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Dose Omissions in Hospitalized Patients in a UK Hospital

An Analysis of the Relative Contribution of Adverse Drug Reactions

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Abstract

Background: The omission of charted (prescribed) doses for hospitalized patients is an important problem in the UK. Inappropriate drug omission can clearly lead to harm from lack of therapeutic effect. However, healthcare professionals administering medicines may decide that omission of a dose is appropriate in certain circumstances, e.g. when patients show signs of a possible adverse drug reaction (ADR).

Objective: The aim of this study was to characterize dose omissions to understand the factors that influence non-administration of therapy and to determine the proportion of doses that are appropriately omitted due to ADRs.

Methods: We used data from a bespoke hospital-wide electronic prescribing and administration system at University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK. We extracted data on 6.01 million drug administrations during 2010 and then randomly selected four 7-day periods, concentrating on doses that were charted but not given. Omitted medicines were counted if either there was a charted 'non-administration' (i.e. an active acknowledgement of the omitted dose) or there was no charting of that dose (i.e. no record of either administration or omission). Paused medicines were not counted. When a dose was omitted, staff indicated the reasons for non-administration using codes ('hard coded') or free text in the electronic system. We used both to compare the contribution of different factors, including ADRs, to the total rates of dose omissions.

Results: In the four 7-day periods analysed, 60 763 (12.4%) of the 491 894 charted doses were omitted. The most common code was 'patient refused drug' (45.4%). Only 1.6% of doses were omitted for reasons of patient safety, of which 4 in 1000 omissions were coded as directly due to an ADR.

Conclusions: Measures to improve the quality of care should seek to reduce dose omissions, but in some cases omission may be rational. Electronic medication administration records allow for detailed analysis of decisions made by healthcare professionals at the point of administration. While dose

omissions related to ADRs are uncommon, they are important both for patient safety and for therapeutic decision making.

Background

The consequences of unwarranted dose omission in hospitalized patients, where there is a failure to administer charted doses, can range from no harm to death.[1] The proportion of omitted doses differs considerably among studies. Calculating the prevalence of dose omissions can be difficult and time consuming, and no single method is entirely satisfactory.[2] Estimates range from 1.4% to 29.5%, which may be due to studies examining different drug classes or drugs used in specific circumstances.[3-10] Electronic prescribing and administration systems have the potential to make the identification of medication administration errors easier.

While unwarranted dose omission may cause patient harm, some doses may be intentionally omitted by staff making appropriate clinical decisions, and so contribute to patient safety. We wished to characterize dose omissions recorded in a hospital-wide electronic prescribing and administration system to understand the factors that influence non-administration of therapy and to determine the proportion of doses that are appropriately omitted due to adverse drug reactions (ADRs).

Methods

Setting and Study Population

This study was carried out at University Hospitals Birmingham National Health Service (NHS) Foundation Trust, which is situated in the West Midlands in England. The Queen Elizabeth Hospital is an academic teaching hospital with approximately 1250 inpatient beds caring for patients in all specialties except obstetrics, paediatrics and mental health. The hospital treated 56 833 inpatients in 2010. The Trust has a locally-developed electronic prescribing and administration system known as PICS (Prescribing, Information and Communication System), which is in use throughout all inpatient beds and for all prescribing except some chemotherapy regimens. The system was first installed in the renal unit more than a decade ago, and now covers all general and specialist medical and surgical specialties.

The PICS system allows for temporary suspension of administration for clinical reasons. Prescribers can 'pause' medications to make them temporarily unavailable for administration until such time that the prescription is subsequently 'resumed'. This allows doses to be omitted for clinically valid reasons (for example, post-operatively) and for this to be recorded and audited appropriately. PICS also provides a visual indicator to show when doses are due and overdue, to indicate and reduce unintentionally omitted doses. Both of these functions were active during the course of this study.

Within PICS, when a dose is charted but not given, staff indicate why the dose was not administered by selecting one of 36 codes from a drop-down menu. Free text can also be used to provide clinical information outside the scope of the pre-specified codes.

Data Extraction and Analysis

We extracted data on all dose omissions from four randomly selected 7-day periods during 2010. All patients entered into PICS and all drug types except for dietary products were eligible for inclusion. Omitted medicines were counted if either there was a charted 'non-administration' (i.e. an active acknowledgment of the omitted dose) or there was no charting of that dose (i.e. no record of either administration or omission). Paused medicines – medicines whose administration was temporarily halted – were not counted. Data on the drug name and the reason the dose was omitted, as a code or free text or both, were extracted onto an Excel® (Microsoft Corporation, Redmond, WA, USA) spreadsheet.

