Legislative Barriers to Outpatient e-Prescribing in a Randomized Trial

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Abstract
Newer outpatient electronic prescribing software programs produce typewritten paper prescriptions with electronically created signatures. Current Canadian federal legislation forbids static (unchanging) signature images on prescriptions.

We conducted a randomized trial of electronic prescribing in outpatients at a university-affiliated hospital. The application was a wireless Palm-based system that creates a prescription that is either printed and given to the patient or faxed to a pharmacy. Using the software, the physician creates a unique signature image for each prescription.

We successfully overcame challenges related to wireless network reliability, local printer availability and physician training. However, to comply with federal legislation and provincial regulations, we were required to design workarounds to create acceptable prescribing processes.

Our experience suggests that the legality of the electronic signature must be clearly defined to realize the full potential of standalone outpatient electronic prescribing systems and fully integrated hospital-wide electronic medical records.

Recent Canadian data estimate that approximately 9,250 to 23,750 patients die annually due to preventable adverse events (harm experienced by patients given a drug but not necessarily caused by the drug) (Nebeker et al. 2004). Adverse drug events (ADEs) refer to episodes of harm caused by a drug, whether used appropriately or not, whereas potential ADEs refer to episodes of potential harm caused by a drug that did not actually materialize. Many such events are related to medication errors or inappropriate drug use (Bates et al. 1995). Studies suggest that ADEs and potential ADEs related to preventable medication errors are common (Foundation for eHealth Initiative 2004; Gandhi et al. 2003).

In response to these data, enthusiasm for electronic systems to reduce errors at the point of medication prescribing has increased (Baker et al. 2004; Bates and Gawande 2003). The end product of outpatient electronic prescribing (e-prescribing) is a typewritten prescription that is either printed for the patient or faxed directly to a pharmacy without being printed first. However, there are many potential methods to create the electronic prescription, ranging from word processing programs to more sophisticated server-based prescribing applications (on...
a desktop or handheld device) containing a drug database that automatically checks for drug interactions and allergies.

Although many articles on e-prescribing and decision support tools discuss theoretical benefits (Bates et al. 2003), the few studies documenting clinically important benefits (decreased medication errors, increased adherence to evidence-based prescribing) have been largely restricted to single institutions with long histories of locally developed in-patient computerized physician order entry systems integrated into electronic medical records (Halama et al. 2006; Overage et al. 2001; Wu et al. 2006). We have found no randomized controlled trials (RCTs) of outpatient e-prescribing.

Our objective was to evaluate the effect of a commercially available outpatient e-prescribing system on medication errors in an RCT. In this article, we describe implementation challenges related to regulations concerning electronic signatures.

The most unexpected and difficult challenge was related to current Canadian legislation governing electronic prescribing.

Methods

Trial Setting

We conducted the RCT in six outpatient clinics in a large university-affiliated hospital in Toronto, Ontario, from August 2005 to October 2006 (ClinicalTrials.gov identifier NCT00252395). Investigators contacted medical department heads and individual physicians to solicit participation in the trial. Participation was voluntary; participants received a Palm Tungsten C handheld personal digital assistant (PDA) loaded with the intervention software.

Design

This RCT had time as the unit of allocation; access to and use of the e-prescribing system was switched on and off for randomly chosen weeks. Allocation was concealed until the end of the Friday of the previous week, at which time access to the software (see below) was switched on or off through the centralized servers, according to the allocation.

Intervention

We implemented e-prescribing software (Drugmagnet, Toronto, Ontario) in a wireless local area network environment. The software was loaded onto the trial PDA, allowing physicians to prescribe anywhere they wanted within wireless coverage, including in the examination room. Following a one-hour training session (with follow-up sessions where necessary), physicians prescribed using the application. Prescriptions were either sent wirelessly over the hospital network to independent centralized servers for processing and transmission to a local printer (for delivery to the patient) or sent to a pharmacy (by facsimile), depending on the patient’s preference.

In both manual and electronic prescriptions, the physician’s signature finalized and validated the prescription. Most e-prescribing systems store a scanned image of a handwritten signature as an image file. This is a static (unchanging) picture of the signature, which is different from a handwritten signature that is unique each time it is written. In contrast, the study application required the physician to sign each prescription on the PDA’s touch screen. This signature was digitized and stored as a temporary image, but the physician had to re-sign for each subsequent prescription, just as with handwritten prescriptions. Therefore, the study application captured a unique electronic signature for each prescription rather than inserting a stored static signature image.

During intervention weeks, physicians could use the study application for e-prescribing. During control weeks, the software did not work and physicians had to handwrite prescriptions on standard pads.

