

# **Joint Commission Resources Quality & Safety Network (JCRQSN)**

## ***Resource Guide***

### **Solutions Part 2: How to Meet the Most Challenging Medical Records and Infection Control Standards**

**April 24, 2014**

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## Program Summary

This page provides an overview of the program content and learning objectives. Please refer to the Table of Contents and Program Outline for a detailed list of the topics covered. The information included in this Resource Guide is intended to support but not duplicate the video presentation content. There may be additional information available online for this topic.

### *Program Description*

Each year, The Joint Commission collects data on organizations' compliance with standards, National Patient Safety Goals, the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™, and Accreditation and Certification Participation Requirements to identify trends and focus education on challenging requirements. These data also help The Joint Commission identify risk areas to highlight in the Focused Standards Assessment (FSA) process.

Many of the standards data collected revealed that some of the more challenging standards identified as non-compliant include Medical Records and Infection Control standards.

Through in-depth expert panel discussion and featured case studies, this 60-minute live event identifies the most common standards compliance issues related to medical records and infection control standards.

### *Program Objectives*

After completing this activity, the participant should be able to:

1. Identify the most problematic medical records standards and strategies for achieving compliance.
2. Identify the most problematic infection control standards and strategies for achieving compliance.

### *Target Audience*

This activity is relevant to the entire hospital and medical staff, particularly organization leaders, managers and supervisors, and staff responsible for performance improvement (PI), patient safety, and risk management initiatives.

## Program Outline

Solutions Part 2: How to Meet the Most Challenging Medical Records and Infection Control Standards

April 24, 2014

- I. Introduction
  - A. Program Content
  - B. Objectives
  - C. Faculty
- II. Problematic Medical Record Standards and Compliance Strategies
- III. Problematic Infection Control Standards and Compliance Strategies
- IV. Conclusion
- V. Post-Program Live Question and Answer Session
  - A. Audio only telephone seminar with program faculty – for 30 minutes following the program.
  - B. Call 1-888-206-0090; enter conference code: 7925428.  
Or e-mail your questions or comments to: [Questions@jcrqsn.com](mailto:Questions@jcrqsn.com)

|                        |  |
|------------------------|--|
| Program Broadcast Time | <b>Eastern:</b> 2:00 p.m. to 3:00 p.m.<br><b>Central:</b> 1:00 p.m. to 2:00 p.m.<br><b>Mountain:</b> 12:00 p.m. to 1:00 p.m.<br><b>Pacific:</b> 11:00 a.m. to 12:00 p.m. |
|------------------------|--|

### *Program Question and Answer Session*

During the live airing of this program on April 24, 2014, you may be able to talk directly with the faculty when prompted by the program's host. After this date, your message will be forwarded to the appropriate personnel.

Immediately following the program, we invite you to join in a live discussion with the program presenters. Call 1-888-206-0090 and enter Conference Code: 7925428 to be included in the teleconference.

To submit your question ahead of time or for additional details, please send an e-mail to [questions@jcrqsn.com](mailto:questions@jcrqsn.com). If you submit your questions after this date, your message will be forwarded to the appropriate personnel.

You can also receive answers to your questions by calling The Joint Commission's Standards Interpretation Hotline at 630-792-5900, option 6.

## Continuing Education (CE) Credit

After viewing the JCR Quality & Safety Network presentation and reading this Resource Guide, please complete the required online CE/CME credit activities (test and feedback form). The test measures knowledge gained and/or provides a means of self-assessment on a specific topic. The feedback form provides us with valuable information regarding your thoughts on the activity's quality and effectiveness.

**NOTE:** Effective April 1, 2012, the Learning Management System web site URL changed as noted below.

### *Prior to the Program Presentation Day*

1. Login to the JCRQSN Learning Management System web site at <http://twnlms.com/>
2. Enroll yourself into the program
  - Note:** Your administrator may have already enrolled you in the program
    - Select *All Courses* from the courses menu.
    - Select the course category for the current year, *2014 Programs*.
    - Select the course for this program, *Solutions Part 2: How to Meet the Most Challenging Medical Records and Infection Control Standards*
    - When prompted, choose *Yes* to confirm that you would like to enroll yourself.
3. Display and print the desired documents (Resource Guide, etc.).

### *Online Process for CE/CME Credit*

1. Read the course materials and view the entire presentation.
2. Login to the JCRQSN Learning Management System web site at <http://twnlms.com/>
3. Select *Solutions Part 2: How to Meet the Most Challenging Medical Records and Infection Control Standards* from the courses menu block.
  - Note:** This assumes you have already been enrolled in the program as described above.
4. If you didn't view the broadcast video presentation, view it online.
5. Complete the online post test (see Appendix E).
  - You have up to three attempts to successfully complete the test with a minimum passing score of 80%.
  - Physicians must take the post test to obtain credit.
6. Complete the program feedback form.
7. On the top right corner of the main course page, you will see your completion status in the *Status* block.
8. Select *Print Certificate* from within the *Status* block to print your completion certificate.

