents reported to result in moderate harm, severe harm or death for the patient(s) (as identified in the first phase of the analysis) were systematically coded using the Primary Care Patient Safety (PISA) classification system in order to identify the underlying contributing factors associated with their occurrence.[39] Three members of the research team (GHA, RNK and DMA) familiarised themselves by reading the medication incident free-text description for a 10% random sample of the incident reports before reaching consensus on coding using the PISA-contributory factor framework to ensure consistency. Following this, the remaining reports were coded by the first author and any uncertain cases identified were returned to the wider research team for further review. The PISA classification system is adapted from the World Health Organization's International Classification for Patient Safety (WHO ICPS), which was developed by a multidisciplinary team from the UK, USA and Australia who used multiple coding frameworks to classify the type of patient safety incident, contributory factors and severity of harm.[39] Although the classification system was originally created to target safety incident reports in primary care, it has also been applied to incidents occurring in a range of other health care contexts.[40-43]

Ethical approval

Given the anonymised nature of the data, the University of Manchester's Ethics Committee has exempted this study from formal ethical approval (Reference number: 2018-2165-6022).

Results

Of 94,571 anonymised medication incident reports received from the National Patient Safety Team, a total of 94,134 were included in the phase 1 quantitative analysis. The remaining reports were excluded because those medication incidents were caused by ADRs (437; 0.4%), as shown in Figure 1. Of the 94,134 medication error related incidents, 10.4% (9,811/94,134) were reported to result in patient harm. More specifically, 8,741 (9.3%) of these reports described low harm, 1,028 (1.1%) described moderate harm, and 42 reports (0.04%) described severe harm or fatal outcomes. Examples of harmful medication incidents are presented in Table 1.

Figure 1: Flow chart shows how reports were selected.

