Approaches to Improving the Safety of the Medication Use System

Stacy Ackroyd-Stolarz, Nicole Hartnell and Neil J. MacKinnon

Abstract

Problems associated with medication use have been consistently identified in the patient safety literature internationally. The purpose of this paper is to review components of the medication use process and offer suggestions for transforming it into a safer system. Prevention strategies are suggested for improving medication use at each stage of the system. Decision criteria are proposed that can be used by administrators and healthcare providers to allocate resources for prevention strategies that will improve medication safety.

Introduction

The body of literature concerning the safety, or lack thereof, of the medication use system, has increased substantially in the last decade. In Canada, some recently published studies have provided insight into the safety of our medication use system. The Canadian Adverse Events Study, a systematic review of hospital charts from randomly selected hospitals in five provinces, revealed an adverse event rate of 7.5 per 100 hospitalizations, which extrapolates to 141,250 to 232,250 hospital admissions per year in Canada that are associated with an adverse event (Baker et al. 2004). Drug- or fluid-related events were the second single largest category of adverse events, accounting for 23.6% of all events. In a prospective study of 328 patients, Forster et al. (2004) used telephone interviews and chart reviews to determine the incidence, severity, preventability and ameliorability of adverse events among patients recently discharged from hospital. In this study, 23% of patients experienced an adverse event after discharge from hospital, 72% of which were attributable to medications. The most common preventable adverse events in this patient population involved the concomitant use of medications with known interactions, contraindicated medications and inadequate monitoring of medication-related treatments. In a sample of 253 patients from the Moncton Hospital in New Brunswick, Nickerson et al. (2005) determined that patients averaged 3.5 drug-related problems at the time of hospital discharge. The most common problems were noncompliance, the need for additional drug therapy, and drug treatment that was not indicated.

The clinical impact of adverse drug-related complications is undoubtedly of first and foremost concern, but the economic impact of these problems cannot be ignored. Adverse drug events (ADEs) have been found to result in an additional average length of stay of 2.2 days for hospitalized patients; this increase was even higher for preventable ADEs (4.6 days). Furthermore, ADEs have been found to result in excess costs of $3,244 USD for hospitalized patients ($5,857 for preventable ADEs) (Bates et al. 1997). Drug-related morbidity (DRM) and mortality is estimated to cost the US healthcare system $177.4 billion US each year (Ernst and Grizzle 2001), and preventable drug-related morbidity and mortality in older adults costs the Canadian healthcare system $11 billion each year (Kidney and MacKinnon 2001).

Given the scope of the problem, it is understandable that public attention has been drawn to the issue of medication safety. Patients often express concern over the safety of the medication use system. Sixty-one percent of people surveyed by the American Society of Health-System Pharmacists (ASHP) said they were "very concerned" about "being given the wrong medicine" when asked about concerns related to receiving care in a hospital (ASHP 1999). In a sample of 920 employees and retirees of the University of Michigan, 18% reported having experienced a medication error at sometime during their lifetime (Nau and Erikson 2005). The results of the 2002 Commonwealth Fund Survey found that 20% of Canadians surveyed said a medical mistake had been made in their own care, while 11% said they had been given the wrong medication at one time or another (Schoen et al. 2003). Furthermore, 60% of those who had experienced a medical mistake believe it had a serious impact on their health (Blendon et al. 2003).

Despite the increase in research and increased public attention in medication safety, much confusion remains about this topic. With the rapid growth in the number of studies that have focused on methods to improve the medication use system, there is some confusion over how best to optimize medication safety, given the limited number of resources available to healthcare decision makers and professionals and the wide variety of possible intervention strategies proposed in the literature. The purpose of this paper is to review components of the medication use process and offer suggestions for transforming it into a safer system. Prevention strategies are suggested for improving medication use at each stage of the system.

The Medication Use Process

The Medication Use Process is a model that describes the typical course of action related to drug therapy in ambulatory care. It begins when a patient enters the healthcare system after recognizing some health-related problem. After assessing the patient's concern and forming a clinical impression, a treatment plan is developed and implemented in two steps. When the treatment plan involves medications, the medication is prescribed and dispensed with advice to the patient. Next, the patient consumes or administers the plan (medication) and typically exits the healthcare system (Hepler and Grainger-Rousseau 1995).

Because medication safety has become a significant concern of patients and healthcare professionals alike, it is important to highlight the connections between the medication use process and the five stages — ordering, transcription and verification, dispensing, medication administration, and consumption — of the delivery of medicines.