## Standard RC.01.01.01 (Hospital Accreditation Program)

**The hospital maintains complete and accurate medical records for each individual patient.**

### *Standard Introduction and Rationale*

Rationale, Introduction, or Goal are not available for this standard.

### *Elements of Performance*

1. The hospital defines the components of a complete medical record.
4. The medical record contains information unique to the patient, which is used for patient identification.
5. The medical record contains the information needed to support the patient's diagnosis and condition.
6. The medical record contains the information needed to justify the patient's care, treatment, and services.
7. The medical record contains information that documents the course and result of the patient's care, treatment, and services.
8. The medical record contains information about the patient's care, treatment, or services that promotes continuity of care among providers.

Note: For hospitals that elect The Joint Commission Primary Care Medical Home option: This requirement refers to care provided by both internal and external providers.

9. The hospital uses standardized formats to document the care, treatment, and services it provides to patients.
11. All entries in the medical record are dated.
12. The hospital tracks the location of all components of the medical record.
13. The hospital assembles or makes available in a summary in the medical record all information required to provide patient care, treatment, and services. (See also MM.01.01.01, EP 1)
19. For hospitals that use Joint Commission accreditation for deemed status purposes: All entries in the medical record, including all orders, are timed.

## Five Sure-Fire Methods: Complying with Standard RC.01.01.01

A complete medical record\* should include all data and information gathered about a patient† from the time he or she is admitted to an organization to the time of discharge or transfer. Record of Care, Treatment, and Services (RC) Standard **RC.01.01.01** requires accredited organizations to maintain complete and accurate medical records for each individual patient (see “Related Requirements” on page 9 for the complete standard); however, this standard continues to be problematic for behavioral health care organizations, hospitals, and critical access hospitals.

Peggy Lavin, LCSW, senior associate director, Behavioral Health Care (BHC) Accreditation Program, The Joint Commission, says that one of the reasons that organizations accredited under the BHC program are having difficulty complying with Standard RC.01.01.01 is that the information needed to justify care, treatment, or services is not always documented in the clinical/case record. “The clinical or case record should read like a novel with a beginning, middle, and an end,” says Lavin. “Sometimes, it isn’t clear in the record why care, treatment, or services are being provided or what is happening with the individual served now, even though the staff members are able to clearly articulate those things to the surveyor.”

According to Cynthia Leslie, APRN, BC, MSN, associate director, Standards Interpretation Group, The Joint Commission, this is also true in hospital settings. “Sometimes there’s not enough information documented in the medical record to support the patient’s diagnosis and to justify the patient’s care,” she says.

Human error is also a contributing factor in failure to comply with RC.01.01.01. “The EPs [elements of performance] that organizations seem to find the most challenging are EP 11, which requires that all entries in the medical record be dated, and EP 19, which requires that for all hospitals that use Joint Commission accreditation for deemed status purposes, all entries in the medical record be timed,” says Leslie. “One of the top reasons why organizations are being cited is that people forget to date and time their entries.”

Lavin says that another reason that organizations accredited under the BHC program may be having difficulty complying with Standard RC.01.01.01 is the layout of some settings. “In behavioral health care, some settings are pretty spread out,” she says. “For example, there might be a separate school building, a dorm where the residents live, another building where care is provided, and yet another building that’s used as an infirmary. One of the requirements of RC.01.01.01 is that organizations be able to track the location of all components of the clinical or case record. In these types of settings, components of the clinical or case record may end up in different physical locations.”

Lavin and Leslie offer the following five strategies to help organizations to comply with Standard RC.01.01.01:

- 1 Conduct audits.** The auditing process should have two tiers,” says Lavin. “First, conduct a paper audit to make sure all of the required information is in the record. Second, review the record—beginning, middle, and end—to make sure all of the required documents are not only there, but that they also justify the care, treatment, and services provided.” Leslie adds, “Real-time audits are also a good way to help organizations determine, in real time, if there’s a problem.”
- 2 Provide staff education.** “Make sure that all staff is aware of the requirements, including all of the EPs,” Leslie says. “Staff needs to be told what a complete medical record is and what the expectations are.” Lavin adds, “It’s important to teach staff that what they are recording in the clinical or case record needs to justify the care, treatment, or services being provided. In today’s world, one of the goals of health care organizations is to be very person-centered. “Staff training needs to cover what that means and how it trickles down into documentation.”

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\* In the behavioral health care setting, the term is *clinical/case record*.

† In the behavioral health care setting, the term is *individual served*.

**3** *Involve staff in compliance discussions.* “Frontline staff can be very helpful in uncovering issues that may lead to compliance problems,” says Leslie. “For example, staff may be struggling with timing and dating of records because the forms they’re using don’t have a designated place for a date and time.”

**4** *Develop a plan for improvement.* “If a compliance issue is discovered during an audit, make sure there’s a process in place to educate staff about the issue and what can be done to correct it,” Leslie says. “Also, share audit information with the staff so they can learn from it.”