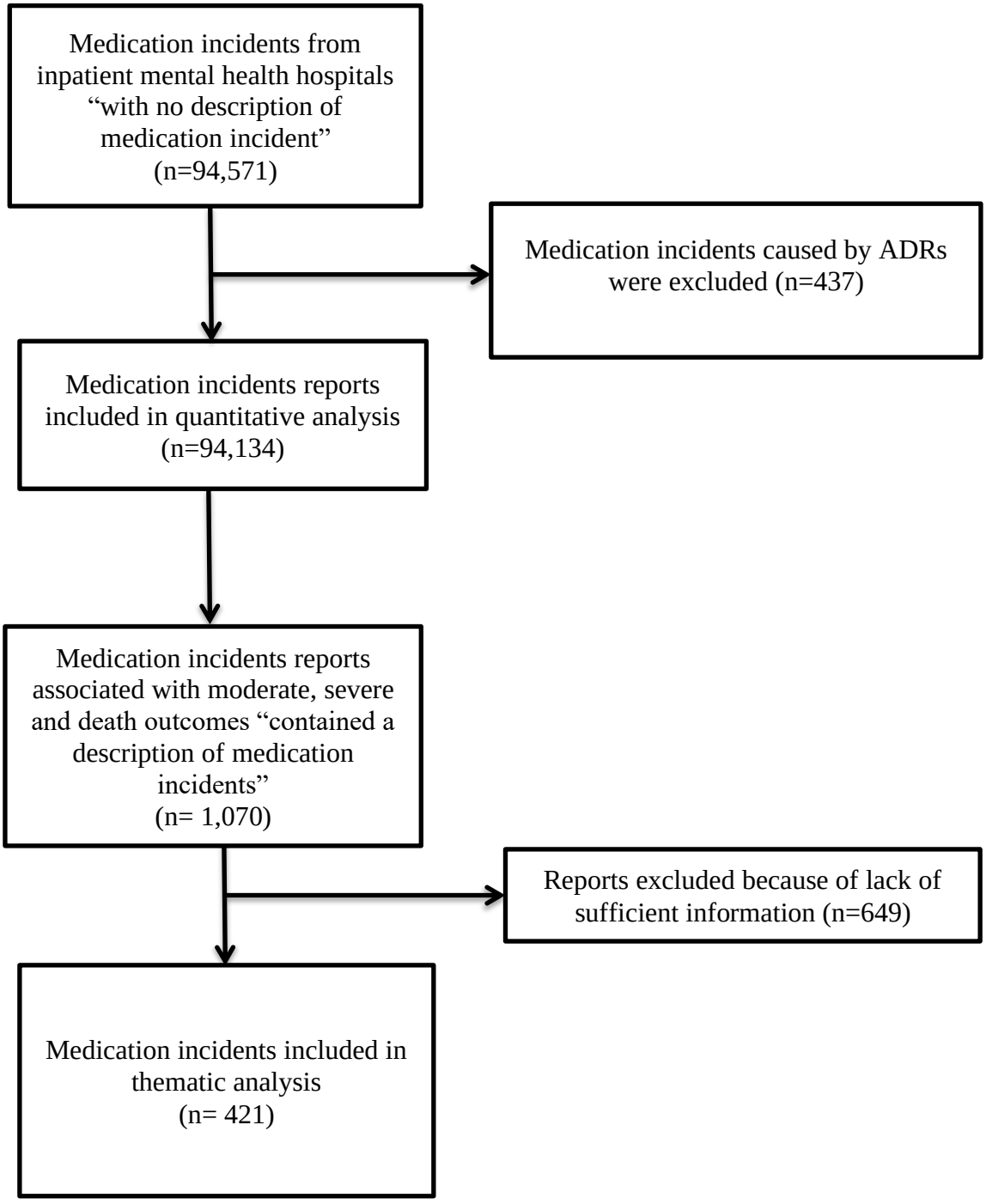


Table 1: Report examples (edited for clarity) and contributory factors of medication incidents reported to be associated with harmful outcomes

Examples	Contributory factors generated using PISA classification scheme
"The patient reported to be feeling dizzy and nauseous following medication administration and started vomiting in a sink. The patient blamed this on the dose of medication received, feeling that the dose is too high (40 mg administered in accordance with the prescription chart). The doctor was informed who found that the dose of Escitalopram prescribed on the chart was too high. The highest dose of this medication permitted under the British National Formulary is at 20 mg."	Staff-related factors: Inadequate skill set/knowledge.
"The patient was prescribed chloramphenicol eye drops 0.5% four times daily. These were ordered from and delivered by the pharmacy. The patient was going on leave and so eye drops were administered. The patient complained of discomfort, and the drops were checked again. The drops were labelled as chloramphenicol 0.5% but were in fact ear drops chloramphenicol 5%."	Staff-related factors: Cognitive shortcoming: Similar medication names / appearances confused
"The patient suffered from withdrawal symptoms secondary to clozapine stopping. Originally the doctor had prescribed medication and in [the] stop date box had written another date in which the dose would be changed. Since then it was decided clozapine was to remain at the prescribed dose and no change was to be made. However, the doctor had not amended the stop date and accordingly the pharmacy reviewed the medication card and stopped clozapine. The medical team did not know this had happened and the patient did not receive any clozapine. The patient was not physically well and started having symptoms of withdrawal including insomnia, sweating, diarrhoea and headache."	Staff-related factors: Failure to follow protocol - failure to adhere to procedures or regulation for task-a piece of work to be done or undertaken.
"The patient experienced a petit mal seizure that was followed 30 min[utes] later by an epileptic seizure. The staff attended to the patient by maintaining an open airway, and after three minutes of unabated seizure activity, an ambulance was called. The investigation appears to suggest that the anticonvulsant medication for this patient had not been delivered to the ward and therefore three doses have been omitted due to lack of stock."	Equipment-related factors: Lack of stock

Phase 1 (Quantitative analysis): Characteristics of medication incidents

Specialty of medication incident reports

The specialty where the medication incidents occurred was provided in 98.5% (n=92,803) of the reports. Most medication incidents were occurred in adult inpatient units (46,546; 50.1%), followed by older adult units (16,743; 18.0%), and forensic units (14,813; 15.9%). Child and adolescent (2,729; 2.9%) as well as rehabilitation (2,358; 2.5%) units accounted for a smaller proportion of the medication incidents (see Table 2 for details of all settings where incidents were reported).

