Case Report ∎

Comprehensive Analysis of a Medication Dosing Error Related to CPOE

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A b s t r a c t   This case study of a serious medication error demonstrates the necessity of a comprehensive methodology for the analysis of failures in interaction between humans and information systems. The authors used a novel approach to analyze a dosing error related to computer-based ordering of potassium chloride (KCl). The method included a chronological reconstruction of events and their interdependencies from provider order entry usage logs, semistructured interviews with involved clinicians, and interface usability inspection of the ordering system. Information collected from all sources was compared and evaluated to understand how the error evolved and propagated through the system. In this case, the error was the product of faults in interaction among human and system agents that methods limited in scope to their distinct analytical domains would not identify. The authors characterized errors in several converging aspects of the drug ordering process: confusing on-screen laboratory results review, system usability difficulties, user training problems, and suboptimal clinical system safeguards that all contributed to a serious dosing error. The results of the authors' analysis were used to formulate specific recommendations for interface layout and functionality modifications, suggest new user alerts, propose changes to user training, and address error-prone steps of the KCl ordering process to reduce the risk of future medication dosing errors.

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Recent advances in pharmacology research have brought to market a number of new drugs that manage therapy more effectively or relieve previously untreated disease symptoms. As an effect of increased drug use, there is also a greater incidence of adverse effects of medications on hospitalized patients, frequently due to prescribing errors[1] and often preventable. Incorrect dosing or the administration of an inappropriate drug can cause adverse drug events (ADEs) ranging from mild discomfort to serious injury. Preventable ADEs are also associated with higher hospital costs to cover increased length of stay and additional treatment and almost two times greater risk of death.[2]

The ordering phase of patient drug therapy is the most common source of serious medication error.[3] Computer-based physician order entry (CPOE) systems can dramatically reduce the number of these errors[4] by ensuring legibility and also by integrating decision support and safety-related functions.[5] CPOE systems often check in real time for drug interactions, alert to known patient allergies, and calculate dose adjustments according to patient's weight or renal function, decreasing significantly the likelihood of erroneous or unsafe doses.[6–8]

This positive effect of CPOE on prescribing safety, however, can be compromised by the possibility of new kinds of error,[9] specific to the inherent cognitive complexity of human–computer interaction. For example, inadequate user training and poor conceptual understanding of data handling by an application may prevent clinicians from using a system as its designers intended. Inconsistencies in the behavior of controls such as buttons, menus and entry fields, or suboptimal screen layout may unnecessarily prolong order completion time or allow user errors by concealing or misrepresenting stored information.[10]

Simple mistakes at various stages of the electronic ordering process may not endanger the patient as isolated events but can interact and accumulate to produce a serious medical error. Tracing the development of such errors requires a comprehensive and detailed analysis. For example, a close reconstruction of the succession of events, their temporal relationship and interdependencies, and personal accounts of involved actors can shed light on the way data may be misread or misinterpreted in the context of a specific patient order.[11] Effective safeguards against such events can be developed and implemented only if the possible courses of error propagation through the entire system are well described and understood. Insight into the perceptions of users at critical points of the incident is extremely valuable for the characterization of cognitively based errors.

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The process of improving patient safety includes the investigation of medical errors. Analyses of incidents often identify problematic areas in the process of care and suggest changes. For example, in the domain of organizational culture, researchers advocate establishing a nonpunitive incident-reporting system[12,13] or the weekly collection of safety-critical data by a team of executives and safety personnel.[14] Other approaches use electronic searches to detect ADEs in computer-based records[15] or cognitive methods to investigate problems with human–computer interaction and usability of clinical information systems[16] and medical instruments.[17] Analytical methods centered on their distinct areas of interest, however, tend to miss the interaction of errors across domains and the ensuing complexities that may cumulatively produce a serious error.

In contrast, the methodology that we used in our analysis comprises several techniques that collect information on different aspects of the prescribing process and combines it into a rich, detailed description of events leading to the resulting error. In this article, we describe the case of a serious medication error that was identified at a large academic medical center and explain how we analyzed its causes. We regard clinicians and information systems in our analysis as a single functional unit in which faults in interaction among human and system agents may produce a medical error. For example, failures in several separate but converging aspects of the drug ordering process such as computer-based laboratory results review,[18] system usability, and user training,[19] communication between covering providers,[20] and clinical system safeguards[21] may all contribute to a dosing error. Characterization of the entire process and its failures can generate specific recommendations for changes to the system and to the clinical ordering procedures.

