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Multicentre study to develop a medication safety package for decreasing inpatient harm from omission of time-critical medications

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Abstract

Quality issue: Omitting time-critical medications leads to delays in treatment and may result in patient harm.
Initial assessment: Published studies show that omission of prescribed medication doses is common. Although most are inconsequential, up to 86% of omitted medications place patients at some risk of harm.
Solution: Funding was obtained to develop a medication safety package to facilitate decreasing omitted dose incidents by audit, education and feedback.
Implementation: A panel of nursing and pharmacy hospital staff in Victoria, Australia, reviewed existing audit tools and published studies to develop a critical medication list and audit tool. The tool, definitions and instructions were tested in 11 rural, urban and teaching hospitals. Qualitative feedback was sought to refine the tool using a Plan-Do-Study-Act model. An educational presentation was developed using reported incidents.
Evaluation: Staff in 11 hospitals tested the audit tool in 321 patients receiving 17 361 doses of medication. Feedback indicated audit data were useful for informing improvements in practice and for accreditation. The educational material consists of the User Guide, plus a presentation for nursing staff illustrated by six cases with questions, with instructions on how to decrease harm from omitted doses by ensuring correct documentation and prioritising time-critical medications.
Lessons learned: A medication safety package using standard definitions and a critical medication list was successfully tested. It is now used by nursing and pharmacy staff across the state. Several interstate hospitals are using the tools as part of their hospital medication safety programmes.

Key words: quality improvement, quality management, patient safety, drug errors, adverse events, complications, hospital care, setting of care, pharmacy, nursing

Quality issue

Omitted doses account for a large percentage of all medication errors. Of 5 437 999 medication incident reports across the National Health Service from 2005 to 2010, 15.6% were due to missed or delayed medication [1]. Between September 2006 and June 2009, the UK National Patient Safety Agency (NPSA) received reports of 27 deaths,

Table 1 NIMC codes for reason a dose is not administered [16]

Reason for not administering Codes MUST be circled	
Absent	Ⓐ
Fasting	Ⓕ
Refused—notify prescriber	Ⓡ
Vomiting	Ⓥ
On leave	Ⓛ
Not available—obtain supply or contact prescriber	Ⓝ
Withheld—enter reason in clinical record	Ⓦ
Self-administered	Ⓢ
Parent/carer administered	Ⓟ

68 severe episodes of harm and 21 383 other patient safety incidents relating to omitted or delayed medicines. Subsequently, the NPSA identified specific medications with a greater potential for harm when omitted or delayed and published recommendations to decrease omitted medication rates [1].

Initial assessment

The NPSA report along with a review of locally reported incidents, indicating that up to 25% of all reported medication errors were dose omissions, prompted an initial local study to develop an audit to evaluate the extent of omitted doses, focusing on time-critical medications [2]. Other Australian studies have shown up to an 11% dose omission rate [3–8], with 86% of omitted medications placing patients at some risk of harm [4]. Observational studies in the UK [9] and USA [10] had shown similar rates. However, comparisons are unreliable, as there is no uniform definition nationally or internationally for what constitutes an 'omitted' dose.

Choice of solution

As there was growing concern about omitted medication doses and their consequences, a more co-ordinated effort was indicated. Funding was sought to develop a medication safety package that could be used state wide by nursing and pharmacy staff to determine the rate of omitted doses using standard definitions and a standard data collection tool and method. An education module describing the importance of prioritising time-critical medications was included for nursing staff, as nurses are the health carers that most often are in charge of administering medications.