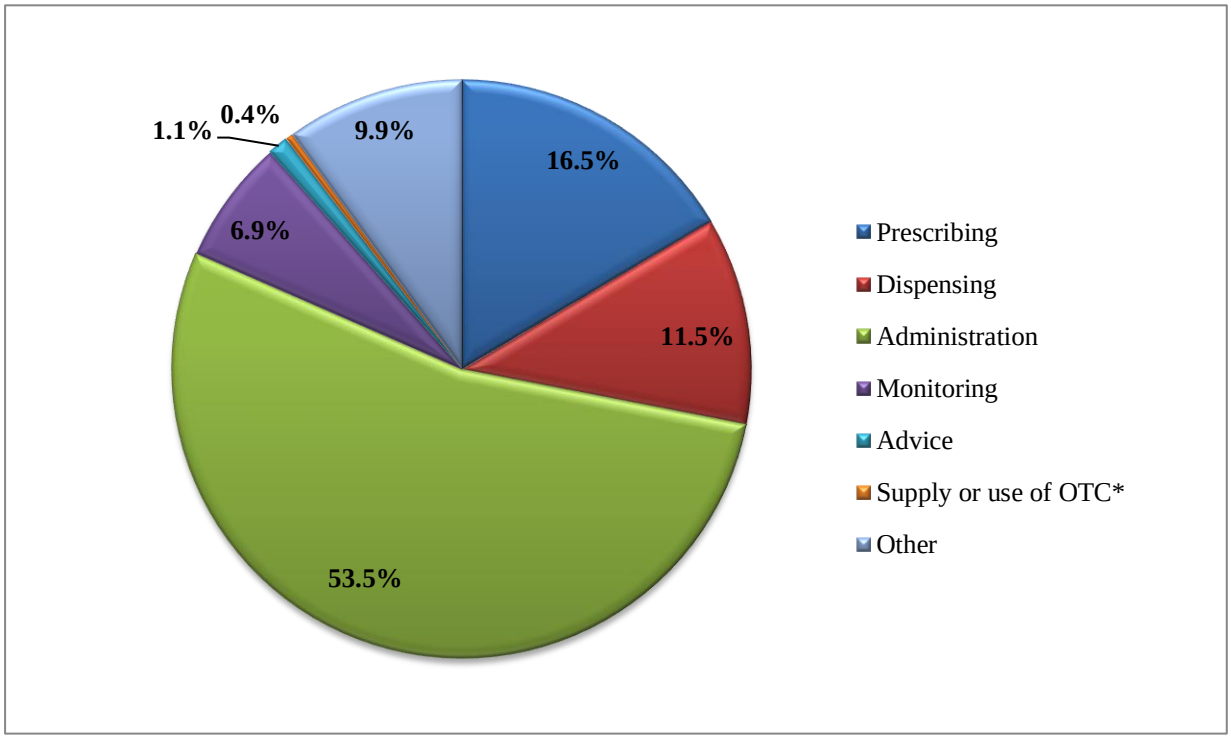
Table 2: Number of medication incidents by specialty

Specialty	Frequency (n)	Percentage (%)
Adult mental health	46,546	49.45
Older adult mental health	16,743	17.79
Forensic mental health	14,813	15.74
Child and adolescent mental health	2,729	2.90
Mental health rehabilitation	2,358	2.50
Pharmacy (inpatient)	1,916	2.04
Drug and alcohol service	1,057	1.12
Care of older people	65	0.07
Other	6,576	6.99
Missing	1,331	1.41
Total	94,134	100.00

Stage and type of medication incident reports

More than half of the medication incidents were reported to occur during administration of medication (50,361, 53.5%). The second highest category of reported medication incidents was reported to involve prescribing (15,511; 16.5%), followed by medication dispensing (10,905; 11.5%) and monitoring (6,531; 6.9%). The frequency of medication incidents by medication use stage is shown in Figure 2. Of all included reports, the most frequent types of incident were reported to involve omission of medication (17,302; 18.3%), wrong frequency (11,882; 12.6%) and wrong/unclear dose (10,272; 10.9%). Details of the types of medication incidents and their associated reported severity are summarised in Table 3.

