Grant Final Report

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Improving Patient Safety/Quality with HIT Implementation

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West Bend Clinic
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Abstract

Purpose: To improve patient safety and quality of care through the implementation of HIT and the design of a new hospital focused on safety, enhancing safety culture and safety driven processes for the benefit of St. Joseph's Community Hospital and other organizations.

Scope: Studies on eight latent conditions, nine adverse events, and three outcome measures were undertaken prior to the new hospital and Epic implementation, and through the grant study period.

Methods: Pre and post studies were undertaken, utilizing mixed methods such as surveys, direct observations, interviews, focus groups, and chart audits. In addition, routine hospital data was reviewed, such as incident reports, financial data, and patient satisfaction reports.

Results: The safety focused design of the new hospital as well as Epic implementation had a positive impact on latent conditions. Key adverse events (medication errors, fall, and infections) were lowered. The interplay between safety culture, management focus, process change, facility design, and Epic may all contribute to the impact on adverse events. In this study, other variables besides adverse events had a stronger impact on length of stay and costs.

Key Words: HIT, Epic, safe design, safety culture, latent conditions, adverse events, National Learning Lab, St. Joseph's Community Hospital

Final Report

Purpose

Just prior to the period of research funded by this AHRQ grant,[a] St. Joseph's Community Hospital of West Bend, Wisconsin, began building a new 80-bed hospital with a design focused on patient safety.

St. Joseph's has identified health information technology (HIT) as a necessary component of our safety-driven design. To this end, the AHRQ grant has been used to support the implementation of an Epic system between the hospital, West Bend Clinics, and The Kathy Hospice. In addition to implementing the Epic system,[b] our goal is to conduct research on the impact of HIT and hospital design on latent conditions, adverse events, and hospital outcomes, so that other small community hospitals may benefit from our experience. Our desire is not only to improve patient safety and quality of care within our own facility, but to share our learning experiences with others in the health care industry, in order to contribute to overall improvement in the health care industry.

We have identified the following aims necessary to achieve this goal:

1. Implement Epic, diffused across a community and service area-wide system of St. Joseph's Community Hospital of West Bend.

2. Document latent conditions, and discuss the roles Epic and safe design principles have in meeting them, either directly or indirectly.

3. Identify the prevalence of adverse events, specifically medication errors, near misses, and preventable adverse drug events, before and after Epic was implemented.

4. Measure the length of stay, patient satisfaction, and cost in the current system, and then after Epic was implemented and the new hospital was built.

5. Develop an Epic implementation plan that can be utilized by other small community hospitals.

a This project was supported by grant number UC1HSO15284 from the Agency for Healthcare Research and Quality, for the project period October 2004-December 2008.
b Epic Computer Systems, Verona, Wisconsin

Scope

Background

As efforts are made to reduce error throughout the health care industry, the focus of this study is to identify those conditions that affect quality and safety. Reason classifies errors found in complex systems such as health care as either *latent conditions* or *active failures*.[1] Latent conditions are those conditions that are present in the system -- the facility, equipment, and processes that contribute to or combine with active failures to cause error. Latent conditions typically arise from decisions made by management, architects, and equipment designers. Active failures, or adverse events, are errors made by those who provide direct care to patients, such as physicians, nurses, and technicians.

Health Information Technology. The committee on the Quality of Health Care in America believes HIT must play a central role in the redesign of the health care system if a substantial improvement in health care quality is to be achieved in the next decade.

In addition to reducing errors, HIT enhances the ability to collect and analyze reporting data when adverse events do occur. Automated surveillance of data can detect triggers that identify adverse events which may not have been detected through chart review or reported voluntarily.

Epic Implementation. For these reasons, St. Joseph's studied and planned for the implementation of Epic. The hospital implementation began in our existing small community hospital and continued at the replacement hospital. It also connected the Epic system to multi-location clinics (West Bend Clinic) and a residential hospice facility (The Kathy Hospice). The original intent was to extend Epic to a pharmacy (which was never acquired), and a subacute care facility (Cedar Crossings, owned by Cedar Community), but due to regulatory impediments, this was not possible.[c]

Epic is an integrated inpatient clinical system providing electronic support to both direct and indirect patient care. The Epic system includes electronic documentation for nurses and physicians, clinical pathways and protocols, efficient patient management tools for the emergency department, electronic medical records (EMR), automated pharmacy communication and workflow, electronic Medication Administration Records (eMAR), computerized provider order entry (CPOE), bar-coding, and centralized scheduling.

Context and Setting

St. Joseph's Community Hospital of West Bend is an independent, non-profit, acute care hospital located in West Bend, Wisconsin with annual patient admissions of approximately 4000.

[c] In 2004 when this research began, St. Joseph's was partnered with other institutions within SynergyHealth. On June 30, 2008, SynergyHealth ceased to exist and St. Joseph's and West Bend Clinic became affiliated with Froedtert and Community Health of Milwaukee, Wisconsin. Another partner, The Kathy Hospice, was and is managed by the hospital, and ownership was transferred from the SynergyHealth Foundation to St. Joseph's Hospital in 2008. Cedar Community is an independent non-profit organization.