Ordering cannot occur until after the patient has entered the healthcare system and the physician or other healthcare provider has adequately assessed the patient. Once this has occurred, the healthcare provider is able to develop a therapeutic plan and can subsequently order any needed medications by writing a prescription for the patient. The remaining stages in the delivery of medications all coincide with implementation of the therapeutic plan. Transcription, verification and dispensing of the medication from the pharmacy occur during the first stage of plan implementation; administration and consumption of the medication occur during the final stage of plan administration.

Before any improvements related to medication safety can be suggested, it is important to understand where in the delivery of medications problems occur. Leape et al. (1995) performed a systems analysis of ADEs among a sample of hospitalized patients and found that the majority of events occurred during the ordering and administration stages (39% and 38% respectively). Twelve percent of events occurred during the transcription and verification stage, and 11% of events occurred during the pharmacy dispensing stage. Lack of knowledge about the drug and lack of information about the patient were the two most common attributable causes to ADEs identified in this study. Bates et al. (1995b), in their analysis of the incidence of both actual and potential ADEs, found similar results. Of the actual ADEs that were considered preventable, 49% occurred during the ordering stage, 11% occurred during the transcription stage, 14% occurred during the dispensing stage and 26% occurred during the administration stage. While room for improvement obviously exists at every stage in the delivery of medications, perhaps the most significant effects would be felt if resources were focused at improving processes used during the ordering and administration stages.

Perhaps the most rudimentary way to improve medication safety is to transform the medication use *process* into a medication use *system*. The fundamental component lacking from the process, as described previously, is a feedback loop between the last stage of plan implementation (consuming the medication) and the first stage of plan implementation (developing the therapeutic plan). The addition of a feedback loop at this stage of the process allows for ongoing monitoring of patient care and progress rather than simply allowing the patient to exit the healthcare system after receiving needed care. While the rate of ADEs in inpatient settings is shocking, evidence exists to suggest the rate of adverse events is four times higher out in the community (Gandhi et al. 2003). Therefore, a feedback loop that encourages patient monitoring turns the *process* into a *system* and is the first step in improving medication safety.

Strategies to Improve the Medication Use System

While transforming the medication use process into a system is the first step, there are many opportunities to enhance safety in all stages in the medication use system. The overall goal of

doing so is to optimize patient outcomes. There are strategies that can be used at each step in the delivery of medications, as well as strategies that focus on system-wide changes.

Ordering

Given the high proportion of injuries that occur at this stage in the process, much work has focused on the development of prevention strategies. In general, ordering is more likely to be appropriate if there is a clear therapeutic plan with objectives that are understood by the physician, the patient and the pharmacist (Hepler and Grainger-Rousseau 1995; MacKinnon 2002a).

One of the most frequently recommended approaches to preventing problems associated with this stage is computerized physician order entry (COPE) (Bates et al. 1995a; Cullen et al. 2000; Gurwitz and Rochon 2002; Conference Proceedings 1995; Anderson and Webster 2001; Bobb et al. 2004). The structured, ordered input that allows the physician to select from a menu of options is designed to reduce dosage errors by only offering those that are appropriate. The program can be linked to guidelines for the use of drugs and can provide prompts to check on such things as drug allergies or potential drug-drug interactions. Moreover, this technology eliminates the need for transcription, thus reducing the possibility of errors at this stage in the medication use process. Despite these advantages, widespread adoption will be limited by the cost of implementation and the willingness of physicians and/or organizations to adopt this technology. There is also evidence to suggest that the introduction of the technology introduces new opportunities for error. In their review of the CPOE system at a tertiary-care teaching hospital, Koppel et al. (2005a) identified 22 types of medication error risks that were facilitated by the use of CPOE (e.g., delay in information on drug allergies). The authors acknowledge that there have been technological advances to the system since the data were collected, but they emphasize that users must continually seek to improve the system (Koppel et al., 2005b). Although computerized order entry will not eliminate all errors, and may even result in different types of errors, the current evidence indicates that it can reduce the rates of medication errors (Kaushal et al. 2003; Oren et al. 2003). Oren et al. (2003) caution that in addition to their contribution to error reduction, technological advances should also be evaluated in terms of their appropriate application and impact on patient outcomes.

