Preventing Perioperative Medication Errors and Adverse Drug Events Through the Use of Clinical Decision Support

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STRUCTURED ABSTRACT (250 word maximum)

Purpose: To design, build and implement platform-independent perioperative clinical decision support that interfaces with existing electronic health records.

Scope: Medication errors in the operating room are common and have high potential for patient harm. While perioperative medication error rates (4%–9% of medication

administrations) are consistent with rates in other hospital areas, the number of medications given during surgery is so high that up to every second operation may contain a medication error. Almost half of these involve observed patient harm, and the remainder have the potential for harm.

Methods: We used iterative user-centered design principles to build and refine a real-time perioperative clinical decision support (CDS) software platform. We then conducted a randomized controlled trial to compare the usability of the CDS software platform to the current standard Electronic Health Record medication administration and documentation workflow.

Results: The perioperative CDS software platform outperformed the standard medication administration and documentation workflow by improving efficiency and quality of care while receiving higher usability ratings from clinicians. Specifically, the CDS software resulted in 20% faster task time, >50% fewer mouse clicks, and fewer pixels traveled on the monitor. The CDS group practiced tighter blood pressure control, which has been shown to prevent end-organ damage, such as acute myocardial injury and renal injury. Also, the CDS group was more likely to appropriately renally-adjust medication doses when necessary. The CDS software's SUS score (78.1614.3) was excellent compared to industry benchmarks.

Key Words: Medication Safety, Patient Safety, Usability, Efficiency, Clinical Decision Support

PURPOSE (Objectives of the study)

The purpose of this research was to design, build and implement platform-independent clinical decision support in the perioperative setting at a 1,046 bed tertiary care academic medical center that performs over 40,000 operations annually, and to evaluate whether the decision support improves quality of care and workflow efficiency. The specific aims were to:

Aim 1: Design, prioritize and tier evidence-based clinical decision support rules for the perioperative setting. We hypothesize that validated, evidence-based clinical decision support rules can be developed for the perioperative setting using a modified Delphi approach.

Aim 2: Build and implement a perioperative clinical decision support tool that interfaces with existing electronic health records. Our hypothesis is that an integrated clinical decision support system can be designed, prototyped and iteratively revised in the perioperative setting to optimize usability and minimize disruption to patient care workflow. When the prototype is optimized, it can be widely implemented throughout the 90 operating rooms at our center.

SCOPE (Background, Context, Settings, Participants, Incidence, Prevalence)

Medication errors in the opeating room are common and have high potential for patient harm. Perioperative medication error rates (4–11%)[1,2] are consistent with medication error rates in other hospital areas, such as inpatient wards (5-19%)[3-6] and outpatient clinics (7-12%).[7-9] However, 10 to 13 medications are administered per operation,[1,10] resulting in a high percentage of operations involving medication-related incidents.[1] With more than 50,000 operating rooms conducting 27 million operations annually, this suggests that approximately 15.75 million perioperative MEs occur annually in the U.S. alone. Almost half of medication-related incidents involve observed patient harm and the remainder have the potential for harm.[1,9,11] More than two thirds of the harm caused by perioperative medication errors is serious or life-threatening. Thus, preventing MEs in the operating room (OR) is of great public health importance and has become a priority locally, nationally[12,13] and internationally.[14]

Medication use in the OR today presents particular patient safety challenges because it often bypasses standard safety checks, such as electronic order entry with decision support and nursing double checks prior tomedication administration. In fact, the OR is one of the few locations where every step of themedication use process (medication selection, dispensing, preparation, administration, documentation, and monitoring) is typically completed by a single clinician (the anesthesia clinician), without safety checks by a second clinician or by

clinical decision support (CDS) with alerts to warn of MEs. Two main features of the OR limit the use of existing medication-related electronic CDS. First, there are typically no prospective medication orders in the OR. Documenting medication in the anesthesia information management system (AIMS) functions as both a retrospective order and documentation that the medication was administered. Second, surgical patients are often among the highest acuity patients in the hospital, and due to the nature and potency of medications administered in the OR, patients' conditions can quickly change while under anesthesia. Thus, intraoperative CDS is often limited to reminders to redose antibiotics, monitor blood glucose when necessary, and administer postoperative nausea and vomiting prophylaxis.[15-17] It is notably missing medication-triggered alerts and patient-specific dosing suggestions.[15-18]

