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Stepped-Wedge Cluster RCT to Assess the Effects of an Electronic Medication System on Medication Administration Errors

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Abstract. Medication errors are a leading cause of preventable harm in hospitals. Electronic medication systems (EMS) have shown success in reducing the risk of prescribing errors, but considerable less evidence is available about whether these systems support a reduction in medication administration errors in paediatrics. Using a stepped wedge cluster randomized controlled trial we investigated changes in medication administration error rates following the introduction of an EMS in a paediatric referral hospital in Sydney, Australia. Direct observations of 284 nurses as they prepared and administered 4555 medication doses was undertaken and observational data compared against patient records to identify administration errors. We found no significant change in administration errors post EMS (adjusted Odds Ratio [aOR] 1.09; 95% CI 0.89-1.32) and no change in rates of potentially serious administration errors (aOR 1.18; 95%CI 0.9-1.56), or those resulting in actual harm (aOR 0.92; 95%CI 0.34-2.46). Errors in administration of medications by some routes increased post EMS. In the first 70 days of EMS use medication administration error rates were largely unchanged.

Keywords. Adverse drug event, electronic health record, nurses, medication administration, paediatrics

1. Introduction

Medication errors in paediatric inpatients continue to be a major safety issue [1]. Electronic medication systems (EMS) are designed to facilitate the medication process and reduce errors. The majority of studies of EMS effectiveness have been undertaken among adult inpatients and have largely investigated the impact on prescribing error rates. There are very few studies which have examined whether the introduction of EMS is associated with reductions in medication administration errors [2,3]. We could find no studies undertaken in paediatric hospitals where changes in medication administration error rates before and after EMS have been reported. Further, many studies of changes in medication error rates following implementation of EMS have been uncontrolled studies, reducing the capacity to draw strong conclusions about study outcomes. Our aim was to conduct a stepped wedge cluster randomized controlled trial of the effect of EMS

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on medication administration error rate, including errors with the potential to cause harm, and errors associated with actual harm in a paediatric hospital.

2. Methods

We conducted a stepped wedge cluster randomized controlled trial(SWCRCT) [4] at a 310-bed paediatric referral hospital in Sydney which provides a complex and comprehensive range of services for children and adolescents across the state of New South Wales (NSW). It is one of only two paediatric hospitals serving the 8.2 million population of NSW.

Nine inpatient wards organised into 8 clusters were included in the trial. Oncology, emergency and intensive care units were excluded. EMS implementation occurred over eight weeks with data collection continuing over two additional weeks to make a total of 10 steps (70 days). The duration of each step was one week. The order in which clusters implemented the EMS was randomized by the research team. During the control period wards used paper medication charts for medication prescribing and administration.

The intervention was an EMS module added to the hospital's existing clinical information system (Cerner Corporation). The EMS allows electronic prescribing, recording of drug dispensing, drug administration and medication reconciliation and monitoring.

2.1. Direct observation of nurses preparing and administering medications

Information sessions for nurses on the study wards were held and nurses were invited to participate and sign consent forms. Once the study commenced, nurses on study wards were also directly approached and invited to consent. Participating nurses provided details regarding their age, gender, qualifications, and years of clinical experience. Trained research nurses prospectively observed ward nurses preparing and administering medications to patients in each cluster during the trial. All medication preparation and administration data were recorded on handheld computers with specialised software – the Precise Observation System for the Safe Use of Medicines POSSUM. All observers were experienced registered nurses or pharmacists and participated in multiple training workshops as well as extensive pilot observational sessions in the field to ensure accuracy and consistency in data recording. Inter-rater reliability assessments were undertaken in the field and continued until all observers achieved a kappa score >0.80 against the gold standard (a registered nurse with extensive POSSUM experience).

Observers attended wards during the core medication drug rounds: 07:00-10:00; 11:00-13:00; 13:00-15:00; 1700-1900; 1930-22:00. Observers were pre-allocated an observation period to ensure coverage of all study wards across the day and the week. Consenting nurses were randomly assigned to be observed. Nurse observers would arrive on their allocated study ward and identify the nurse to be observed. If that nurse was not present, they would go to the next nurse on their list.

For each observation researchers recorded the medical record number and then details of each medication as it was prepared and then administered. Observers did not view patients' medication charts. If observers noticed an error with the potential to cause serious patient harm (e.g., a ten-fold dose of a medication), they were instructed to follow

a 'serious error' protocol and intervene. Each observation was defined as a dose administration event.

Medication administration observations commenced when a nurse picked up a medication chart or opened a chart on the computer. A medication event ended when a drug dose was administered, or the medication was left for the patient to take later.

Observational data were later matched against individual patients' medication charts to determine whether any MAE had occurred. MAEs were classified according to pre-defined error categories previously applied [3]. Clinical errors included wrong timing errors (medication administered >60 minutes before or after the prescribed time). Dose errors were assessed as those 10% over or under the prescribed dose. MAEs were also classified according to their potential for harm using a five-point scale.

2.2. Assessment of actual harm associated with medication administration errors

Errors with an initial potential harm severity score of ≥3 were reviewed by multi-disciplinary harm assessment panels to determine actual harm associated with errors. Detailed case reports (e.g., the patient's medical history, medication administration errors, relevant test results) were prepared. The harm panel reviewed and discussed these cases to gain consensus about any actual harms. Where harm was identified, severity was classified using the Harm Associated with Medication Error Classification (HAMEC) [5].