Australian hospital medication management systems generally involve commonly used medications kept as stock on each ward. Medication orders in the majority of hospitals are hand-written by prescribers, using the National Inpatient Medication Chart (NIMC) [11]. The prescriber orders medications and the nurse initials the administration section on the same chart to indicate a dose has been administered or enters a standard 'not administered' code if a dose is omitted (Table 1). Only a small percentage of hospitals have electronic medication management systems. In the majority of Australian hospitals, a pharmacist is available to review each patient's medication chart at least daily from Monday to Friday from ~0800 h to 1730 h. During these hours, prescribed medications are accessed from ward stock or from the pharmacy. Non-ward stock medications are ordered and dispensed on a named patient basis by a pharmacist or pharmacy technician. In some hospitals, nurses order required medication from the central pharmacy. Only a few hospitals have a clinical pharmacy service after-hours and weekends. For supply after-hours, patient's own medication is used; medications are obtained from a limited-access after-hours medication storage area, from another ward, or sourced from the pharmacy via the on-call pharmacist.

Implementation

A steering group was formed from the Victorian Therapeutics Advisory Group (VicTAG), Quality Use of Medicines group, which appointed the project lead (L.G.) and project officer (C.I.). The nine Steering Group members included: four medication safety/Quality Use of Medicines pharmacists (W.E., B.S., L.G., J.C.), a senior clinical pharmacy technician (C.I.), two pharmacist administrators (M.V., T. O'S.), a senior nurse (J.C.) and a clinical pharmacist (T.B.).

An expression of interest (EOI) was sent to VicTAG member hospitals to conduct test audits with the audit tool. Ethics approval was sought and granted as a low-risk application by the project lead's hospital Human Research Ethics Committee.

The steering group reviewed audit tools and data from studies carried out in seven Australian hospitals [2–8]. This information was used to inform the project methodology, definitions and number of patients and total doses required to be audited. A practical audit tool was developed, tested and refined by initially auditing 10 patients' medication charts in each steering group hospital. In addition, a rural hospital volunteered to test the audit for applicability in a non-urban setting. The aim was to develop a tool that could be used routinely by hospital staff to audit omitted doses and enable hospitals to measure both their own medication safety performance over time and, by standardization, be able to compare results against other hospitals.

Changes were made to the tool after each test based on usability and qualitative feedback and discussion with the steering group using Plan-Do-Study-Act cycles of audit and feedback [12]. The audit tool consists of one double-sided page with data collection sheet on one side and a summary of instructions on the reverse. Basic data included total number of prescribed doses and number of preventable omitted doses. Further data were collected for time-critical medications including: name of medication, number of doses omitted, route of administration, time of omission and any resulting outcome. The final tool, shown in Fig. 1, and instructions for audit ('User Guide') were emailed to the 11 EOI Victorian hospitals. An audit of 30 patients per hospital was deemed to be adequate to test the audit tool in the time frame available. A larger sample size would improve sensitivity of the data, but data collection was not the aim of the project. De-identified audit data were entered by each auditor onto an Excel® spread sheet and emailed to the Project Officer.

Benchmarking was beyond the scope of this project, but data were collated and de-identified results sent to participating hospitals, to illustrate the potential for using comparative data. Feedback on the usefulness of the data was requested.

The education module was initially developed using a *Powerpoint*® presentation format for review by two nurse educators, as well as by the steering group members. Actual medication incidents resulting in harm outcomes were used as illustrative cases, along with instructions on how to prioritize time-critical medications to ensure they are not omitted, as well as reminding nursing staff to check that each administration box is signed or the correct 'not administered' code has been used. Also included in the presentation was the rationale for the audit and suggestions for targeting areas or improving systems to reduce omitted doses.

Definitions

An 'omitted dose' was defined as a dose not administered before the next scheduled dose and did not include delayed administration. For