While not yet widely used in operating rooms, clinical decision support software has been shown to prevent medication errors and associated patient harm in other patient care areas, and has the potential to reduce perioperative medication errors by providing tools such as dose calculators and clinical alerts for serious allergies and drug/drug interactions. Overall, alerts and specific drug decision support have the potential to prevent more than 50% of MEs and 95% of ADEs in the operating room.[1,2]

METHODS

Study Design

We used a modified Delphi approach to create, validate and prioritize clinical decision support software algorithms using candidate algorithms that were derived from our prior work. Using use-centered design principles, we build and iteratively revised and tested a fully integrated real-time clinical decision support software prototype for the OR. We then completed a 2 parallel arm randomized controlled superiority trial conducted in a simulation setting to compare the usability of our CDS software prototype to the standard medication administration and documentation workflow in the Anesthesia Information Management System (AIMS). The study was registered on clinicaltrials.gov (NCT04988737).

Data Sources/Collection

Anesthesia clinicians (anesthesiologists, CRNAs, residents, and house staff) at our hospital were eligible to participate; medical students and study staff were excluded. With approval from our Institutional Review Board (IRB), we recruited 40 participants by sending an email including the time and location of the study to all 276 anesthesia clinicians at our hospital. Each participant completed a one-page demographic simulation survey.

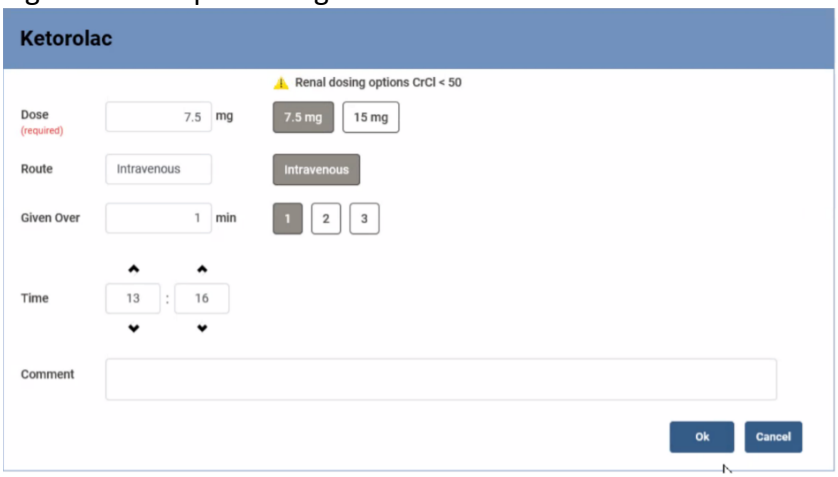
A moderator facilitated the usability test and gave participants in the CDS group a brief demonstration of how to use the CDS software. Participants were then given a short, written description of each task and asked to read it aloud before beginning the task. Morae Usability Testing Software (TechSmith, Okemos, MI, USA) was used to video- and audio-record the participants to capture both quantitative data (time on task, mouse clicks, distance traveled on the screen in pixels) and qualitative data, including think-aloud verbalizations on each task. Think-aloud verbalization requires subjects to talk aloud while solving a problem and has been used extensively to gain insights on system usability, problems encountered by system users and how these problems were solved.[19,20] After the final task, the CDS group completed the previously-validated post-test System Usability Scale (SUS; range 0-100).[21-24] The SUS is the industry standard measurement of technology usability among first-time users, and has been used in more than 1,300 studies to evaluate hardware, software, websites, mobile telephones and automated telephone systems.[22,24,25] The control group did not complete the SUS because the SUS has been designed and validated only for first-time system users. While SUS scores range from 0 to 100 (higher score indicates higher usability), the scores are not percentiles, and benchmarking to other technologies is helpful for interpretation.[24]