Figure 2: Medication incidents involved in different stages of the medication treatment process



*****OTC: Over the counter medication.

Table 3: Type of medication incidents and their associated severity

Type of medication incidents	No harm n (% of incident type)	Low harm n (% of incident type)	Moderate harm or worse n (% of incident type)	Total
Omitted medicine / ingredient	15,338 (88.6)	1,755 (10.1)	209 (1.2)	17,302 (100)
Wrong frequency	10,198 (85.8)	1,591 (13.3)	93 (0.7)	11,882 (100)
Wrong/unclear dose or strength	9,037 (87.9)	1,121(10.9)	114 (1.1)	10,272 (100)
Wrong drug/ medicine	5,693 (87.7)	687 (10.5)	109 (1.6)	6,489 (100)
Wrong quantity	5,330 (88.1)	645 (10.6)	70 (1.1)	6,045 (100)
Mismatch between patient and medicine	2,465 (84.1)	394 (13.4)	71 (2.4)	2,930 (100)
Wrong method of preparation/ supply	1,641(91.9)	131 (7.3)	12 (0.6)	1,784 (100)
Wrong/omitted /passed expiry date	1,682 (94.9)	80 (4.5)	9 (0.5)	1,771 (100)
Wrong formulation	1,436 (89.5)	152 (9.3)	15 (0.9)	1,603 (100)
Wrong storage	1,311 (94.9)	58 (4.1)	12 (0.8)	1,381 (100)
Wrong route	772 (91.5)	63 (7.4)	8 (0.9)	843 (100)
Wrong/transposed /omitted medicine label	753 (94.7)	37 (4.6)	5 (0.6)	795 (100)
Contraindication to the use of medicine in relation to drug or condition	519 (85.2)	66 (10.8)	24 (3.9)	609 (100)
Patient allergic to treatment	404 (82.7)	64 (13.1)	20 (4.1)	488 (100)
Wrong /omitted patient information leaflet	223 (94.1)	14 (5.9)	-	237 (100)
Wrong /omitted verbal patient direction	153 (88.4)	17 (9.8)	3 (1.7)	173 (100)
Other type of incident	26,106 (92.9)	1,754 (6.2)	271 (0.9)	28,131 (100)
Unknown	1,262 (90.2)	112 (8.0)	25 (1.7)	1,399 (100)
Total	84,323 (89.5)	8,741 (9.2)	1,070 (1.1)	94,134 (100)

Class of medication involved in incidents

A total of 62,278 drug names were reported to have been involved with incidents. Thirty-five percent (34,168/96,446; 35.4%) of drug names were coded as unknown whenever the drug name was not provided. Medicines from the CNS class were reported as frequently involved (42,609/62,278; 68.4 %); of these, the most frequently reported were antipsychotics (14,934/42,609; 35.0%), followed by anxiolytics/hypnotics (8,129/42,609; 19.1%) and antidepressants (5,776/42,609; 13.5%). The number of psychotropic medications (30,611; 49.1%) involved with incidents was found to be comparable with non-psychotropic medications (31,667; 50.8%). The remaining most frequently reported medication classes included drugs used for cardiovascular (4,537/62,278; 7.2%) and endocrine (3,669/62,278; 5.8%) systems, as well as for infectious diseases (2,646/62,278; 4.2%). Details over the different classes of medication involved in these incidents and their reported severity are presented in Table 4.