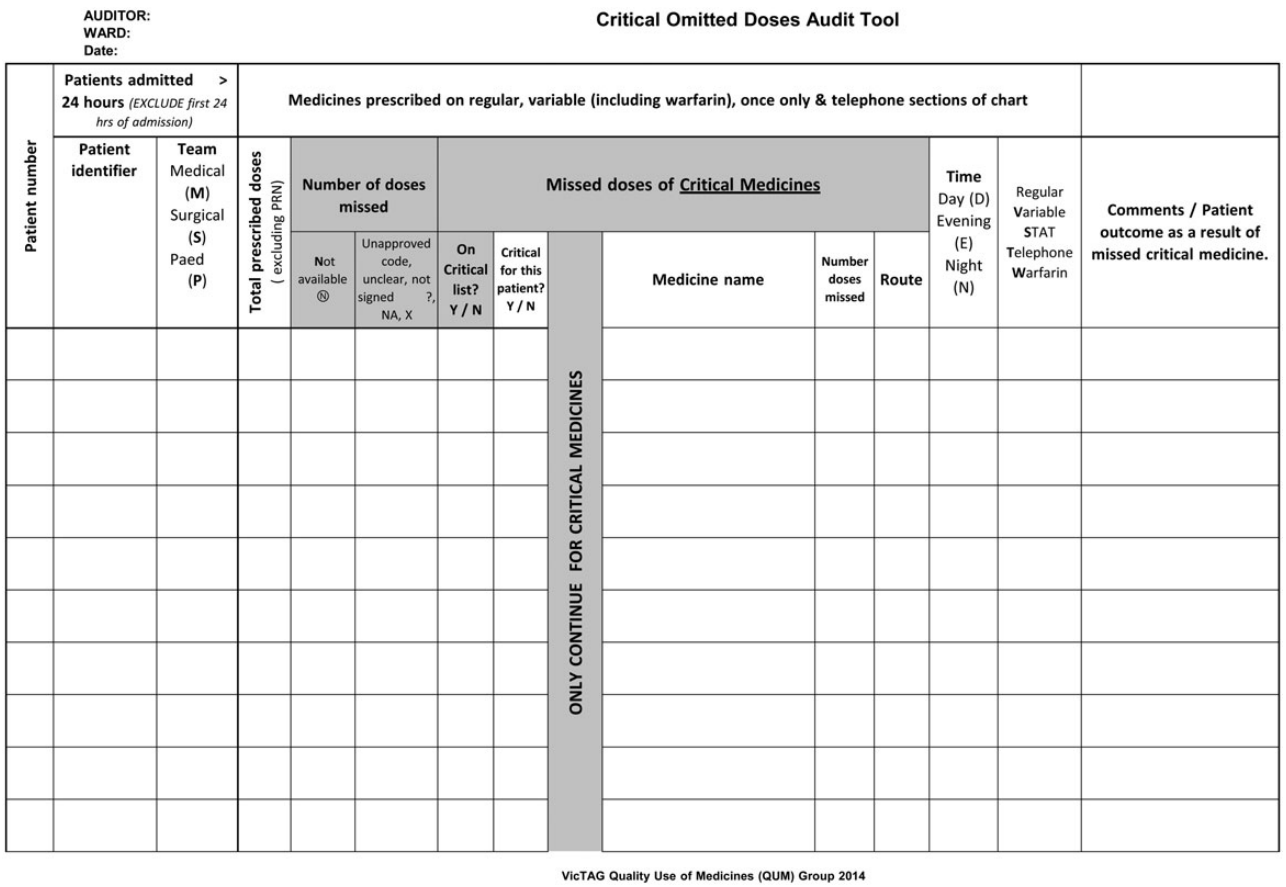

Figure 1 Critical omitted doses audit tool.

example, an intended 'statim' dose not given, or an antibiotic prescribed every 8 h but only given twice in a 24-h period.

A 'preventable omitted dose' was defined as a dose omitted either because the medicine was not available on the ward, a standard 'reason for not administering code' was not used [12], or it was otherwise unclear whether dose administration had occurred. Doses not given because of patient refusal, withheld doses or other 'therapeutic' omissions were not considered preventable, therefore not included in the audit. We concentrated on a practical definition of an omitted dose, as occurring during one dosing interval, which allowed completion of medication administration rounds, and gave a practical time frame in which an omitted dose could cause clinically relevant harm, for example omitted antibiotic in a febrile patient. Timing of prophylactic antimicrobial agents before skin incision is recognized as time-critical dose administration, but was not covered in this audit.