The National Learning Lab. When St. Joseph's started designing a replacement facility in 2002, it hosted a conference called "Charting the Course for Patient Safety: A Learning Lab." The Learning Lab generated four sets of recommendations: latent conditions, adverse events, safety culture, and safety design processes.

Also, the Learning Lab identified three areas that enhance safety in hospitals:

1. A robust safety culture
2. Processes focused on safety
3. Facilities with their equipment and technology focused on safety

In 2007 and 2008, a National Advisory Committee met in Boca Raton, Florida, and affirmed the model developed in the Learning Lab. In addition, the group prioritized that model, with safety culture ranked first, processes second, and facilities third. They also emphasized the importance of leadership, including CEO and top management, medical staff, and the board.

Participants

Partner #1: The lead organization for this project is St. Joseph's Community Hospital of West Bend. *Partner #2*: The second partner is the West Bend Clinic, a not-for-profit multi-specialty clinic serving Washington County and the surrounding area with five clinics. *Partner #3*: The third partner is The Kathy Hospice, an 8-bed residential hospice facility which was constructed during the first year of the grant award period. *Partner #4*: Fourth, Cedar Community, with three campuses and seven operating facilities throughout Washington County, provides several levels of care for seniors; it is independently owned and run. Cedar Community agreed to partner with St. Joseph's Community Hospital to improve the quality of care to seniors in an 18-bed subacute nursing facility attached to the hospital (Cedar Crossings).

Incidence and Prevalence

Medication-related errors are one of the most common types of errors occurring in hospitals, according to the IOM report, *To Err Is Human: Building a Safer Health System*.[2] This IOM report cites studies showing that in 1992, approximately 7,000 deaths were attributable to medication errors, and that 1 out of 854 inpatient hospital deaths resulted from a medication error. While not all medication errors result in harm, those that do can be costly. The IOM estimates that increased hospital costs resulting from preventable ADEs affecting inpatients are approximately $2 billion for the nation as a whole.

St. Joseph's has identified medication errors, near misses, and preventable adverse drug events (ADEs) as the adverse events that will be most significantly impacted by the implementation of Epic. As a result, this study will focus on these types of error.

Prior to the implementation of Epic and the opening of the new hospital, around 12,000 near misses and medication errors were reported in a 12-month period. This was a period of heightened awareness and screening due to St. Joseph's participation in the Institute of Health Improvement (IHI) Impact Project and the results of the National Learning Lab. The number of acute admits during that same period was about 4000, so there were approximately 3 near misses

and/or errors per patient. The board of directors agreed to invest over $10 million dollars during a 5-year period to implement specific products in Epic, with the goal of lowering adverse events and decreasing harm to patients, which is both prevalent and costly to hospitals nationwide.

Methods

Study Design

This research project was a pre-post assessment of two interventions, Epic implementation and the design of the replacement hospital. For each of the studies undertaken in this research project, baseline data collection reflected the original hospital facility prior to Epic implementation. Post assessment data was collected at the new hospital, two or three years after baseline data collection. Given the significant length of time between pre and post-test data collection, intervening variables affected the results.

The study documents the level at which eight latent conditions identified by the Learning Lab existed in the original facility and then how the design of the new hospital and the role of Epic was successful in meeting these, either directly or indirectly. (Noise reduction, the ninth latent condition, was studied under a separate grant.)[d]

Similarly, the study documents the prevalence of nine adverse events identified during the Learning Lab. Our expectation was to show improved results for each of these adverse events, both before and after Epic was implemented. Emphasis has been placed on documentation of medication errors, near misses, and preventable adverse drug events (ADEs).

In order to assess hospital outcomes, we measured the length of stay, cost, and patient satisfaction.

Next, a number of focus groups were facilitated to determine what medication issues occurred across the partner institutions, and to assess the impact of Epic implementation on the partners.

Finally, this study includes documentation of a detailed Epic implementation plan, including the infrastructure needed, stages of implementation, training, challenges and barriers faced, and evaluation procedures.

Data Sources/Collection

The following chart summarizes how the data for all the studies was collected, from whom, and from where.

d A grant was awarded by Medicare through Meta Star in 2005 for a noise reduction study at St. Joseph's Community Hospital.

