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CONTROLS IN THE NICU

Completed Research Paper

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Abstract

Medication dosage errors cause too many adverse clinical events in both inpatient and outpatient settings. In this disguised and partially fictionalized teaching case a hospital administrator considers whether the skills she recently acquired in an MBA Accounting Information System class could be adapted for use in a quality improvement program related to medication errors. The case illustrates how the preparation of a system flowchart mapped to a control matrix – a technique that auditors commonly use to support analysis of the adequacy of controls over financial processes – can be adapted to support analysis of clinical process controls and controls over related information. The case offers an opportunity for students to discuss some of the benefits and limitations of this technique, and possible extensions of it to non-financial processes in health care and elsewhere.

Keywords: Health Care, clinical information systems, process, controls, AIS

Introduction[1]

On her upcoming vacation, Sandy Payne planned to turn off her Blackberry. It was nearly 7:30 on Thursday morning, July 11, 2008. The vacation was still a few weeks away, but as she sipped her coffee and prepared for her first meeting of the day, Payne indulged in a daydream. How lovely it would be to sail off the coast of Maine with her husband, away from the pressures of this job. Payne had worked as a nurse in neonatal (newborn) care for 15 years before turning onto the administrative track, first as a nurse manager and then in progressively more demanding administrative positions. To further her career she enrolled in an MBA program at Bristol University as an evening student. Payne had completed nearly two thirds of the courses she needed for her MBA when she was appointed Compassionate Care Hospital of New England (CCHNE)'s Vice President for Administration, following the tragic accidental death of her predecessor in a plane crash. While she had hoped to reach this position some time in her career, Payne felt she was catapulted into the job a few years before she was fully ready for it. CCHNE, like so many community hospitals, was under intense pressure to improve quality of care while reducing costs.

The hospital was due for an accreditation review by The Joint Commission in 2009 (Exhibit 1), and Payne and the hospital's Medical Director, Sudha Mehta, were meeting at 9:00 am to discuss next steps in preparing for that review. The last review had earned CCHNE the "Gold Seal of Approval," and they certainly did not want to lose that status. The Joint Commission had added some new requirements and was considering introducing others, such as a proposed standard related to medication errors: a hospital would have to demonstrate that all medication errors and adverse drug events were reported immediately to the attending physician and recorded in the hospital's performance improvement files. While the hospital did track errors and adverse events, Sandy Payne was not certain that every such event was recorded.

The light on her Blackberry flashed and Payne glanced at the subject line for an incoming email from Compassionate Care's CIO, Henry Sharp. "ANOTHER TWIN DIED IN TEXAS!" it shouted. Payne understood the reference. Last night's news had reported that a second infant twin at a hospital in Corpus Christi, Texas had died after being accidentally overdosed with an anticoagulant (a blood thinner such as Heparin, which is often used to clear intravenous lines so blood won't clot and block the delivery of other medicines). Apparently, a pharmacist had made a mixing error (Vonfremd and Ibanga, 2008). The tragedy left Payne both sad and angry, because she knew that blood thinner had been implicated in similar tragedies and near-tragedies at other hospitals. In September 2006 three infants died at Methodist Hospital in Indianapolis when nurses inadvertently administered adult doses of an anticoagulant instead of pediatric doses. A little over a year later, at Cedars-Sinai Hospital in Los Angeles the actor Dennis Quaid's twin infants nearly died from the same kind of mistake. In those latter two cases, pre-measured vials of the pediatric form of Hep-Lock should have been placed in a medication cabinet on the floor of the neonatal intensive care unit ("NICU"). Instead, a pharmacy employee had inadvertently delivered vials of adult Heparin, which was 1,000 times stronger. Busy NICU nurses had not noticed the error; they dosed the actor's babies twice with the adult form before nurses noticed signs of internal bleeding. Quaid's twins survived, but his prominence as a movie star had kept that mistake in the spotlight. "How many babies have to die before hospitals conquer this medication dosage problem?" Payne thought, and the next thought hit her like a brick: "Could it happen here?" As a nurse, she knew the answer to that question and it was not reassuring.

