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Evaluating Health Information Technology's Clinical Effects

Editor's note: In 2009 the federal government appropriated \$34 billion in stimulus-related funding to promote the "meaningful use" of health information technology among Medicare and Medicaid providers and hospitals. One of the key elements of this technology is the adoption of computerized physician order entry (CPOE) systems for inpatient drug prescribing. The potential for CPOE to improve prescribing patterns and prevent adverse events is large, and as yet, unrealized. Amidst enthusiasm for the benefits of CPOE, providers and policymakers are becoming aware that CPOE could introduce new errors into the system and cannot simply be assumed to "work." This Issue Brief reports on the experience of one hospital system that used its CPOE to reduce the incidence of a serious drug interaction. This rigorous test of a specific CPOE intervention shows that an electronic alert system can be effective in changing prescribing, but may also have unintended consequences for patient safety.

Computerized Physician Order Entry (CPOE) offers technical solution to many medication safety issues, but it is not a panacea

Several studies have shown that CPOE, paired with computerized clinical decision support, can reduce medication errors in hospitalized patients. The concept is intuitively appealing: for example, CPOE can eliminate errors due to bad handwriting, and its underlying decision support software can flag incorrect dosages and identify potentially harmful drug interactions. Alerts pop up automatically on the computer screen to notify the prescriber about potential problems and to suggest safer alternatives.

- However, the clinical effects of a CPOE system depend critically on how physicians use and react to it. An ongoing challenge for CPOE implementation is to alert the prescriber to clinically significant errors and adverse events, without overwhelming the prescriber with alerts of little practical significance. Studies show that clinicians exhibit "alert fatigue" and tend to ignore most pop-up alerts.
- To prevent adverse drug events, CPOE systems can also produce "hard-stop" alerts, in which the medication order is blocked until the prescriber takes steps (usually calling the pharmacy) to override the alert. Hard stops may be more effective than "soft" alerts in preventing adverse events, such as serious drug interactions, but also run the risk of delaying or blocking necessary care.

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- The overall impact of CPOE on patient safety depends on both the intended and unintended consequences of CPOE implementation. A number of studies have identified new errors that CPOE can introduce, such as delays in care due to workflow disruption or incorrect orders due to the design of the human-computer interface.

Researchers implement and evaluate a CPOE intervention for a significant drug interaction

To test the effectiveness of a specific CPOE intervention, Strom and colleagues chose a drug interaction with serious consequences, and implemented a nearly hard-stop CPOE alert. The drugs they chose were warfarin (an anticoagulant, also known as Coumadin™) and trimethoprim-sulfamethoxazole (TMP/Sulfa, an antibiotic, also known as Bactrim™ or Septra™). Patients who take both medications are much more likely to develop bleeding from the warfarin. To reduce the likelihood of these drugs being prescribed together, the Hospital of the University of Pennsylvania had implemented a policy in which pharmacists notify the clinician by phone about the risk of bleeding when the drugs are prescribed concurrently. Despite the intervention, some clinicians continued to prescribe the drugs together.

- The hard-stop alert appeared as a pop-up window that notified the clinician that the order could not be processed because of a significant potential drug interaction. The alert read:

The prescription of warfarin and TMP/Sulfa together is completely prohibited except in cases of urgent need for the TMP/Sulfa. If you are attempting to prescribe warfarin and the patient is already on TMP/Sulfa, discontinue the TMP/Sulfa and your order for warfarin will be processed. If you are attempting to prescribe TMP/Sulfa and feel that your patient has an urgent need, then contact the inpatient pharmacy and you will be directed as to how to process the order for TMP/Sulfa.

- Clinicians could override the alert in two ways. One way was to bypass the CPOE altogether by calling the pharmacist directly. The other way, which did not involve a pharmacist, was to enter into the computerized alert window that the reason for the sulfa prescription was to prevent *Pneumocystis carinii* pneumonia. Just seven alerts over the course of the study were overridden for this reason.
 - To evaluate the effects of the nearly hard-stop alert, Strom and colleagues randomly assigned clinicians to either the new CPOE alert system or to continue with standard practice of the pharmacist notifying clinicians by phone.
 - Initially, the University of Pennsylvania Institutional Review Board (IRB) was so convinced that the CPOE alert had to work, that it questioned whether it was ethical to conduct the study, even though the control group was current standard clinical practice. It eventually approved the study with a monthly monitoring plan in place.
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Randomized trial evaluates nearly hard-stop alert for warfarin and TMP/Sulfa

The study included 1,971 clinicians (1,872 resident physicians and 99 nurse practitioners) involved in patient care at one of two hospitals affiliated with the University of Pennsylvania Health System. The clinicians were randomly assigned to either the intervention group (985 clinicians) or the control group (986 clinicians). The study began in August of 2006 and was to last seven months.