Table 4: Medication classes identified in medication incident reports and their associated severity*

Medication class	No harm n (% of drug class)	Low harm n (% of drug class)	Moderate harm and worse n (% of drug class)	Total n (%)
Central Nervous system	37,095 (87.0)	5,024 (11.7)	490 (1.1)	42,609 (100)
Antipsychotics	12,924 (86.5)	1,830 (12.2)	180 (1.2)	14,934 (100)
Anxiolytics and hypnotics	7,179 (88.3)	882 (10.8)	68 (0.8)	8,129 (100)
Antidepressant	5,017 (86.8)	695 (12.0)	64 (1.1)	5,776 (100)
Analgesic (strong)	3,633 (88.8)	401 (9.8)	54 (1.3)	4,088 (100)
Antiepileptic	3,196 (85.4)	499 (13.3)	46 (1.2)	3,741 (100)
Analgesics (weak)	1,839 (88.3)	227 (10.9)	15 (0.7)	2,081 (100)
Anticholinergics	832 (89.0)	97 (10.3)	5 (0.5)	934 (100)
Mood stabilisers	697 (83.3)	116 (13.8)	23 (2.7)	836 (100)
Drugs used for dementia	462 (80.6)	98 (17.1)	13 (2.2)	573 (100)
Drugs used for Parkinson's disease	342 (83.6)	59 (14.4)	8 (1.9)	409 (100)
CNS stimulant and drug used for ADHD	307 (90.2)	29 (8.5)	4 (1.1)	340 (100)
Other[1]	666 (86.8)	91 (11.8)	10 (1.3)	767 (100)
Cardiovascular system	3,936 (86.7)	549 (12.1)	52 (1.1)	4,537 (100)
Endocrine system	3,101 (84.5)	487 (13.2)	81 (2.2)	3,669 (100)
Infection	2,258 (85.3)	359 (13.5)	29 (1.1)	2,646 (100)
Gastro-intestinal system	1,880 (87.1)	263 (12.1)	15 (0.7)	2,158 (100)
Respiratory system	1,917 (90.1)	199 (9.3)	11 (0.5)	2,127 (100)
Blood and nutrition	1,700 (89.0)	192 (10.0)	18 (0.9)	1,910 (100)
Musculoskeletal and joint diseases	868 (89.2)	95 (9.7)	10 (1.0)	973 (100)
Skin	484 (90.4)	46 (8.6)	5 (0.9)	535 (100)
Eye	358 (86.0)	53 (12.7)	5 (1.2)	416 (100)
Obstetrics, Gynae-Urinary Tract Disorders	221 (93.6)	14 (5.9)	1 (0.4)	236 (100)
Ear, nose and oropharynx	202 (86.3)	32 (13.6)	-	234 (100)
Malignant Disease & Immunosuppression	86 (80.3)	17 (15.8)	4 (3.7)	107 (100)
Vaccine	66 (90.4)	7 (9.5)	-	73 (100)
Anaesthesia	27 (84.3)	4 (12.5)	1 (3.1)	32 (100)
Emergency treatment of poisoning	16 (100.0)	-	-	16 (100)
Unknown	32,162 (94.1)	1,627 (4.7)	379 (1.1)	34,168 (100)
Total	86,377 (89.5)	8,968 (9.2)	1,101 (1.1)	96,446 (100)

[1]Other: medications used for alcohol, nicotine, opioid dependence and medications used for Meniere disease, migraine, nausea and labyrinth disorder,*some of medication incident reports have more than one medication involved.
ADHD: attention deficient hyperactivity disorder.

Medication incidents with moderate, severe or death outcomes

In total, 1,070 medication incidents were reported to result in either moderate (1,028; 96.1%) or severe harm including death (42; 3.9%). The majority of these incidents were reported to occur in adult (559; 52.2%) and older (253; 23.6%) mental health units. In total, 45.3% (n=485) were reported to involve drug administration, followed by prescribing (185; 17.2%) and monitoring of medication (169; 15.7%). Wrong storage (271; 25.3%), omission of medication (209; 19.5%) and wrong/unclear dose (114; 10.6%) were the three most common types of medication error reported among these incidents.

