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Regional Patient Safety Initiatives: The Missing Element of Organizational Change

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Abstract

Data-sharing systems—where healthcare providers jointly implement a common reporting system to promote voluntary reporting, information sharing, and learning—are emerging as an important regional, state-level, and national strategy for improving patient safety. The objective of this chapter is to review the evidence regarding the effectiveness of these data-sharing systems and to report on the results of an analysis of data from the Pittsburgh Regional Healthcare Initiative (PRHI). PRHI consists of 42 hospitals, purchasers and insurers in southwestern Pennsylvania that implemented Medmarx, an on-line medication error reporting systems. Analysis of data from the PRHI hospitals indicated that the number of errors and corrective actions reported initially varied widely with organizational characteristics such as hospital size, JCAHO accreditation score and teaching status. But the subsequent trends in reporting errors and reporting actions were different. Whereas the number of reported errors increased significantly, and at similar rates, across the participating hospitals, the number of corrective actions reported per error remained mostly unchanged over the 12 month period. A computer simulation model was developed to explore organizational changes designed to improve patient safety. Four interventions were simulated involving the implementation of computerized physician order entry, decision support systems and a clinical pharmacist on hospital rounds. The results of this study carry implications for the design and assessment of data-sharing systems. Improvements in patient safety require more than voluntary reporting and clinical initiatives. Organizational changes are essential in order to significantly reduce medical errors and adverse events.

Patient Safety

For more than a decade studies in the U.S. (Brennan et al., 1991; Leape et al., 1991; Gawande et al., 1999; Thomas et al., 2000) and other countries (Wilson et al, 1995; Vincent et al., 1999; Davis et al., 2002, 2003; Baker et al., 2004; WHO, 2004) have reported that adverse events in health care are a major problem. These studies estimate that anywhere from 3.2% to 16.6% of hospitalized patients in the U.S. and Australia respectively experience an adverse event while hospitalized. A recent Canadian study of hospital patients estimated a rate of 7.5 adverse events per 100 hospital admissions (Baker et al., 2004). Over 70% 0f these patients experience disability and 14% die as a result of the adverse event. The Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System* (Kohn, Corrigaan & Donaldson, 2001), 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 medical errors increased between 1983 and 1998 by 243% (Phillips & Bredder, 2002).

A significant number of these errors involve medications. A meta-analysis of 39 prospective studies indicated that adverse drug reactions from medication errors account for a significant proportion of these events in the U.S. (Lazarou, Pomeranz & Corey, 1998). 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; seven percent of the errors could have resulted in adverse drug events (ADEs) (Barker et al., 2002)). ADEs also occur among outpatients at an estimated rate of 5.5 per 100 patients. A recent analysis of hospital emergency departments in the U.S., estimated that ADEs account for 2.4 out of every 1000 visits (Budnitz et al., 1006). Based on these studies the Institute of Medicine recommended that confidential voluntary reporting systems be adopted in all health care organizations (IOM, 2001).

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 (Cullen et al., 1995). As a result little progress has been made since the IOM report five years ago (Leape & Berwick, 2005).

Data Sharing Systems

Studies have indicated that adverse events in health care settings primarily result from deficiencies in system design (Anderson, 2003). A study of adverse drug events in Utah and Colorado estimated that 75% of ADEs were attributable to system failures (Gawande et al., 1999; Thomas et al., 2000). Consequently, there is growing consensus that improvements in patient safety require prevention efforts, prompt reporting of errors, root-cause-analysis to learn from these errors and system changes to prevent the errors from reoccurring.