Another technological approach to improving the process at the ordering stage involves the use of computerized pharmacy systems (Bates 1996). The systems are designed to alert the pharmacist to potential problems associated with a prescription, although it does not obviate the need for the pharmacist to have direct contact with either the physician and/or the patient to discuss the best prescribing solution. In healthcare facilities without this technology, this task can be performed by manual review of orders by the pharmacist. It is important that the electronic system flags (e.g., to warn of drug-drug interactions) are appropriately sensitive and clinically important, otherwise there is a risk that the flags will be ignored (Kaushal et al. 2003), thus limiting the effectiveness of the intervention (Galanter et al. 2005). Clinical decision support technologies are most effective when integrated with CPOE systems and clinician workflow (Galanter et al. 2005; Garg et al. 2005).

Academic detailing refers to targeted physician education, usually conducted by a pharmacist. The thrust of this approach is to change physician-prescribing practices by providing objective information on specific medications. This can be used in conjunction with computer physician order entry, as the system flags can reinforce information provided in the academic detailing, to reduce problems at the ordering stage of medication delivery (Bates 1996).

Transcription & Verification

The use of physician order entry eliminates this stage of the process; however, it is not available to all facilities and providers. Ragan et al. (2005) report that only 7% of US hospitals have adopted the technology, so it is also necessary to consider simpler, nontechnological approaches to reducing problems at this stage. The age-old recommendation of writing legibly for written orders and speaking clearly for verbal orders is still applicable (Conference Proceedings 1995). As well, ensuring sufficient and well-trained personnel in a work environment that minimizes distraction will provide optimal conditions for minimizing problems at the transcription and verification stage of the process (Zellmer 1993). Another simple and economical approach is the avoidance of abbreviations or the use of standard abbreviations (Conference Proceedings 1995; Bates 1996).

Dispensing

Several advances have successfully been applied at this stage of the medication use process. Perhaps most notable is the use of the unit dose. Medications are dispensed in either a single unit or a unit dose in a ready to administer format. Usually no more than 24 hours of medication are dispensed at one time. Several studies have demonstrated that the use of the unit dose system reduced medication error, and in one study it did so by more than 80% (Simborg and Derewicz 1975; O'Brodovich and Rappaport 1991). Nurses have indicated a strong preference for the system, as it also results in some time saving for drug administration (O'Brodovich and Rappaport 1991; Gaucher and Greer 1992).

Pharmacy control systems play a role in the prevention of medication misadventures (Conference Proceedings 1995). Automated dispensing systems ensure that medications are only given to patients who should receive them, and the system

maintains a record of what has been given, to whom and when it was given. These systems are linked with inventory and reduce the potential for error (Conference Proceedings 1995; Bates 1996; Oren 2003). The packaging and labeling of products are other important elements that can be modified to reduce error (Conference Proceedings 1995). One of the major impediments to the use of automated dispensing systems is the cost.

A nontechnological approach to minimizing problems associated with dispensing medications is for the pharmacist to exercise care in making calculations and have a second person check the accuracy of the calculations. A work environment that has limited distractions and adequate lighting and space can also contribute to the prevention of calculation errors (Conference Proceedings 1995).

> **… including providers, patients, leaders, purchasers, industry and regulatory bodies, professional bodies, licensing and accreditation bodies …**

Administration

This stage of the process represents one of the most high-risk activities for nurses in healthcare facilities (Anderson and Webster 2001; Preston 2004). As in other steps in the process, the work environment and availability of adequate personnel are important factors in the safety of the system (Zellmer 1993; Conference Proceedings 1995). Technological approaches such as unit dosing and bar coding medications can also reduce the potential for error (Conference Proceedings 1995; Bates 1996; Oren 2003). Bar coding technology has also demonstrated time-savings in work processes and fewer system errors (Oren 2003; Ragan 2005). In preliminary estimates following the introduction of bar coding at Brigham and Women's Hospital in Boston, drug errors have been reduced by 50 percent, or approximately 20 adverse drug events per day (Wright 2005). There are several factors that limit the adoption of bar coding technology, including cost and potential changes to work-flow patterns. There remain inconsistencies in industry standards for packaging and coding of products (Oren 2003; Ragan 2005). However, it is anticipated that the problem will be alleviated in the United States, at least, with the introduction of FDA regulations requiring the inclusion of bar codes on most prescription drugs (Ragan 2005).

Consumption

One of the most critical strategies to ensure that patients are using medications as prescribed is by ensuring that they have adequate education from the pharmacist (Conference Proceedings 1995). This is enhanced when there is a collaborative relationship between the prescriber and the pharmacist, as well as direct access to the pharmacist by the patient (Gurwitz and Rochon 2002). Also, ongoing communication with patients once they leave the healthcare facility, whether it is a hospital, physician's office, or outpatient clinic, is essential to prevent problems with medication use from happening out in the community. The introduction of medication reconciliation processes has been promoted as a mechanism to prevent medication errors that occur at transitions of care (Barnsteiner 2005).