'Time-critical medications', shown in Table 2, are medications at a greater risk of causing harm if not administered in a timely manner, and based on the NPSA list [1]. This list was thought to be more relevant for time-critical medications, rather than limiting the list to 'high risk', or 'high alert' medications known by the acronym 'APINCH' [13]. This grouping includes: anti-infectives, potassium (and other electrolyte injections), insulin, narcotics (opiates and related sedatives), chemotherapeutic agents and heparin (and anticoagulants).

Auditors investigated whether the omission resulted in an adverse outcome, by asking the patient's doctor or nurse, looking at relevant pathology and/or reading the patient's medical notes for 24 h after the dose had been missed.

Table 2 Critical medication list; medications for which timing is critical; adapted from [1]

Medication group	Example	Possible outcome if missed
Anticoagulants	Warfarin, heparin	Deep vein thrombosis
Anticonvulsants	Phenytoin	Seizure activity, especially if omitted peri-operatively
Antidotes	Folinic acid	Methotrexate toxicity
Antimicrobials	intravenous antibiotics	Prolong infection
Corticosteroids	Cortisone	Adrenal insufficiency
Antipsychotics	Clozapine	Re-titration, recurrence of symptoms
Cytotoxics	Methotrexate	Disease recurrence
Hypoglycaemic agents	Insulin, glibenclamide	Ketoacidosis, hyperglycaemia
Immunosuppressants	Tacrolimus	Transplant rejection
Antiparkinsons	Levodopa combinations	Rigidity, falls

Evaluation

Eleven hospitals provided audit data. A total of 17 361 doses were audited for 321 patients (54.8% medical, 35.8% surgical and 9.4% paediatric). The majority of units used pharmacy staff as auditors. One used nursing staff. Omitted dose rate was 4.3% of total doses, the majority of missed doses were due to unclear documentation of

dose administration (633, 3.6%) and medication not being available was 0.7% (116). There were only 45 time-critical medication doses missed (0.3% of all doses). Results from the 11 hospitals are shown in Fig. 2 and Table 3. No negative outcomes resulted from omission of time-critical medications listed. However, there were seven negative outcomes identified by auditors from medications not on the 'critical' list, but considered critical for the patient (66 doses missed). Outcomes included increased pain (oxycodone omitted), exacerbation of psoriasis (topical steroids omitted), atrial fibrillation or increased blood pressure (beta blockers), exacerbation of airways disease/pneumonia/asthma (beta agonist inhalers), hypokalaemia (oral potassium) and aggressive patient (olanzapine).

The education package consisting of 15 Powerpoint® slides includes 6 reports with adverse clinical outcomes from omitted doses of: vitamin K in the setting of warfarin overdose, Parkinson's disease medication, intravenous antibiotic initial dose, anti-seizure medication, steroid doses peri-operatively and poor documentation of insulin dosing, resulting in a double dose and delay on discharge. Important medication safety messages included recognising which medications require timely administration and dispensing and the importance of communication between prescribers, pharmacy and nursing staff to ensure availability of medications. Actions suggested to prevent an omitted dose included: using nationally approved standard codes for documentation of dose administration, ensuring new orders are communicated without delay to nursing and pharmacy staff, transporting medications together with patients on transfer and ensuring time-critical medication doses are administered as part of handover.

Feedback and satisfaction with the audit package

After collated data were sent to the 11 project hospitals, 9 hospitals responded with feedback. All nine had used the data. Three had already submitted the data to their hospital's relevant medication safety committees. Feedback included: 'We can create a report on missed doses and drugs involved so that might be the future for us.' 'We would use multi-centre data as well as using it to compare improvements on a ward/hospital level.' 'I will use it for educational purposes as dose omissions and failure to document has been identified as a very common theme in reported medication incidents . . . results were also fed back to clinical staff in our clinical newsletter.' 'The time critical medications list is now part of the hospital's medication administration guideline'.

