



Risk Factors Associated with Medication Administration Errors in Children: A Prospective Direct Observational Study of Paediatric Inpatients

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Abstract

Introduction Limited evidence exists regarding medication administration errors (MAEs) on general paediatric wards or associated risk factors exists.

Objective The aim of this study was to identify nurse, medication, and work-environment factors associated with MAEs among paediatric inpatients.

Methods This was a prospective, direct observational study of 298 nurses in a paediatric referral hospital in Sydney, Australia. Trained observers recorded details of 5137 doses prepared and administered to 1530 children between 07:00 h and 22:00 h on weekdays and weekends. Observation data were compared with medication charts to identify errors. Clinical errors, potential severity and actual harm were assessed. Nurse characteristics (e.g. age, sex, experience), medication type (route, high-risk medications, use of solvent/diluent), and work variables (e.g. time of administration, weekday/weekend, use of an electronic medication management system [eMM], presence of a parent/carer) were collected. Multivariable models assessed MAE risk factors for any error, errors by route, potentially serious errors, and errors involving high-risk medication or causing actual harm.

Results Errors occurred in 37.0% ($n = 1899$; 95% confidence interval [CI] 35.7–38.3) of administrations, 25.8% ($n = 489$; 95% CI 23.8–27.9) of which were rated as potentially serious. Intravenous infusions and injections had high error rates (64.7% [$n = 514$], 95% CI 61.3–68.0; and 77.4% [$n = 188$], 95% CI 71.7–82.2, respectively). For intravenous injections, 59.7% (95% CI 53.4–65.6) had potentially serious errors. No nurse characteristics were associated with MAEs. Intravenous route, early morning and weekend administrations, patient age ≥ 11 years, oral medications requiring solvents/diluents and eMM use were all significant risk factors. MAEs causing actual harm were 45% lower using an eMM compared with paper charts.

Conclusion Medication error prevention strategies should target intravenous administrations and not neglect older children in hospital. Attention to nurses' work environments, including improved design and integration of medication technologies, is warranted.

Key Points

Over one-third of medications administered to children contained one or more errors and 25.8% were potentially serious.

Risk factors included intravenous medications, oral medication requiring solvents and children ≥ 11 years of age.

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1 Introduction

Medication errors among paediatric inpatients continue to be a significant safety issue in hospitals around the world [1]. Medication administration errors (MAEs), compared with prescribing errors, pose particular risk as opportunities for detection and prevention are reduced. While several studies examining the prevalence of MAEs in neonatal and paediatric intensive care units have been undertaken [1, 2], much less is known about MAEs occurring on general paediatric medical and surgical wards, including factors that increase the risk of errors [1, 3].

The quality of evidence about MAEs is limited, with many published studies relying on retrospective analysis of incident reports, which have been consistently shown to significantly underrepresent errors that occur in practice [4, 5]. Chart reviews have also been used to identify the prevalence and nature of MAEs, however the accuracy of these estimates are reliant on good documentation in patient records when an administration error has been detected, and thus are also likely to underestimate error rates [1]. Direct observation of the administration process is the most reliable and accurate method for measuring MAEs, but it is resource intensive and few studies have applied this method on general paediatric wards [1, 6].

Knowledge of factors associated with errors is central to developing and applying effective strategies for prevention. Multiple factors have been proposed as increasing the risk of errors. A systematic review of studies in neonatal intensive care identified six studies that reported causes or contributory factors (defined as any factor that study authors identified as contributory) [7]. Non-adherence to policies and guidelines, and rule or knowledge-based mistakes, along with ‘error-provoking’ environments (including noise, lighting, staff mix, training, and fatigue) were described; however, quantification of these effects was not made.

Increased nurse education and experience were found to be associated with self-reports of MAEs in a Canadian survey of 375 randomly selected nurses in three paediatric hospitals [8]. Nurses with a longer history of working on a ward reported more administration errors than those who had spent less time on the ward, and those with greater clinical experience reported fewer potentially severe errors compared with nurses with less clinical experience. However, no relationship between nursing education and frequency of MAEs or severity of errors was found.

In adult hospitals, intravenous medications have been identified as at significantly greater risk of error, but there is limited equivalent contemporary evidence for children [9–12]. A systematic review of the causes of in-hospital intravenous medication errors identified a range of factors

implicated in administration errors, including nurse knowledge and skills (e.g. lack of knowledge of the drug, calculation skills); equipment problems (e.g. poor standardisation in electronic medication systems or ineffective decision support); confusion in identifying similar looking equipment (e.g. syringes, infusion bags, tubing); and procedural deviations (e.g. failures in double-checking, communication errors) [9]. None of the 11 studies included related to intravenous administration on general paediatric wards. Information on risk factors for intravenous administration errors among children is virtually non-existent.

Our aim was to undertake a prospective, direct observational study on general paediatric wards to identify the prevalence of MAEs and nurse, medication and work-environmental factors associated with MAEs.

2 Methods

2.1 Sample

We conducted a prospective direct observational study of medication administrations at a 340-bed, tertiary paediatric referral hospital in Sydney, Australia. The hospital provides a complex and comprehensive range of services for children and adolescents and is one of only two paediatric hospitals serving the 8.2 million population of the state of New South Wales. The study was part of an investigation on the effects of the introduction of an electronic medication management system (eMM) at the hospital [13, 14], but data collection was extended in the present study to include weekends as well as weekdays. Ethics approval was granted by Sydney Children’s Hospital Network Human Research Ethics Committee (HREC/15/SCHN/370).