System-Wide Approaches

In addition to the specific strategies described previously, broader, system-level approaches to improving safety have been widely recommended (Baker et al. 2004; Hepler and Strand 1990; Hepler and Grainger-Rousseau 1995; Cullen et al. 2000; Gurwitz and Rochon 2002; Conference Proceedings 1995; Anderson and Webster 2001; Bates 1996; Leape et al. 2002; MacKinnon 2002b). The healthcare system is comprised of a multitude of individuals. Cohen (2002) makes a cogent argument that all members of the system, including providers, patients, leaders, purchasers, industry and regulatory bodies, professional bodies, licensing and accreditation bodies share accountability for safety. In addition, the academic institutions that train healthcare professionals also need to assume part of the shared accountability and to teach about patient safety.

The routine addition of ongoing monitoring to the medication use process through the provision of pharmaceutical care is a fundamental element in optimizing patient outcomes (Hepler and Grainger-Rousseau 1995; MacKinnon 2002 a; Conference Proceedings 1995). However, there are currently few financial incentives for pharmacists to do this. Routine monitoring can be more readily achieved through ongoing collaboration amongst a multidisciplinary team of healthcare providers, including physicians, pharmacists and nurses (Hepler and Grainer-Rousseau 1995; Gurwitz and Rochon 2002). This approach can lead to the provision of care that is less fragmented, particularly at the transitions from one setting to another (MacKinnon 2002a). This so-called "seamless care" greatly enhances the quality of care, and ultimately health outcomes for patients. Pharmacists have a significant role to play in the process. Several authors have suggested that pharmacists need to become more visible members of the healthcare team (Zellmer 1993; Hepler and Grainger-Rousseau 1995; Conference Proceedings 1995; Cohen 2002). Another strategy related to ongoing monitoring is the development of reporting systems. The reports can be used to understand those factors that contribute to adverse events so that specific interventions can be put in place to prevent them from occurring again (Conference Proceedings 1995; Anderson and Webster 2001).

Attention must also be given to the work environment in healthcare (Zellmer 1993; Conference Proceedings 1995). There have been severe fiscal restraints throughout the healthcare system in the last decade or longer. Inadequate personnel and insufficient time for training have the potential to weaken system efficiency, thus contributing to the potential for adverse events. The success of other interventions will be limited if these factors are ignored.

A plethora of technological advances have demonstrated that there is potential to improve safety in all steps in the system. While not all of these technologies are in use throughout the system, nor have they all been comprehensively evaluated, they nonetheless offer direction for future development and implementation.

Decision Criteria for Allocating Resources

Resources in healthcare are focused on the provision of diagnostic and therapeutic care for patients. Difficult decisions must be made about how to allocate increasingly scarce resources. And while most would agree that improving patient safety is a laudable goal, there may be less agreement on where to find the resources to achieve this. Runyan (1998) suggests a number of decision criteria that can be applied in the decision-making process for injury prevention that can also be applied in the context of patient safety. The criteria include whether or not the intervention works (effectiveness) or is feasible to implement, as well as its cost. Decision-makers also need to consider if the strategy can be implemented in an equitable manner. For example, only some hospitals within a jurisdiction may be able to afford the expense of the physician computer order entry system. Consideration must also be given to the preferences of stakeholders and whether or not use of the strategy will have an impact on their freedom. Using the same example, some physicians may not want to use computer order entry because they may perceive it as limiting their freedom to prescribe the way they would like to. These criteria can be systematically applied to the decision-making process and they make the values that have guided the process more transparent (Conference Proceedings 1995; Anderson and Webster 2001; Runyan 1998).

Conclusions

The medication use system is highly complex. It faces increasing challenges with an aging population, direct-to-consumer advertising, the introduction of new drugs, technologies and over-the-counter products (Cohen 2002). There is a growing understanding of the problem. However, judging from the limited actions of patients, providers and decision-makers, more needs to be done to raise awareness of the magnitude of the problem and its costs.

There are many approaches to the problem, but there seems to be consensus that a systems approach will be far more effective than trying to change the behaviour of individuals. The greatest potential for change within the medication use system is to ensure that each patient has a clear therapeutic plan that is understood by the patient, pharmacist and physician. Finally, there should be a commitment and mechanisms in place for ongoing monitoring of the patient.

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