Table 1. Summary of methods

Table 1a. Latent conditions

Study	Methodology	Subject	Location
Visibility of Patients to Staff	Observation	Patients, Staff	Med/Surg
Standardization	Survey	Hospital/Processes	Med/Surg
Automate Where Possible	Survey	Hospital/Processes	Med/Surg
Scalability and Adaptability	Survey/Observation	Hospital/Processes	Med/Surg, ASU, ED, ICU, OPPA
Immediate Accessibility of Info	Survey/Observation	Hospital/Processes	Med/Surg
Patients Involved with Care	Survey	Patients	Med/Surg
Minimize Fatigue	Survey	Staff	Med/Surg, ICU, ED
Minimize Patient Transfers/Handoffs[3]	Interviews	Hospital Processes	Med/Surg, ED, ICU

Table 1b. Adverse events

Study	Methodology	Subject	Location
Medication Errors, Near Misses	Observation	Medication Administration Processes	Med/Surg, ED, ICU
Adverse Drug Events	Chart audit	Medication Administration Processes	Med/Surg, ICU
Incident Reporting of adverse events: Operative/Post-op Complications & Infections Deaths of Patients in Restraints Inpatient Suicides Transfusion-related Events Correct Tube, Correct Connector, Correct Hole Patient Falls Deaths Related to Wrong-site Surgery MRI Hazards	Incident Reporting		Hospital

Table 1c. Hospital outcomes

Study	Methodology	Subject	Location
Length of Stay	Review of Data	Patient Data	From Hospital Financial Data
Costs:	Review of Data	Patient Data	From Hospital Financial Data
Patient Satisfaction	Survey	Hospital Inpatients and Outpatients	Hospital

Table 1d. Focus group surveys

Study	Methodology	Subject	Location
Standardization of Medication Processes between Partners	Written Surveys, Focus Group Interviews	Medication Administration Processes	Med/Surg, ICU, ED, Case Management, Medical Staff, Hospice Staff, West Bend Clinic Staff, Cedar Subacute
Medication Issues and Processes between Partners	Written Surveys, Focus Group Interviews	Medication Administration Processes	Same as above
Immediate Accessibility of Information between Partners	Written Surveys, Focus Group Interviews	Medication Administration Processes	Same as above

Interventions, Measures

For all studies, baseline data collection took place before the opening of the new hospital and the implementation of Epic. Post-test data occurred after the new hospital opened and after implementation of select Epic packages.

Latent Conditions.

1. Visibility of patients to staff. The level of visibility was observed and documented in the Medical-Surgical units of the old hospital prior to the implementation of Epic. The study employed the methodology of direct observation on the Medical-Surgical units, using a data collector stationed outside a randomly selected group of patient rooms. Forty-five baseline observation sessions were completed with 97 patient rooms observed and a total of 578 patient room observation hours, and similar data was collected post-test.

2. Standardization. The standardization study measured the level of standardization in hospital structure, as well as in medication and care processes. The combined methodologies for this study were direct observation of the facility as well as interviews of key stakeholders from multiple perspectives. The first component of the study was to determine the perceived level of standardization of key structures, equipment, and procedures that support patient care on the Medical-Surgical units, through interviews of hospital leaders and Medical-Surgical staff. If staff who were initially interviewed were no longer part of the organization post-test, the current individual in that position was interviewed.

   The second component of this study measured the difference in standardization for medication and other care processes between the system's partners. The methodology applied the use of a survey, as well as focus group sessions.

3. Automate where possible. Using a combination of interviews and observation, this study measured the perceived level of automation in ten key clusters which impact the Medical-Surgical unit, such as patient admissions, processing of physician orders, and handoff communicating/reporting. Each clustered area was broken into functional activities and these activities were scored against five stages of automation, such as information storage and selection of decision. The purpose of this study was to measure the impact that technology has on reducing reliance on short-term memory, providing barriers against errors, near misses, and adverse events, and improving communication.

4. Scalability and adaptability. This descriptive study was designed to determine scalability and adaptability of the Medical-Surgical unit. The methodology utilized for this study combined interviews of those who were most knowledgeable about the hospital's med-surg unit structure and design, as well as direct observation and measurement. Additionally, a focus study comparing the adaptability between the Intensive Care Unit (ICU), Emergency Care Center (ECC), Ambulatory Surgery Unit (ASU), and Outpatient Pre-Admission (OPPA) was added.

5. Immediate accessibility of information, close proximity to the patient. This study was designed to determine whether patient information is more readily available to caregivers at the bedside with the new Medical-Surgical Unit design and with Epic. The observers from the visibility study also interviewed the staff and physicians who exited the room, to determine whether there was any patient information that was needed but not available at the bedside. These questions helped determine what type of information is often lacking or delayed, and whether availability improved. Another component of this study was to determine from staff of all the partners how often handoffs, phone calls, faxes, and other methods of communication occurred without access to information from the patient medical record. This information was gathered from the staff (nurses, unit clerks, physicians) of St. Joseph's Medical-Surgical units, ICU, and Emergency Department as well as from the partner institutions.

6. Patients involved with care. Medical-Surgical patients who were discharged to their homes, competent to care for themselves, and were at least 21 years of age or older were asked to participate in an interview to determine their level in participation in their care. A variety of questions were asked of patients, about their medication schedules, care plans, discharge planning, and hand washing, for example.