Henry Sharp had recently tried to enlist Payne's support for two IT projects, one for computerized provider order entry (CPOE), and another to use a "tagging" technology called RFID. "With your help on these two projects, we can dramatically reduce medication errors," he had stated. Sharp further explained that his proposal was unlikely to receive the Board's approval unless he collaborated closely with Payne, since "It's necessary to design new processes to go along with new IT capabilities." Sandy Payne had felt that she had enough to do without taking on someone else's pet projects. Now, she reconsidered; perhaps she should have another conversation with Compassionate Care's CIO. She shot him a reply: "Lunch tomorrow, okay?"

Quality of Care at Compassionate Care Hospital of New England

CCHNE, located a few hours' drive from Boston, admits about 11,000 patients to its inpatient facilities and performs about 6000 surgical procedures a year. About 1500 babies are born at CCHNE each year, and it is one of

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[1] This case is based on field research combined with secondary sources. Identities and some facts, figures and dates have been disguised or fictionalized, including "CCHNE" and "Bristol University".

only a few hospitals in the region with a NICU facility for premature babies (capacity: 15 infants). Sandy Payne was pleased that the hospital had a lower employee attrition rate than others in the region, and an atmosphere that "fits our name. People who work here really care about the patients and their families."

Every year the hospital had a quality improvement competition, in which teams of employees would identify a problem, analyze root causes and offer solutions. These competitions complemented other quality initiatives. For example, along with many other US hospitals CCHNE was participating in a national quality initiative, the two year *Protecting Five Million Lives from Harm Campaign*, sponsored by the Institute for Healthcare Improvement (see www.ihi.org). An IHI brochure stated:

"The 5 Million Lives Campaign defines "medical harm" as unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment or hospitalization, or that results in death. Such injury is considered harm whether or not it is considered preventable, resulted from a medical error, or occurred within a hospital."

Hospital leaders were asked to review a list of quality practices proven to help avoid harmful healthcare errors. Each participating hospital was to commit to adopting and measuring the effectiveness of some of these practices (knowing that hospitals face resource constraints, the Campaign did not pressure hospitals to implement every recommendation all at once). Compassionate Care's leadership team had committed to focus first on reducing hospital-based Methicillin-Resistant Staphylococcus Aureus (MRSA) Infections. To do so had involved compiling pre-intervention data about the incidence of MRSA infections, then training nurses, physicians and other personnel in five practices known to help prevent MRSA infections:

1. Hand hygiene (washing hands, use of alcohol-based hand rubs)
2. Decontamination of the environment and equipment
3. Active surveillance testing
4. Contact precautions for infected and colonized patients
5. Use of central line and ventilator bundles

Implementation of these changes involved making sure that dispensers of alcohol-based rubs were installed throughout the hospital and someone assigned to keep them full, provisioning of central line/ventilator bundles, and other changes. After making these changes, MRSA infections dropped 24% in 2007. The goal was to reach a 30% drop in MRSA infections by the end of the Campaign (December 2008).

Another quality practice that the hospital had started work on was *Prevention of Adverse Drug Events by Implementing Medication Reconciliation* and *Prevention of Harm from High Alert Medications.* Everyone involved agreed that reducing adverse drug events (including those related to dosage errors, drug-drug interactions, drug allergies, and failure to administer prescribed drugs) was imperative. The Institute of Medicine (2007) reported that 400,000 preventable medication-related injuries occur in US hospitals each year, with effects ranging from minor patient discomfort to death. Among the causes: illegible physician handwriting on prescriptions, mixing errors at the pharmacy, and administering a drug to the wrong patient.