**5** *Move toward electronic records, when feasible.* “Electronic records include alerts that can help flag information that’s missing in the record,” says Lavin. “They can also help to ensure that all portions of the record are in one place and accessible to all staff members at all times. However, the cost may be prohibitive for some organizations.”

## Related Requirements

### Standard RC.01.01.01

The organization maintains complete and accurate medical records for each individual patient.

### Elements of Performance for RC.01.01.01

1. The organization defines the components of a complete medical record.
4. The medical record contains information unique to the patient, which is used for patient identification.
5. The medical record contains the information needed to support the patient’s diagnosis and condition.
6. The medical record contains the information needed to justify the patient’s care, treatment, and services.
7. The medical record contains information that documents the course and result of the patient’s care, treatment, and services.
8. The medical record contains information about the patient’s care, treatment, and services that promotes continuity of care among providers.
9. The organization uses standardized formats to document the care, treatment, and services it provides to patients.
11. All entries in the medical record are dated.
12. The organization tracks the location of all components of the medical record.
13. The organization assembles or makes available in a summary in the medical record all information required to provide patient care, treatment, and services.
19. **For hospitals that use Joint Commission accreditation for deemed status purposes:** All entries in the medical record, including all orders, are timed.

## Enhancing Electronic Health Record Usability in Pediatric Patient Care: A Scenario-Based Approach

Emily S. Patterson, PhD; Jiajie Zhang, PhD; Patricia Abbott, PhD, RN, FAAN; Michael C. Gibbons, MD, MPH; Svetlana Z. Lowry, PhD; Matthew T. Quinn, MBA; Mala Ramaiah, MD, MS; David Brick, MD

Although hospitals, clinics, and small-group medical practices are accelerating their adoption of electronic health records (EHRs),<sup>1</sup> there has been a slower adoption rate in pediatric care.<sup>2</sup> Anecdotal reports also suggest that these systems often are not ideal for supporting children's health care needs. Moreover, unintended consequences with the use of systems primarily designed for adult populations to provide care to children is documented in the literature.<sup>3</sup> Pediatric care differs substantially from adult care because of differences in age representations, developmental status, size, and the measurements used to convey this type of information, and the ability to communicate. These differences make the selection and arrangement of information displays, definition of "normal" ranges, and thresholds for alerts more challenging than for EHR use with adult populations. Technical guidance for stakeholders in the EHR design and implementation process has therefore been identified as a national need to improve the design of EHRs for pediatric patients, in particular, to enhance EHR usefulness, usability, and patient safety.

Given the importance of developing technical guidance, in November 2011, the National Institute of Standards and Technology (NIST) invited experts [the authors] in human factors engineering (HFE), usability, informatics, and pediatrics in ambulatory care and pediatric intensive care to participate in an effort to generate consensus recommendations. The focus of this effort was not on all aspects of EHR design but rather on those that are part of "critical user interactions," defined as interactions "between a user, such as a physician, nurse, pharmacist, caregiver, or patient, and the EHR, which can potentially lead to errors, work-arounds, or adverse events that are associated with patient harm." Several of the experts had also participated in previous efforts funded and coordinated by the NIST Information Technology Laboratory, including the development of a guideline to evaluate, test, and validate<sup>4</sup> the usability of EHRs and to document the results from summative usability testing.<sup>5</sup> The current effort was informed by previously published recommendations made to improve the usefulness,<sup>6-9</sup> patient safety,<sup>6,10,11</sup> interoperability,<sup>12</sup> and ability to conduct research<sup>13</sup> of EHRs for pediatric patients and previous recommendations made to enhance usability and patient safety with the use of health information technology for all patient populations.<sup>14</sup>

### Article-at-a-Glance

**Background:** Usability of electronic health records (EHRs) is an important factor affecting patient safety and the EHR adoption rate for both adult and pediatric care providers. A panel of interdisciplinary experts (the authors) was convened by the National Institute of Standards and Technology to generate consensus recommendations to improve EHR usefulness, usability, and patient safety when supporting pediatric care, with a focus on critical user interactions.

**Methods:** The panel members represented expertise in the disciplines of human factors engineering (HFE), usability, informatics, and pediatrics in ambulatory care and pediatric intensive care. An iterative, scenario-based approach was used to identify unique considerations in pediatric care and relevant human factors concepts. A draft of the recommendations were reviewed by invited experts in pediatric informatics, emergency medicine, neonatology, pediatrics, HFE, nursing, usability engineering, and software development and implementation.

**Recommendations:** Recommendations for EHR developers, small-group pediatric medical practices, and children's hospitals were identified out of the original 54 recommendations, in terms of nine critical user interaction categories: patient identification, medications, alerts, growth chart, vaccinations, labs, newborn care, privacy, and radiology.

**Conclusion:** Pediatric patient care has unique dimensions, with great complexity and high stakes for adverse events. The recommendations are anticipated to increase the rate of EHR adoption by pediatric care providers and improve patient safety for pediatric patients. The described methodology might be useful for accelerating adoption and increasing safety in a variety of clinical areas where the adoption of EHRs is lagging or usability issues are believed to reduce potential patient safety, efficiency, and quality benefits.