Reasons that were entered only as free text and without an associated code were hand-coded

independently by two researchers (JJC, SMcD) using a coding framework that used and expanded upon the existing 36 codes. When the free text mentioned more than one reason for the dose omission, the most clinically relevant code was used (e.g. 'patient sleeping after vomiting' was coded as sleeping). Two researchers attempted to reach consensus when the meaning of the free text was unclear and where this failed, the cause was coded as 'unknown'.

Development of Themes and Construction of an Ishikawa Diagram

We grouped the dose omission reason codes into common themes and domains to establish the contribution of different patient, pharmacy, environmental, and other factors, including ADRs, to the total rates of dose omission. For example, the codes 'awaiting x-ray results', 'awaiting sodium levels', 'awaiting INR', were collapsed into an overall 'awaiting results' code. We identified 54 common themes, collapsed into eight domains.

We constructed an Ishikawa (fish-bone) diagram to provide a graphical summary of the themes and domains for dose omissions.[11]

Subgroup Analysis

We identified a subset of drug omissions where both a reason code and free text were entered. This allowed us to compare the nature of the information in the two records for a single dose omission.

Results

In 2010, 6.01 million medication doses were prescribed, of which 491 894 medication doses were due in the 4 weeks selected for analysis. In these four 7-day periods, 60 763 (12.4%) doses were charted but not administered. The most common drug omitted (15.8%) was paracetamol (acetaminophen).

Almost 70% (42 277) of the omitted doses were assigned a reason code in the PICS system; reasons for omission of the remaining doses were entered as free text. The most common reasons involved patient-specific issues (such as patient refusal or self-medication), the perceived clinical

Table I. Reasons for missed doses (N = 60 763) from 491 894 doses due for administration

Reason for missed dose	n	% of all missed doses
Patient-specific issues	**27 586**	**45.4**
Patient administered/self-medicating	242	0.4
Patient refused medication	27 342	45.0
Unable to communicate with patient	2	0.0
Clinical needs and appropriateness	**6 775**	**11.1**
Awaiting results or further instruction	376	0.6
Bowels open, diarrhoea or GI disturbance	1 238	2.0
Eating and drinking normally	2	0.0
MRSA-negative or having screening	154	0.3
Nausea/vomiting	761	1.3
No longer indicated	719	1.2
Not clinically safe/appropriate to give	277	0.5
Not needed/not clinically necessary	1 453	2.4
Not to be given due to procedure or investigation	496	0.8
Patient too drowsy or asleep	1 004	1.7
Patient unwell or terminal	295	0.5
Time and technology issues	**6 474**	**10.7**
Administered after time due	54	0.1
Administered but not signed for	188	0.3
Admission delay	205	0.3
Delay or issue with electronic prescription	61	0.1
Dose timing/time incorrect	1 992	3.3
Indicated with other treatment	77	0.1
Not administered related to previous administration	568	0.9
Technical error with prescription	92	0.2
Unclear whether administered	3237	5.3
Drug availability	**6 162**	**10.1**
Medication not stocked in hospital	167	0.3
Medication not stocked on ward (on order)	5 995	9.9
Administration and route issues	**5 173**	**8.5**
Administered via an alternative route	31	0.1
Inappropriate route	4	0.0
Intravenous access problem/availability	409	0.7
Intubated and/or ventilated	132	0.2
Oral/enteral intake	225	0.4
Oral/enteral route unavailable	4 271	7.0
Route or delivery mechanism not available	101	0.2

Continued

Table I. Contd

Reason for missed dose	n	% of all missed doses
Patient or staff availability	**5 161**	**8.5**
Patient away from ward	4 485	7.4
Patient not available	662	1.1
Staffing issues and/or training	14	0.0
Prescribing issues	**2 099**	**3.5**
Administered at a different dose	5	0.0
Administered or should be administered as PRN	49	0.1
Formulation issue	279	0.5
Instruction not communicated	149	0.2
Medical decision not to administer	427	0.7
Prescription error	306	0.5
Prescription incorrect or has been changed	183	0.3
Receiving alternative therapy which precludes current drug	253	0.4
Therapeutic duplication	448	0.7
Patient safety	**1 000**	**1.6**
Adverse drug reaction	247	0.4
Bradycardic	13	0.0
Clinically contraindicated	33	0.1
Drug levels out of therapeutic range	148	0.2
Hyperglycaemic	12	0.0
Hypertensive	6	0.0
Hypoglycaemic	115	0.2
Hypotensive	417	0.7
Medication error	2	0.0
Rash or allergic reaction	7	0.0
Unknown	**333**	**0.5**