Hospitals participating in the Five Million Lives Campaign had to measure progress toward attaining each goal, compared with baseline data at "time zero." To that end, CCHNE had encouraged clinicians to report adverse drug events, but it was not easy to get busy clinicians to consistently fill out event forms on a voluntary basis. However, all prescribed medications and all clinical procedures were recorded in the patient's medical record. If a patient received a harmful overdose and then showed symptoms of an adverse effect, clinicians would administer various antidotes or take other steps to help the patient, and those medications and procedures were recorded. Since the record of these corrective measures indirectly point to the adverse drug events that caused them, a new approach was adopted: a software application was used to search through the electronic medical records for a given period, noting every time a known antidote was administered (for example) or other corrective measures taken. For each record with such a flag, an audit of the patient's record was done to determine if an adverse drug event had indeed occurred. Studies showed that this technique could help reveal some unrecorded adverse drug events, but would not catch every one. If a patient did not show signs of being affected by a medication error and was not given an antidote, caregivers would not record an adverse event in the medication error database.

Thinking about the NICU

As a former NICU nurse, Sandy Payne had great respect for the doctors and nurses who cared for the hospital's littlest patients. News of the Texas NICU tragedy saddened her greatly. Apparently, a pharmacist inadvertently mixed a batch of adult-dosage Heparin instead of the pediatric dose. More than a dozen babies were overdosed, and infant twins had died. Payne made a note to meet with CCHNE's pharmacy staff and the hospital's safety coordinator to learn how they prevented such mistakes from happening. She recalled that in the Dennis Quaid twins' incident and the tragic deaths of the Indiana babies, a different mistake had occurred. Those hospitals stocked pre-measured vials of adult Heparin and pediatric Hep-Lock. Somehow, 100 vials of the adult version were placed in NICU medication cabinets instead of Hep-Lock[2]. Although the medication vials had different labels, they were not strikingly different; one was dark blue, the other light blue[3]. Apparently the California nurses who administered the Heparin did not notice that it was not Hep-Lock. She hoped her hospital's nurses were more attentive and careful, yet Payne could empathize with the California nurses. When you've been working a long shift with a high patient census, she thought, it's easy to make that type of a mistake. While she felt the pharmacy should prevent such errors from occurring, Payne also wondered: What could be done on the nursing unit to prevent this type of mistake?

Before leaving work that evening, Payne took a few minutes to search for articles about the medication error problem and steps other hospitals had taken to address it. A few caught her eye. Years ago, a study by Folli, et al., (1987, p. 718) reported that "involving pharmacists in reviewing drug orders significantly reduced the potential harm resulting from errant medication orders." That suggestion sounded like a good idea to Payne, albeit time-consuming and thus, unfortunately, expensive. More recently, a study in Britain (Ross, et al., 2000) reported that nurses were responsible for 59% of medication errors that were reported on pediatric units, and "Errors involving the intravenous route were commonest (56%), with antibiotics being the most frequent drug involved (44%). Eight percent involved a tenfold medication error." "Gosh," thought Sandy Payne. "That's exactly what happened with Dennis Quaid's children!" The Ross, et al. study (op cit.) reported that a policy of double checking all drugs dispensed by pharmacy staff could reduce medication errors somewhat. Studies of online prescribing suggested that software could reduce medication errors by checking for drug-drug interactions, correct dosages and other aspects, and that such systems were most effective when implemented in combination with "ward-based clinical pharmacists and improved communication among physicians, nurses, and pharmacists" (Fortescue, 2003). Finally, another study argued for the inclusion of pharmacists on medical rounds (Leape, et al., 1999). From reviewing the research, Payne concluded that any solution to the medication error problem would require a multi-pronged approach.

As a hospital administrator Payne felt she needed to understand how to analyze and control costs, so she had taken several accounting courses in her MBA program. In an Accounting Information Systems (AIS) course, students learned that in order for managers to make well-informed decisions and in order for a company to accurately report on its performance it is essential for financial data to be valid, accurate, and complete. Students were taught to analyze business processes to identify and assess the controls that protect the quality of financial information and the company's valuable resources (such as cash and inventory). The instructor, Professor Cash, had stated, "In this course you are going to acquire and practice skills that you can put to good use in a range of activities that go way beyond accounting systems. You are going to learn how to analyze a process and offer recommendations for changing it so that it does a better job of supporting an organization's goals, whether financial or non-financial." Now Payne wondered: Can I put those skills to use in the NICU? Can I use them to analyze clinical systems and processes? Will that analysis help me identify control strengths and deficiencies? Of course I can, she thought.