In relation to this focused work, on July 11, 2012, a technical report, *A Human Factors Guide to Enhance EHR Usability of Critical Care Interactions When Supporting Pediatric Patient Care* (NISTIR 7865),<sup>15</sup> was published. This report provided 54 detailed recommendations to improve critical user interactions

with an EHR when providing pediatric care and described their relation to concepts in the human factors and usability literature. The recommendations were grouped into the nine themes of patient identification, medications, alerts, growth chart, vaccinations, labs, newborn care, privacy, and radiology. In addition, 14 areas for innovation were suggested as useful EHR features for supporting the provision of pediatric care. Finally, four clinical scenarios that highlight unique risks for pediatric patients and human factors concepts were provided in NISTIR 7865 via an appendix for use in formative user-centered design processes or summative usability evaluations.

In this article, we summarize the methods and findings from NISTIR 7865 and then suggest how the specific recommendations could be translated into practice. In addition, we reflect on how to translate the methodologies to similar efforts in a variety of other areas where EHRs are being designed and implemented. Specifically, we summarize the methodology employed to generate the recommendations that are provided, and include one of the four representative, fictional clinical scenarios that was used to identify unique pediatric needs and the related human factors concepts<sup>15</sup> (Appendix 1, page 17)

We also highlight a small number of selected recommendations for three specific stakeholder groups—EHR vendors and developers, small-group pediatric medical practices, and children’s hospitals—to aid in implementation of these insights as quickly as possible into the work setting. Finally, we discuss reflections on the process of partnering human factors experts with clinical experts to identify the unique needs of pediatric patients in the quest to reduce the risks of unintended consequences from the use of a generalist EHR for pediatric populations.

## Methods

### MEETINGS

To derive the critical user interactions and associated recommendations and to gain group consensus, we conducted a series of one-hour teleconferences during a six-month period (February-July 2012). The effort included all-group meetings, meetings between the human factors experts and individual clinical experts, and subgroup meetings regarding particular scenarios and recommendations. We conducted a literature review for existing recommendations published in pediatrics and informatics journals, which we referenced in the report<sup>15</sup> and used during the consensus process. We also conducted iterative discussions with pediatric clinical experts and in-depth reviews of the human factors literature. In addition, we obtained extensive peer review of the

recommendations from experts in pediatric informatics, emergency medicine, neonatology, pediatrics, HFE, usability engineering, and software development and implementation (see the acknowledgments, page 16).

***Clinical Expertise: Special Considerations for Pediatric Patients.*** Insights from the clinical experts whom we consulted regarding special considerations for providing pediatric care using an EHR were as follows:

- High variability in physiology and disease states on the basis of age and weight generates unique requirements for information displays and alarm and alert thresholds.
- Deviations from standardized vaccination schedules are extremely complex because of interactions among events and would benefit from automated decision support and reminders.
- Growth charts are centrally important in providing care. they require a standardized display and easy access to allow physicians to employ expert strategies to detect patterns that indicate potential abnormalities.
- Limited ability to communicate with pediatric patients increases the reliance on the EHR to accurately identify patients, detect erroneous assumptions, discover symptoms, and access historical information.
- Increased options for medication orders need to be supported, including weight-based dosing, alternative medication formats, combined prescriptions, and sophisticated rounding strategies for dosing.

***Human Factors Expertise: Relevant Concepts from Human Factors Engineering.*** A number of concepts in HFE were distilled and presented by human factors experts to the authors as particularly relevant to the area for recommendations. These distilled human factors concepts were as follows:

- Methods for conducting risk assessments of the potential for human error in a given setting, such as human reliability analysis (HRA)<sup>16</sup>
- Strategies to reduce mode errors, which are actions performed in one mode that were intended for another mode<sup>17</sup>
- Signal detection theory and the associated phenomenon of “alert fatigue,” in which alerts, reminders, and warnings tend to be overridden about 90% of the time<sup>18</sup>
- The contextualized nature of expertise and the related “representation effect,” in which specialized knowledge is difficult to apply when information is not represented in the way in which professionals are trained to use it<sup>19</sup>

- The relation of increased complexity in a scheduling task with more interdependencies among tasks, often referred to as *task coupling*<sup>20</sup>
- The importance of providing information displays that accommodate distinct work flows for high-stakes tasks

The expertise derived from the clinical providers and the human factors experts among the authors, combined with support from the literature, provided a foundation for the deeper exploration of the unique challenges inherent in use of the EHR in pediatric populations. This foundation was used as the panel began to compile and analyze scenarios that captured unique challenges of providing pediatric care with an EHR and to generate and group recommendations to address these challenges.