The audit package was perceived as being useful by staff testing the tool. Although not intended for benchmarking, the multi-centre project data indicated variability amongst hospitals in the rate of missed doses. A more extensive literature search was carried out to add more recent studies (Table 4). Although not inclusive of all reports in the literature, it served as a comparator to our state-wide data. Our range of 1–9% of doses omitted was similar to rates found in published studies. However, comparison of data across studies is difficult. Large variability in dose omission rates across centres is due to non-standardized definitions, disagreement as to what an important time period is and what actually constitutes an 'omitted' dose. Use of standard definitions decreases this variability and allows multi-centre data to be compared, as well as to monitor local trends over time.

In addition to feedback of audit data, and reminders for nurses to use the nationally agreed standard codes for dose administration should reduce time taken to clarify whether a dose has been administered.

Ideally, an initial audit is carried out to determine a baseline rate of omitted doses, either in one ward or over a campus. The audit result allows targeting of doses 'not available' or omitted due to poor documentation. After implementing the educational package, follow-up audits should indicate if improvements have occurred and highlight areas to target further systems changes, such as improving supply of medication after-hours, changing handover strategies or improving documentation. If missed doses are not found to be a problem, this positive result can be fed back to hospital governance, to indicate that current processes are adequate. Incidents resulting from poor documentation, as well as those indicating harm due to omitted doses, should be monitored along with the audit results. Focussing educational interventions to prioritize time-critical medications

Table 3 Critical medications omitted doses

Medication group	Specific medication	Number of doses omitted $n = 45$
Antimicrobials	Intravenous antibiotics	16
Anticoagulants	Heparin or enoxaparin	11
Corticosteroids	Both intravenous and oral	10
Hypoglycaemic agents	Insulin	3
Anticonvulsants	Levetiracetam, sodium valproate	2
Antidotes	Vitamin K	1
Antiparkinsons	Levodopa/carbidopa	1
Cytotoxics	Hydroxyurea	1
Antipsychotics		0
Immunosuppressants		0

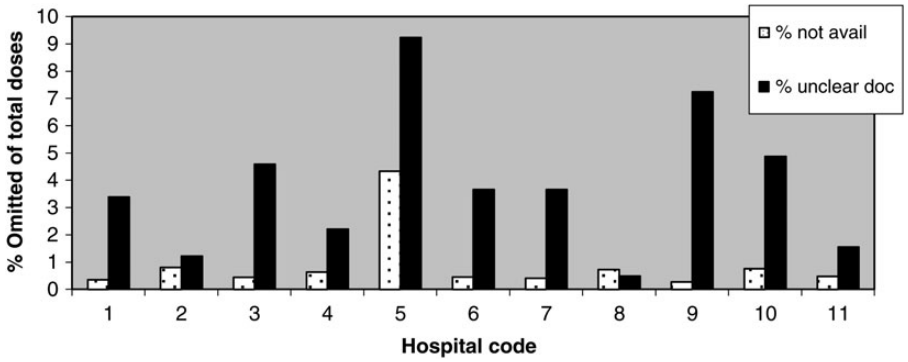

Figure 2 Preventable omitted dose rates in 11 hospitals.