Sandy Payne Reviews her AIS Notes

That evening at home, Sandy Payne dug out her notes from her AIS course. She recalled: In assessing controls over financial processes and information systems, accountants check to ensure that when a transaction takes place, the transaction data is correct when first input to the applicable files in the system, and that as the data flow through

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[2] According to a report of the California Department of Health, before the Quaid twins incident occurred, Cedars-Sinai Hospital announced plans to place labels warning that Heparin is a "high-alert, high-risk medication" and to double check all deliveries of Heparin to the nursing units. However, according to the report, these procedures were not yet in place when the Quaid twins were admitted to the hospital (Department of Public Health, 2007).

[3] Baxter Pharmaceuticals contends that the Heparin and Hep-Lock labels had already been changed by the time of the Quaid incident; however apparently Cedars-Sinai Hospital was still using medications that remained in stock from an earlier delivery.

enterprise systems and databases, it continues to correctly represent each and every transaction. Payne did not see any reason why an analyzed process would need to be financial. She thought, "Our NICU has very well established processes that can be documented every bit as easily as an accounts-payable process." As she continued to review her notes, the applicability of the AIS techniques to clinical work became clearer.

Validity, accuracy, and completeness, three important dimensions of data quality (or "correctness") that accountants examine when doing a control assessment (ISACA, 1998; Kaplan, et al., 1998), are defined as follows:

- *Validity*: the data describes an event which was properly authorized and actually occurred. To assess validity, accountants check that there are controls which ensure, for example, that unauthorized price discounts are not given and payments are not made to fictitious entities.
- *Accuracy:* the data correctly describes relevant aspects of a transaction. To assess accuracy, accountants check that there are controls which ensure that all aspects of each transaction record are correct, including price, amount, customer billing address, etc.
- C*ompleteness*: a record is captured for every relevant transaction. To assess completeness, accountants check that there are controls which ensure that every transaction is recorded and that deletions can only be made with appropriate approvals.

A process that auditors employ to document a process and controls within it is as follows (Gelinas and Dull, 2009; Romney and Steinbart, 2008):

1. Interview managers and employees and observe the workflow associated with this process.
2. Prepare a narrative describing the process, and verify with managers and employees that it correctly describes the workflow. The auditor may also create a Table of Entities and Activities to describe the narrative in a structured form.
3. Model the process, using physical and logical data flow diagrams, entity-relationship models, systems flowcharts, REA models, or other semantic modeling tools.

Once documentation is complete, then auditors examine the process to identify and assess the controls as follows:

4. Identify behavioral and system controls at work that help to protect data quality and/or process quality.
5. Record information about those controls on a Control Matrix (described below), mapping the controls to various information (or data) quality and operational quality goals.
6. Identify opportunities to utilize additional behavioral or system controls in the defined workflow, and/or to redesign the workflow so as to achieve stronger control over information quality and operational quality.

Sandy Payne had done well in the AIS course, and it seemed to her now that such an approach could be employed to analyze the quality of processes and information systems in the hospital, and from that analysis to identify areas for improvement. To test out the idea, she prepared the following narrative (based on the details she recalled from the Quaid twins' highly-publicized incident, along with her knowledge as a former NICU nurse).

This hospital purchases blood thinner in both adult (Heparin) and pediatric (Hep-Lock) versions, in prepackaged doses prior to the manufacturer changing the label colors. Pharmacy technicians are supposed to stock Hep-Lock and Heparin in different medication cabinets. But, 100 vials of Heparin were mistakenly placed in a pediatric cabinet.