2.2 Procedures

Information sessions were held on nine medical and surgical wards to explain the study and invite nurses to participate, followed by directly approaching nurses to invite them to participate. Oncology and intensive care units were excluded from the study. In total, 298 nurses agreed to participate (representing > 95% of nursing staff on those wards). Nurses provided written consent to be observed while preparing and administering medications. Information about nurse characteristics was recorded (e.g. age, sex, years of nursing experience, nurse role, employment status [full-time/part-time], ward, and whether they usually worked on the ward on which they were observed). Nurse role was defined according to their employment grade, which ranges from Grade 1 (first-year nurse) to Grade 8+. Specialist nurses (e.g. nurse practitioners, clinical nurse consultants, clinical nurse educators, and clinical nurse specialists) were grouped together.

Observers attended wards to conduct observations at the key medication administration times between the hours of 07:00 and 22:00 on weekdays and weekends over 22 weeks. Observation shifts were arranged into five blocks (07:00–10:00 h, 11:00–13:00 h, 13:00–15:00 h, 17:00–19:00 h, and 19:30–22:00 h). Observers randomly selected a nurse to shadow (from a list of consented nurses on that ward). We have applied this technique in a previous study in adult hospitals [15].

Observers ($n = 7$) were all health professionals (nurses or pharmacists) who underwent extensive training in undertaking observations. This training included a range of scenario cases in workshops, and simulated cases using videos and in-field practice sessions over several weeks. All observers were trained to use the study electronic data collection tool, the Precise Observation System for the Safe Use of Medicines (POSSUM), provided on a handheld tablet device [16]. This tool provides a range of dropdown menus and radio buttons to support observers to record information quickly and accurately in the field. Observers were required to record all details of the medication being observed (e.g. name, strength, dose, and route of administration) and were not permitted to view patients' medication charts during observations. Observers were instructed not to intervene unless they witnessed an administration error that was potentially dangerous. If intervention was required, observers followed a predefined protocol (Online Resource File 1). Observers also recorded compliance with specific administration-related procedures (e.g. double-checking) and these results have been reported elsewhere [17]. If a parent or carer was at the patient's bedside during administration, this was recorded by observers.

One observer was chosen as the gold-standard data collector. This individual had extensive clinical nursing experience and was involved in all stages of observation protocol development, observer training and pilot testing. Interrater reliability was assessed on multiple occasions until all the other observers reached substantial to perfect consistency with the gold-standard observer (kappa scores > 0.83 for medication strength, > 0.93 for medication form, 1.0 for route).

Following the completion of observation sessions, one researcher compared the observational data against individual patients' medication records to identify MAEs. MAEs were defined as administrations that deviated from the prescriber's medication order documented in the patient's chart, the manufacturers' preparation/administration instructions, or relevant hospital medication administration policies (Online Resource File 1). MAEs were classified according to predefined error categories (Online Resource File 1); they included wrong timing errors (defined as medication doses administered > 60 min before or after the prescribed time). Dose errors were administrations more than 10% over or

under the prescribed dose. Wrong rate of intravenous injection was defined as an injection administration time that was over 15% faster or slower than recommended. During the chart review, each patient's age and sex were recorded. All intravenous infusions were administered with a pump, while intravenous injections were administered with a manual push and not a syringe driver.

The potential severity of MAEs was classified according to their potential for harm using a five-point scale adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [18] [Online Resource File 1]. If multiple errors occurred in the same dose administration, potential harm severity was based on the cumulative effect of all errors. MAEs with a potential severity score of ≥ 3 were reviewed by a clinical panel comprising a paediatrician, paediatric nurse and pharmacist and/or clinical pharmacologist to determine whether there was evidence in the patient's record that actual harm had resulted from the errors [19].

2.3 Statistical Analysis

Nurse characteristics examined included age group, role, employment status, years of experience, and sex (Online Resource File 2). Medication factors included route of administration, use of a high-risk medication, and use of a solvent/diluent. Patient characteristics used were age and sex, and work-environment factors were weekend/weekday, nurses working on their usual ward, time of actual administration, whether a parent/carer was at the bedside at time of administration, ward, and use of eMM system or a paper medication chart. High-risk medications were defined by the hospital as anti-infectives, potassium and other electrolytes, insulin, narcotics/opioids and sedatives, chemotherapy agents, and heparin and other anticoagulants [20].

Descriptive analyses were undertaken to report the frequency and characteristics of medication administrations, medication error types by route, nurse and patient characteristics, and work-environment contextual factors. For analyses, all clinical errors rated as ≥ 3 on the 5-point severity scale were categorised as potentially serious.