GI = gastrointestinal; **MRSA** = methicillin-resistant *Staphylococcus aureus*; **PRN** = *pro re nata* (as needed).

appropriateness of receiving the drug by the person administering the drug (for example patient too unwell), and time and technology issues (such as administration being too close to the last dose given). The most common code was 'patient refused drug' (table I). The factors contributing to dose omissions are also displayed in an Ishikawa diagram (figure 1). The omission of doses for any patient safety reason represented a small proportion (1.6%) of the total number of missed doses, of which 4 in 1000 omissions were coded as directly due to an ADR.

A small sub-sample of the doses (6767; 11.1%) had a reason provided both as a code and free text in PICS. In this subgroup of omitted doses, 32 pre-defined codes within PICS and 4152 individual free text codes were used. The reason code was often restated in a different form in the free text. For example, a range of free text entries matched the code 'Vomiting', including 'pt vomiting', 'pt vomited after given', 'vomitting', 'vomiting', and 'vomited'. In a small number of cases, free text entries indicated an ADR but the associated code did not. For example, there were 19 free text entries of 'coffee-ground vomit' that were coded as vomiting or nil-by-mouth; one entry of 'rash' was coded as 'patient refused drug'.

Discussion

The medication process is complex. For it to be safe, many stages and operators have to work effectively. This articulation work[12] – the coordination of all of the coordinating tasks involved in the safe provision of a prescribed medication – can fail at different stages, including failure to administer the dose. The omission of medication doses can harm patients and has been the focus of a national patient safety initiative.[1]

We demonstrated that 12.4% of prescribed medication doses were omitted. The majority of dose omissions were recorded as 'patient refused treatment', which may reflect the prescribing practice of the use of regular rather than 'as required' medications particularly for symptomatic treatments such as analgesia. Intentional non-administration for patient safety reasons accounted for a small proportion of omitted doses.

Prior work to characterize dose omissions has focused primarily on paper-based records.[4,13-15] We have used data from an electronic prescribing and administration system to understand factors that are associated with dose omissions. Certainly, electronic prescribing systems allow for easy auditing of missed doses. However, there are challenges associated with the use of such systems. First, the introduction of electronic prescribing systems may introduce new hazards to the administration of medicines.[1] For example, the first dose of a medicine may be delayed because the system has automatically scheduled the

