Effect of Computerized Physician Order Entry on Medication Prescribing Errors in the Hospital Inpatient Setting

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Problem Definition

Strong federal financial incentives have led many US hospitals into a veritable frenzy to adopt, implement, and demonstrate meaningful use of electronic medical records (EMR). One key component in meaningful use certification is the implementation of computerized physician order entry (CPOE). To support this requirement, government regulators frequently reference early research findings that CPOE decreases medication errors and improves patient safety in comparison to paper ordering systems (Dean-Franklin et al., 2007 and Ammenwerth et al., 2008). However, in its recently released report *Health IT and Patient Safety*, the Institute of Medicine found that "designed and applied inappropriately, health IT can add an additional layer of complexity to the already complex delivery of healthcare, which can lead to unintended adverse consequences (IOM, 2011)." Indeed empirical studies have confirmed that in some situations CPOE can actually increase the risk of medication errors (Koppel et al., 2005). Also, in a recent comprehensive review, Reckmann et al. (2009) pointed out that "Evidence of the effectiveness of CPOE systems to reduce prescribing errors is limited, and the sample sizes and study methods applied reduce the generalizability and strength of the evidence." There remains a need for rigorous evidence-based clinical trials to further evaluate the hypothesis that CPOE really does reduce the frequency and severity of medication prescribing errors and their consequences (Reckmann et al., 2009).

Study Design

Randomized controlled trials remain the gold standard for clinical study design. In real life clinical settings, it is usually impossible to apply the CPOE intervention only to specific sets of patients while excluding others. Therefore in the context of CPOE, controlled pre-and post-intervention comparison is the most rigorous study design that can practically be used. I propose

a before and after study to be carried out at Community Hospital, a private, nonacademic 400 bed County hospital which records an average of 1500 acute care admissions per month. Community Hospital already operates a robust electronic medical record which contains the clinical, laboratory, care plan, radiology, and clinician narrative data on its inpatients. The hospital is preparing to add a commercial CPOE system to its EMR, with go-live planned in the fourth quarter of 2012. The study will involve two time periods of increased monitoring of all medication orders written on the adult medical and surgical wards of the hospital to detect and record medication errors, a period of four weeks just prior to the implementation of CPOE (pre-CPOE) and a second four week period starting three months after the go-live, in order to give the hospital clinicians time to develop skill and familiarity with the CPOE system (post-CPOE). A research pharmacist will train staff inpatient pharmacists (who already monitor all inpatient medication orders as part of their current duties) to assess those orders for medication errors using definitions, classifications, and methods previously defined in the literature (Dean et al., 2002). Study investigators will score the severity of each recorded error based on a scale from 0 (no harm) to 10 (death) using a previously validated scoring system (Dean and Barber, 1999). Adverse drug events are medication errors that cause temporary harm to the patient requiring intervention or prolongation of hospitalization, cause permanent or life threatening harm to the patient, or cause the death of a patient. The pharmacists will also be trained to determine and record the total number of adverse drug events (ADE) using a validated ADE detection tool from the literature (Rozich et al., 2003).

Analysis

The unit of analysis will be the individual inpatient medication order, and the primary outcome (dependent) variable will be the total number of medication orders with errors during

each measuring period. Because it is conceivable that CPOE might lower the total number of medication errors mainly by lowering the rate of minor errors that have little or no consequence for the patient, secondary outcome variables will include total number of adverse drug events and mean error severity score. The independent variable is the presence or absence of CPOE.

The number of orders with errors pre- and post-CPOE will be compared using the χ^2 test with hypotheses:

H_0: $p_1=p_2$, $\alpha=0.05$ (proportion of orders with errors is equal pre-CPOE and post-CPOE)

H_1:$p_1\neq p_2$ (proportion of orders with errors is not equal pre-CPOE and post-CPOE).

Exactly the same χ^2 analysis can be applied to the number of orders with associated ADEs in the pre- and post-CPOE measuring periods:

H_0: $p_1=p_2$, $\alpha=0.05$ (proportion of orders with associated ADE is equal pre- and post-CPOE)

H_1:$p_1\neq p_2$ (proportion of orders with associated ADE is not equal pre- and post-CPOE)

Error severity scores pre- and post-CPOE will be compared using the unpaired t-test with hypotheses:

H_0:$\mu_1=\mu_2$, $\alpha=0.05$ (Mean error severity scores pre and post-CPOE are equal) and

H_1:$\mu_1\neq\mu_2$ (Mean error severity scores pre and post-CPOE are not equal).

In two representative studies from the literature, pre-CPOE medication error rates were 2% (Dean et al., 2002) and 3.8% (Dean-Franklin et al., 2007). To identify a decrease in the medication error rate from 2% to 1% with $\alpha=0.05$ and $\beta= 0.2$ would require study of 2314 newly written medication orders in each phase of the study, and to identify a decrease from 4% to 2% would require study of 1136 newly written medication orders in each phase (D'Agostino et al., 2006, p.331, Formula 7.16). In their study of a 550 bed teaching hospital in the United Kingdom, Dean et al. (2002) found that approximately 1300 new medication orders were written each day,

equivalent about 950 such orders per day at Community Hospital, adjusting for the difference in bed capacity. A four-week study should therefore acquire more than enough data to achieve the desired statistical power. Since the pre-and post-CPOE phases are of equal length, there is not likely to be a significant difference in the total number of medication orders written during each phase, but this will be verified in the data set.

Summary

Reckmann et al. (2009) suggested that all future studies regarding the effectiveness of CPOE in reducing inpatient medication order errors should contain a definition of prescribing errors, should report absolute error rates pre-and post-CPOE implementation, should report denominators for prescribing error rates including total number of orders reviewed, should characterize errors by a defined standardized severity scale, should allow error rates per severity category to be calculated, and should incorporate appropriate significance testing. The proposed study meets all of these criteria and will be well powered to detect significant changes in serious errors. It will therefore be well-suited for accurate comparison with previous and contemporary studies and for incorporation into meta-analyses.

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