We used multilevel logistic regression models to examine the association between nurse, patient and contextual work-environment characteristics and error occurrence, including ward as a random effect to account for the correlation of drugs administered in the same ward. The dependent variable was whether an administration had one or more errors, because the number of opportunities for error depended on the route of administration. Variables with a p -value of < 0.1 in univariable models were included in a multivariable model and removed if $p > 0.05$ (likelihood ratio test). Type of medication chart (eMM or paper) used was retained in multivariable models regardless of its significance. Separate

models were fit for potentially serious errors and for administrations involving high-risk medications. Similarly, associations with MAEs that led to actual harm were modelled using multilevel logistic regression. Associations between characteristics and errors for specific routes of administration (oral, intravenous infusion, intravenous injection) were assessed using multilevel Poisson regression models of the number of errors for each administration, considering the number of opportunities for error occurrence by different routes. The same modelling strategy described above was applied. We also assessed the association between characteristics and dose errors applying a multilevel logistic model using the same modelling strategy. The data manipulation was completed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA) and analysis was conducted using R (The R Foundation for Statistical Computing, Vienna, Austria).

3 Results

In total, 5137 medication administration doses were observed for 1530 unique patients. Table 1 reports descriptive statistics for the sample and shows that the majority (72.2%, $n = 3711$) of medications were administered orally. Nurses between the ages of 18 and 29 years (45.2%, $n = 2320$) and those with 4 years or less clinical experience (43.5%, $n = 2234$) administered the greatest proportion of medications to patients.

3.1 Medication Administration Errors by Route, Type and Potential Severity

Of the 5137 medication administrations observed, 37.0% ($n = 1899$, 95% confidence interval [CI] 35.7–38.3) contained one or more errors. Of all errors, 25.8% (95% CI 23.8–27.9) were rated as potentially serious. Intravenous medications had a high frequency of errors. Overall, 64.7% of intravenous infusions and 77.4% of intravenous injections had one or more errors and a high proportion of these intravenous injections (59.7%) were rated as potentially serious (Table 2).

Table 3 reports error rates by type and shows wrong timing errors were the most frequent (12.2%, $n = 622$; 95% CI 11.4–13.2). Of oral medications requiring a solvent/diluent ($n = 875$) 14.7% had the incorrect solvent/diluent and 33.3% had the incorrect volume of solvent/diluent (Table 4). Wrong solvent/diluent volume errors were also common (43.9%, $n = 274$) for intravenous infusions (Table 5). Over two-thirds (68.3%, $n = 164$) of intravenous injections were administered faster than the recommended duration and 24.9% ($n = 60$) were administered via the incorrect route (Table 6).

Table 1 Descriptive details of the sample

| | Medication administrations [$n = 5137$] (%) |
|-------------------------|---|
| Route | |
| Oral | 3711 (72.2) |
| Intravenous infusion | 794 (15.5) |
| Intravenous injection | 243 (4.7) |
| Inhalation | 177 (3.4) |
| Other non-injectable | 145 (2.8) |
| Other injection | 67 (1.3) |
| eMM | |
| Yes | 3013 (58.7) |
| No | 2124 (41.3) |
| Time of day | |
| Morning (07:00–09:59 h) | 1719 (33.5) |
| Day (10:00–15:59 h) | 1434 (27.9) |
| Evening (16:00–22:00 h) | 1984 (38.6) |
| Weekend/weekday | |
| Weekday | 4113 (80.1) |
| Weekend | 1024 (19.9) |
| Parent/carer at bedside | |
| Yes | 4610 (89.7) |
| No | 527 (10.3) |
| High-risk drug | |
| No | 4671 (90.9) |
| Yes | 466 (9.1) |
| Nurse sex | |
| Female | 4792 (93.3) |
| Male | 345 (6.7) |
| Nurse age, years | |
| 18–29 | 2320 (45.2) |
| 30–39 | 1105 (21.5) |
| 40–49 | 1125 (21.9) |
| ≥ 50 | 587 (11.4) |
| Nurse role | |
| RN Grade 1 | 552 (10.7) |
| RN Grade 2–3 | 1142 (22.2) |
| RN Grade 4–5 | 519 (10.1) |
| RN Grade 6–7 | 387 (7.5) |
| RN Grade 8+ | 1503 (29.3) |
| EN | 383 (7.5) |
| NP/CNC/CNE/CNS | 651 (12.7) |
| Nurse employment status | |
| Full-time | 3968 (77.2) |
| Part-time, FTE ≥ 0.5 | 968 (18.8) |
| Part-time, FTE < 0.5 | 201 (3.9) |
| Nurse experience, years | |
| 0–1 | 958 (18.6) |
| 2–4 | 1276 (24.8) |
| 5–9 | 869 (16.9) |
| 10–14 | 486 (9.5) |

Table 1 (continued)

| | Medication administrations [<i>n</i> = 5137] (%) |
|---------------------|---|
| ≥ 15 | 1548 (30.1) |
| Nurse on usual ward | |
| Yes | 4891 (95.2) |
| No | 246 (4.8) |
| Patient sex | |
| Female | 2592 (50.5) |
| Male | 2545 (49.5) |
| Patient age, years | |
| 0 | 828 (16.1) |
| 1–2 | 749 (14.6) |
| 3–5 | 610 (11.9) |
| 6–10 | 894 (17.4) |
| 11–15 | 1205 (23.5) |
| ≥ 16 | 851 (16.6) |
| Ward ^a | |
| A | 616 (12.0) |
| B | 877 (17.1) |
| C | 618 (12.0) |
| D | 707 (13.8) |
| E | 444 (8.6) |
| F | 671 (13.1) |
| G | 576 (11.2) |
| H | 628 (12.2) |