- The investigators defined the desired outcome as not re-ordering an alert-triggering drug within 10 minutes of the alert (or what would have triggered an alert in the control group). This time frame was chosen because it was a reasonable period within which the clinician would have reacted to the alert.
- They also checked for two adverse outcomes: a delay in obtaining TMP/Sulfa when it was indicated, and unintentional cessation of warfarin therapy in a patient requiring long-term warfarin therapy.

Intervention was highly effective in reducing simultaneous use of warfarin and TMP/Sulfa

During the study period, clinicians ordered 8,826 prescriptions for warfarin or TMP/Sulfa through the CPOE system. Fifty-five clinicians triggered alerts in the intervention group (involving 52 patients) compared to 45 clinicians (who would have triggered an alert) involving 44 patients in the control group. Overall, 194 alerts popped up in the intervention group and 148 in the control group.

- Of the 194 hard-stop alerts issued to the intervention group, the percentage of the desired response by the clinicians (not reordering the alert-triggering drug within 10 minutes of firing) was 57%, compared to 13.5% of those who would have triggered an alert in the control group. After adjusting for type of provider and clustering of providers, the intervention group was 88% less likely to re-order the triggering drug.
- The greatest proportion of desired responses was observed in the first three months of the intervention, after which it steadily declined, suggesting that the effectiveness of the alerts may have started to wear off. The intervention and control groups remained different, however, at the end of the study.

Study halted for ethical reasons because of potential for patient harm

Each month, the investigators monitored the unintended consequences of the intervention. These consequences included a delay of treatment when TMP/Sulfa was determined to be necessary, or inadvertent discontinuation of warfarin. They looked for consequences that were likely or definitely related to the intervention.

- Four unintended consequences were identified among patients in the intervention group: a three-day delay of TMP/Sulfa treatment in one patient, a failure to prescribe appropriate TMP/Sulfa prophylaxis in a critically ill patient; and a one-day and three-day delay in warfarin treatment in two patients.
- Review of the electronic medical records of the four patients did not indicate any specific infectious or thrombolytic event that could have been caused by the delays in therapy.
- Nevertheless, the Institutional Review Board deemed these adverse consequences in the intervention group sufficiently serious to warrant discontinuation of the intervention and early termination of the study. This was a dramatic finding, given the IRB's initial concern that depriving the control group of the intervention would be unethical.

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POLICY IMPLICATIONS

These results illustrate the importance of formal evaluation and monitoring for unintended consequences of policies intended to improve prescribing habits. New pharmaceuticals are subjected to evaluation of their safety and efficacy because their intended effects might not be achieved, or because their unintended effects might be harmful. Similarly, health information technology also has clinical effects, and ought to be evaluated too.

- In this trial, it is not clear whether the benefits of reducing the incidence of concomitant prescription of warfarin and TMP/Sulfa outweigh the harms observed in this trial. Further review of the medical records of the patients who went on to receive both drugs would be needed to ascertain the adverse events associated with the drug interaction.
- But this study illustrates why formal evaluation should be included and funded as part of the push to implement health information technology. We cannot assume that these interventions work just because they are well meaning and plausible.
- The Leapfrog Group, an employer-based advocacy organization and one of the foremost proponents of CPOE as a patient safety intervention, recently called on the federal government to require testing and monitoring of CPOE as part of “meaningful use.”

This Issue Brief is based on the following article: B.L. Strom, R. Schinnar, F. Aberra, W. Bilker, S. Hennessy, C.E. Leonard, E. Pifer. Unintended effects of a computerized physician order entry nearly hard-stop alert to prevent a drug interaction. Archives of Internal Medicine, September 27, 2010, vol. 170, pp. 1578-1583. See also: R. Koppel, J.P. Metlay, A. Cohen, et al. Role of computerized physician order entry systems in facilitating medication errors. Journal of the American Medical Association, March 9, 2005, vol. 293, pp. 1197-203.

This Issue Brief was supported by the Agency for Healthcare Research and Quality, Centers for Education and Research on Therapeutics, University of Pennsylvania School of Medicine (U18 HS10399). The opinions expressed are those of the authors and not the funding agency.

Published by the Leonard Davis Institute of Health Economics, University of Pennsylvania, 3641 Locust Walk, Philadelphia, PA 19104.

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Published by the
Leonard Davis Institute
of Health Economics
University of Pennsylvania

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