#### SCENARIO-BASED ANALYSIS OF UNIQUE CLINICAL CONSIDERATIONS AND HUMAN FACTORS CONCEPTS

We collected relevant case experiences as a series of miniscenarios in a “corpus of cases” approach, similar to Flanagan’s critical incident technique.<sup>21</sup> We drew on the miniscenarios, each of which described use of an EHR in the provision of care for pediatric patients, and identified emerging themes. We combined these miniscenarios into related, integrated longer scenarios. For example, the three miniscenarios from our corpus of cases related to the theme of patient identification were as follows:

1. Twin newborn patients are admitted to a neonatal ICU. When the physician reviews the chart, the name of each patient does not appear on all screens, and the physician confuses the patients, resulting in Twin’s medications being listed in Twin B’s chart.
2. Unrelated and unnamed infants in a newborn nursery share the same birth date and the same name. For example, Baby Girl Smith DOB (date of birth) 1/1/2011 is used for three different babies from three different families being cared for at the same time in a single newborn nursery. In several cultures, a small number of last names are identical. The EHR listed patients by last name and date of birth.
3. The simultaneous treatment of siblings, particularly multiple birth children with the same last name and same birth date, has resulted in numerous unintended actions. Filing reports in the correct chart, ordering specific treatments and medications, and administering the proper therapies have a heightened risk of not being done correctly in this situation. The level of risk is heightened as patients move through the system, are transferred to other units, or are taken to external departments for therapy.

Human factors concepts relevant to patient identification were identified. In the three miniscenarios, the human factors concept of mode error,<sup>17</sup> in which patient care or documentation intended for patient A is done for patient B, was relevant.

Subsequent steps included the compilation of a variety of miniscenarios, each demonstrating one or more human factors concepts, into four larger, integrated scenarios and the determination of the human factors elements that emerged. This assembly allowed the panel to fully frame and understand the problem and arrive at a consensus on recommendations for action in the scenario, “Newborn with Sepsis Treated by the Emergency Department,” as adapted from NISTIR 7865<sup>15</sup> (Appendix 1). The human factors concepts are provided at the end of each sequence.

The “Newborn with Sepsis” scenario serves as an example of (1) the potential areas of error for pediatric patients when an EHR is being used and (2) the human factors-based guidance for recommendations likely to improve the system. As we generated recommendations and linked them to guidance provided by the human factors literature, we continually reviewed the corpus of cases and their relation to human factors concepts to clarify the issues and potential solutions. These scenarios were particularly helpful in identifying when more than one issue was being covered by a single recommendation and where it would be better to separate the concerns. We formulated the recommendations provided in the next section on the basis of the cases represented by the four scenarios, the human factors identified, and consultation with the reviewers and other experts.

#### Recommendations

For the purpose of this article, we identified three stakeholder groups as particularly relevant to facilitate rapid translation into practice: EHR developers, small-group pediatric medical practices, and children’s hospitals. We then selected and tailored a maximum of 6 recommendations for each stakeholder group from the original 54 recommendations.<sup>15</sup>

#### RECOMMENDATIONS FOR EHR DEVELOPERS

1. **Avoid Truncating Information.** Display information in menu items and on charts/graphs without truncating critical information; the full name of the medication and dose should be viewable without actively selecting an item. For limited space displays, rollover interactions that show the full text when the user moves the mouse or other input device over the items can be used.
2. **One-Click Growth Chart.** Support one-click access to the growth chart in the standard format (that is, the

World Health Organization international growth chart for patients between the ages of 0 and 24 months and the Centers for Disease Control and Prevention clinical growth chart for patients older than 2 years of age).<sup>22</sup>

3. **No Automated Changes to Default Dose.** Eliminate automated changes to adult dose defaults for medication orders for patients under the age of 18 years; automatically employing defaults for standard doses in the event of what appears to be an erroneous dose entry is extremely risky for low-weight patients.
4. **Protect Against Mode Errors.** Add protections against ordering medications in the wrong units; mode errors have been reported because of the confusion in prescribing a medication when the volume is specified in milliliters (mL) rather than milligrams (mg). Because of this type of mode error, 10-fold iatrogenic overdoses for young children receiving intravenous acetaminophen for pain relief have been publicly reported.<sup>23</sup>
5. **Support High-Precision Dosing for Low-Weight Patients.** Low-weight patients can experience toxicity if medications are rounded to the nearest digit.<sup>24</sup> In particular, medications with narrow therapeutic indices such as digoxin or insulin have a great potential for adverse consequences if dosed improperly. For example, for a 575-gram (20.28-ounce) infant, kilogram units need to be accommodated to three decimal places.
6. **Allow Data Entry for Vaccinations Given at Other Institutions.** In the event that systems are not completely integrated across institutions, at a minimum, it should be possible to document vaccinations given at other institutions. Similarly, printouts of vaccination records should incorporate data from all institutions where vaccinations are given. This ability would reduce the risk of double vaccinations.

#### RECOMMENDATIONS FOR SMALL-GROUP PEDIATRIC MEDICAL PRACTICES

Although small-group pediatric medical practices typically purchase EHR software from vendors, there are often degrees of freedom during the implementation and customization processes to increase EHR usefulness, usability, and patient safety.