7. Minimize fatigue. This study utilized the Piper Fatigue Survey to measure the subjective level of fatigue in the nursing staffs of the Medical-Surgical units, ICU, and Emergency Department. To determine fatigue as it related to work, staff were instructed to take this online survey after working their entire shift.

8. Minimize patient transfers/handoffs. For this descriptive study, flow diagrams were created through interviews with the managers of the Medical-Surgical Units, Emergency Care Center, and the Intensive Care Center about the handoffs of patients and of patient information which typically occurred as patients moved through care processes, such as the Emergency Care Center to Radiology to the Medical-Surgical Units and to Surgery. Managers were also questioned about the coordination of handoffs that occur with shift changes between nursing staff, weekend on call physician coverage, consultation of a specialist, and treatment by Respiratory Therapy and Physical Therapy. Data was categorized by the type of handoff (transfer of patient information only, transfer of patient care from one caregiver to another, or a handoff where the patient is physically moved from one department to another).

9. Noise reduction. Noise is one of the latent conditions identified in the National Learning Lab. Epic implementation was thought not to affect noise, so we studied noise reduction under a separate grant.

The study was designed to measure noise levels on the Medical-Surgical Units, Intensive Care Unit, and Emergency Care Center. Noise levels were measured for 24-hour periods of time with a dosimeter in multiple locations including Medical-Surgical patient rooms and nursing stations.

Adverse Events.

1. Medication errors, near misses, and preventable adverse drug events. The impact of Epic on medication errors was the primary focus of our study. Two separate studies concentrating on errors and preventable adverse events were developed.

    a. The first study examined medication errors and near misses, utilizing the method of direct observation. Observers--registered nurses and pharmacy technicians--were taught to observe the preparation and administration of medications on the Medical-Surgical Units, ICU, and ED, and record what they observed. Next, they recorded what was ordered, and from their comparison of what was ordered to what was given, they determined the number of medication errors and near misses that occurred.

    b. The second study examined preventable adverse events (ADEs), based on a trigger tool methodology for detecting ADEs.[3] Using this methodology, charts were made of randomly selected discharged patients who met certain specific criteria.

2. Incident Reporting of all ADEs. The hospital had a pre-established process for tracking, recording, and grading medication safety reports using the IHI harm scales A - I. For the study, all ADEs that could cause harm to the patient--level D and above--were recorded on a monthly basis from 2004 to 2008.

Hospital Outcomes. Existing coding, surveys, and tracking mechanisms were used to track length of stay, costs and expenses, and patient satisfaction.

Focus Groups. Medication administration and other patient care issues that occurred as patients flowed within this hospital and between the system partners were studied pre and post-test. This was done through written and focus surveys of employees (unit clerks, nurses, physicians) of the hospital's Medical-Surgical Units, Emergency Department, and Intensive Care Unit, Case Management, and staff from the partner institutions.

These surveys were designed to determine:

a. What medication-related issues occurred due to lack of information integration between system partners

b. The level of standardization for medication processes between system partners

c. What issues (medication and otherwise) that occurred between system partners were due to limited access to patient information.

A focus group with facilitated discussion methodology was used to gather qualitative data. At the beginning of the focus group session, participants were asked to complete a brief survey that elicited quantitative data. For post-test data collection, a written survey had to be used instead of focus interviews for physicians and Clinic staff due to limited availability.

Limitations

The entire study has certain limitations that need to be taken into account when considering the study results and its contributions. There are three major limitations that need to be acknowledged and addressed.

The first limitation concerns the design of this evaluation project: a one-group pre-test-post-test design. While this is a widely used design, it can be confounded by several extraneous variables that can jeopardize the validity of the study results.

The second major limitation has to do with the extent to which the findings can be generalized beyond the current study. Only one institutional unit (a small community hospital) was used in this study, so it is possible that this specific institution may not be representative of other small community hospitals attempting to implement a similar HIT system.

The third major limitation is a sampling limitation. Due to the small number of cases/observations available for this study, many of the results may suffer from Type II error or lack the sensitivity to statistically demonstrate effects. These limitations suggest that the study findings should be interpreted cautiously. By considering the shortcomings associated with this methodology, this study could perhaps serve as a basis for further research and analysis of HIT in smaller medical institutions.

Results

Principal Findings

The analysis of latent condition data demonstrated improvement in all but one condition—fatigue. The adverse events of falls and infections declined since 2002. Any adverse events that were zero before the opening of the new hospital stayed at zero throughout the study period. The number of transfusion related events stayed flat over the entire study period, averaging 0.3%; most of these were considered non-preventable. Within the samples we took, medication errors and adverse drug events declined since 2002. Due to the small number of cases available for the medication error observation study, the results lack the sensitivity to statistically demonstrate effects.

The objective of implementing the Learning Lab recommendations was to reduce harm to patients by changing latent conditions, lowering adverse events, creating safety culture, and changing processes focused on safety. Therefore, the safety design process met these objectives to a great extent.