CNC clinical nurse consultant, CNE clinical nurse educator, CNS clinical nurse specialist, eMM electronic medication management system, EN enrolled nurse, FTE full-time equivalent, NP nurse practitioner, RN registered nurse

^a Two wards were grouped together due to their similar patient mix

3.2 Risk Factors Associated with Medication Administration Errors (MAEs)

Using a multivariable model, we found that MAEs overall were significantly higher for medications administered: via an intravenous route, with the use of an eMM, on the weekend, or to children ≥ 11 years of age (Table 7). For oral medications, errors were significantly higher for children ≥ 11 years of age or for those medications administered in the evening. Oral medications that required a solvent or diluent had an error rate three times higher than oral medications that did not require a solvent/diluent (adjusted incident rate ratio [aIRR] 3.09, 95% CI 2.78–3.43). These errors were also significantly more likely to be rated as potentially serious (aIRR 1.65, 95% CI 1.37–2.00) [Table 8].

Medications administered using an intravenous injection were more than 19 times as likely to have an MAE compared with oral administrations, and intravenous infusions were more than six times as likely to have an error (Table 7). Intravenous administrations of high-risk medications had significantly greater error rates than oral administrations of these medications (intravenous injections: adjusted odds ratio [aOR] 37.73, 95% CI 7.47–190.53; intravenous infusions: aOR 9.04, 95% CI 4.73–17.28; *p* < 0.001). No nurse characteristics were associated with risk of MAEs.

Given that dose errors have been consistently identified in the literature as one of the most frequent MAEs, we investigated factors associated with these errors. We found dose errors were significantly more frequent in the morning (07:00–09:59 h) compared with during the day (10:00–15:59 h; aOR 1.49, 95% CI 1.02–2.19) and evening (16:00–22:00 h; aOR 1.80, 95% CI 1.26–2.56) [*p* < 0.001].

Table 2 Crude percentage of medication administrations with one or more errors

| | Number of administrations ^a | Administrations with error | | | | Administrations with a potentially serious error | | | |
|-----------------------|--|----------------------------|------|--------|--------|--|------|---------|------|
| | | <i>N</i> | % | 95% LL | 95% UL | <i>N</i> | % | 95% CIs | |
| All | 5137 | 1899 | 37.0 | 35.7 | 38.3 | 489 | 9.5 | 8.7 | 10.4 |
| High-risk medications | 466 | 89 | 19.1 | 15.8 | 22.9 | 33 | 7.1 | 5.1 | 9.8 |
| Route | | | | | | | | | |
| Oral | 3711 | 1116 | 30.1 | 28.6 | 31.6 | 232 | 6.3 | 5.5 | 7.1 |
| Intravenous infusion | 794 | 514 | 64.7 | 61.3 | 68.0 | 83 | 10.5 | 8.5 | 12.8 |
| Intravenous injection | 243 | 188 | 77.4 | 71.7 | 82.2 | 145 | 59.7 | 53.4 | 65.6 |
| Inhalation | 177 | 44 | 24.9 | 19.1 | 31.7 | 11 | 6.2 | 3.5 | 10.8 |
| Other non-injectable | 145 | 28 | 19.3 | 13.7 | 26.5 | 13 | 9.0 | 5.3 | 14.7 |
| Other injection | 67 | 9 | 13.4 | 7.2 | 23.6 | 5 | 7.5 | 3.2 | 16.3 |

LL lower limit, UL upper limit, CIs confidence intervals

^aNumber of administrations for which the error is relevant and was assessed, i.e. those administrations where there was an opportunity for error of this type

Table 3 Crude percentage of medication administrations with errors, by type

| Error type | Number of administrations ^a | Administrations with error | | | |
|---|--|----------------------------|------|---------|------|
| | | N | % | 95% CIs | |
| Wrong drug | 5137 | 42 | 0.8 | 0.6 | 1.1 |
| Wrong dose | 5095 | 200 | 3.9 | 3.4 | 4.5 |
| Wrong form | 5095 | 113 | 2.2 | 1.8 | 2.7 |
| Wrong strength | 5095 | 75 | 1.5 | 1.2 | 1.8 |
| Drug incompatibility | 5095 | 26 | 0.5 | 0.3 | 0.7 |
| Patient allergy | 5094 | 2 | 0.0 | 0.0 | 0.1 |
| Wrong timing | 5088 | 622 | 12.2 | 11.4 | 13.2 |
| Wrong route | 4410 | 174 | 3.9 | 3.4 | 4.6 |
| Oral method not according to instructions | 2970 | 232 | 7.8 | 6.9 | 8.8 |
| Wrong solvent or diluent | 1725 | 279 | 16.2 | 14.5 | 18.0 |
| Wrong volume of solvent or diluent | 1724 | 612 | 35.5 | 33.3 | 37.8 |
| Wrong IV rate or duration | 1028 | 461 | 44.8 | 41.8 | 47.9 |
| Wrong IV line type | 823 | 1 | 0.1 | 0.0 | 0.7 |
| Wrong IV infusion device | 791 | 4 | 0.5 | 0.2 | 1.3 |
| Wrong IV additive | 788 | 4 | 0.5 | 0.2 | 1.3 |
| Wrong IV additive volume | 783 | 3 | 0.4 | 0.1 | 1.1 |