1. **Minimize Displayed Options for Medication Orders in Menus.** With most paper-based ordering systems, medications are ordered by physicians without the specificity used in pharmacies. When pharmacy-specific information is displayed to physicians, there can be as many as 17 choices for a common

medication, creating complexity that can lead to erroneous selection of medications. For children, medications are often given together or with complex dosing regimens, thereby increasing the number of potential ordering options. Practices could either create an interdisciplinary committee (consisting of, for example, one or two physicians, a nurse, and an information technology staff person) or work with other practices to have a local committee (as with a Health Information Exchange), which would determine the displayed options to be used, as well as medication options that can be ordered but not shown on a primary display.

2. **Display Normal Ranges for Medication Doses and Lab Values.** Normal ranges can be based on weight, height, body surface area, body mass index, and age information, while also differing on the basis of information source (adult normal, pediatric normal, weight-based normal, age-based normal, body surface area normal). Even in cases in which EHRs do not have normal ranges for medications based on weight and age information available, the practice could incorporate this additional information and display it.
3. **Do Not Permit Automated Changes to Measurement Systems.** Measurement systems (for example, lb versus kg) should not automatically change. For infants, it is common in the United States to use the English pound measurement system for data collection and then convert to the metric system when ordering medications. To reduce mode error risks from working in different measurement systems, displays should not automatically default to a different measurement system. In addition, displaying units of measure along with data values reduces risks for confusion about the current measurement system and scale.
4. **Annotate Corrections to Plotted Data Directly on Chart.** There are a number of reasons why plotted data, such as weight, may be inaccurate and need to be corrected to aid decision making, such as when a premature infant's chronologic age is evaluated on the basis of a younger age group. One technique is to "move back" data points by a time period (for example, two months) to assess growth, given the premature birth. Data quality issues might also arise on the basis of where measurements were taken, how the data were collected, and errors in data entry. Annotating corrections to plotted data needs to be done such that the next user accessing the information can see them easily.

5. **Support Managing Privacy Settings.** Particularly for small-group practices, complex distinctions in privacy settings access to areas of EHR might not be needed and could be avoided either during purchase or when the settings are defined locally. Many levels of confidentiality for different notes can make it difficult for users to understand what privileges are provided with each level, particularly if the distinctions are not well defined in the online help documentation. For example, systems can have confidential notes, sticky notes, private notes, and internal notes, each of which has different definitions regarding access for viewing and transferring to other systems. On the other hand, features with different privacy settings with relation to patients and their family members may be needed. Access issues are particularly complicated for adolescent patients based on age, assent status, and nontraditional caregiving arrangements.
6. **Support Physicians' Timely Access to Specialized Radiologic Expertise When Ordering Diagnostic Imaging.** It is important for pediatricians and radiologists to directly communicate whenever possible to clarify in real time which scan variation to order for high-stakes sedation and intubation procedures. Radiology is a particularly important specialty in pediatric care. Knowing which test to order is an important decision because the risk associated with exposure to radioactivity is particularly high for infant patients whose cell division is very active and whose cumulative lifetime exposure is just beginning. Sedation, intubation, and radiation for pediatric patients are much higher-risk activities than for adult patients. Having multiple scans because of inaccurate selection of correct procedures can have many negative clinical implications.

#### RECOMMENDATIONS FOR CHILDREN'S HOSPITALS

Although children's hospitals and pediatric wards in adult hospitals typically purchase EHR software from vendors, there are often degrees of freedom during the contracting, implementation, and customization processes to increase usefulness, usability and patient safety.

1. **Unit-Specific Banners.** On the basis of the unit's population, the following variables might be included: name, gender, weight, age, gestational age, postconceptual age, and date of birth. For pediatric patients, it is common practice for family members with the same last name to be cared for by the same providers and/or same organizations during the same appointment. To prevent "wrong patient" errors, constant-identification banner headers should include gender, weight (in kilograms), and age as well as the units for age, which can range from "days of life" to "months" to "years" in scale. Note that for same-age siblings due to multiple births, first name, medical record number, and unique medical events, such as birth time in minutes, can be the main distinguishing elements and therefore should be easily accessible if not included on the banner header.
2. **Specialized Threshold Settings.** Support flexibility in unit-based settings for alerts, reminders, and warnings based on weight, height, body surface area, body mass index, and age. Specialized units focusing on pediatric care, including pediatric ICUs, pediatric emergency departments, labor and delivery, and pediatric outpatient clinics, need to be able to adapt threshold settings appropriate for their patient demographics, particularly with respect to weight and age. A committee is recommended to be responsible for determining these settings for groups rather than for individuals in collaboration with staff members, including pharmacists, physicians, nurses, and administrators, and with periodic updates to thresholds and underlying logic.
3. **Soft Stops for Adult Dose.** Dosages should be capped at the standard adult dose while allowing overrides with justification (such as for the ordering of medications for obese adolescents). When an order is entered for a child younger than 14 years of age that exceeds the standard adult dose, provide a real-time and visible alert that the adult dose has been exceeded. Alerts should not be "hard stops" in that they should be allowed to be overridden with a justification.
4. **Support Communications to Change Inaccurate Normal Ranges.** It is recommended that one contact person be designated to receive requests in regard to inaccurate normal ranges for medications and labs. Notification of errors in ranges is recommended to be facilitated by EHR features, which automatically directs the notice to the designated person or group.
5. **Support "Break the Glass" Privacy Law Violations for Urgent Care Situations.** In urgent care scenarios, it might be necessary to access critical health information that is available in an EHR yet restricted for privacy or security purposes. In the event that this is needed, the system should support access as long as a detailed audit trail with rationale is documented.
6. **Monitor Cumulative Radiation Exposure over Time.** A listing in one location of all radiology tests, done at any location, for each patient would help to monitor and reduce exposure to ionizing radiation. The use of computed tomography, which delivers