Currently only 5-10% of medical errors are reported (Cullen et al., 1995). Incident reporting represents a major strategy to address growing concerns about the prevalence of errors in healthcare delivery (Billings, 1998). The Patient Safety and Quality Improvement Act was signed into law in 2005. This act encourages health care providers to report medical errors to patient safety organizations that are being created. Patient safety organizations are authorized to analyze data on medical errors, determine causes of the errors, and to disseminate evidence-based information to providers to improve patient safety. Currently, over 24 states have mandated some form of incident reporting (Comden & Rosenthal, 2002). Also, there has been a steady increase in the number of regional coalitions of providers, payers, and employers working to improve patient safety (Halamka et al., 2005). These efforts are driven by the premise that the identification of unsafe conditions is an essential first step toward analyzing and remedying the root causes of errors. Such reporting systems often occur in the context of an infrastructure for inter-organizational sharing of these data. The emphasis on data-

sharing is based on the premise that when organizations share such data about incidents and the lessons learned from them, it will lead to accelerated improvements in patient safety across the board. In other words, data-sharing is expected to result in community-wide learning. Indeed, patient safety centers in states that have created them are charged with facilitating such data-sharing. Not surprisingly, these data-sharing systems vary widely. They differ in the data that is shared (from specific processes/outcomes such as medication errors and/or nosocomial infections to a broad range of incidents); the participants (individual clinicians to entire healthcare organizations); geography (regional, state, and national); technology (paper-based to online); and regulatory expectations about participation (voluntary or mandatory) (Rosenthal et al., 2004; Flowers & Riley, 2001).

Despite such differences, data-sharing systems are typically based on the premise that threats to patient safety arise from the unwillingness/discomfort of healthcare providers to openly discuss errors and their resulting lack of awareness of the magnitude of the problem. The identification and reporting of unsafe conditions is a necessary first step in a systemic approach to revamping patient safety. But technological, psychological, cultural, legal, and organizational challenges pose formidable barriers to the blame-free identification and discussion of unsafe conditions. Whereas individual organizations by themselves may not be able to take on these challenges, participation in a data-sharing coalition provides a shared rationale and the subtle benefits of peer influence. Second, the data from increased reporting facilitates the diagnosis of systemic causes of unsafe conditions and the implementation of systemic solutions. So data-sharing, it is assumed, will accelerate the identification of unsafe conditions, encourage analysis of the underlying causes, and enable continuous process improvement. Although different organizations may benefit differently from participating in a data-sharing system, a strong implicit assumption underlying these systems is that they will benefit the entire community of participating organizations.

To date few studies have examined the anticipated benefits of medical error data-sharing systems. Below we report the results of a study of developmental trends in two indicators of the effectiveness of one regional data-sharing coalition. The indicators are the reported number of medication errors and the number of corrective actions taken by hospitals as a result of these errors. The objectives of the study were to examine whether hospitals that participated in medication error data-sharing consortium experienced increased reporting over time. The second objective was to determine whether error reporting resulted in organizational actions aimed at reducing future errors. A third objective was to explore organizational interventions designed to reduce mediation errors in hospitals.

The Pittsburgh Regional Healthcare Initiative (PRHI)

A consortium of providers, purchasers, insurers and other stakeholders in healthcare delivery in southwestern Pennsylvania was formed in 1997 (Siro et al., 2003). Its purpose was to improve patient care by working collaboratively, sharing information about care processes and their links to patient outcomes, and using patient-centered methods and interventions to identify rapidly solve problems to root cause at the point of care. Clinicians, 42 hospitals, four major insurers, several large and small-business healthcare purchasers, corporate and civic leaders, and elected officials make up the consortium.

In order to improve clinical practice and patient safety PRHI created a regional infrastructure for common reporting and shared learning. The consortium focuses on two patient safety goals, reducing nosocomial or hospital acquired infections and medication errors.

The organizational learning model that underlies the PRHI strategy is based on the science of complex adaptive systems (Plsek, 2001). Healthcare delivery systems are viewed as a collection of individual agents whose actions are not always predictable. At the same time agents are

interconnected so that the actions of one agent can change the organizational context for other agents. Accordingly sustainable system-wide improvements in patient safety require real-time error reporting and decentralized problem solving. PRHI has relied on several strategies to promote improvements. The system chosen for reporting of medication errors was the USP's Medmarx (Hicks et al., 2004) . The system standardizes medication error reporting by using the national coordinating council for medication error reporting and prevention (NCCMERP) error categories. The Medmarx system is anonymous and voluntary. Health care providers can report medication errors online using a standardized format. The following information is collected on each reported order:

(1) Inpatient or outpatient setting

(2) Type of error

(3) Severity

(4) Cause of error

(5) Location

(6) Staff and products involved

(7) Contributing factors

(8) Corrective actions taken

Data reported by consortium members is analyzed and quarterly reports are provided to participating hospitals. These reports contain facility-specific regional and national data. The quarterly reports provided data on reporting volume reflecting the early strategic emphasis on increasing reporting. The reports also contain data on the corrective actions being reported by each hospital. These reports provided an opportunity to compare the trends in reporting of errors with reporting of corrective actions. It was hypothesized that growth in the reporting of medication errors

reported through the data sharing system would predict growth in corrective actions taken by the hospitals in response to the reported errors.

Effectiveness of Data Sharing

We set out to examine the effects of data-sharing on the group of participating hospitals. The data analyzed consisted of approximately 17,000 reports of medication errors submitted over a 12 month period by 25 hospitals that are participating in PRHI. There were two outcome variables: the number of medication errors reported by each hospital each quarter and the ratio of corrective actions reported by each hospital to the number of errors reported each quarter. Control variables included the hospital's teaching status (i.e., teaching versus non-teaching), the hospital size in terms of the number of beds, and the latest JCAHO accreditation score. A latent growth curve analysis was used to examine longitudinal trends in error reporting and organizational corrective actions (Anderson et al., 2007). This analysis permitted the investigators to determine whether statistically significant changes in error reporting and corrective actions occurred over time; whether these trends varied significantly among the hospitals; and whether hospital characteristics were associated with these trends.

Figure 1 shows the distribution of medication errors reported by severity. Fifty one percent of the events had the capacity to cause harm but did not affect the patient. Another 41% of the errors reached the patient but did not cause harm. The remaining medication errors caused patient harm and in two cases may have resulted in the patient's death.

Figure 2 shows the trends in error reporting and corrective actions over the four quarters. During the first quarter hospitals reported on average 45 medication errors. The number of errors reported rose steadily and had almost doubled by the fourth quarter. In contrast, the number of corrective actions taken by the hospitals in response to the errors remained fairly constant and, in fact, decreased slightly by the fourth quarter.

Furthermore, our analysis indicated that, although there were significant differences between hospitals in error reporting at the baseline, subsequent error reporting increased at similar rates among the hospitals. By contrast, while there were significant differences among hospitals in their base line reporting of corrective actions, the number of corrective actions reported per error remained unchanged during subsequent quarters. The finding that the increase in reporting rates were similar across participating hospitals is consistent with the notion that data-sharing provides opportunities for organizations to observe others' actions and adjust their behaviors. This is especially likely because in focus groups conducted during this period, informants from 8 of these hospitals stated that medication error reports were reviewed by senior managers and that their typical response was "how are we doing with respect to others?" If the response of participating hospitals was to initiate actions to increase the reporting rate in line with the regional trend, it would partly explain how the reporting trends across hospitals moved in tandem. This finding is important because our analysis controlled for differences in baseline reporting, hospital size, teaching status, and accreditation scores.

Corrective actions taken by hospitals as a result of medication errors indicate how important patient safety is to the institution. First-order interventions include individual interventions such as:

(1) Informing staff who made the error

(2) Informing other staff involved in the error

(3) Providing education/training

(4) Informing the patient's MD

(5) Informing the patient/caregiver

(6) Instituting policies/procedures

(7) Enhancing the communication process

Second-order interventions include system changes such as:

      (1) Computer software modified/implemented

      (2) Staffing practice/policy modified

      (3) Environment modified

      (4) Policy/procedure instituted

      (5) Formulary changed

      (6) Policy/procedure changed

First- order interventions are aimed at individuals and are likely to have short-term effects and thus are unlikely to be effective in preventing future errors from occurring. Second-order interventions involve system changes and are much more likely to prevent errors from reoccurring. Figure 3 shows the types of actions taken in response to reported medication errors. Eighty-five percent of the actions taken by the hospitals in response to reported errors involved individuals. Only 15% of the organizational actions involved system changes.

A second analysis was based on a computer simulation model constructed to model medication error reporting and organizational changes needed to improve patient safety (Anderson et al., 2006).