In the next section, we describe a dosing error event that occurred at our hospital. The details of the event were obtained from quality assurance reports, case and review reports provided by the organization's Significant Events Committee, recollections by involved parties obtained from interviews, and our own reconstruction from entries in ordering system usage logs.

Case Description

The temporal progression of actions and events is presented in Table 1. An elderly patient who had been initially admitted to a medical intensive care unit with septic shock and respiratory failure the week before the event was transferred to a pulmonary service unit. On a Saturday morning, a house officer (Provider A), after examining routine laboratory test results showing a serum KCl of 3.1 mEq/L in the setting of renal insufficiency (Cr 1.7) correctly diagnosed the patient as hypokalemic and decided to replete potassium by an intravenous (IV) bolus injection. Provider A ordered 40 mEq of KCl [1] (numbers in brackets index order numbers in Table 1) to be delivered via an IV route over 4 hours as indicated by an institutional guideline, using the hospital's computer order entry system. However, immediately after this order was entered, the provider realized that the patient already had an IV fluid line inserted and therefore decided to deliver the KCl as an additive to the currently running IV fluid, which would be less painful for the patient (the patient had previously experienced pain with IV potassium bolus admin-

istration). Provider A then entered a new order to infuse 100 mEq of KCl in 1 L of D5W solution at the rate of 75 mL/hr [3–6]. The preceding IV bolus injection order [1] was to be discontinued at that point, but the provider mistakenly discontinued a similar order from two days before that was entered by another clinician [7]. The dose in order [6] was higher than the maximum allowed by hospital policy. After a call from the pharmacy, Provider A discontinued the order for IV fluid containing 100 mEq/L KCl and wrote a new order for fluid with 80 mEq/L KClr [10–12]. This medicated drip order [12] was not entered correctly, however: Provider A intended to order exactly 1 L of fluid, but the order did not contain a specific stop time or the maximum volume of fluid to be delivered. As a result, the fluid continued to be administered for 36 hours [12], delivering a total of 216 mEq KCl (36×75 mL = 2.7 L; 2.7×80 mEq = 216 mEq). Including the first bolus of 40 mEq KCl [1] that ran to completion, Provider A had inadvertently caused the patient to receive a total of 256 mEq KCl over 36 hours.

On Sunday morning, there was a change of coverage. Provider A notified the incoming covering house officer (Provider B) to check the patient's KCl level. Provider B reviewed the patient's most recent available serum potassium value, which was 3.1 mEq/L. Even though the date and time (i.e., Saturday, the previous morning) of the result were displayed on the clinical information system screen, Provider B did not realize that the laboratory test result was in fact from before the last potassium repletion and acted as though the patient was hypokalemic. Provider B ordered an additional 60 mEq KCl to be given as an IV injection [13–15], even while the previous potassium drip was still running. Order entry logs also indicated that another 40 mEq KCl IV injection was ordered by Provider B about 30 minutes later [16], but there is no clear evidence from other sources that it was in fact administered to the patient.

As a result, the patient received a total of 316 mEq KCl over 42 hours. On Monday morning, when the KCl laboratory values were checked, the patient was found to be severely hyperkalemic (serum K level at 7.8 mEq/L). Once the error was identified, all appropriate measures were taken, and the patient was immediately treated.

Methods and Examples

This case was initially reviewed by the hospital Significant Event Committee, which decided to invite experts in cognitive evaluation of information systems to analyze it. The goals of the experts were to characterize possible cognitive errors in the series of actions that led to the medication error and make recommendations to change procedures, system interface design, and user training so that the likelihood of similar events would be eliminated or reduced.[22,23]

Our analytical approach used several complementary data collection and interpretation methods that are described in detail in the following sections. We combined information from several sources to create a reconstruction of events that took place over three days.