When adverse events decline, L.O.S. and cost of an admission can also be affected positively. However, there are other variables that affect outcomes, and in this study the effect of the reduction in adverse events was outweighed by variables such as management of care processes and volume.

It is important to note that although the changes in many latent conditions are attributable to Epic implementation and/or the design of the new hospital, the lowering of adverse events cannot be attributable to any specific cause. The interplay between safety culture, management

focus, process change, facility design, and the implementation of Epic *may* all contribute to the impact on adverse events.

A detailed Epic implementation plan was developed, including the infrastructure needed, stages of implementation, training, challenges and barriers faced, evaluation procedures, and lessons learned. These lessons include establishing the reality that the implementation team owns and markets the project, and maintaining an awareness of the project with administration and management. The eMAR project was successfully rolled out in January 2006, 5 months after moving into the new facility. (Subsequent stages of the project - ClinDoc for nursing and physicians and CPOE - were slated to occur following this project. Financial impact post new facility impacted the organization's decision to temporarily postpone these projects. ClinDoc for nursing was implemented in the summer of 2008, but CPOE has not been implemented to date.) The debate on whether implementation should be "phased" or a "big bang" is ongoing, but St. Joseph's experience leads to the belief that whenever possible, "big bang" is the preferred approach because full benefits (communication, availability of information, automated data for quality initiatives, and resources for enhancing safety) are realized sooner, and intermediate processes do not have to be established to support the HIT transitions.

Outcomes

Latent Conditions.

1. Visibility of patients to staff. The most important process change affecting visibility was the location of the chart in the alcove, with a phone, computer, and chair. In addition, a portable computer on wheels (COW) is located in each room, allowing the Epic implementation to support visibility of patients to staff. The mean time for when patients were visible to the nursing staff changed from 5.3 minutes pre-test, to 10.7 minutes post-test, an increase of approximately 100%. At the same time, the number of caregiver visits to the patient room decreased from a mean of 12.5 to 5.6 times, or a decrease of 55%. So caregivers observed their patients about twice as long as before, but the number of times they visited patient rooms dropped by about a half. The total time a patient was visible to the nursing staff remained about the same pre and post: 1 hour for every 6 hours. It should also be mentioned that nursing stations as such were not included in the design of the new hospital, so an expected consequence was that the change adversely affected the nurses' ability to confer and socialize.

2. Standardization. Compromising standardization is not in the best interest of patients and staff providing care; lack of standardization leads to complexity and error causing more harm, lower efficiency, and less effective quality outcomes. Comparing pre and post studies on perceived standardization indicate that St. Joseph's is perceived by staff and leaders as more standardized around facilities, data and process. The implementation of Epic also had a positive effect on standardization because of the need to program a common process for any application that is implemented.

3. Automate where possible. St. Joseph's clustered processes that could be automated and asked participants to assess the level of automation. The perceived percentage of

automation increased in all clusters. Processing of physician orders had the smallest increase (due to CPOE not being implemented); and medication administration, documentation, and discharge communication had the largest increase. Epic was a key influence in the staff's perception that automation was improved at St. Joseph's Hospital.

4. Scalability and adaptability. The new hospital is more scalable and adaptable than the original hospital. Examples are the common and adjacent spaces for ECC, ICU, OPPA, and ASU, which allow for adaptable and scalable services and the infrastructure to put another Medical/Surgical floor on the existing bed tower. In addition, Epic supports scalability and adaptability because it creates the conditions where information can be immediately accessible to all caregivers and patients, no matter what the physical configuration and geographic separation of services and care providers.

5. Immediate accessibility of information, close proximity to the patient. During the pre-test period, 7.14% of care providers indicated that patient information was needed but not in the room or alcove. During the post-test period, 0% indicated that this was so. Probable reasons for this change are that most patient information is now in Epic, thus accessible at all times, and the hardcopy records of patient charts must be kept in the patient alcove (rather than taken to nursing stations or elsewhere).

6. Patients involved with care. Compared to pre-test data, there is a higher expectation by St. Joseph's patients to be involved with their care. Patients are more comfortable asking questions about their care and about important processes of caregivers, such as medications and hand washing. Generally, there is an improving trend in processes such as discharge planning, hand washing, and medication management as it relates to patient involvement. External factors such as better informed consumers or insurance company policies may also be influencing this improvement. The improvements have yet to yield a statistically significant improvement in the quality of care but the trend is in the right direction.

7. Minimize fatigue. Though most questions on the pre and post tests did not show a statistically significant difference, there were trends to most of the information gathered. The staffing ratio is the only factor that had a statistically significant change pre and post; the staff felt that changes in staffing ratios have caused significantly more fatigue. Epic was intended to reduce fatigue by locating information near the provider. Although there was not a statistically significant difference, Epic showed a positive trend in reducing fatigue.