^aNumber of administrations for which the error is relevant and was assessed, i.e. those administrations where there was an opportunity for error of this type. Some error types do not apply to specific routes of administration. Where the error was 'wrong drug' ($n = 42$), no other errors were assessed. Other errors may not have been assessed if the observer was unable to record a relevant detail. Online Resource File 3 provides further details of each error type

CI confidence intervals, IV intravenous

3.3 Factors Associated with MAEs Rated as Potentially Serious, and MAEs Resulting in Actual Patient Harm

Compared with oral medication administrations, intravenous infusion administrations were significantly more likely to have an MAE rated as potentially serious ($p < 0.001$), as were administrations via intravenous injection (aOR 28.79, 95% CI 20.59–40.25) [Table 7]. MAEs that occurred when nurses used the eMM were more likely to be rated as potentially serious compared with those errors that occurred when a paper medication chart was used (aOR 1.29, 95% CI 1.03–1.61; $p = 0.024$) (Table 8).

Actual harm was identified in 67 administrations with errors (24 oral, 14 intravenous infusions, 29 intravenous injections). Compared with oral administrations, harm was significantly more likely with intravenous injection (aOR 8.02, 95% CI 4.33–14.87) or intravenous infusion (aOR 6.52, 95% CI 3.35–13.08). When the eMM was used, the risk of actual harm was 45% lower than when paper medication charts were used (aOR 0.55, 95% CI 0.32–0.95). Excluding wrong timing errors produced a similar pattern of results (see Online Resource File 3).

4 Discussion

4.1 Prevalence and Types of MAEs

MAEs were highly prevalent, with 37% of medications administered containing one or more clinical error. Intravenous administrations were at substantial risk, with errors identified in 65% of intravenous infusions and 77% of intravenous injections, of which more than half were rated as potentially serious errors. Intravenous injections had an error rate 19 times greater than oral administrations and these errors were more than 28 times as likely to be potentially serious. High-risk medications delivered via intravenous injection had more than 38 times the risk of an error compared with oral administration of these medications. Our findings confirm concerns about the higher prevalence of administration errors in children relative to prescribing errors. MAE rates were more than double the 17.6% (95% CI 17.0–18.2) prescribing error rate reported from the same hospital during the same period [19].

Comparative contemporary data on MAEs from paediatric general wards are very limited. The 2019 systematic review by Gates et al. identified six studies of MAEs on general paediatric wards, with one rated as good quality

Table 4 Crude percentage of oral administrations with error, by type ($n = 3711$)

| Error type | Number of administrations ^a | Administrations with error | | | |
|---|--|----------------------------|------|---------|------|
| | | <i>N</i> | % | 95% CIs | |
| Not requiring solvent | | | | | |
| Wrong drug | 2825 | 15 | 0.5 | 0.3 | 0.9 |
| Wrong timing | 2810 | 338 | 12.0 | 10.9 | 13.3 |
| Wrong dose | 2810 | 112 | 4.0 | 3.3 | 4.8 |
| Wrong form | 2810 | 61 | 2.2 | 1.7 | 2.8 |
| Wrong strength | 2810 | 46 | 1.6 | 1.2 | 2.2 |
| Drug incompatibility | 2810 | 2 | 0.1 | 0.0 | 0.3 |
| Allergy | 2810 | 1 | 0.0 | 0.0 | 0.2 |
| Wrong route | 2418 | 36 | 1.5 | 1.1 | 2.1 |
| Oral method not according to instructions | 1945 | 68 | 3.5 | 2.8 | 4.4 |
| Requiring solvent | | | | | |
| Wrong drug | 886 | 11 | 1.2 | 0.7 | 2.2 |
| Wrong timing | 875 | 168 | 19.2 | 16.7 | 21.9 |
| Wrong solvent or diluent | 875 | 129 | 14.7 | 12.5 | 17.2 |
| Wrong volume of solvent or diluent | 874 | 291 | 33.3 | 30.2 | 36.5 |
| Wrong form | 875 | 46 | 5.3 | 4.0 | 6.9 |
| Wrong dose | 875 | 39 | 4.5 | 3.3 | 6.0 |
| Wrong strength | 875 | 21 | 2.4 | 1.6 | 3.6 |
| Drug incompatibility | 875 | 8 | 0.9 | 0.5 | 1.8 |
| Allergy | 875 | 0 | 0.0 | 0.0 | 0.4 |
| Oral method not according to instructions | 854 | 161 | 18.9 | 16.4 | 21.6 |
| Wrong route | 663 | 22 | 3.3 | 2.2 | 5.0 |

^aNumber of administrations for which the error is relevant and was assessed, i.e. those administrations where there was an opportunity for error of this type. Some error types do not apply to specific routes of administration. Where the error was 'wrong drug', no other errors were assessed. Other errors may not have been assessed if the observer was unable to record a relevant detail (Online Resource File 3)

CIs confidence intervals, *IV* intravenous

conducted in 2004 [1]. Five studies were undertaken in hospitals with paper medication charts and reported MAE rates ranging from 8.6 to 44.3 errors per 100 administrations [1]. Heterogeneity across studies in terms of error definitions and data collection methods hinder accurate comparisons. However, our results would suggest that interventions to date appear to have had limited effect in reducing overall MAE rates in paediatric patients. A 2020 systematic review of intravenous medication errors in the UK [11] contained four studies of intravenous administrations to paediatric inpatients and estimated a pooled MAE rate of 45.1% (95% CI 42.0–48.2). Across adult and paediatric studies, a very consistent finding is the high rate of errors among intravenous medications compared with oral medications regardless of setting or country [10, 11, 21, 22].