The basic timeline was established from analysis of computer order entry logs, followed by a visual and cognitive evaluation of selected order screens as they were likely seen by the clinicians at the time of ordering and an inspection of their transfer and sign-out notes. We then interviewed the

Table 1 ■ Orders and Actions by Providers A and B over Two Days

Time	Provider	Action	Type	Description	Notes/Findings	Order No.
Saturday 13:30 7 min		ACT	IV injection	40 mEq KCl IV injection over 4 hr Decision	Correct order Provider wants to change IV injection of KCl to a medicated drip to avoid pain on administration	1
		DC	Drip	D5W nonmedicated fluid	Discontinues an older standing order (not in table)	2
		ACT	Drip	D5W with 40 mEq KCl 1,000 mL @ 75 mL/hr	Intended for 1 L of fluid only; free-text volume limit, auto stop in 7 days	3
	A	DC	Drip	Preceding order discontinued	Realizes the preceding order [3] was incorrect and discontinues it	4
		ACT	Drip	D5W nonmedicated fluid	Enters order identical to the one just discontinued [2]	5
		ACT	Drip	D5W with 100 mEq KCl 1,000 mL @ 75 mL/hr	Second attempt to enter drip order, similar to order [3]; now with a higher dose (100 mEq)	6
		DC	IV injection	KCl 20 mEq	Meant to discontinue order [1] but discontinued an expired order from 2 days before (not in table)	7
49-min time lag					Pharmacy calls to warn about order [6], which has dose over limit (100 mEq, max. allowed 80 mEq)	
Saturday 14:26 16 min		DC	Drip	D5W nonmedicated fluid	Discontinues nonmedicated fluid order [5] in response to the call from pharmacy	8
	A	DC	Drip	D5W with 100 mEq KCl 1,000 mL @ 75 mL/hr	Discontinues erroneous drip order [6] in response to the call from pharmacy	9
		ACT	Drip	D5W with 80 mEq KCl 1,000 mL @ 75 mL/hr	Enters recommended 80 mEq. Intended for 1 L only, but no stop time entered; auto stop in 7 days	10
52-min time lag						
Saturday 15:34		DC	Drip	D5W with 80 mEq KCl 1,000 mL @ 75 mL/hr	The preceding order [10] discontinued	11
	A	ACT	Drip	D5W with 80 mEq KCl 1,000 mL @ 75 mL/hr	The same order [cf. 10, 11] re-entered, runs for 36 hr and delivers **216 mEq** KCl	12
27-hr time lag **Change of providers**						
Sunday 18:36	B	ACT	IV Injection	40 mEq KCl IV injection	Misperceived older potassium laboratory values as current; did not notice a running KCl drip [12]	13
34-min time lag						
Sunday 19:10		DC	IV Injection	40 mEq KCl IV injection	The preceding order [13] discontinued	14
	B	ACT	IV Injection	60 mEq KCl IV injection	Increased IV injection dose to 60 mEq	15
27-min time lag						
Sunday 19:37	B	ACT	IV Injection	40 mEq KCl IV injection	Another IV injection of KCl ordered; however, no clear evidence that it was in fact administered	16

ACT = activate; DC = discontinue; IV = intravenous.

clinicians in person using a semistructured questionnaire format developed from the information that we had collected and interpreted.

Data from one analysis often informed and elucidated the interpretation of results from other analyses. Together they formed a basis for our characterization of the initial error progression through the system and helped to determine the likely cause of the resulting medication error. Finally, we worked with representatives of the hospital's quality assurance, information systems, pharmacy, medical staff, and the hospital's clinical system training group to formulate specific recommendations for changes in the ordering system interface and suggested improvements to user training and KCl ordering procedure.

Analysis of Order Entry Logs

First, we examined all medication orders for the patient over the three days that the incident took place and extracted those that involved the administration of KCl. We then identified the providers who activated or discontinued these orders, compared order starting times, intended and actual stop times, routes of administration, and computed total dose amounts. These data were sufficient to establish the exact timeline of events and characterize several aspects of user behavior. From our reconstruction of the events, for example, it was evident that Provider A interacted with the order entry system on three occasions, entering and discontinuing orders 1–7, 8–10, and 11–12 within about a two-hour period. Provider B interacted with the system the following day also on three separate occasions, manipulating orders 13, 14–15, and 16 within the span of an hour. Some improper use of the CPOE application was also evident, such as the use of a free-text comment field to limit total fluid volume to 1 L.