approximately 100 times the radiation dose as a traditional x-ray,<sup>25,26</sup> has increased more than 20-fold in the United States since 1975.<sup>27</sup> For newborn patients, it is possible that new sources of radiation will emerge in future decades, further raising the cumulative exposure over a lifetime. High cumulative radiation exposures create cancer and other undesirable consequences. Therefore, The Joint Commission has recommended capturing “dose information in the patient’s electronic medical record.”<sup>27</sup> It would be useful for physicians, nurses, radiologists, and, ideally, caregivers and patients if the EHR provided a cumulative plot of radiation exposure over time.

## Discussion

We selected a maximum of 6 recommendations each for EHR developers, small-group pediatric medical practices, and children’s hospitals out of 54 consensus recommendations. For EHR developers, we generated recommendations that are sensitive to specialized patient safety risks for low-weight patients and unique patient safety concerns when ordering medications for young children. For small-group pediatric physician practices, we created recommendations primarily to reduce complexity, efficiency, and reduce the chances of displaying inaccurate information. For hospitals, we created recommendations to primarily increase flexibility in how the elements of the EHR are implemented in a pediatric unit.

We suggest that EHR vendors developing systems for children’s hospitals and medical practice clinics consider rapidly implementing these recommendations to enhance the usefulness, usability, and safety of their products when providing care to pediatric patients. In December 2012 the Office of the National Coordinator (ONC) added a new requirement for safety-enhanced design to achieve certification of EHR technology.<sup>28</sup> Hospitals will be required to have certified EHRs by 2014 to meet meaningful use Stage 2 criteria. Therefore, an additional potential benefit of implementing these recommendations is to meet this new requirement. In addition, the ONC certification requirement stipulates that vendors document their quality management systems.<sup>28</sup> Our experience with one another and the reviewers and other experts suggests that human factors, informatics, and usability specialists are important team members in a quality management system. The nonclinical experts on the panel brought important knowledge to bear in terms of problematic design elements in other complex, sociotechnical settings; efficient identification of relevant human factors concepts; a synthesis of lessons learned that are not concisely or

usefully conveyed in the published literature; and, in collaboration with the clinical experts, valid, useful scenarios for formative design and usability evaluation.

In addition to the application of human factors expertise, we feel that there are potential lessons learned for a quality management system. We generated these recommendations by consensus during a series of remote one-hour meetings held in a six-month period. Notable elements of the process included the collection of miniscenario incidents and near misses; collection of the miniscenarios, which were created on the basis of clinical experience, and abstracted into emerging themes; and integrating miniscenarios into longer, more elaborate scenarios that could be useful for design and evaluation efforts. Draft recommendations were generated by individual panel members, and debate continued until consensus was reached on a final recommendation. Finally, extensive peer review was provided by experts in pediatric informatics, emergency medicine, neonatology, pediatrics, HFE, usability engineering, and software development and implementation. The peer review process identified potential disagreements with aspects of the recommendations, recognized the need to clarify the description of particular issues, and revealed previously unknown best-practice design and implementation strategies for avoiding issues.

There are limitations to this effort. Most notably, none of the recommendations have yet been validated to improve patient safety or usability. Following all of these recommendations is unlikely to guarantee that all important patient safety or usability aspects have been addressed or that adoption of EHRs would be accelerated for all providers of pediatric care. In particular, the following topics were outside the scope of this effort: challenges associated with supporting collaborative work and shared situation awareness among interdisciplinary panel members, transitions across care settings, interoperability between systems, integration with bar code point of care and other medical devices, quality improvement and research using data pulled from EHRs, integration with social media and hand-held devices, and software designed exclusively for use by caregivers or nontraditional health care providers.

## Conclusion

Usability of EHR systems has been identified as an important factor in patient safety. The adoption of EHRs by providers specializing in pediatric patient care has lagged behind adoption for general population providers. Pediatric patient care has unique features, and many aspects of care are exceedingly complex and have significantly lower

margins for error. In this article, we highlighted unique critical user interactions important for providing pediatric care with the support of an EHR. We also provided specific guidance distilled from the human factors literature to increase the usefulness, usability, and patient safety of an EHR for three relevant stakeholder groups when designing, purchasing, customizing, or implementing EHRs.