Our study provides new insights into the specific types of intravenous errors occurring that warrant attention. We found errors in the selection and volume of solvents and diluents were considerable. Oral administrations requiring a solvent/diluent were more than three times as likely to have an error compared with those that did not. Solvents/

diluents were also associated with a high proportion of errors in intravenous infusions, with 44% having an incorrect volume of a solvent/diluent. A particular challenge in preparing paediatric doses is the need to often reconstitute adult preparations requiring multiple, time-consuming steps. The lack of paediatric-specific formulations for many oral medications means adult formulations must be modified using methods such as crushing and dissolving in liquid to give a partial dose. The added complexity of smaller intravenous doses requiring partial vials, combined with different guidelines for administration based on the age of the child, may increase the risk of errors. Greater availability of ready to use (including patient-specific, formulations and standardised guidelines for modifying and administering partial doses of adult dosing forms) may assist in the prevention of some of these errors. Studies have demonstrated this is feasible in paediatric settings, including incorporating standardised medication preparation guidelines in the eMM [23, 24].

Intravenous rate or duration errors were also frequent, occurring in 38% of intravenous infusions and 68% of intravenous injection administrations. The intravenous injections

Table 5 Crude percentage of administrations by intravenous infusions with error, by type ($n = 794$)

| Error type | Number of administrations ^a | Administrations with error | | | |
|------------------------------------|--|----------------------------|------|---------|------|
| | | <i>N</i> | % | 95% CIs | |
| Wrong drug | 794 | 3 | 0.4 | 0.1 | 1.1 |
| Wrong route | 791 | 52 | 6.6 | 5.0 | 8.5 |
| Wrong dose | 791 | 22 | 2.8 | 1.8 | 4.2 |
| Drug incompatibility | 791 | 15 | 1.9 | 1.2 | 3.1 |
| Wrong IV infusion device | 791 | 4 | 0.5 | 0.2 | 1.3 |
| Wrong strength | 791 | 3 | 0.4 | 0.1 | 1.1 |
| Allergy | 791 | 2 | 0.3 | 0.1 | 0.9 |
| Wrong form | 791 | 2 | 0.3 | 0.1 | 0.9 |
| Wrong IV rate or duration | 788 | 297 | 37.7 | 34.4 | 41.1 |
| Wrong IV additive | 788 | 4 | 0.5 | 0.2 | 1.3 |
| Wrong IV additive volume | 783 | 3 | 0.4 | 0.1 | 1.1 |
| Wrong timing | 787 | 56 | 7.1 | 5.5 | 9.1 |
| Wrong solvent or diluent | 624 | 143 | 22.9 | 19.8 | 26.4 |
| Wrong volume of solvent or diluent | 624 | 274 | 43.9 | 40.1 | 47.8 |
| Wrong IV line type | 597 | 0 | 0.0 | 0.0 | 0.6 |

^aNumber of administrations for which the error is relevant and was assessed, i.e. those administrations where there was an opportunity for error of this type. Some error types do not apply to specific routes of administration. Where the error was 'wrong drug', no other errors were assessed. Other errors may not have been assessed if the observer was unable to record a relevant detail (Online Resource File 3)

CIs confidence intervals, *IV* intravenous

Table 6 Crude percentage of intravenous injections with error, by type ($n = 243$)

| Error type | Number of administrations ^a | Administrations with error | | | |
|---------------------------|--|----------------------------|------|---------|------|
| | | <i>N</i> | % | 95% CIs | |
| Wrong drug | 243 | 2 | 0.8 | 0.2 | 3.0 |
| Wrong route | 241 | 60 | 24.9 | 19.9 | 30.7 |
| Wrong dose | 241 | 14 | 5.8 | 3.5 | 9.5 |
| Drug incompatibility | 241 | 1 | 0.4 | 0.0 | 2.3 |
| Wrong form | 241 | 1 | 0.4 | 0.0 | 2.3 |
| Wrong strength | 241 | 1 | 0.4 | 0.0 | 2.3 |
| Allergy | 241 | 0 | 0.0 | 0.0 | 1.6 |
| Wrong IV rate or duration | 240 | 164 | 68.3 | 62.2 | 73.9 |
| Wrong timing | 240 | 10 | 4.2 | 2.3 | 7.5 |
| Wrong IV line type | 226 | 1 | 0.4 | 0.0 | 2.5 |
| Wrong solvent | 185 | 5 | 2.7 | 1.2 | 6.2 |
| Wrong volume of solvent | 185 | 45 | 24.3 | 18.7 | 31.0 |