Visual and Cognitive Evaluation of Ordering Screens

The data captured by computer order entry logs did not contain information about what values were visible on screen at the time the order specifics were being filled in. Screen layout and visual salience of presented information may critically affect the way it is interpreted by users.[24–26] Six orders in the logs were identified as ambiguous or potentially erroneous, but it was not clear what the users' intentions were for activating and discontinuing them. We therefore retrieved and displayed them on the order entry system exactly the way they were seen by the providers at the time of ordering and analyzed their visual layout. For example, we compared screen entry forms for IV medication injections and those for IV fluids with medication additives, each of which could be used to order KCl. Specifically, we looked for consistency of screen controls behavior, clarity of meaning of data labels within the context of the ordering task, and evaluated other cognitive aspects of the interface that could contribute to user confusion and error.

Semistructured Interviews with Clinicians

The objective of these interviews was to enrich the collected data by personal observations and to find out how the clinicians interpreted information available to them during ordering. We wanted to know what was communicated between them during their sign out activities and what was their conceptual understanding of system functions in response to the entry of specific dose and time values. For example, we asked about their understanding of the "Total Volume" label in the entry forms in conjunction with the associated "Ordered Start" and "Ordered Stop" labels and how they thought the drug dose would change when the values were manipulated. Other issues of interest were their recollection of any verbal exchanges they may have had about the patient and an explanation of the reasons for making changes in the orders that we had identified as problematic. Although the interviews were conducted several months after the events took place, we were able to obtain detailed answers to most of our questions.

Results and Discussion

We found that this medication error was due to the confluence of several factors, including errors by physicians in the use of the clinical information system, the absence of automated safeguards that help prevent errors, and uncertainty on the part of physicians about how to manage unusual ordering scenarios. The timeline and description of actions such as the activation or discontinuation of orders, decision points, time lags, and pharmacy intervention are represented in Table 1. Specific findings and their interpretation are described in the following sections.

Misconceptions about the Relation between Intravenous Volume and Time Duration

Potassium chloride can be administered intravenously either as a bolus injection or as an additive to drip fluid (such as saline or dextrose). The first Provider (A) intended to order KCl as an additive to D5W drip fluid and control the amount of drug to be delivered (in mEq) by specifying the rate and concentration and by limiting the total volume of IV fluid to 1 L [3]. However, in the current CPOE application, drip fluid orders are specified only by their duration, with a default stop time period of seven days and cannot be limited by total volume of fluid delivered even when they contain medication additives. The IV fluid data entry screen includes a field labeled "Total Volume" to specify the size of the IV bag that should be used in the order. The meaning of "Total Volume" could be easily misinterpreted in the context of this order and in specific instances of time and dose combination would not represent the total amount of fluid that would actually be delivered to the patient.

The screen entry forms for drip and IV injection orders are visually very similar yet with important functional differences in constraining the amount of delivered medication: by time duration (drip) and by dose (IV injection). While there were only subtle differences in layout and appearance of data labels and values between bolus entry forms and drip order forms, the way default stop times were calculated by the system was very different, allowing for erroneous interpretation.

It is our contention, based on log analysis and user interviews, that the distinction between time-limited (drips) and amount-limited (boluses) dosing was not sufficiently clear from the way information in the entry dialog box was presented. In this case (orders 3, 5, 6, and 12), Provider A was apparently working under the assumption that entry screens for medicated drips behave the same way (i.e., controlled by volume specification) as IV bolus entry screens. This misconception was in part reinforced by the ambiguity of the "Total Volume" data label. There is no direct quote from the users about this issue, and the evidence is interpreted from logs and interviews.

Users without robust conceptual knowledge of the system may not realize that IV flow will stop only at the end of the specified time period (the default is seven days) and will exceed the displayed value labeled as "Total Volume." Users may ascribe meaning to data labels or procedural concepts differently from what is assumed by the system designers. This divergence in interpretation is known in the human–computer interaction research literature as a user-designer mismatch.

Provider A also wrote an instruction to limit the dose to 1 L in the comments field [3]. Free-text entries are "invisible" to the system's time or amount-related functions; a coded entry is usually necessary to activate internal processing.