Phase 2 (Analysis of contributory factors using content analysis approach): Contributory factors reported to be associated with moderate, severe harm and death outcome medication incidents

Among 1,070 medication incidents associated with at least moderate harm severity, 60.6% of reports (n=649) were excluded as they did not explicitly describe any reasons why the incident may have occurred and thus it was not possible to identify any contributory factors. The remaining 421 reports (39.4%) were analysed using the PISA framework which identified 458 factors that contributed to the occurrence of these medication incidents across four categories: patient, staff, organisation and equipment-related factors. A total of 8.7% (n=37) medication incident reports had two contributory factors. Table 5 summarises the reported contributory factors associated with these medication incidents.

Table 5: The contributory factors identified in the medication incident report*

Contributory factors	**Contributory factor (subcategories)**	**Total (n,%)**
Staff-related factors (n=191; 41.7%)	Failure to follow protocol - failure to adhere to procedures or regulation for task-a piece of work to be done or undertaken	93 (20.3)
	Cognitive shortcoming, e.g. distraction/inattention/oversight, similar patient names, similar medication names and appearances	72 (15.7)
	Inadequate skills or knowledge	14 (3.0)
	Violation: deliberate breaking of a rule	6 (1.3)
	Illegible handwriting	2 (0.4)
	No or poor supervision or assistant from staff	4 (0.8)
Organisation-related factors (n=114; 24.8%)	Lack of continuity of care - the delivery of a 'seamless service' through integration, coordination and the sharing of information between different providers	92 (20.0)
	Working condition, e.g. busy/work overload, insufficient number of staffs	13 (2.8)
	Protocols/Policies/Standards/Guidelines inadequate, inefficient	3 (0.65)
	Long wait for services	4 (0.8)
	Training and education	2 (0.4)
Patient-related factors (n=90; 19.6%)	Patient behaviour: the way in which patients/family act or conduct themselves	62 (13.5)
	Pathophysiological factors related to the patient's physical and medical wellbeing and health: allergy, drug interactions, previous health or medication history, multi-morbidity	26 (5.6)
	Language barrier	2 (0.4)
Equipment-related factors (n=63; 13.8%)	Lack of stock	51(11.1)
	Medication storage	9 (1.9)
	Poor equipment design and maintenance	3 (0.6)
	Total	458

*Some medication incidents involved more than one contributory factor.

Staff-related factors

Almost 41.0% of medication incidents (n=172/ 421) were reported to be associated with staff-related factors (191/458; 41.7%). Failure to follow protocols (93/191; 48.6%) was the most frequent factor implicated. Inadequate skills or knowledge amongst staff (14/191; 7.3%), illegible handwriting (2/191; 1.0%) and staff violations (6/191; 3.1%) were also reported. For example, the following incident was related to a situation involving accurate measurement of a prescribed dose of medication:

"*The patient was not feeling too well after administering chloral hydrate. After investigation, the patient informed the staff that the responsible staff had confirmed that chloral hydrate had been given without being measured; it was poured directly into the wax pot because there were no syringes in the clinic room and the patient was tired and wanted to go to bed.*"

Organisation-related factors

The origins of more than a quarter of medication incidents (n=109/421) were reported to be associated with organisation-related factors (114/458; 24.8%). A lack of continuity of care (92/114; 80.7%) between health care interfaces was the most commonly reported issue, which was found to be associated with 91 (21.6 %) reports. For instance, some reported incidents resulted from a lack of communication between general practice or community mental health care services and mental health hospitals, which resulted in delays accessing details of the patient's current medications. Failure to offer the appropriate medication on discharge or during temporary 'leave' periods was also reported. In another example, inappropriate discontinuation of antiplatelet medication was described, where the patient suffered another myocardial infarction:

"*The patient had a myocardial infarction, and after the heart attack, clopidogrel and aspirin were commenced within the coronary care unit of the acute hospital trust. On transfer back to the psychiatric ward, the medication was inadvertently stopped when the drug card was rewritten. The patient then went on to have another heart attack.*"