Several potential organizational interventions were simulated (Anderson et al, 2002; Anderson, 2004). First, baseline conditions were simulated. Intervention 1 involved introducing a basic computerized physician order entry (CPOE) system with minimal decision support for medication prescribing and administration. The second intervention assumed implementation of a CPOE system with decision support. Intervention 3 involved the inclusion of a clinical pharmacist on physician rounds who reviewed all medication orders. The fourth intervention assumed an organizational commitment to undertake root-cause analyses and system changes to prevent errors from reoccurring.

Figure 4 shows the results of the simulation. The model predicts that the introduction of a basic CPOE system will have little effect on the number of medication errors that could result in adverse drug events. Even the addition of decision support to the CPOE system is likely to result in only about a 20% reduction in medication errors. The inclusion of a clinical pharmacist on hospital physician rounds is like to reduce errors by only about 27%. Finally, the model predicts that when a commitment is made to root-cause-analysis of errors and system changes to prevent errors from reoccurring medication errors can be reduced by as much as 70% over time.

Conclusions

The results of this study carry implications for the design and assessment of data-sharing systems. Organizational actions taken in response to errors indicate how aggressive the organization is in responding to errors. Efforts that only affect individual staff and involve voluntary reporting and clinical initiatives are likely to have little effect in reducing errors long term. System--wide organizational changes are essential in order to significantly reduce medical errors and adverse events. In general, there is a mismatch between patient safety goals and hospital actions to reduce the risk of future medication errors. Hospitals increasingly recognize the need to implement error reporting systems. At the same time they fail to implement organizational changes needed to improve patient safety. Actual error reduction will require organizational changes to be carefully institutionalized and integrated into long term plans.

Currently only 5-10% of medical errors are reported. There are a number of barriers that must be overcome in order to implement data-sharing systems designed to improve patient safety (Rosenthal & Booth, 2004; Ferris, 2006). First, competition inhibits provider participation. There is a lack of trust of other providers. Also, concerns about information ownership and reliability and privacy of data impede cooperation. Second, there is lack of a business case for patient safety.

Healthcare delivery systems are complex. Implementation of information technology such as EHRs, electronic prescribing, clinical decision support, bar coding is expensive. Providers do not perceive a return on their investment in new technology such as electronic medical records and electronic prescribing.

Third, the culture of medicine presents significant barriers. Medicine is committed to individual professional autonomy. This results in a hierarchical authority structure and diffuse accountability. Furthermore, there is a culture of "blame and shame." The fear of malpractice litigation inhibits reporting of errors. Fourth, there are technical barriers to implementation of data-sharing. There is a lack of an accepted error reporting system and standards. Also there is a lack of agreement of what constitutes an error. The difficulty in identifying problems, measuring progress and demonstrating improvement makes many healthcare institutions reluctant to participate in data-sharing coalitions. Moreover, voluntary reporting does not support comparative analysis of institutions on overall safety performance. What is more, the current reimbursement structure militates against improving safety.

Some of the steps that need to be taken to overcome these barriers to data-sharing include (Institute for Healthcare Improvement, 2006):

(1) Diffusion of safe practices such as those identified by the NQF.

(2) Training on safety and team work.

(3) Implementation of error reporting systems.

(4) Establish a National Patient Safety Agency similar to the one established in the UK.

(5) Change reimbursement policies to provide incentives to hospitals and physicians for safe care.

(6) Provide disincentives for unsafe practices and adverse events (e.g., Minnesota's decision to stop paying hospitals for preventable adverse events).

(7) Bring together the JCAHO, NQF, AHA, AMA, Leapfrog Group, the Centers of Medicare/Medicaid services and major payers to set explicit goals for patient safety to include a 90% reduction in nosocomial infections, a 50% reduction in errors associated with medications, and a 100% elimination of errors on NQF "Never" list.

Leape and Berwick (2005) have observed "The primary obstacles to achieving these[improved safety] results for the patients who depend on physicians and health care organizations are no longer technical; the obstacles lie in beliefs, intentions, cultures, and choices."