Suboptimal Display of IV Bolus Injection and Medicated Fluid Drip Orders

While these two types of KCl administration may be ordered and run concurrently, our clinical information system does not effectively help the user manage this complex clinical scenario. At the time of the case, IV fluids were not displayed on the screen that physicians used most commonly to review the patient's medication list. As a result, IV fluid orders were seen less often by users, and medications administered via that route were more likely to be missed in the decision-making process for new orders.

This conceptual misunderstanding was also partly responsible for allowing the mistake in ordering to propagate through the system and across providers. Provider B was not explicitly informed by Provider A in the cross-coverage note that KCl was being delivered in the fluid drip because Provider A believed the drip had stopped running after 1 L of volume.

Misconception of Latest and "Dated" Laboratory Results

The covering Provider B on the second day checked laboratory data for serum KCl and read the latest available value, but that information was already 24 hours old and did not reflect the current medical condition of the patient. Even though the system shows the date and time of laboratory results, the display does not visually emphasize when the most recent available result is not in fact a current result. In active inpatient environments, where electrolytes are frequently ordered on a daily basis, providers often assume that the most recent values are from that day. In this case, Provider B incorrectly interpreted the information and followed up with an erroneous action (i.e., ordered another KCl injection). This error contributed to the magnitude of the resulting overdose.

Lack of Certain Automated Checking Functions

The pharmacy system detected an out-of-bounds KCl concentration error (100 mEq/L vs. the maximum recommended 80 mEq/L) from the electronic order but not the fact that this order was running for 36 hours, delivering an excessively large dose of potassium. Ostensibly, either the CPOE application or the pharmacy application could have detected that the patient would be receiving a large amount of potassium over a period of time. However, neither system was programmed to do this.

Inadequate Training of Safe and Efficient Ordering Practices

Computer logs of user activity indicated multiple attempts by both providers to enter orders into the system correctly, five

and three times, respectively. These attempts are represented in Table 1 as items 3, 5, 6, 10, and 12 for Provider A and as items 13, 15, and 16 for Provider B. For example, there are orders that were activated and immediately discontinued (3 and 4, 5 and 8, 10 and 11). Inconsistent interactive behavior in the repeated attempts suggested that the users could be engaging in trial and error rather than using a skilled strategy. Procedural knowledge gained mostly from experience is often not sufficient to ensure appropriate interaction with the system. Adequate training is necessary to learn efficient and safe ordering practices.

Specific Recommendations for System and Ordering Procedure Changes

The findings and analysis were referred for further action to the Hospital's Medication Safety and Informatics Committee responsible for addressing issues of medication safety that involve information systems. This committee includes representatives from the departments of quality assurance, pharmacy, information systems, nursing, organizational learning and training, as well as medical staff. The house staff, who write the majority of orders and are active users of the laboratory and medication review functions, were especially involved in the recommendations related to this case.

The Committee made the following recommendations for changes:

- Screens for ordering continuous IV fluid drips and drips of limited volume need to be clearly distinct so that the ordering of each is unambiguous.
- Screens that list active medication orders also should list IV drip orders.
- Laboratory results review screen needs to clearly visually indicate when the most recent results are not from the current day.
- Add an alert that would inform users, ordering potassium (drip or bolus) when the patient already has another active order for potassium.
- Add an alert informing users ordering potassium when there has not been a serum potassium value recorded in the past 12 hours or the most recent potassium value is greater than 4.0. This would reduce the likelihood of ordering potassium when the patient is hyperkalemic.
- Make other minor changes to increase the consistency of ordering screen behavior.

The Committee also suggested that training for the order entry application should not be limited to procedural knowledge but should emphasize conceptual understanding and safe entry strategies. Real working cases with various levels of problem difficulty should be used.

The recommendations were intended for the in-house team of software engineers, but it would be possible to suggest more extensive changes to the layout or appearance of screens and alerts that the vendor may consider for future versions of the software.

Conclusions

The cause of this medical error was the product of failures in interaction among human and system agents. Methods limited in scope to distinct analytical domains could not identify these failures. We could not have made appropriate recommendations for the improvement of the ordering process

without a multifaceted and detailed analysis. Our proposed improvements to the user interface could be implemented by hospital system developers.

The nature and classes of errors that we described are likely to occur in similar systems at other institutions. Increasingly complex information systems require comprehensive analyses of human errors for design changes that emphasize clarity of communicated information and implement effective safeguards against patient injury.

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