

Title of Project

Real-time assessment of risk factors for medication errors

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Abstract.

Purpose. Our objective was to use ecological momentary assessment to assess the extrinsic (workload, experience, task demand) and intrinsic (mood, fatigue, stress) risk factors for medication errors among nurses and physicians in the inpatient setting.

Scope. Over a 15-month period, 304 consenting subjects participated (185 physicians and 119 nurses) from the medicine or pediatric wards of four academic hospitals.

Methods. Consenting subjects agreed to carry a palm handheld unit for a 1-week period. On workdays, each participant completed a daily sign-on assessment inquiring about sleep and patient load. Across the workday, the handheld software prompted the user to complete work and mood assessments randomly within 90-minute blocks. Medication errors involving participating subjects were identified through institutional reports, clinician self-report, or automated capture of infusion pump programming events (for nurses).

Results. The mean age of physician participants (n=185) was 30.2; 54% were women. The mean age of nurse participants (n=119) was 39.3; 89% were women. Subjects were sampled over 2,706 workdays (mean 8.9 days). The mean length of workdays was 10.3 hours. Subjects provided complete information in 73% of sampled intervals and partial information in 12% of intervals. The median time to complete the survey tool was 93.0 seconds. During sampled intervals, 151 error reports were obtained involving 56 (29 physicians and 27 nurses) of the 304 study participants. From these preliminary data, subsequent analyses will examine the predictive relationships between workplace and psychosocial variables and the occurrence/type of medication error events.

Keywords. Medication errors; patient safety; ecological momentary assessment

Purpose.

Medication errors, including preventable adverse drug events, are especially common in the inpatient hospital setting, where patients' clinical problems and medication regimens are complex. Although the risk factors most closely associated with errors have not been fully elucidated, many strategies have been proposed for preventing them, including pharmacists on inpatient rounds, computerized physician order entry, and barcode administration systems. The relative costs and benefits to a specific facility of the many possible mitigation strategies remain unclear, and the success of an intervention will invariably depend on each hospital's unique environment, processes, and personnel. Therefore, tools must be developed to elucidate the specific risk factors associated with medication errors in specific clinical environments (e.g., a hospital's critical care unit). To identify interventions most likely to reduce medication errors, these tools must be used to examine the relationship between medication errors and the various extrinsic and intrinsic performance shaping factors unique to that clinical context.

Our objective was to assess risk factors for medication errors in four academic hospitals using ecological momentary assessment (handheld survey tool). These techniques permit a multidimensional description of the interplay between clinicians and clinical work processes that will provide an understanding of factors contributing to medication errors and inform the design of interventions to prevent them. Medication errors were captured through both conventional approaches (self-report and pharmacist intervention) and emerging methods (self-report using handheld computers and software checks of infusion pump programming). Because they are a key part of the final common pathway for virtually all medication errors, our study focused on clinicians at the "sharp end"—the nurses and physicians caring for acutely ill patients. For these clinicians, extrinsic factors include clinical work processes and working conditions, whereas intrinsic factors include clinicians' cognition (memory capacity), mood, fatigue, stress, and perceptions of workload. We hypothesize that safety threats posed by the extrinsic factors are, in fact, mediated through their effects on or interaction with the intrinsic factors. We propose to delineate these inter-relationships by assessing both intrinsic and extrinsic factors during actual clinical work using real-time measurement tools.

The specific aims of the project were to 1) demonstrate the feasibility of a novel handheld instrument (Dynamic Handheld Survey Tool) for real-time assessment of risk factors for medication error; 2) identify the types of medication errors occurring among different disciplines (physicians and nurses) in multiple hospital settings and characterize the risks they pose to patient safety; and 3) identify factors in the inpatient adult and pediatric medical contexts that contribute to medication errors and that will be amenable to intervention through characterization of extrinsic and intrinsic factors.

Scope.

Background.