Intervention: Use of the CDS Software

To use the software, the anesthesia clinician scanned the barcode on any type of medication syringe label (manufacturer label, hospital pharmacy-applied label, or point-of-care printed label) immediately prior to medication administration. The scan triggered the CDS to display a dosing window with pertinent patient-specific information and/or alert(s) when necessary to prevent an ME prior to the medication being administered (see Figure 1). Dosing

windows were populated with individualized dosing information, so that the user simply confirmed the dose, or entered an alternative dose if needed. Medication data were then sent from the CDS software to the patient's anesthesia record for automated documentation in real time via an interface that is supported by the electronic health record (EHR), eliminating the need to manually document the medication in the Anesthesia Information Management System (AIMS). The CDS software launched instantaneously from the patient's chart in the EHR and received patient context (medical record number, OR case ID, and clinician/user ID) from the EHR. It also received vital signs, ventilator data, and incoming laboratory results in real-time to generate medication-specific alerts (eg, heart rate may be too low for the proposed medication) or reminder alerts (eg, reminders to treat hypotension at individualized blood pressure nadirs or to check glucose when appropriate). Upon receiving an alert, the anesthesia clinician could accept the alert and revise the action that generated the alert or override the alert and continue with the planned action.

Figure 1: Example Dosing Window for Ketorolac



Measures:

The primary outcome was the time taken to complete all the simulation tasks. Secondary outcomes were the total number of mouse clicks and the total distance traveled on the screen in pixels. Our hypothesis was that the CDS group would have shorter task time, fewer mouse clicks, and less distance traveled on the screen in pixels than the Control group. In post hoc

analyses, task time, mouse clicks, and pixels traveled were also analyzed at the individual task level.

Limitations:

This work has several limitations. First, we did not assess what portion of the observed efficiency improvement was due to the various features of the CDS software such as the customized dosing windows with patient-specific renal-, age- and weight-based dosing suggestions, the barcode scan, or the pop-up alerts. While future research can determine the relative benefits of each feature, the current work shows that in combination these features result in a workflow that is faster, more efficient, and leads to higher quality of care (tighter blood pressure control, and more accurate renal dosing adjustments) than the existing workflow. Second, while participants had extensive training and familiarity with the existing EHR over several years of daily use, they were interacting with the CDS for the first time, which may have advantaged their speed and comfort with the existing EHR workflow. Furthermore, because the CDS software was a prototype, it was running on a test server that did not reliably support full clinical application demand, and thus the CDS group experienced occasional server errors and time-outs that resulted in delays in screens loading, sometimes requiring the software to be refreshed or restarted. Despite these server inefficiencies, the CDS software was still quicker, with fewer mouse clicks and pixels traveled than the standard EHR workflow. We performed sensitivity analysis to account for these server inefficiencies and found that while our overall results were unchanged, the effect size (efficiency improvement) was larger when removing the server delays. Future research should test the CDS software on the production server with full clinical bandwidth.

Third, the presence of a moderator and knowledge that the sessions would be recorded may have distracted participants and/or altered their performance due to the Hawthorne effect (the effect of the observer on the observed). However, prior research demonstrates the Hawthorne effect to be negligible with trained and experienced moderators (as in this study),[26] and any residual effect is likely present equally in the CDS and Control groups. Fourth, the study setting

was a large tertiary care academic medical center, where anesthesia was administered by residents, fellows, CRNAs, and attending anesthesiologists, with distributions of gender, race, and clinical experience. As the CDS software is disseminated outside of our institution and implemented more broadly, our findings should be tested in care centers with different clinician population characteristics. Finally, while our study was powered to detect differences in total task time, the sample was not large enough to detect differences at the individual task level. Future research can evaluate which tasks contribute most to the increased efficiency of the CDS software compared to standard workflow.