8. Minimize patient transfers/handoffs. The number of information handoffs and patient handoffs were calculated by creating a flow diagram of each patient admission through ECC to Medical/Surgical to Surgery. With the exception of handoffs with rehabilitation treatment, the number of handoffs stayed the same pre and post. Epic, however, without exception, improved the efficacy of all handoffs by making information readily available in a standardized form.

9. Noise reduction. The design of the new St. Joseph's Hospital made it materially quieter than the old facility. In fact, St. Joseph's is one of the quietest hospitals in Wisconsin. An unintended consequence of a quiet hospital is the perception of some patients that they are isolated and alone. Given the small amount of hours that caregivers are actually in patient rooms, partly because of the new alcove design, patients are in fact alone for much of the time (unless a loved one is staying with them). So it is understandable why some patients react with anxiety to the feeling that nobody is around.

Adverse Events.

1. Medication errors, near misses, and preventable adverse events.

    a. Medication errors and near misses. At St. Joseph's, Epic implementation was organized to create a process that would minimize most of the medication errors studied: unauthorized dose, omission of dose, wrong dose, extra dose, wrong route, wrong form, wrong time. The Epic applications that apply to medication errors are pharmacy, bar-coding, ClinDoc, and POE (not implemented). In addition, many physical facility design and process changes were implemented. The medication error that was studied and not affected by Epic was wrong technique (e.g. neglecting to take vital signs before administration of a medication, when this assessment was needed). Below is the data pre and post, with and without the wrong technique.

        i. Medical/Surgical. The medication error rate declined 16.5%; without wrong technique it declined 21.2%. Wrong time accounted for 58% of the errors (6% error rate) pre and 63% (5.4% error rate) post.

        ii. Emergency Care Center. The medication error rate increased by 51%, and without wrong technique decreased by 58%. Wrong techniques accounted for 36.6% of the errors (23% error rate) pre and 81.8% (8.3% error rate) post.

        iii. ICU. The medication error rate declined by 56% and without wrong technique decreased by 63%. Wrong time errors accounted for 81% (9.2% error rate) pre and 54% (2.7% error rate) post.

For all three areas, Medical/Surgical, Emergency Care Center and ICU, omission errors declined from 18 to 11 errors or a 38.9% decline.

    b. Preventable adverse drug events. The comparison between ADEs pre (February 2004 through January 2005) and post (March 2007 through August 2007) for Med/Surg and ICU, yielded a dramatic decline in ADEs.

For Med/Surg patients, ADEs dropped from 17.9% to 2.8%, an 84% decline, and preventable ADEs dropped from 13.1% to .4%, or a 97% decline. For ICU patients, ADEs dropped from12.9% to .5%, a decline of 96%, and preventable ADEs declined from 6.9% to 0%, a 100% decline. Incident reports for ADEs greater than D (those causing harm to patients) started at 43

reports in January 2005, and dropped materially throughout 2005; from 2006-2008, they averaged less than 1 per month, and the highest in any given month was 3.

2. Incident reporting. The following five adverse events had zero occurrences reported in 2002, and the incidence rate stayed at zero during the study period:

   i. MRI hazards

   ii. Deaths related to wrong site surgery

   iii. Correct tube-correct connector-correct hole

   iv. Inpatient suicides

   v. Deaths of patients in restraints

   vi. Patient falls. The number of patient falls steadily declined during the study period, from 149 to 31 (almost 80%), with one spike in 2006 of 115 falls (the new hospital opened in 2005).

   vii. Transfusion related events. The number of transfusion events stayed consistent throughout the study period, at 0.3%. Almost all of these were considered not preventable.

   viii. Infections. The only consistent data recorded for infections during the 5 years of this study were for ventilator pneumonia and surgical site infections.

Of these, surgical site infections have declined from 3.6% infections of hips, knees, cholecystectomy, and C-sections to .5% (with one year that spiked to 2.1%). The overall decline from 2002 to 2008 is 76.2%, and since the opening of the new hospital in 2005 to the present, the decline has been 66.6%. The trend line continues to fall. The ventilator pneumonia infection rate from 2002 to 2008 has declined. Of all the hospital days in 2002, 5.6% of the days had infections; in 2003, the rate was 10.9%; in 2004 the rate was 5.6%; in 2005 it was 11.5%. In contrast, for the years 2006, 2007, and 2008, the infection rates were 0%, 2.6%, and 3.9% respectively. Recently, all infections have begun to be recorded, so there will be more complete data in the future.

Hospital Outcomes. The outcome measures we chose to investigate for this study were length of stay (L.O.S.), costs, and patient satisfaction. A reduction in adverse events can have a positive effect on length of stay and costs, but in this study, other variables had a stronger impact, such as case management, volume, and hourly rate of pay.

During the study period, L.O.S. declined from 5.25 days to 4.43 days for Medicare patients, and 4.14 days to 3.64 days for acute patients.