Medical error has become a prominent concern since the Institute of Medicine (IOM) published *To Err is Human* in 1999. Among the most common medical errors are those involving the prescribing and administration of medications, which lead to avoidable patient injury and considerable healthcare costs, particularly for inpatient care. In contrast to nonpreventable

adverse drug reactions (due to the inherent properties of the agent), *medication errors* may occur as a result of human fallibilities and system flaws. A medication error is a preventable event that occurs in the process of ordering, processing, or administering a medication, regardless of injury. The reported incidence of errors in medication treatment for adults ranges from 1% to 30% of all hospital admissions (Raschke RA, Gollihare B, Wunderlich TA. A computer alert system to prevent injury from adverse drug events: development and evaluation in a community teaching hospital. *JAMA*. 1998;280:1317-1320). Similar patterns are observed in the pediatric setting.

Understanding the influence of the clinical environment upon physicians and nurses who are the final common pathway, or “sharp end,” for medication errors is key to preventing or reducing many such errors. Clinical experience plays an important role, as performance of tasks by experts is superior to that of novices in a variety of nonclinical and clinical settings. Workload also may be a key factor to errors, affected also by cognitive, psychological, and physical factors. Last, work schedule (e.g., work hours) may also influence errors and has been the focus of new guidelines for residency hours.

Factors intrinsic to individual clinicians are also believed to affect performance in the clinical workplace. Best documented are the effects of fatigue and sleep. Stress and negative affect have also been linked to clinician performance. Lacking, however, are data specifically correlating these factors with medication errors.

To assess the interplay of extrinsic and intrinsic factors, real-time assessment methods are required. Ecological momentary assessment (EMA) permits the capture of dynamic changes in individual mood, behavior, and work tasks in real time, eliminating the bias of retrospective assessments or the expense of intensive, direct observation. In EMA, subjects in the clinical setting are *intermittently* prompted to provide data to generate a representative picture of the work context, which can be used to accurately reconstruct the details of time allocation and work activities. Handheld computers now make it possible to perform such random sampling in real time to capture multiple dimensions of work in an efficient and reliable manner.

New technologies also assist in the capture of medication errors. In particular, programmable infusion pumps identify attempts that fall outside the established parameters, recording these “near-misses” in a searchable database. This information can supplement traditional methods of event detection, such as clinician self-report or pharmacist interventions.

Context.

This project focuses on medication errors in the inpatient adult and pediatric medical settings of academic hospitals.

Settings.

Adult medical care settings included the inpatient medical (adult) units of a large, urban teaching hospital with a total of 496 beds and almost 20,000 annual patient admissions as well as the inpatient medical (adult) units of an affiliated VA hospital with 238 beds. The pediatric medical care setting was a 233-bed acute care hospital, also an academic affiliate, which provides tertiary inpatient services to the pediatric population.

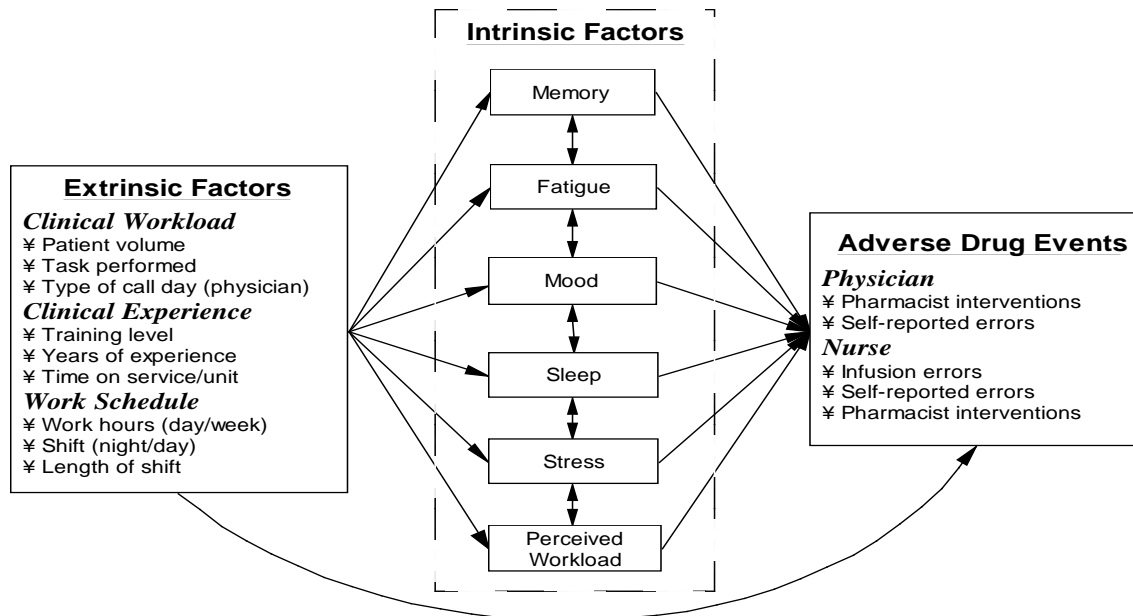
Participants.