Table 4 Selected omitted dose studies

References Year	Definition 'omission'	Setting	Number audited* *n* = no. of doses, unless otherwise stated	Percentage (number) of preventable omissions
Australia				
Lawler *et al.* [4] 2004	Regular dose not given before the next scheduled dose	Metropolitan teaching hospital Pre-electronic medication management. Chart review	4887	7.6% (369) omitted 2% (96) no documented reason
O'Shea *et al.* [5] 2009	Not available, chart not signed, withheld for clinical reasons, refused by patient or nil oral	Metropolitan teaching hospital Pre-/post-nursing education	Pre-20 451 Post-24 337	Pre-4.2% ('unavailable' = 1.4%) Post-2.9% ('unavailable' = 1.1%)
Latimer *et al.* [6] 2011	'Non-therapeutic' = dose not administered before the next due dose, including absence of a signature	Regional teaching hospital. 288 randomly selected medical and surgical patients	15 020	11% (1687)
Wembridge *et al.* [7] 2011	Blank on administration chart, or not available	Metropolitan teaching hospital	7625	2.9% (220)
Seaton and Adams [8] 2010	No definition	Regional 30-bed medical ward pre-/post-ward pharmacy technician	Pre-657 Post-1687	8.9% pre 0% post
ACSQHC [11] 2013	No signature on the administration section (excludes those with a standard code)	312 hospitals (241 public hospitals, 71 private hospitals) across Australia. Chart audit with centralized database	110 690 medicine orders	10% doses
Munzner *et al.* [14] 2012	'Non-valid' = not available or missed completely	Metropolitan teaching, post-electronic medication management	70 774	7.5% (5308) omitted 11% (571) 'non-valid' Unavailable: 19% (111/571)
UK				
Haw *et al.* [9] 2007	Omission for non-valid clinical reason	450-bed hospital Psychiatric care observational audit	32 patients, 1423 doses	27.1% Failing to sign: 23.6%
Warne *et al.* [17] 2010	Non-therapeutic = reason either not provided or non-clinical. 'Missed medication' = dose not administered within 1 h of the prescribed time included therapeutic reasons, e.g. 'clinical reason documented' and 'patient comatose'	Four acute hospitals	132 patients	Median: 4% (1077), Range: 0–65% Unavailable: 11% (119) of omissions Not given at all = 99 Given > 1 h = 20
Green *et al.* [18] 2009	All medicines prescribed and not given in the first 48 h	All admitted medical patients on 2 days	1642 orders	20% (329) orders Not available = 38% of omissions Nil by mouth = 32%, patient refusal = 10% No reason = 19%
Coleman *et al.* [19] 2012	Non-administration = an active acknowledgement of the omitted dose, or no record of either administration or omission. Aim: 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	University teaching hospital Electronic prescribing and administration system. Randomly selected periods over 1 year	491 894	12.4% (60 763) doses not administered 1.6% of doses were omitted for reasons of patient safety; 4 in 1000 omissions were coded as directly due to an ADR