Newborn twins were admitted to a NICU for treatment of a staph infection. Before administering antibiotics, it is standard procedure to flush the intravenous line with Hep-Lock. The attending physician prescribed several rounds of Hep-Lock in 10-unit doses. The nurse who retrieved the medication from the cabinet did not notice that it was adult Heparin. She administered it. The same sequence of events occurred a few hours later (a nurse removed Heparin from the cabinet and administered it). Some hours later a nurse noticed that the babies were bleeding and alerted a doctor, who examined them and ordered a lab test of blood clotting function, which revealed the error.

Corrective treatment was undertaken and thankfully in this particular case the children recovered.

Payne recalled that Professor Cash usually had students prepare idealized narratives (that is, describe the process as it is supposed to work, with error routines captured separately). However, she felt that in this instance it was helpful to chronicle a process containing an error. Now she decomposed the narrative into seven clinical events:

1. *Technician stocks medication cabinet (*incorrectly puts adult Heparin in spot reserved for pediatric HepLock).

2. *Doctor prescribes medicine,* using computerized physician order entry (CPOE) combined with a software application that alerts the physician to possible allergies and drug-drug interactions for this patient.

3. *Nurse Retrieves Medication*: A nurse goes to a locked, computer-controlled medicine cabinet to retrieve the prescribed medication. She gains access by typing a user ID and password, then retrieves a vial of adult Heparin in a 10,000-unit dose (she believes it is Hep-Lock in the appropriate dose). The cabinet automatically re-locks once the medication is retrieved, preventing the nurse from pulling out additional drugs and also preventing others from accessing drugs until they provide a username and password.

4. *Nurse administers medication:* Nurse goes to the patient and checks that the Patient ID on the prescription matches that on the infant's wristband. Having verified that this is the correct patient (and believing the correct drug is at hand), Nurse administers Heparin. (Event 4 is repeated a second time a few hours later).

5. *Nurse examines patient:* Some hours after the second dose of Heparin, a nurse notices bleeding and alerts a doctor.

6. *Doctor orders a lab test:* On examining the babies, the doctor orders a test of each patient's blood clotting function, to verify a hunch that the patients are bleeding internally.

7. *Corrective treatment begins:* The lab test verifies a blood clotting problem, so the doctor prescribes protamine sulfate to reverse the effects of blood thinners. Kept under close observation for a few days, the babies recover.

Payne started to sketch out a system flowchart to depict these seven steps, but after a few attempts, she grew drowsy and set it aside. The next day was packed with meetings, but on Saturday morning she rose early and got back to it before her husband and son woke and convinced her to join them for a sail. Her flowchart is presented below.