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Figure 1. Percentage of Medication Errors Reported by Severity
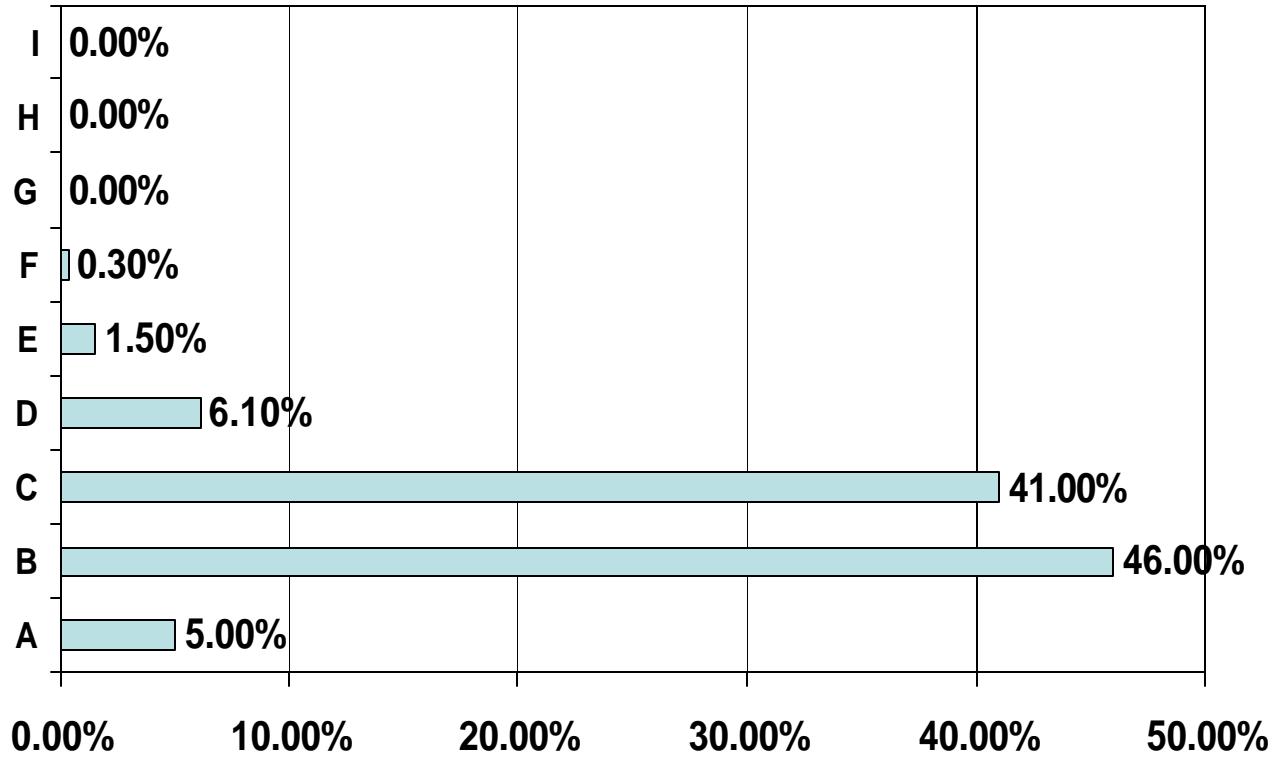
Type of Error
A: Circumstances of events that have the capacity to cause error.
B. An error occurred but the error did not reach the patient.
C: An error occurred that reached the patient but did not cause patient harm.
D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.
G: An error occurred that may have contributed to or resulted in permanent patient harm.
H: An error occurred that required intervention necessary to sustain life.
I: An error occurred that may have contributed to or resulted in the patient's death.