Continues

Table 4 Continued

References Year	Definition 'omission'	Setting	Number audited* *n* = no. of doses, unless otherwise stated	Percentage (number) of preventable omissions
Coleman *et al.* [20] 2013	As above Aim was to evaluate interventions using data from the electronic prescribing system	As above Retrospective time series analysis over 4 years Intervention: electronic dashboard, feedback of data	2 121 765 antibiotic 25 668 583 non-antibiotic	Omission rates reduced from 10.3 to 4.4% for antibiotics, 16.4 to 8.2% for non-antibiotics
Carayon *et al.* [21] 2014	Late or omitted: STAT dose; >1 h after time, routine dose > 2 h after scheduled time. Omitted medicines investigated for potential and preventable ADEs	Intensive Care Unit (ICU)	45 658 doses	1732 medication errors 1184 potential and preventable ADEs Omitted administration Potential ADE = 105 (8%) Preventable ADE = 5 (10%)
Isaac *et al.* [22] 2012	No set definition	Small study in paediatric ICU. Multidisciplinary panel opinion of the clinical significance of omission using the National Reporting and Learning Scheme scoring system.	1995 prescribed doses for 18 patients	6.5% (129) doses
Wright [23] 2013	Delayed and omitted doses allocated to six categories: blank space on administration record, drug not available, patient refused, route not available, patient away from ward, other	Point incident audit across 45 acute trusts, 4 community health trusts and 5 mental health trusts	6062 patients prescribed 21 825 antimicrobial doses	5.3% (1,151) were omitted 19% (221) of omitted doses due to drug not available
North America				
Barker *et al.* [10] 2002	Failure to give an ordered dose. Not including refusal or therapeutic omissions	36 American hospitals randomly selected. Direct observation 50 doses per Unit	3216 doses	19% (605/3216) doses given in error 30% (183/605) of errors were omissions
Shermock *et al.* [15] 2013	Dose of pharmacologic VTE prophylaxis drugs not administered including those refused by the patient	Retrospective review electronic medication administration records, computerized provider order entry system data	103 160 ordered VTE prophylaxis doses	11.9% (12 239) of ordered doses not administered, including 7217 refused. 4.8% (5,022) omitted without valid reason
Hou *et al.* [24] 2012	Incorrect administrations defined as: (1) missing doses or (2) incorrect schedule from that ordered by physicians, with a discrepancy of less than or greater than 30 min	Parkinson's Disease Research, Education and Clinical Center A barcode-based computerized medication administration system within the electronic medical record provided information of the exact time the medication was given to a patient	3873 doses, 89 patients with Parkinson's Disease	8.3% of total (322) 7.7% of total prescribed (300 doses) were given >30 min late whereas 53 doses (7.9% of incorrect administrations, 1.4% of total prescribed doses) were given >30 min earlier than scheduled.
ISMP Canada [25] 2013	Reported incidents: -doses not given, including inadvertent discontinuation. -'dose omission' causing harm	National System for Incident Reporting over 2.5 years	No denominator	159 incidents

should decrease medication-related incidents, although this has not been tested. Further funding has allowed the education package to be further developed into a self-learning module for nursing staff.

The introduction of electronic prescribing may not necessarily decrease risk of omitted and delayed medicines. An Australian audit of an electronic medication prescribing and administration system indicated that missed doses were not eliminated by electronic systems [14]. Similarly, an American audit of venous thromboembolism (VTE) prophylaxis in a hospital using fully electronic medication management systems showed an 11.9% omitted dose rate, but this included doses refused by patients [15]. The rates of omitted doses in our study using the paper-based audit tool are similar to the rates in these studies using electronic systems, which captured tens of thousands of doses. The audit tool thus reflects trends and may be used to evaluate the impact of electronic medication management systems on the rates of omitted doses. To improve usability, the paper-based audit tool can be adapted to an electronic format, as both a stand-alone audit and as part of a comprehensive chart audit, such as the Australian Commission on Safety and Quality in Health Care (ACSQHC) NIMC audit [11].

The major limitation to the audit is the interpretation of 'outcome'. Negative outcomes were noted, but it was difficult to ascertain whether these were solely due to dose omission. In addition, outcomes may not be immediately apparent. The study by Louis *et al*. found that omitting two or more enoxaparin prophylaxis doses significantly increased the risk of VTE [16]. As it is important to investigate clinical outcomes, this limitation may be overcome by a clinician review of each critical missed dose incident. This was not undertaken for the project, as its main aim was to develop the audit tool. The absence of a signature on the administration section of a chart may be a 'failure to document' rather than a genuine medication omission, thus overestimating omission rates. However, this information is still important to collect, as poor documentation often involves increased time taken to check whether administration has occurred or lead to double dosing.

Lessons learned

Omitted doses in health care facilities are a global medication safety issue. The many studies published show an omitted dose rate of around 1 dose in 10, some of which harm patients, many of which take time to resolve and all of which are preventable. Although developed in one Australian state, the audit package is simple and applicable to wherever medications are dispensed and administered. In addition, the package focuses on time-critical medications, using practical definitions and the clinically meaningful outcome of patient harm. The time-critical medication list can be adapted to local settings and integrated into medication administration guidelines. As nursing staff is responsible for the administration of most medications, the audit ideally should be part of a suite of nursing bedside audits. The package can be integrated as part of ongoing medication safety quality improvement activities and can be used for accreditation purposes.

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