Patient-related factors

Patient-related factors (90/458; 19.6%) were identified in 19.2% of medication incident reports (81/421). These factors were primarily related to the behaviour of patients (62/90;68.8%); examples include patients who were reported not to take their medication as instructed and showed resistance to adhering to treatment. In other instances, patients were reported to show aggression or violence toward the health care team; this was found in seven reports which sometimes led staff to exceed the maximum dose of "as required, PRN" medication in order to control patient behaviour:

"*[patient initials] was administered olanzapine 10 mg PRN [as needed] as prescribed and was presented as violent and aggressive. Two hours after the last dose, patient had been given another dose of Olanzapine. On the prescription card, it stated 4 hours in between doses.*"

Equipment-related factors

Equipment-related factors (63/458; 13.8%) were reported to be associated with 41.0% (n=59/421) of reported medication incidents. A lack of medication stock was the most frequently reported factor (51/63; 80.9%). In some instances, the lack of supply/stock of critical medications such as antibiotics and insulin was the main cause of patients being admitted to acute hospitals, as described in this example:

"*The patient was found to suffer from […] infection sensitive to ciprofloxacin. He was prescribed ciprofloxacin which was never supplied to the ward. The patient was found to be febrile and upon admission to the acute hospital, patient was diagnosed with sepsis.*"

Discussion

This is the first detailed analysis of medication safety incidents that were reported from mental health hospitals to the NRLS in England and Wales over a period of eight years. Our results highlight the risk posed by medication incidents to patient safety in this setting, which were mainly reported to occur during the drug administration and prescribing stages as well as being associated with antipsychotics, which are used frequently in this setting. Our findings also illuminate the origins of some of these more harmful incidents, which were influenced by distinct factors related to staff, organisation, patients and related equipment. We identified contributory factors unique to the mental health hospital setting and its patient population that may help drive more tailored improvements in medication safety.

A comparison with earlier literature is challenging, as this is the first study of its kind to have examined the nature of medication incidents reported to the NRLS from inpatient mental health care settings. Earlier studies concerning medication incidents in mental health settings have either examined a small subset of medication incidents over a short period of time that were reported from a wide variety of services including primary care organisations [28] or reported locally in specific hospitals which may not reflect patterns of events at national scale.[44-46]

Implications and recommendations for improvement

The study findings provide insight into the nature and contributory factors for medication incidents in mental health hospitals. Medication administration and prescribing-related medication incidents were frequently reported and have emerged as an important target for improvement. It is not surprising as medication administration errors and prescribing errors were previously found to be a common occurrence in epidemiological studies in inpatient mental health hospitals.[7] These incidents could be targeted by the use of technology such as electronic prescribing and medicine administration as suggested by the NHS Long Term Plan,[47] which is also supported by previous studies in general hospitals which demonstrated reductions in wrong dose [48] and omission error.[48,49] The current roll out and implementation of such technology across all NHS mental health hospitals would be an opportunity for future studies to test its effectiveness in reducing such incidents in mental health hospitals, with limited numbers of mental health hospitals using this technology.[50]

Our findings found that medication incidents were frequently reported to be associated with the CNS medication class including antipsychotics and antidepressants. Yet, it has been reported that both antipsychotics and antidepressants were among the most commonly identified prescribing safety indicators related to patient with mental health illnesses[51] that could be integrated with informatics tools into everyday clinical practice to identify patients at risk of medication incidents as seen in general hospital and primary care.[52]