2.3. Analyses

Multilevel logistic regression was used to estimate the effect of EMS on the occurrence of medication administration errors with adjustment for relevant patient and clinical characteristics (including patient age, route and time of medication administration). Random effects were included in models to consider the correlation of multiple medications administered by the same nurses to the same patients on the same wards during the same study week. Subgroup analyses used multilevel Poisson models with similar adjustments to investigate the EMS effect for specific routes (Oral, intravenous (IV) infusion and IV injection). The occurrence of actual harm was modelled using a similar approach. Data manipulation and analyses were conducted using SAS (9.4) & R.

3. Results

During the SWCRCT trial, there were 4555 medication administrations observed (2098 using paper; 2457 using EMS) being administered by 284 unique nurses. There were 1380 unique patients observed receiving medications; 698 were observed in more than 1 dose administration, and 450 were observed in more than 1 observation session.

Implementation of EMS had no association with medication administration errors (aOR 1.09; 95% CI 0.89-1.32), medication administration errors with serious potential harm (aOR 1.18; 95%CI 0.9-1.56), or administration errors involving high-risk drugs (aOR 0.74; 95%CI 0.34-1.6). There was also no association between EMS and actual harm (aOR 0.92; 95%CI 0.34-2.46).

However, examining routes separately showed errors were higher with EMS for both IV infusion (IRR 1.29; 95%CI 1.08-1.53) and IV injection (IRR 1.38; 95%CI 1.05-1.82).

Table 1. Description of the observed dose administrations, patients and nurses.

	Paper		EMS		IRR, EMS vs Paper (95%CI)†
Route*	Drug events	Total errors	Drug events	Total errors	
Oral	1485	481	1792	899	1.07 (0.88-1.30)
Intravenous infusion	338	316	371	444	1.29 (1.08-1.53)
Intravenous injection	120	127	108	146	1.38 (1.05-1.82)

* Inhalation, Other non-injectables, and Other injections not shown.

†Adjusted for time of day and patient age, with random effects for ward, study week, nurse and patient.

FTE – Full time equivalent

Table 2. Effect of EMS on medication administration errors for the three most frequently used routes.

	Paper (N=2098)	EMS (N=2457)	Overall (N=4555)
High-risk drug	212 (10.1%)	202 (8.2%)	414 (9.1%)
Route of administration			
Oral	1485 (70.8%)	1792 (72.9%)	3277 (71.9%)
Intravenous infusion	338 (16.1%)	371 (15.1%)	709 (15.6%)
Intravenous injection	120 (5.7%)	108 (4.4%)	228 (5.0%)
Inhalation	75 (3.6%)	73 (3.0%)	148 (3.2%)
Other noninjectable	64 (3.1%)	67 (2.7%)	131 (2.9%)
Other injection	16 (0.8%)	46 (1.9%)	62 (1.4%)
Time of day			
Morning (07:00--11:59)	1082 (51.6%)	1026 (41.8%)	2108 (46.3%)
Afternoon (12:00-16:59)	399 (19.0%)	451 (18.4%)	850 (18.7%)
Evening (17:00-22:00)	617 (29.4%)	980 (39.9%)	1597 (35.1%)
Parent not at bedside	202 (9.6%)	234 (9.5%)	436 (9.6%)
Number of patients	739	761	1500
Female patient	332 (44.9%)	327 (43.0%)	659 (43.9%)
Patient age (months)			
Mean (SD)	80.1 (66.1)	94.6 (66.9)	87.5 (66.9)
Median [Q1, Q3]	62.6 [18.1, 137]	98.3 [27.1, 155]	81.8 [21.5, 147]
Number of nurses	221	236	457
Female nurse	208 (94.1%)	219 (92.8%)	427 (93.4%)
Nurse age (years)			
18-29	91 (41.2%)	104 (44.1%)	195 (42.7%)
30-39	55 (24.9%)	56 (23.7%)	111 (24.3%)
40-49	49 (22.2%)	49 (20.8%)	98 (21.4%)
50-59	22 (10.0%)	21 (8.9%)	43 (9.4%)
>=60	4 (1.8%)	6 (2.5%)	10 (2.2%)
Nurse role			
RN	178 (80.5%)	189 (80.1%)	367 (80.3%)
EN	17 (7.7%)	16 (6.8%)	33 (7.2%)
NP/CNC/CNE/CNS	26 (11.8%)	31 (13.1%)	57 (12.5%)
Nurse employment			
FTE 1.0	149 (67.4%)	167 (70.8%)	316 (69.1%)
FTE >= 0.5	54 (24.4%)	52 (22.0%)	106 (23.2%)
FTE < 0.5	18 (8.1%)	17 (7.2%)	35 (7.7%)
Nurse experience (years)			
<2	38 (17.2%)	42 (17.8%)	80 (17.5%)
2-4	44 (19.9%)	51 (21.6%)	95 (20.8%)
5-9	43 (19.5%)	51 (21.6%)	94 (20.6%)
10-14	24 (10.9%)	27 (11.4%)	51 (11.2%)
≥15	72 (32.6%)	65 (27.5%)	137 (30.0%)

4. Discussion

We found no significant reduction in overall rates of medication administration errors in the first 70 days following EMS. Increases in administration errors for IV medications occurred following EMS. This increase is likely due to changes in IV prescribing practices that required prescribers to select the IV form (e.g., IV bolus) in the EMS. Nurses frequently did not follow the prescribed IV form. A before and after study on a geriatric ward in UK hospital also observed increases in some types of medication administration errors, which they attributed to work practice changes, such as fewer visual cues in the EMS regarding additional administration information [6]. A further before and after retrospective study of patient records in an adult hospital in Spain [7] reported a decrease in administration errors, while a controlled before and after study at two adult hospitals in Australia [3] also reported an overall decrease in medication administration errors, largely driven by a reduction in wrong timing errors.

5. Conclusions

Greater attention on how EMS can provide greater safety support to the medication administration process is required.

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