Physician and nurse subjects were recruited among volunteers on the inpatient medical services of the participating institutions. Physician subjects included interns, residents, and attending physicians, including hospitalists. When possible, sampling included all members of the care team.

Methods.

Study Design.

The core of the project is the real-time assessment of intrinsic and extrinsic risk factors for medication errors among these nurse and physician subjects. For EMA, subjects were sampled intensively over an extended period, as intermittent sampling requires a large number of observations from which to reconstruct typical workdays or shifts. Carrying handheld computers for 1-week intervals, subjects provided multidimensional information regarding demographic information, clinical experience, workload, work activities, and mood/affect. Multiple handheld computers were deployed to each site to allow sampling of three to four physicians and three to four nurse subjects concurrently. When possible, clinicians on the same care team were sampled together. Simultaneously, medication events were captured through self-report (institutional or via the handheld tool), automatic capture by programmable infusion pumps (for nurses only), or pharmacist intervention. These events are related according to the following conceptual framework:



Data Sources & Measures.

Medication event detection.

Similar methods were used by each of the participating institutions to report and capture medication errors, including voluntary self-report and pharmacist intervention. During the study, all sites implemented the ALARIS Guardrails Software System to capture infusion-related medication errors involving nurses. Also, voluntary reporting by nurse and physician subjects was augmented by deployment of the handheld Medication Event Reporting System (called MERT) on the Dynamic Handheld Survey Tool. All captured errors were linked to the ordering physician or administering nurse, facilitating the analytic objective of understanding the causal relationship between extrinsic and intrinsic factors among specific clinicians and the occurrence of medication errors. Each of the participating sites also had established procedures for clinicians to report medication errors. These hospital-based incident and occurrence reporting mechanisms remained in place during the duration of the study and were used to capture errors. These data allow errors to be linked to the ordering physician or administering nurse. Finally, each institution had in place mechanisms by which pharmacists intercept medication errors and intervene appropriately, both before and after adverse events.

Retrospectively, matches were identified between subjects' periods of participation in the study and events captured by these methods. These matched reports were submitted in a de-identified manner to the study coordinating center through a web-based reporting tool that captured detailed information regarding the specific attributes of the event.

Dynamic Handheld Survey Tool (DHST)/EMA.

Each physician and nurse subject was issued a Dynamic Handheld Survey Tool, a handheld computer containing custom software that administered the survey instruments. Subjects were prompted by a handheld-generated audible alarm to initiate a survey. Subjects were presented an activity survey randomly within consecutive 90-min intervals throughout each duty shift, a sampling rate found to be acceptable in terms of response burden. Sampling occurred during all work hours, although residents were able to turn the computer off during periods of sleep. In addition, at the start and end of each duty shift, subjects responded to a full set of survey instruments, including work schedule and sleep queries. The sign-on surveys occurred at the beginning of each day and queried subjects regarding type of call day (for physicians), current number of patients being cared for, admissions or new patients in the prior 24 hours, and hours of sleep the preceding night. Subjects also completed an initial, one-time sign-on at the beginning of their participation to capture baseline information, including demographic factors (e.g., age, gender, clinical experience, marital status) as well as a test of memory adapted from the Wechsler Memory Scale.