RESULTS (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

The perioperative medication-related CDS software prototype substantially outperformed the standard medication use EHR workflow by decreasing clinician task time by 20% (see Table 1), improving efficiency and quality of care metrics (blood pressure control and renal dosing adjustments). These results suggest that perioperative CDS could improve clinician efficiency and quality of patient care, while giving clinicians helpful information, such as patient-specific weight-, age-, and renal-based dosing at the point of care. Future research should further evaluate the CDS' efficiency benefits and ability to prevent medication errors, making surgery and anesthesia safer for patients.

Table 1: Efficiency Metrics

	Task Time (seconds ±SD)				Mouse Clicks (n±SD)				Thousands of Pixels Traveled (n±SD)			
	Control	**CDS**	**Mean Effect (95%CI)**	**P value**	**Control**	**CDS**	**Mean Effect (95%CI)**	**P value**	**Control**	**CDS**	**Mean Effect (95%CI)**	**P value**
1	48.1 (17.6)	27.0 (6.2)	21.1 (6.0 – 36.3)	0.007	4.5 (1.6)	2.1 (0.7)	2.4 (0.3 – 4.4)	0.026	12.7 (5.7)	4.1 (1.5)	8.6 (3.5 – 13.6)	0.001
2	109.4 (36.8)	108.3 (22.4)	1.1 (-14.1 – 16.2)	0.892	15.2 (3.4)	8.9 (2.1)	6.3 (4.2 – 8.4)	<0.001	26.1 (8.4)	19.3 (7.9)	6.8 (1.8 – 11.8)	0.008
3	60.9 (16.2)	45.0 (11.4)	15.9 (0.7 – 31.1)	0.040	11.6 (5.6)	3.6 (1.2)	7.9 (5.9 – 10.0)	<0.001	21.2 (10.2)	7.7 (2.9)	13.5 (8.5 – 18.5)	<0.001
4	72.3 (17.7)	55.5 (11.6)	16.8 (1.6 – 32.0)	0.030	13.4 (3.7)	4.6 (1.1)	8.8 (6.8 – 10.9)	<0.001	24.6 (9.0)	10.3 (4.8)	14.2 (9.2 – 19.2)	<0.001
5	42.3 (19.8)	31.3 (21.1)	11.0 (4.1 – 26.2)	0.153	1.4 (2.8)	1.3 (0.9)	0.1 (-1.9 – 2.2)	0.889	4.4 (8.6)	3.8 (3.1)	0.6 (-4.4 – 5.6)	0.816
6	112.2 (36.1)	96.2 (33.7)	16.0 (0.6 – 31.7)	0.041	3.9 (2.7)	3.0 (1.4)	0.9 (-1.3 – 3.0)	0.425	7.6 (5.4)	7.2 (4.9)	0.4 (-4.8 – 5.1)	0.887
7	64.6 (41.2)	48.6 (18.2)	16.0 (0.9 – 31.2)	0.038	6.0 (8.0)	2.8 (1.6)	3.3 (1.2 – 5.4)	0.002	12.8 (19.2)	6.6 (4.0)	6.2 (1.2 – 11.2)	0.015
Total (all tasks)	509.8 (103.6)	402.2 (85.9)	107.6 (60.5 – 179.5)	<0.001	56.0 (15.0)	26.4 (4.5)	29.6 (23.2 – 37.6)	<0.001	109.3 (40.8)	59.5 (20.0)	49.8 (33.0 – 73.7)	<0.001

LIST OF PUBLICATIONS and PRODUCTS

Roberto S, Bayes J, Roberto S, Morley M, and **Nanji KC.** Patient Harm in Cataract Surgery: A series of adverse events in Massachusetts. *Anesthesia & Analgesia.* 2018 May 1; 126(5):1548-50. PMID: 28991108. ***The journal selected this paper as the "article of the month"***

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