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The need for organizational change in patient safety initiatives

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ABSTRACT

Objectives: This study describes a computer simulation model that has been developed to explore organizational changes required to improve patient safety based on a medication error reporting system.
Methods: Model parameters for the simulation model were estimated from data submitted to the MEDMARX medication error reporting system from 570 healthcare facilities in the U.S. The model's results were validated with data from the Pittsburgh Regional Healthcare Initiative consisting of 44 hospitals in Pennsylvania that have adopted the MEDMARX medication error reporting system. The model was used to examine the effects of organizational changes in response to the error reporting system. Four interventions were simulated involving the implementation of computerized physician order entry, decision support systems and a clinical pharmacist on hospital rounds.
Conclusions: Results of the analysis indicate that improved patient safety requires more than clinical initiatives and voluntary reporting of errors. Organizational change is essential for significant improvements in patient safety. In order to be successful, these initiatives must be designed and implemented through organizational support structures and institutionalized through enhanced education, training, and implementation of information technology that improves work flow capabilities.

1. Introduction

The Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System* [1], estimated that between 44,000 and 98,000 deaths occur in the U.S. each year as a result of medical errors. In fact, there is evidence that morbidity and mortality from prescription errors increased between 1983 and 1998 by 243% [2]. A significant number of these errors involve medications. A meta-analysis of 39 prospective studies indicated that adverse drug reactions may rank between the fourth and seventh leading cause of deaths in the U.S. [3]. One study of medication errors in 36 hospitals and skilled nursing facilities in Georgia and Colorado found that 19% of the doses were in error; 7% of the errors could have resulted in adverse drug events [4]. Recognizing the magnitude of the medication error problem, a subsequent IOM report, *Crossing the Quality Chasm:*

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A New Health System for the 21st Century [5] recommended that confidential voluntary reporting systems be adopted in all health care organizations. At present the Veteran's Administration, about half of the states, many hospitals and private organizations have developed error reporting systems in an effort to improve patient safety [6].

Traditionally, efforts to reduce errors have focused on training, rules and sanctions. Also, hospitals have relied on voluntary reporting of errors. Currently only 5–10% of medication errors that result in harm to patients are reported [7]. As a result little progress has been made since the IOM report 5 years ago [8].

1.1. *Error reporting systems*

The first step in reducing medication errors is standardized reporting of the necessary data to understand the nature of the problem. A number of reporting systems have been developed. Some of these systems are voluntary, others mandatory. The most successful systems are modeled after the Aviation Safety Report System (ASRS). This system is anonymous, voluntary and administered by the NASA for the Federal Aviation Administration [9]. The Veterans Administration Patient Safety Reporting System (PSRS) is patterned after the ASRS system [10,11]. The Institute for Safe Medical Practice (ISMP) also has developed a voluntary reporting system for medication errors [12]. Another system has been developed by the Food and Drug Administration (FDA) called Data Watch for the reporting of adverse events arising from medications and medical devices [6].

Other reporting systems have been developed for ICUs [13], at the Ohio State University Health Care System [14], and for primary care clinics [15,16]. Some states in the U.S. have mandatory medical error reporting databases. However, these systems require the identification of the responsible parties and are used for disciplinary actions [6]. Medical error reporting systems are also being implemented in other countries such as Korea [17], Japan [18] and France [19].

In some instances error reporting systems are being implemented among multiple institutions in order to share learning regarding incidence and types of errors and ways to improve patient safety. For example, Johns Hopkins University designed and implemented a Web-based ICU safety reporting system in 18 ICUs across the United States [20]. The Pittsburgh Regional Health Care Initiative is a consortium of 44 hospitals that share data on nosocomial (hospital acquired) infections and medication errors [21].

This study uses data from the MEDMARX system [22]. The United States Pharmacopoeia (USP) introduced MEDMARX in 1998. It is an internet-accessible, anonymous medication error reporting system. Currently 775 hospitals and health systems use the system. Medication errors are reported in a standard format. A medication error is defined as "... any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare practice; healthcare products' procedures, and systems including prescribing; order communication; product labeling; packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use" [23].

1.2. *Organizational actions*

The majority of medical errors result from poorly designed healthcare systems rather than from negligence on the part of health care providers. Successful patient safety initiatives require cognitive, social and organizational changes as well as reporting [24,25]. Current health care systems are complex and fragmented, involving interactions among a number of health care professionals with various levels of education and training [26]. The discontinuous nature of patient care fosters errors [27]. Remedying the systemic problems that lead to error will require organizational changes at the point of care [28].

Members of the study team were associated with an Agency for Healthcare Research and Quality (AHRQ) funded research project. The purpose of the project is to achieve sustainable improvements in health care on a regional basis by sharing information. The objective of the project is to improve patient care and safety in over 44 hospitals [21,26]. The hospitals, working in a collaboration called the Pittsburgh Regional Healthcare Initiative (PRHI), have been sharing information about their medication errors for the past 3 years. The overall objective is to leverage the data from reporting to initiate region-wide process improvements. The assumptions underlying this regional reporting system are described using a learning chain model as shown in Fig. 1.

The framework suggests that the link between reporting and learning requires that data about medication errors are reported voluntarily by all classes of care providers (reporting system). The effectiveness of this system depends on the quantity and quality of data reported. Quality in particular refers to data not just about serious errors that cause patient errors but also about "near misses" that fail to reach the patient. The latter kind of data enables organizations, in principle, to proactively address root causes of errors in a blame-free manner.

Data from the reporting system is disseminated to the appropriate people in a timely manner (information-sharing system). The effectiveness of this system depends on the proportion of people involved directly/indirectly with medication delivery who receive the information within a reasonable time from the occurrence of errors. When a greater proportion of people receive the information, awareness about the magnitude of the problem increases and, in turn, encourages further reporting. This also increases the involvement of different classes of providers in analyzing the data.

Information about errors is used by frontline care providers to identify root causes and initiate corrective actions (problem solving system). The effectiveness of this system depends on the ability of care providers to diagnose underlying process issues (in other words go beyond assigning individual blame in identifying causes), design appropriate corrective actions, and implement these actions. When data about errors results in such process improvements, organizational learning is said to occur.

A useful feature of the PRHI experiment is that the participating hospitals implemented a standardized medication