Figure 2. Medication Errors and Organizational Changes
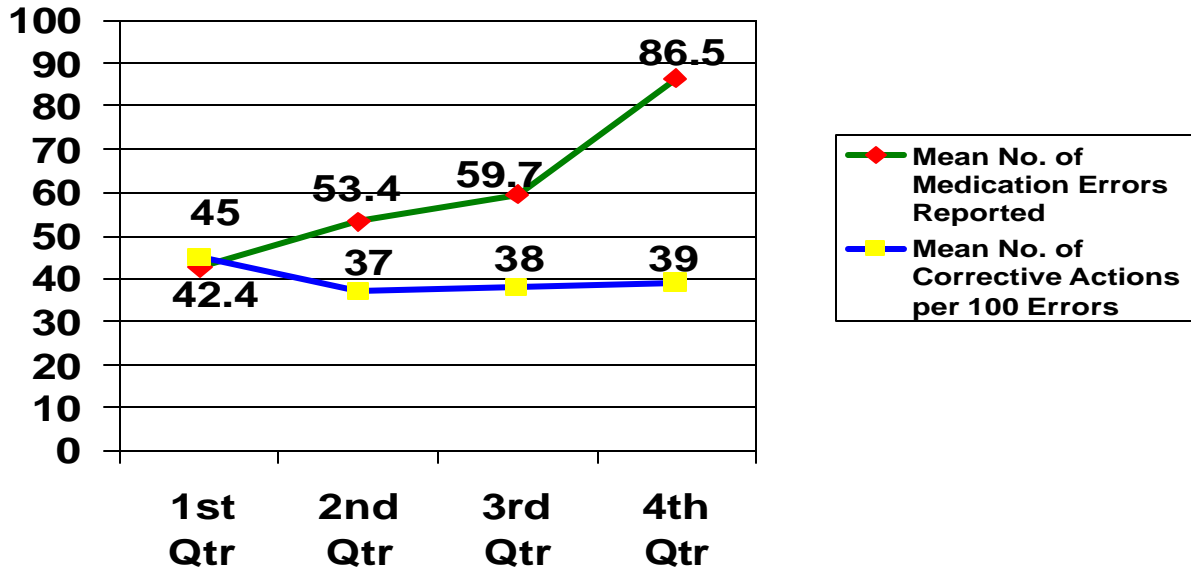## Reported over Four Quarters

Figure 2. Medication Errors and Organizational Changes Reported over Four Quarters