Whilst the contributory factors identified in this study appear to be similar to those identified in prior error causation studies in general hospital settings such as staff and equipment-related factors,[53,54] some of which were unique to mental health settings. Patient behaviours (e.g. aggression and consistent demanding) were recently identified by nursing professionals as one of the underlying causes of medication administration errors in this setting.[55] In another study, patients' refusal to take medicines was found to be the most common reason for dose omissions in two English NHS mental health trusts.[56] Supporting measures should be put in place to help hospital staff and patients mitigate such challenging scenarios which they may frequently experience in this setting.[57,58] Another important factor identified in this study was the lack of continuity of care when patients are transferred between different care settings or providers. Whilst this might be a common issue across different health care settings, this is of particular concern for patients with mental health illnesses as they may cross health care boundaries more frequently. Crossing healthcare boundaries can result in inaccurate transfer of medication information, [59] and are commonly implicated in 56.2 % of hospital admissions [60] and in 20.8% of discharge prescriptions.[61] Shared electronic health records which contain a patient's medication list can support important processes to mitigate medicines-related incident like medication reconciliation [62,63] and may also have a role for the accurate and timely transfer of information across health care boundaries.[64,65]

Staff-related factors such as the failure to follow protocols, cognitive shortcoming due to distraction or similar patient/medication names, and inadequate skills were commonly reported. This could be mitigated by considering system-level interventions particularly those that target interruptions/distractions and reducing workload [66] as well as providing specific patient safety training that draws on human factors and systems thinking that will help provide insight to the right approaches to reduce risk of medication incidents.[67]

The equipment-related factors, and in particular lack of stock, was frequently described. Lack of stock was featured in an earlier review as a contributor of medication administration [68] and

found to be the main cause of clozapine-related incidents reported to the NRLS in 2007.[69] In addition, our findings highlight further equipment-related factors such as poor medication storage and equipment design which could be considered an important target for future intervention.

Another important recommendation arising from this project for policy makers, managers and staff is to pursue efforts to improve the quality of incident reporting. Our findings showed that less than half of the medication incident reports with at least moderate harm severity contained a description of contributory factors. This indicates limited potential for using the reports for improvement purposes, along with the possibility of insufficient knowledge of the purpose of the reporting system that requires further exploration. Previous studies have demonstrated that pharmacists considered reporting system too cumbersome and time consuming to complete and acknowledged the need for a simpler reporting system.[70,71] However, in mental health settings, staff described that patient aggressive behaviour that associated with mental health diagnosis is linked to the probability of under reporting.[72] Therefore, implementing efficient reporting systems alongside education and training to support a better understanding of the rationale behind reporting is needed. This could be informed by providing an explicit framework of common contributory factors to prompt / support improvement in the incident descriptions provided by staff .[73,74]

Strengths and Limitations

Our study is the first and largest detailed analysis of medication incidents reported by inpatient mental health settings across England and Wales. We used a large sample size to provide a valid and broad overview of medication incidents that occurred in mental health hospitals, thereby allowing us to highlight areas for future improvement. However, the NRLS reporting system is potentially limited by data quality factors such as under-reporting, selective reporting and incomplete reporting.[23,24,75] In this study, many reports had missing data (e.g. 35.4% of drug names were unknown) as well as variable levels of detail concerning the contributory factors in the free-text description which resulted in only 40% of reports describing incidents of at least moderate harm outcomes undergoing analysis. In addition, the NRLS' original classification of harm was used which mainly relied on the reporter's personal judgment and may not reflect actual harmful consequences.[76] Moreover, the classification of harm was limited by a lack of distinction between potential and actual harm.

However, the National Patient Safety Team is currently developing a project entitled "Development of the Patient Safety Incident Management System (DPSIMS)" that is designed to replace the NRLS with more advanced functionality and enhanced impact on safety.[77]

Conclusion

To our knowledge this is the first national mixed-method analysis of medication incidents reported to the NRLS from inpatient mental health settings across England and Wales. This study highlights the most frequent reported types of medication incidents including medication administration and prescribing incidents, with centrally acting medications (particularly antipsychotics) being frequently implicated. We identified a number of underlying contributory factors to more harmful incidents which included those unique to this setting, which can be used to drive improvement efforts. Interventions that have been implemented to improve medication safety in general hospital settings such as electronic prescribing and medicines administration, medication reconciliation and deployment of prescribing indicators could be applicable in mental health hospitals but need to be specifically tailored to meet the unique needs of this setting.

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