Expenses per adjusted admission increased from $5,268 to $7,808 over the study period. Adjusting for inflation, interest, depreciation and corporate overhead/management fee, expenses decreased from $5,540.23 to $5533.95. Case mix was .95 in 2002, and .97 at the end of the

study period. Adjusted admissions increased from 7512 to 8874, and the information system expenses increased from $208 to $260 per inflation adjusted admit. L.O.S. and costs are a result of many variables, such as case management processing, safety, volume, and hourly rate of pay.

Patient satisfaction is difficult to compare over time, due to mandated changes in scales to support CMS reporting and the use of three different surveys and administration techniques during the duration of the project. Therefore we were not able to compare patient satisfaction levels over the study period.

Focus Groups. Interviews and discussions with the staff of the hospital and all partner institutions were designed to address the following questions:

1. Has the level of standardization of medication processes between partners increased from pre to post test? The key medication process of med reconciliation is now standardized in Epic for both the process as well as the hardcopy that is printed for the physician to complete. Any confusion between brand names and generic names of drugs has been resolved, since the med reconciliation forms now print alphabetically by generic name, followed by the brand name, which has made the detection of duplicate medications much easier. Discharge reconciliation is recorded in Epic and is also printed for the patient, and discharge med info in Epic is available to the partners. The issue of illegibility was reported as resolved in post test, except for physician orders which are still handwritten.

2. Have the handoffs between partners without access to the patient chart (or the necessary patient information) decreased from pre to post test? This issue was resolved with Epic--no post test instances were reported. Another improvement noted by multiple partners was the advantage of access to patient info prior to receiving a patient. Partners also reported that they rarely received calls for info after patient transfer in post test, which had happened more often in pre test. One exception to these post test improvements was reported by Subacute. Subacute documentation is not automated, and the information in the Epic chart is not consistent with Subacute needs for information transfer.

3. Have the medication issues arising from lack of integration across partners decreased from pre to post test? All partners reported improvement, with the exception of Subacute, where integration has become worse since ClinDoc implementation (see #2). For the other partners, information is easier to find; lost patient info is now very rare; transfer and discharge flow of medication information has improved. Overall, access to home medication info has improved also, since Epic implementation.

Discussion

It is difficult in a report of this length to do justice to the effort and to discuss thoroughly all of the studies with details on latent conditions, adverse events, outcome measures, and HIT implementation. Those interested in further details may consult the attachments referred to throughout this report.

Given the number and breadth of the studies, and the fact that previous studies did not exist in many areas, many tools were developed specifically for these studies without rigorous testing

of the tools themselves. Also, as discussed in the limitations section, this research had a sampling limitation, due to the small number of cases/observations available for some of the studies, which then lacked the sensitivity to statistically demonstrate effects.

This research study, however, despite limitations, should be able to provide benchmarking data for future studies, generate interest in the medical community around latent conditions and adverse events, and provide measurement tools for use by other organizations.

The basic intent of the research study is to identify whether or not latent conditions, adverse events, and outcome measures change, as a result of designing a new hospital focused on safety and implementing Epic. The Learning Lab stated and the National Advisory Council affirmed the importance, in rank order, of a robust safety culture, processes focused on safety, and facilities with their equipment and technology focused on safety. The NAC also concluded that underlying any achievement in safety improvements in a health care institution is its leadership.

The design process that has been implemented by St. Joseph's Hospital is driven by two key elements: (1) the principles established at the National Learning Lab and (2) the use of multi-disciplinary teams to design processes and the physical plant. While organizational change can be an arduous journey, constancy of purpose around this design process has improved safety culture at St. Joseph's.

Milestones in the creation of this initial safety culture within the hospital include:

1. Recognition that the need for safety is endemic. Early in the journey, there were members of management and staff alike who questioned the need to spend so much time on patient safety. The organizational dynamics that were created by following the NLL recommendations helped correct organizational myopia about safety issues, and the resulting use of multi-disciplinary teams created a feeling of ownership and a belief in the necessity for patient safety.

2. Just Culture is an essential ingredient. Punishment of human error, based on a belief in "perfection" of performance, is too commonplace in health care. The need to recognize the normalcy of human error is key, as is the need to determine level of accountability based on intent of the individual(s) involved.

3. Group process is mandatory. The design process implemented at St. Joseph's Hospital included the presence of multi-disciplinary groups for every department/functional area designed, and at every stage of the design process. Whenever a design team met, a member of the Facility Design Advisory Council, made up of many professional disciplines throughout the organization, was present to assure that the benefits of "cross pollination" were realized.

4. Safety culture takes a whole village. The recognition that safety is a team effort was an important outcome of the design process. The interrelated nature of process design and physical plant attributes created some organizational anxiety; any key work process changes to be made and key facility design attributes for the new facility had to be determined almost simultaneously. In order to minimize any organizational drift during this time, frequent meetings of all disciplines and levels of management with continued focus on the safety guiding principles for both process and facility design were essential.