Work activities of physicians and nurses were measured using a modification of a previously developed and validated software algorithm employing branching logic to provide detailed activity of daily clinical and nonclinical tasks. Workload was assessed using the well-established NASA-TLX survey. Psychological state was assessed using a standard 12-question instrument, in which participants rate different states (e.g., stressed, tired, fearful, depressed, frustrated, apathetic) on a nine-point Likert scale, derived primarily from Diary of Ambulatory Behavioral States (DABS).

Measures captured by DHST are summarized in the table below.

Domain		Measurement Method	Physician	Nurse
<i>Risk Assessment</i>				
Extrinsic Factors	Clinical Workload (# assigned patients, # admissions, # discharges, tasks performed, day type [e.g., call/non-call])	Dynamic Handheld Survey Tool (DHST) Direct Structured Observation (DSO) Behavioral Task Analysis (BTA)	Yes No No	Yes Yes Yes
	Clinical Experience (time on service/unit, training level, years of experience)	DHST DSO/BTA	Yes No	Yes Yes
	Work Schedule (work hours [day/week], shift type [day/night], shift duration)	DHST DSO/BTA	Yes No	Yes Yes
Intrinsic Factors	Memory	DHST – Wechsler Memory Scale	Yes	Yes

Statistical Analysis.

All variables were screened to determine appropriateness for parametric statistics, and data transformations were completed as necessary. For our initial hypotheses concerning response burden and completion rates, we used simple descriptive statistics to determine the percentage of completed work assessments and the mean and variability for completed work samples and to assess the distribution of work category, mood, and perceived workload variables.

Primary analyses will consist of a series of regression models to determine the relationship between (1) workload and work process factors (patient load, provider type, work category, etc.) and medication errors and (2) cognitive, mood, and perceived workload measures in the prediction of medication errors. We will examine between-subject factors, including training level (e.g., intern, resident, attending, etc.), workload (number of patients), demographics, work activities, and institution both as continuous variables (when variables are naturally continuous, such as patient load) and as categorical variables to identify possible thresholds for increased medication error risk. We will follow a similar approach using within-subject mood, fatigue, and perceived workload variables. When predictor variables are highly correlated (e.g., mood and stress), we will aggregate scores and/or explore data reduction methods, such as principle components analyses, to extract more stable composite variables to improve prediction models and reduce the impact of multicollinearity. A detailed description of major hypotheses and associated statistical approaches is outlined below.

In the prediction of adverse medication outcomes based on daily DHST data, our objective is to temporally link self-reported work and mood data with errors as closely as possible. In practice, this will result in an aggregation of two to three DHST surveys that most closely parallel the timing of a medication error. Although most of the adverse drug events that occur during the study period will be linked to a specific provider and captured in the day, hour, and sometimes minute they occur, some will not, making it more difficult to link medication errors to proximal work and mood ratings. In such cases, we will approximate error events to self-report ratings by

aggregating across larger time intervals or across teams of providers at a given hospital site. The latter methods are less powerful for prediction and will only be employed when more precise data estimation is not possible. However, they do permit some level of interpretive analysis, even with incomplete error data points.

Limitations.

This work is subject to potential limitations. The ability to establish a causal link between the risk assessment and medication errors depends upon the accurate and consistent reporting of clinician participants. It is also possible that, because our subjects are volunteers, there may be selection bias whereby, for example, clinicians less likely to make errors chose to participate. Last, some medication events may not have been captured using the methods employed in this study.

The study was conducted in the inpatient settings of four affiliated academic hospitals. Many of the physician subjects will be residents. Consequently, the generalizability of these findings to community, nonteaching settings may be limited. However, the generalizability of our findings is increased by the fact the multiple sites and provider types (physician and nurse) were incorporated in the study design. We believe that the findings are broadly applicable beyond the immediate context of this risk assessment.