Outcomes and Data Collection

The principal outcome measure was number of calls received by physicians’ offices (per number of prescriptions issued) for clarification of prescriptions. Secondary outcomes included the rates of severe interactions, dosing and route of administration errors, errors of prescription duration and pack size and illegibility. Each prescription could contribute more than one type of error, and the denominator was the number of prescriptions issued. An unblinded pharmacist adjudicated secondary outcomes only for prescriptions filled at the study hospital pharmacy. Rates were compared between intervention and control weeks.

Sample Size

The unit of analysis for this trial was the individual prescription, with adjusting for clustering at two levels: prescriptions within patients, and patients within physicians. Given two possible intra-class correlation values of .05 and .1, we required 42 weeks of prescribing to have 80% power of detecting an absolute decrease of 10% from a control baseline error rate of 20%, with a type I error of 5%.

Ethics and Funding

The hospital Research Ethics Board approved the study and waived the requirement for physician and patient informed consent. The study was funded by Health Canada; Drugmagnet provided the application free of charge. The funding sources had no role in the design and conduct of the study; collection, management, analysis and interpretation of the data; or preparation, review or approval of this manuscript.
Preliminary Results: The Challenge of Electronic Signatures

To implement the application, we successfully addressed challenges related to wireless network reliability, local printer availability and physician training. However, we found that the legality of electronic signatures presented the most significant barrier to conducting the trial. Canadian legislation prohibits the use of static signature images (an electronic rubber stamp) in healthcare because of the high risk of fraud (Lambert 2004), a view that was reinforced by advisories from Ontario regulatory authorities, including the Ontario College of Pharmacists (OCP) (Ontario College of Pharmacists 2004) and the College of Physicians and Surgeons of Ontario (CPSO) (Goldig 2005).

In contrast to healthcare, other industries such as shipping and banking have widely adopted dynamic electronic signatures to facilitate consumer transactions.

We also encountered challenges posed by electronic signatures relating to the prescription of “limited use” drugs, which are provided free of charge to certain patients meeting defined clinical criteria, as assessed by the prescribing physician. The previous standard required physicians to prescribe limited use drugs using a separate prescription pad provided by the Ontario Ministry of Health and Long-Term Care and to write a threedigit eligibility code on each prescription. Regular prescription forms with written eligibility codes became acceptable starting in 2005 (Ontario Ministry of Health and Long-Term Care 2005b). The intervention software incorporated these codes and included them electronically with the rest of the prescription. However, the ministry also mandated the specific use of a handwritten eligibility code (Ontario Ministry of Health and Long-Term Care 2005b), and dynamic handwritten text unrelated to the prescriber’s signature is not available in the study application. This limitation restricted the utility of the application to prescribing physicians as limited use drugs are prescribed regularly in the participating clinics.

To facilitate ongoing use of the software while complying with the legislation, we designed two workarounds. First, we strongly encouraged physicians to fax prescriptions to all pharmacies to relieve them of the requirement to distinguish handwritten from static electronic signatures. Second, we advised physicians to handwrite the appropriate limited use code in the signature box. While practical, these workarounds reduced some of the flexibility and advantages of the e-prescribing application under study, and, of course, their compliance with current interpretations of the law could be challenged. Fortunately, these legislative barriers did not force early termination of the trial, and no participating physician dropped out after we implemented and publicized the workarounds.

Discussion

To our knowledge, we are the first Canadian hospital to describe the implementation of a PDA-based electronic prescribing application in outpatient clinics in an RCT. As expected, the project faced numerous technical and process-related challenges during implementation. However, the most unexpected and difficult challenge was related to current Canadian legislation governing electronic prescribing. Fortunately, we designed workarounds that permitted the continuation of the trial.

Federal legislation prohibits the use of static signature images in healthcare. Recently, Health Canada acted to enforce the legislation by conducting compliance inspections of 11 Canadian hospitals.
pharmacies selling prescription drugs over the Internet or by mail order. These inspections resulted in an advisory to the pharmacist community on November 16, 2004. The notice stated in part (Ontario College of Pharmacists 2004):

During the inspections it was observed that sale of drugs was occurring pursuant to prescriptions signed using rubber stamps or electronic prescriptions signed with electronic signatures and not supported at the time of sale by a written prescription transmitted by mail or electronic means. The use of a rubber-stamp or other means of signature which is not distinct for each transaction as the basis for a prescription order is not a valid signature and does not fulfill federal requirements. The sale of Schedule F drugs in this manner is a violation of section C.01.041(1.1)(a) of the Food and Drug Regulations.