^aNumber of administrations for which the error is relevant and was assessed. Some error types do not apply to specific routes of administration. Where the error was Wrong Drug, no other errors were assessed. Other errors may not have been assessed if the observer was unable to record a relevant detail (Online Resource File 3)

CIs confidence intervals, *IV* intravenous

were delivered via manual push and not a syringe driver, and rate errors were often due to pushes that were faster than recommended guidelines. Work time pressures, pushing small

volumes for paediatric patients, as well as lack of knowledge of recommendations or the potential consequences of 'fast' pushes may all have contributed to this practice [25]. Two studies [6, 20] have also suggested poor calculation skills among nurses may be a contributor to both volume and rate errors. During a paediatric simulation study, Jones and colleagues [32] identified that discrepancies in the application of intravenous guidelines (which included not interpreting or applying information in guidelines) were directly implicated in a range of MAEs observed. The authors recommended greater attention be placed on user testing guidelines prior to dissemination to improve their application and reduce MAEs. Subsequently, they undertook an assessment demonstrating the potential cost savings of improving intravenous guidelines in the National Health Service in the UK [33].

Intravenous infusions in our study were administered with traditional infusion pumps. Smart infusion pumps are designed to reduce errors that may occur with infusion pumps by having preset parameters for drugs, concentrations and dosing limits (known as drug libraries) and alerting users to entries outside these limits. The effectiveness of these devices is dependent on the use of the pump library, correct programming and entering of drug names and doses, and also responding to any alerts given [21, 26–28]. In a UK study [29] of intravenous infusions in 16 hospitals, smart pumps were found to have no significant effect on error rates, and greater attention to the use and management of smart pumps has been recommended [30].

Table 7 Factors associated with the occurrence of MAEs and potentially serious MAEs for all administrations

| | One or more MAEs | | | MAEs rated as potentially serious | | |
|---------------------------------|------------------|-------------|-----------------|-----------------------------------|-------------|-----------------|
| | aOR | 95% CIs | <i>p</i> -Value | aOR | 95% CIs | <i>p</i> -Value |
| Route (ref = oral) | | | < 0.0001 | | | < 0.0001 |
| Intravenous infusion | 6.25 | 5.16 7.58 | | 1.87 | 1.42 2.46 | |
| Intravenous injection | 19.24 | 13.46 27.50 | | 28.79 | 20.59 40.25 | |
| Inhalation | 0.70 | 0.49 1.01 | | 0.89 | 0.47 1.67 | |
| Other non-injectable | 0.99 | 0.63 1.57 | | 1.66 | 0.91 3.02 | |
| Other injection | 0.51 | 0.24 1.06 | | 1.61 | 0.63 4.11 | |
| eMM status (ref = paper) | | | 0.02 | | | 0.02 |
| eMM | 1.18 | 1.03 1.36 | | 1.29 | 1.03 1.61 | |
| Weekday/weekend (ref = weekday) | | | 0.04 | | | |
| Weekend | 1.18 | 1.01 1.39 | | | | |
| Patient age, years (ref = < 1) | | | < 0.0001 | | | |
| 1–2 | 1.24 | 0.97 1.58 | | | | |
| 3–5 | 0.95 | 0.73 1.23 | | | | |
| 6–10 | 1.27 | 1.00 1.60 | | | | |
| 11–15 | 1.55 | 1.24 1.94 | | | | |
| ≥16 | 1.69 | 1.30 2.19 | | | | |

aOR adjusted odds ratio, eMM electronic medication management system, CIs confidence intervals, MAEs medication administration errors

All models included 'ward' as a random effect

Table 8 Factors associated with MAEs and potentially serious MAEs for all oral administrations

| | MAEs | | | MAEs rated as potentially serious | | |
|---|------|-----------|-----------------|-----------------------------------|-----------|-----------------|
| | aIRR | 95% CIs | <i>p</i> -value | aIRR | 95% CIs | <i>p</i> -value |
| eMM status (ref = paper) | | | 0.4 | | | 0.045 |
| eMM | 1.05 | 0.93 1.18 | | 1.24 | 1.00 1.54 | |
| Solvent/diluent used (ref = no) | | | < 0.001 | | | < 0.001 |
| Yes | 3.09 | 2.78 3.43 | | 1.65 | 1.37 2.00 | |
| Time of day (ref = day [10:00–15:59 h]) | | | < 0.001 | | | |
| Morning (7:00–9:59 h) | 1.09 | 0.91 1.30 | | | | |
| Evening (16:00–22:00 h) | 1.25 | 1.06 1.47 | | | | |
| Patient age, years (ref = < 1) | | | < 0.001 | | | |
| 1–2 | 1.06 | 0.88 1.27 | | | | |
| 3–5 | 1.01 | 0.81 1.26 | | | | |
| 6–10 | 1.15 | 0.95 1.39 | | | | |
| 11–15 | 1.48 | 1.25 1.75 | | | | |
| ≥ 16 | 1.26 | 1.04 1.53 | | | | |

aIRR adjusted incident rate ratio, eMM electronic medication management system, CIs confidence intervals, MAEs medication administration errors

All models included 'ward' as a random effect

Multisite studies of the use of smart pumps show errors persist, with poor design, usability and integration into local workflows identified as issues requiring greater attention [21, 28, 31]. Thus, the use of smart pumps may have

reduced some errors we identified in our study; however, existing evidence indicates that such technology requires appropriate integration into clinical practice to be effective in practice.