Figure 3. Number of Organizational Actions Taken in Response to
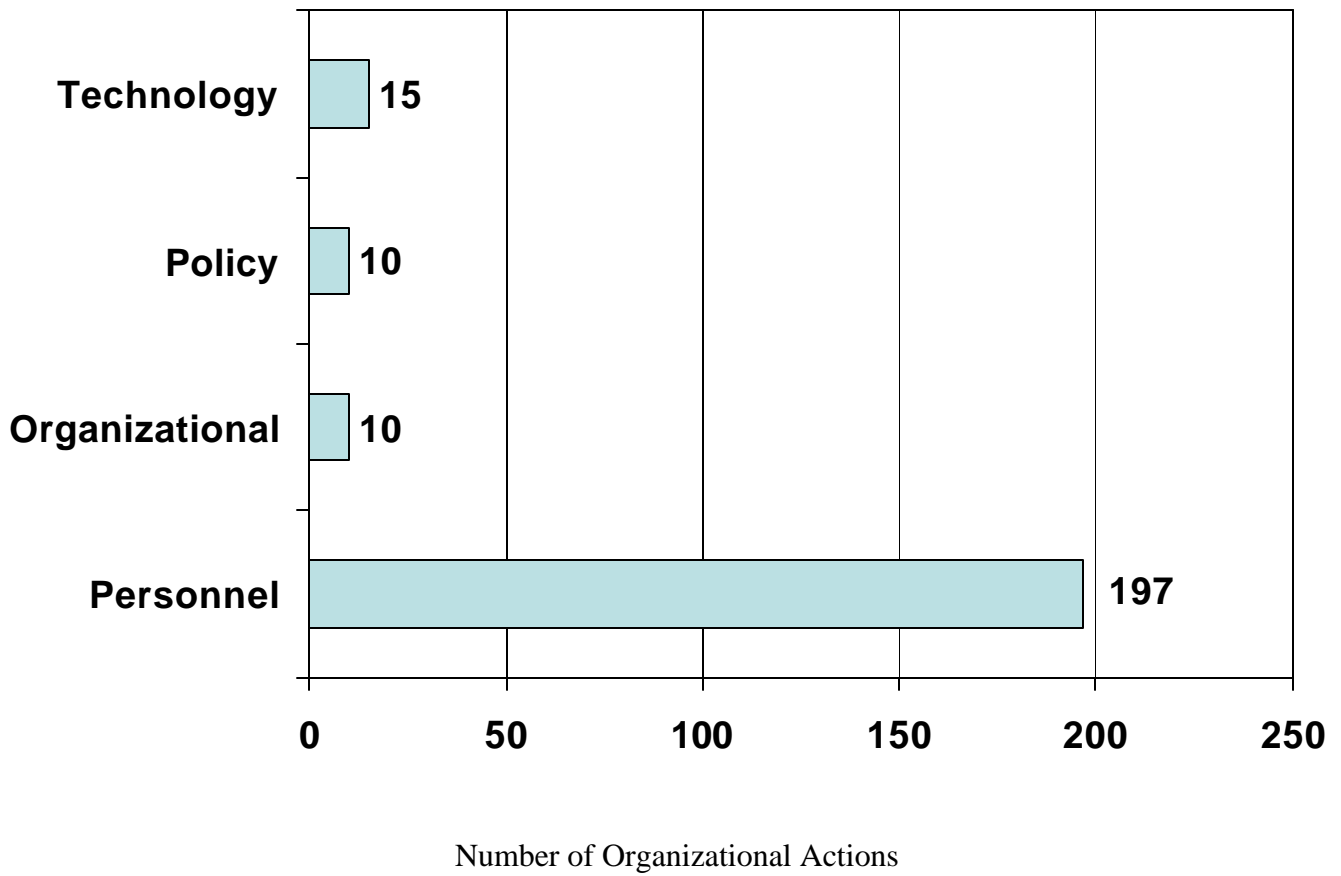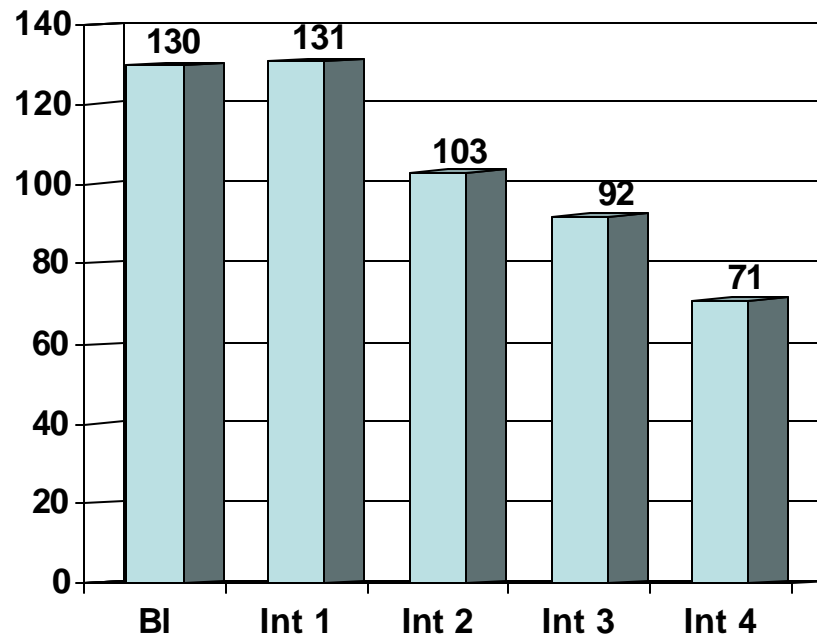
1,760 Reported Errors

Number of Organizational Actions

Figure 4. Estimated Average Number of Medication Errors that Could Have Resulted in ADEs by Quarter

- [**BL**] Existing information system
- [**Int 1**] Computer-based physician order entry system
- [**Int 2**] Computer-based physician order entry system that provides dosing information about drugs at the time orders are written
- [**Int 3**] Pharmacists participation on physician rounds
- [**Int 4**] Pharmacists participation and organizational commitment to identify causes of errors and make system changes to improve patient safety