Figure 1 – Preliminary Flowchart
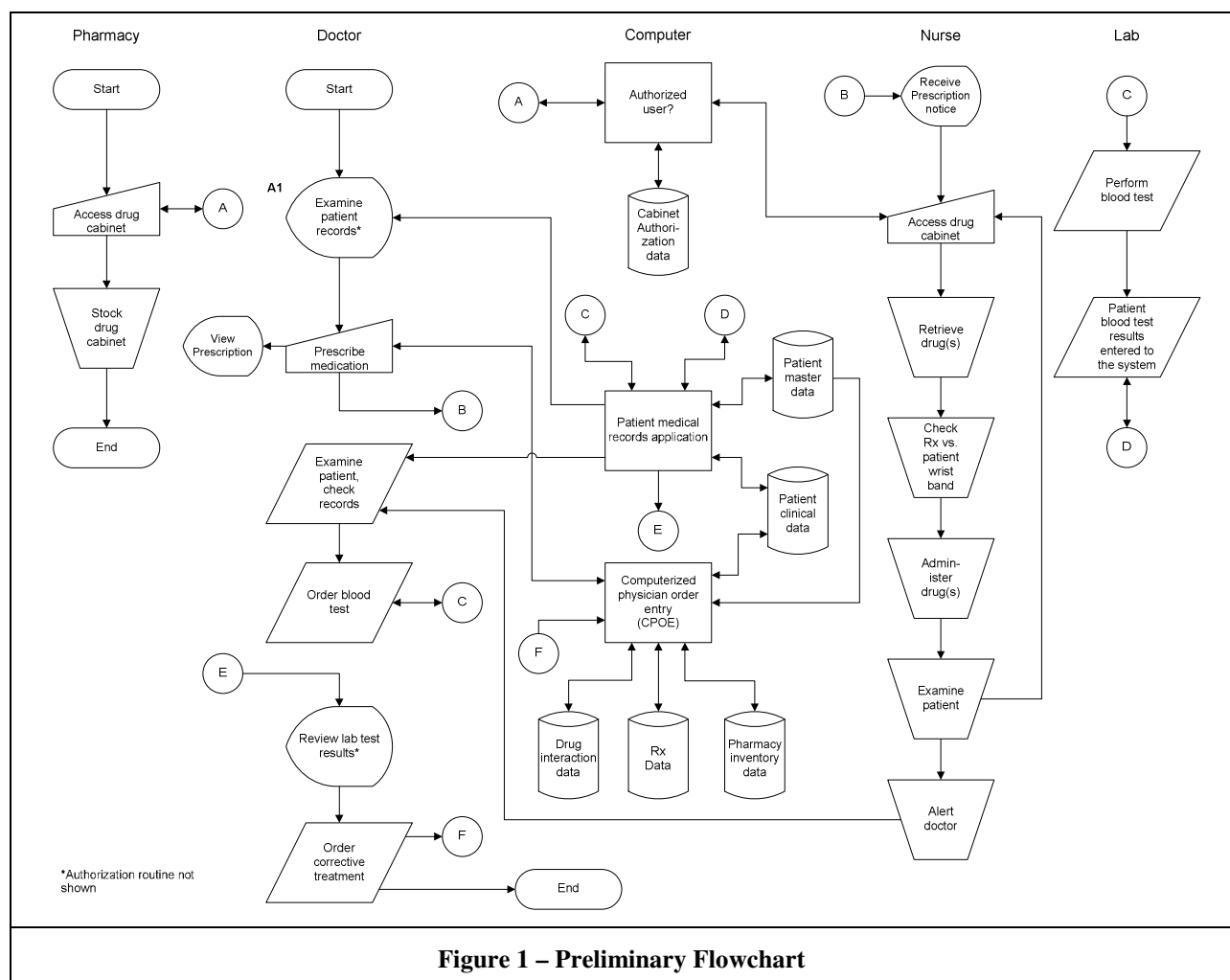
Next, Payne began to prepare a Control Matrix (Gelinas and Dull, 2009, Romney and Steinbart, 2008). Professor Cash had explained that while there are many variants of this tool, most audit firms use it to address both information quality and operational goals. Payne decided to address three specific operational goals: 1. Provide timely care; 2. Ensure patient comfort, 3. Safeguard medications. She addressed three information quality goals : validity, accuracy, and completeness (Payne's control matrix labels don't specify what kind of data, whereas an auditor would separately note these qualities for specific categories of data such as patient identification/standing data, patient clinical data, prescription and laboratory order data, and clinician data).

Payne recalled that the AIS teacher mentioned that a control matrix would usually list more than three operational/process quality goals and also it would distinguish between data quality issues at the point when data are first *input* into the system as well as at the points when various files are *updated*. For now, though, this seemed like a good start. The rows list specific controls identified in the narrative and flow chart, and Payne labeled these A1, A2 etc. because they represent *actual* controls (controls that were in place, according to various news stories).

	← OPERATIONAL GOALS →			← INFORMATION GOALS →		
	Provide timely care	Ensure patient comfort	Safeguard medications	Validity of data	Accuracy of data	Completeness of data
A 1. Doctor examines patient		Dm			Dm	Dm
A 2.						
A 3.						