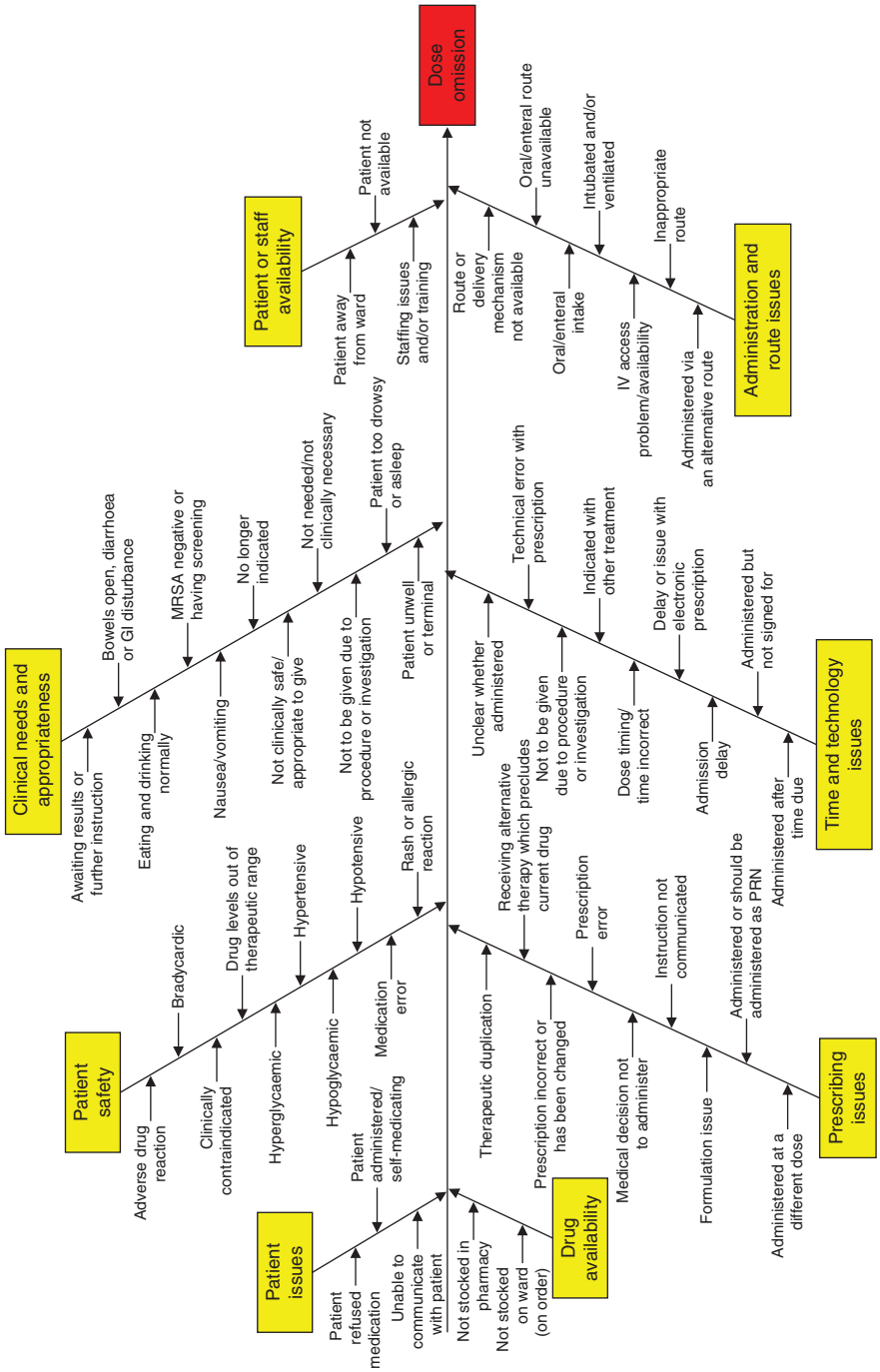

Fig. 1. An Ishikawa diagram of the factors contributing to dose omissions. **GI** = gastrointestinal; **IV** = intravenous; **MRSA** = methicillin-resistant *Staphylococcus aureus*; **PRN** = *pro re nata* (as needed).

time. Indeed, an increase in the rate of dose omissions has previously been demonstrated with the introduction of an electronic prescribing system.[16] Second, there are also challenges in how the reasons for drug omissions are recorded when electronic prescribing systems are used. We and others have demonstrated some differences between coded and free text, which may highlight potential limitations of coding structures from electronic prescribing systems.[17,18]

Limitations

There are some limitations to our analysis. First, the data relied on nurses picking correct and specific coded reasons for dose omissions. Their choices may have been affected by biases. For example, they may have preferred to choose reasons that did not imply deficiencies in practice; or they may have chosen a reason higher up the coded list (picklist bias). Second, we did not seek to verify the true underlying reasons for dose omission by correlating system data with information from other sources. Third, we had no unified schema for the thematic analysis of the free text. Themes were based on expert opinion, but may have been subject to analyst bias. Fourth, the data were extracted during a time of change in the Trust. Several quality improvement measures were introduced, beginning in 2008, to decrease the number of dose omissions. Furthermore, we did not investigate the impact of any drug shortages on the rate of dose omissions. However, we believe that there were very few drug shortages during the study period; when shortages occur, prescribers are redirected by the PICS system (to use other medicines), so as to reduce the effect of any problems in the supply of drugs on dose administrations. Finally, we did not examine the clinical significance or outcomes associated with the dose omissions. Others have demonstrated that these cover a wide range.[19,20]

Conclusions

Electronic prescribing and medication administration records can provide a clear audit trail for dose omission and error research. We analysed 60 763 dose omissions in 491 894 doses due for administration, that is, 12.4% of all scheduled drug administrations during the period of our study. Intentional non-administration to protect patients from drug-induced harm accounted for 1 in 60 omitted doses, and ADRs specifically accounted for 4 in 1000 omitted doses. Some 3200 potential ADRs may be averted each year in the hospital by staff deliberately omitting prescribed medicines. While quality improvement schemes often focus on inappropriate dose omissions, some are rational and do contribute to patient safety.

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All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and accuracy of the data analysis. All authors contributed to the writing of the manuscript, the interpretation of data, and approved the final version.

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