Results.

Principal Findings.

Over a 15-month period, 304 subjects participated in this study (185 physicians and 119 nurses). Physician subjects included 82 attending physicians or hospitalists, 62 residents and 41 interns; 125 physician subjects worked in adult medicine contexts, and 60 worked in pediatric contexts. The mean age of physician participants was 30.2; 54% were women. Of nurse subjects, 71 worked in adult settings, and 48 worked in pediatric settings. The mean age of nurse participants was 39.3; 89% were women.

Overall, subjects were sampled over the course of 2,706 days (physicians 1,706; nurses 1,000). Individual subjects carried the DHST tool an average of 8.9 days (physicians 9.2; nurses 8.4). The mean length of work days was 10.3 hours (physicians 10.1 hours; nurses 10.7 hours).

Clinician subjects provided complete information in response to DHST prompts in 73% of sampled intervals (physicians 76%; nurses 69%) and partial information in response to DHST in 12% of intervals (physicians 12%; nurses 18%). Thus, 85% of prompts resulted in complete or partial information related to work activities, mood, and task demand. The median time to complete the survey tool was 93.0 seconds (physicians 86.4 seconds; nurses 105.2 seconds).

The DHST results also included detailed information concerning provider's emotional characteristics and perceptions of task demand. From preliminary analyses completed to date, we observed a number of statistically significant differences between our physician and nurse samples. Physicians, for example, reported comparatively higher levels of fatigue, stress, tension, unhappiness, and feeling upset and worried (all p 's < .05), whereas nurses reported significantly higher levels of alertness. Nurses also reported higher levels of frustration and physical task demand on the NASA-TLX scale compared with physicians. We did not find differences on our measure of overall sleep hours per night or in terms of reported sleep quality.

During sampled intervals, 151 error reports were obtained involving 56 (29 physicians and 27 nurses) of the 304 study participants.

Subsequent analyses with the emotional characteristic and NASA-TLX data will include the following: (1) examining predictive relationships between psychosocial variables and the occurrence/type of medication error events; and (2) describing associations between specific work activities and psychosocial characteristics to better understand the pattern of differences observed between our nurse and physician provider samples.

Discussion.

These preliminary results demonstrate the feasibility of a novel handheld instrument (DHST) for real-time assessment of risk factors for medication errors. Complex information was efficiently captured in less than 2 minutes in the work context, a reasonable response burden for a tool of this type; 85% of prompts resulted in complete or partially complete information being self-reported by clinician subjects.

Preliminary data regarding intrinsic and extrinsic factors suggest that our psychosocial measures were sensitive to individual differences in the workplace, as supported by the means and measures of variability with these measures. The psychosocial findings also indicated that the workplace experience of nurses and physicians differs in potentially important ways, with physicians, overall, reporting more stressful workdays. We hope that an improved understanding of how these factors are influenced by workplace activity patterns, as well as how psychosocial characteristics affect medication error events, can be used in future research efforts to reduce hospital errors through workplace modifications.

These results also demonstrate success in capturing medication errors through both conventional (institutional self-report) and novel mechanisms, such as self-report via a handheld tool (MERT) and capture of programming errors through computerized infusion pumps.

As the analysis of this very large, robust dataset continues, we are confident that it will lead to the elucidation of important relationships between clinician and workplace factors and the occurrence of medication events, which in turn will inform efforts to improve the safety of medication delivery in inpatient and other settings.

Conclusions.

The Dynamic Handheld Survey Tool is a feasible, efficient instrument for capturing complex information in real time in the clinical work context.

Significance.

Understanding of the factors in the clinical work environment that affect frontline clinicians will inform the design of interventions to reduce errors. Generalizable findings will contribute to patient safety efforts nationwide. Importantly, these efforts provide insights into the usefulness of the novel patient safety methods embodied in this proposal, and these insights will assist in future research.