Table 1. Control Matrix

A complete control matrix would be accompanied by an explanation for each control; for now, Payne prepared an explanation for Control A1:

A1. *Doctor examines patient*: This manual (m) detective (D) control helps the doctor review the patient's condition, which helps ensure both the accuracy and completeness of the clinical data.

The next step would be to assess each control along several dimensions. For example, Professor Cash had noted that it's useful to distinguish between controls that help to *prevent* (P) data quality or operational problems, controls that *detect* (D) problems that nevertheless do arise, and controls that help to rectify the situation when a problem does arise (*correct*, C). It can also be useful to denote whether a control is manual (m), or computerized (c).

Before proceeding further, Sandy Payne felt it would be helpful to show Henry Payne what she'd done so far. After all, Henry was eager to talk about using IT to prevent medication errors; perhaps this flowchart could help them start that conversation. She would have liked to form a task force of nurses, doctors, and others right away to get started on a series of analyses based on these techniques. However, this being July, Payne knew it would be difficult to get anyone's help. New residents and interns had just started their rotations, and veteran clinicians were overburdened just now, supervising them. In August the vacation schedule would get in the way, but hopefully in September she and Sudha Mehta could kick off a new quality initiative.

Professor Cash was teaching AIS this summer. Payne wondered: perhaps he'd be willing to have some of his students help her complete the control matrix and offer some recommendations. The Bristol University students could help to demonstrate the effectiveness of these techniques as applied at CCHNE. "It would be so great if we could get this phase completed before I set sail on my vacation in August," she thought. "I'll enjoy that vacation more if I know we're making progress on our patient safety initiatives."

Exhibit 1 Excerpts from Facts about the Joint Commission (www.jointcommission.org)

Mission: *To continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.*

The Joint Commission evaluates and accredits more than 16,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission is the nation's predominant standards-setting and accrediting body in health care. Since 1951, The Joint Commission has maintained state-of-the-art standards that focus on improving the quality and safety of care provided by health care organizations. The Joint Commission's comprehensive process evaluates an organization's compliance with these standards and other accreditation or certification requirements. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. To earn and maintain The Joint Commission's Gold Seal of Approval™, an organization must undergo an on-site survey by a Joint Commission survey team at least every three years. (Laboratories must be surveyed every two years.)

Accreditation and certification services

The Joint Commission provides accreditation services for the following types of organizations:
- General, psychiatric, children's and rehabilitation hospitals
- Critical access hospitals
- Medical equipment services, hospice services and other home care organizations
- Nursing homes and other long term care facilities
- Behavioral health care organizations, addiction services
- Rehabilitation centers, group practices, office-based surgeries and other ambulatory care providers
- Independent or freestanding laboratories

For more information, see the fact sheets on "Benefits of Joint Commission Accreditation" and "Benefits of Joint Commission Certification."

Standards and performance measurement

Joint Commission standards address the organization's level of performance in key functional areas, such as patient rights, patient treatment, and infection control. The standards focus not simply on an organization's ability to provide safe, high quality care, but on its actual performance as well. Standards set forth performance expectations for activities that affect the safety and quality of patient care. If an organization does the right things and does them well, there is a strong likelihood that its patients will experience good outcomes. The Joint Commission develops its standards in consultation with health care experts, providers, measurement experts, purchasers, and consumers.

Introduced in February 1997, The Joint Commission's ORYX® initiative integrates outcomes and other performance measurement data into the accreditation process. ORYX measurement requirements are intended to support Joint Commission accredited organizations in their quality improvement efforts. Performance measures are essential to the credibility of any modern evaluation activity for health care organizations. They supplement and help guide the standards-based survey process by providing a more targeted basis for the regular accreditation survey, for continuously monitoring actual performance, and for guiding and stimulating continuous improvement in health care organizations. Some accredited organizations are required to submit performance measurement data on a specified minimum number of measure sets or non-core measures, as appropriate, to The Joint Commission through a Joint Commission listed ORYX vendor (also known as a performance measurement system).

For more information, see "Facts about ORYX."

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