4.2 Nurse, Medication and Work-Environmental Factors Associated with MAEs

We found no nurse characteristics were associated with MAE rates. In a study at two Australian adult hospitals, intravenous error rates were highest among less experienced nurses, but we did not find this effect in paediatric patients [10]. Unlike the self-report survey study of Canadian paediatric nurses [8], we found MAE rate was not related to nurses' clinical experience or whether nurses were working on their usual ward.

We found dose errors were significantly more likely to occur during the early-morning medication round (07:00–09:59 h) when a large proportion of medications require administration. Thus, workload and potentially a greater rate of interruptions at this time may be implicated as contributors to this higher rate of errors. Furthermore, we identified two factors not previously reported as being associated with MAEs, namely an 18% increased risk of MAEs on weekends and a 55–69% increased risk among children aged ≥ 11 years. The weekend effect may be due to differences in staff mix or workloads on weekends compared with weekdays and is worthy of investigation. In terms of compliance with medication safety practices on the weekends, we have shown in a previous analysis [17] that nurses were more likely to follow double-checking procedures on weekends, yet, overall, in that study there was no significant association between double-checking and reduced occurrence or severity of MAEs [17]. Reasons for the increased MAE error rate among older children are unclear. There is limited research evidence noting this association and further investigation to understand possible reasons and whether this relationship exists for other types of medication errors would be appropriate.

Effective interventions to reduce MAEs continue to be elusive. The most recent systematic review on the topic found only 7/26 identified studies used a robust study design. Three of the seven interventional studies focused on technology and four on education and training of nurses. Meta-analysis showed no overall effect in reducing MAEs [34]. Our results demonstrate the importance of continuing to focus on medication safety in paediatrics.

eMM systems have been demonstrated to be effective in reducing prescribing errors in both adult and paediatric inpatients [19, 35]. We found MAEs were higher when eMM was used, and errors that occurred were more likely to be rated as potentially serious compared with MAEs when using paper medication charts. However, MAEs associated with actual harm were 45% lower when an eMM was used compared with paper medication charts. New errors, facilitated by the design and/or use of the eMM system, for example incorrect selections from dropdown menus, and reliance on default options and rounding rules in automatic dose calculators,

were identified as potential contributions to new medication errors and may have contributed to the overall higher rates. Reducing these technology-related errors (TREs) is possible through design changes and is critical to optimise eMM. Investigations of TREs has tended to focus on prescribing errors, and the impact of TREs on MAE rates requires further investigation to optimise the safety and effectiveness of eMM systems for nurses [36–39].

Our study had some limitations. We used a direct observational method and this may have increased nurses' attention and compliance to medication administration guidelines. Thus, error rates identified may be an underestimation of true rates that occur when nurses are not being observed. To reduce these potential effects, our observers spent several weeks on the wards practicing their observational methods before formal data were collected. This allowed observers to become familiar with ward layouts and local practices. This period also allowed nurses to grow accustomed to having observers on the wards. The actual observation period ran for more than 5 months and thus sustained change in nurses' usual practice would have been unlikely. Participation of nurses in the study was high and observation sessions were randomly selected. However, the study was conducted at one large paediatric hospital and results may not be generalisable to other hospitals.

5 Conclusions

This is the largest Australian study of paediatric MAEs and one of the few internationally in the last decade that has investigated error rates on general paediatric wards. The study confirms that MAEs occur frequently and that intravenous medications continue to pose significantly increased risk of error and potential harm. In contrast to previous studies of MAEs among children that have focused on those in neonatal or paediatric intensive care, our findings revealed that older children are also at significant risk, with error rates higher among those aged ≥ 11 years. When an eMM system was used, MAEs causing actual harm were significantly fewer, but continued attention needs to be placed on the effective design and better integration of technological interventions into nurse workflows to support safe and efficient medication administration practices [30, 40]. No nurse characteristics in terms of training or experience were identified. However, our findings suggest that workload factors and environments are likely to play a more significant role in facilitating errors and should be a focus of future interventions.

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Author contributions JW, MR, and LL conceived of and designed the study. AW and MR participated in data collection and error classification with input from EF and AM; VM and AW led the harm classification process with additional clinical expertise from EF and AM. LL, TB and JW designed the analysis strategy undertaken by TB. All authors provided input on the interpretation of findings. JW prepared the first draft of the manuscript and all authors provided input and approved the final version.

Conflict of interest Johanna I Westbrook, Ling Li, Amanda Woods, Tim Badgery-Parker, Virginia Mumford, Alison Merchant, Erin Fitzpatrick and Magdalena Z. Raban have no competing interests to declare that are relevant to the contents of this article.

Ethical approval Sydney Children's Hospital Network Human Research Ethics Committee (HREC/15/SCHN/370).

Availability of data and material The datasets generated during the current study are not available to be accessed from researchers as this is not covered by the project's Human Research Ethics Application.

Code availability Not applicable.

Consent to participate Individual patient consent to access retrospective medication and clinical records was waived by the Human Research Ethics Committee. Nurses provided written consent to participate in the observations.

Consent to publish Not applicable.

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