C.01.041 (1.1) Subject to C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F drug unless (a) the sale is made pursuant to a verbal or written prescription received by the seller … Please note that a prescription signed by a Canadian practitioner, then transmitted electronically, by faxing or scanning, and received prior to the sale of a Schedule F drug would not be a violation of section C.01.041(1.1)(a) of the Food and Drug Regulations.

This advisory defined a valid signature as distinct for each prescription, a condition satisfied by handwritten but not static electronic signatures. Physicians who currently use e-prescribing systems would therefore have to print out the electronic prescription, hand sign it and then give it to the patient or fax it to a pharmacy. However, faxed prescriptions may still contain static electronic signatures since a facsimile is a scanned image. Using current technology such as computers and fax servers, it would be virtually impossible to determine if a faxed signature was originally handwritten or applied as a static electronic image.

Although the legislation concerning electronic signatures is federal, Canadian healthcare professionals are provincially regulated. Relevant Ontario regulatory bodies include the CPSO and the OCP. Public statements from the OCP (Ontario College of Pharmacists 2004) and the CPSO (Goldig 2005) followed Health Canada’s advisory and warned their members about electronic signatures. For example, the CPSO stated that “neither Health Canada nor the Ontario College of Pharmacists currently recognizes electronic signatures as acceptable for signing prescriptions. The College [of Physicians and Surgeons of Ontario] endorses electronic record-keeping and the use of technology to assist in the practice of medicine; however, physicians should not use electronic or digitized signatures for prescriptions at this time.” This advisory was more restrictive than the Health Canada citation above in that it specifically prohibited all electronic signatures, whereas the Health Canada advisory did not do so.

Interestingly, in contrast to healthcare, other industries such as shipping (Federal Express 2007) and banking (Verisign 2007) have widely adopted dynamic electronic signatures to facilitate consumer transactions, a practice upheld in US law (Federal Trade Commission 2001). Recently, the Canadian Parliament passed Bill C-6 to support and promote electronic commerce; this bill considers secure electronic signatures a key component when appropriate technological and operational capacities exist (Parliament of Canada 2007).

Although Canadian legislation was designed to combat distance prescribing and other marginally legal activities, it did not anticipate the development of the unique dynamic electronic signature found in more sophisticated electronic prescribing systems. This legislation prohibits electronic signatures without distinguishing between static and unique signatures and, if interpreted strictly, may prohibit e-prescribing. Consequently, there is a significant disincentive for physicians to use innovative e-prescribing systems and associated decision support software. Similarly, pharmacists are unlikely to accept their use despite superior prescription legibility. In our trial, we were able to design workarounds to permit ongoing evaluation. However, reliance on workarounds to maximize legally acceptable practices is not sustainable in a scaled-up implementation of this technology as the risks are too high to warrant the investment in equipment, software, training and support. This situation will likely discourage wider adoption of this technology and undermine one of the main strategies currently touted to improve safety.

Ideally, legislation would strike a balance between protecting the integrity of the healthcare system and being flexible enough to allow for innovation.

Ideally, legislation would strike a balance between protecting the integrity of the healthcare system and being flexible enough to allow for innovation. To date, Canadian legislation regarding electronic signatures in healthcare remains unchanged, although regulatory bodies are starting to appreciate the need for legislative guidance (Kirshin 2007). However, the answer to the question “Can physicians use e-prescriptions now?” is clearly no (Kirshin 2007). In contrast, the United States created standards for an electronic prescription in February 2005 (Department of Health and Human Services 2005), and the United Kingdom has specific legislation governing how electronic prescriptions should be issued, including the use of electronic signatures (Queen’s Printer of Acts of Parliament 2001). Even Canada
Health Infoway (2006) – an independent not-for-profit corporation promoting electronic health records and accountable to federal, provincial and territorial governments – endorsed e-prescribing in its 2006–2007 corporate business plan. Fortunately, despite the legislation, Health Canada (who funded this RCT) ultimately agreed that Drugmagnet’s electronic signature was legal.

In our trial, we addressed the regulatory issues regarding electronic signatures by open communication with participating physicians. In particular, we discussed the regulations of Health Canada, the OCP and the CPSO but also highlighted the approval from Health Canada’s Quality Care, Technology and Pharmaceuticals Division for our study procedures. After these discussions, no physician refused to participate in the study because of medicolegal concerns.

In summary, although electronic prescribing with point-of-care decision support has the potential to increase workflow efficiency, data security and patient safety, many impediments to widespread implementation remain. In our randomized trial, legislation prohibiting electronic signatures proved to be an important barrier. Regulatory clarity regarding electronic signatures is required for the full potential of electronic health records to be realized. Such legislation should acknowledge the innovation of current technologies and permit electronic prescribing applications with unique, dynamic signatures.

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