5. Keep the flywheel spinning. To paraphrase Steven Covey, the "Safety Flywheel" requires some attention to keep it spinning. During the facility design process, a lot of excitement was initially generated within the organization. However, during the two-year construction process, some staff became frustrated because—after many hours spent discussing, debating, and designing the new facility—suddenly the project seemed to disappear. The actual construction site was four miles away and unavailable to anyone except construction trades. One strategy used successfully was to organize tours of the building for employees. This activity was key in maintaining staff interest in the project.

6. Technology – friend or foe. Embracing new technology in the new hospital has benefited the organization's safety culture, including making clinical information immediately available. Technology has also introduced some latent conditions that have been identified as counter to patient safety. For example, electronic medical records require more discipline and structure than a paper-based record. With a paper record, anything can be written anywhere; in an electronic record, data fields may be constrained to either numerical or alpha data. Working through the limiting factors to harvest the benefits had the added benefit of reinforcing the reality and benefits of a safety culture. But this benefit also comes with long-term costs associated with on-going capital costs and human resources to support this technology.

Conclusions

Retrospectively, the consensus among hospital management at St. Joseph's today is that the design process used by the hospital was successful on a number of different levels. The project was brought in on time and under budget, and more importantly, the process was instrumental in the initiation of a safety culture. Therefore, recommended changes to the process would be limited, and related more to our failure to follow the process than a failure of the process.

One example of this would be the "value engineering" process used to manage the budget. The decisions made by the organizational representatives were actually confined to a small group with relatively common skill sets. It is the organization's opinion that having a wider involvement of individuals in this process may have prevented some re-work to the facility.

Will the process used by St Joseph's Hospital deliver positive results to others? Based on our experience, we have confidence that it will. However, ownership of the process is important – probably more important than the actual details of guiding principle content. If an organization has a particular need to pay attention to a problem not identified in our design process, it is recommended that the process allow for institutional specificity.

It is important to note that although the changes in many latent conditions are attributable to Epic implementation and/or the design of the new hospital, the lowering of adverse events cannot be attributable to any specific cause. The interplay between safety culture, management focus, process change, facility design, and the implementation of Epic *may* all contribute to the impact of adverse events.

Significance

Designing around latent conditions and adverse events identified by the National Learning Lab are important to the process of safety by design. Using the awareness of those latent

conditions and adverse events can also help create or enhance safety culture and revise processes focused on safety.

The Learning Lab and the National Advisory Council also identified leadership as key to any safety improvement achievement in health care institutions. This includes the CEO and top management, the medical staff, and the Board. Without strong leadership, safety initiatives will likely fail.

In this study, Epic had a positive impact on latent conditions and on medication errors. It also improved medication administration issues between partners.

One of the important "lessons learned" in St. Joseph's Epic implementation plan was that the "big bang" method may be preferable to the "phased" plan. Continuing to maintain a "divided" environment potentially introduces latent failures for staff, whereas with the "big bang" approach, full benefits can be realized sooner.

Overall, the importance of HIT cannot be overstated. Some form of HIT should be used in health care settings; it is critical to the process of reducing harm.

Implications

Some of the specific recommendations that have emerged from the St. Joseph's experience include:

1. The need for continued organizational growth. The fixed overhead associated with a sophisticated electronic medical record system is significant. While clinical benefits of such a system have been identified and will continue to be identified, the expense has had a significant negative impact on an 80-bed hospital like St. Joseph's.

2. Dissemination to the health system. The knowledge gained from building a unique facility like St. Joseph's Community Hospital should be shared within the health care system in order to promote an organizational culture of safety.

3. Dissemination to the industry. The construction project and the follow-up study results have generated significant interest within the health care industry. It is incumbent upon representatives of St. Joseph's to share the study results through professional meetings and seminars.

4. Continued tracking of the findings to date. While not financially feasible to continue to track every study element, some aspects of the studies should be continued for a quality perspective, including patient falls and medication errors.

5. Continued search to minimize unidentified latent conditions. The organization continues to identify and resolve latent conditions that could potentially manifest as a patient safety error. For example, the implementation of electronic medical records brings many benefits, but a high degree of awareness must be maintained in order to identify operational issues that can silently manifest themselves within the system.

Finally, this St. Joseph's research study has shown that safe by design can work. The changes in latent conditions, through the design of facilities with Epic implementation, create the

environment where people are less likely to make errors. Also, processes and culture, focused on safety, can be engineered through safe design. Therefore, in all health care settings, using safety design principles and HIT should be considered.

Confirming the importance of using HIT, Carolyn Clancy, MD, Director of AHRQ, says: "At AHRQ, we believe Health Information Technology [IT] can save lives, and improve care and efficiency in our health system. Our belief is based on a growing amount of evidence. For example, studies have shown that adverse drug events have been reduced by as much as 80 percent by targeted programs, with a significant portion of the improvements stemming from the use of health IT."[4]

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