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### Appendix 1. Integrated Scenario with Human Factors Concepts Highlighted: Newborn with Sepsis Treated by Emergency Department\*

A six-day old infant is brought to the emergency department (ED) by his mother (Anna Smith), who reports that he has a fever. At triage, he is very irritable, has a rectal temperature of 102°F (38.9°C) and a bulging anterior fontanel. By ED protocol, he is brought to a treatment room immediately to be seen by a physician. The infant’s history is significant for being the Twin A of a term pregnancy delivered by a scheduled cesarean section (in the same hospital). Twin B is reported to be well at home with the father. The physician’s assessment is that the infant may have sepsis/meningitis and requires a workup. On examination, the physician observes respiratory distress and determines that a chest x-ray is indicated.

The mother does not know the hospital assigned a medical record number, so the registrar in the ED asks for the Social Security number. As is characteristic with newborns, the Social Security number has not been issued yet. A search on “Baby Smith” retrieves many different records. The registrar searches on and successfully finds the mother’s electronic chart, which includes a note from the newborn nursery with medical record numbers for both children. Using the medical record number, the physician is then able to successfully pull up the chart. The physician clicks the “sepsis bundle” quick order set on the EHR interface. The system retrieves the standard adult doses for

these medications, which are far too large, as well as an inappropriate procedure for inserting a central line. The physician notes the mismatch and cancels the set of orders.

#### Human Factors Concepts Identified

- **Potential for mode error (wrong patient):** Lack of a Social Security number results in issues with retrieving the patient’s information in a reliable and expedient fashion.
- **Potential for automation surprise:** Unexpected default to standard adult dose

The physician then calls up a feature that supports weight-based dosing. He estimates that the patient weighs 8 pounds and types the number 8 in the weight box entry. The physician does not realize that the system records the weight as 8 kg, a system default feature that, unfortunately, does not display the unit of measurement in the data entry field. The alert that is issued because the weight falls outside the normal value range is located on the “face sheet” screen, not on the screen where the dose is entered, and therefore it is missed by the clinician. At the time of administration of the medication, the ordered dose is not what the nurse expects, and she catches the mistake. She realizes that the weight was entered in pounds, not kilograms, and that the calculated dosage is therefore significantly incorrect. The nurse informs the physician of the errors in the documented weight and calculated dosage.

### Appendix 1. Integrated Scenario with Human Factors Concepts Highlighted: Newborn with Sepsis Treated by Emergency Department\* (continued)

#### Human Factors Concepts Identified

- **Potential for mode error (wrong measurement system):** Defaulting to the metric measurement system is not always expected in pediatric care for the weights for young children.
- **Potential for missed information:** The alert for a high weight is unlikely to be viewed because it is not displayed on the same screen as where the medication dose is entered.

The nurse informs the physician that the exact weight is 4.1 kg (9.0 pounds). The physician remembers that the appropriate dose for the antibiotic is 10 mg/kg/dose, and calculates in his head that the appropriate dose is 41 mg. He accesses the EHR and types in the order for 41 mg of a brand-name antibiotic for the patient. The system automatically changes the dose of 41 mg to the typical adult dose of 2,000 mg and changes the form of the medication from the brand name that was ordered to the generic form of the medication available in the formulary. The clinician then cancels the order. He consults with the nurse to learn how to override the automated changes in the order, enters an order with the intended dose and form, and confirms his order by printing his order sheet to paper.

#### Human Factors Concepts Identified

- **Complexity:** Potential for mode error, calculation mistakes, occurring within a prescribing episode with weight-based dosing
- **Potential for automation surprise:** The unexpected change to dose and form of the medication could be easily missed and result in a patient receiving a medication in an unintended form and/or receiving a significantly lower or higher drug dosage.

The physician needs broad antimicrobial coverage and decides to start a second antibiotic. The physician then enters an order for the second medication in the EHR. The dose and frequency of administration for this particular medication are dependent on the gestational age of the patient, the actual age, the weight, and the renal function. This medication is administered intravenously, so the options available for ordering are reported in mL, but the information regarding concentrations (based on mg/kg) are truncated on the ordering display. In some of the EHR systems that the physician uses, this medication is ordered in mg/kg/day, and in others it is ordered by mg/kg/dose, so the physician has to intently focus on the units of measurement. He clicks on each of the options, until he finds the correct concentration. He calculates the amount of medication needed in his head and orders it. When he reviews the order, the system has automatically rounded the dose amount to the nearest regular dose, which is too high and would be potentially harmful to the child if administered. He cancels the order and manually corrects the dosage in the EHR.

#### Human Factors Concepts Identified

- **Potential for mode error (wrong dose):** Complexity, truncation of critical information, and inconsistent conventions increase the likelihood of selecting an inappropriate dose.
- **Potential for automation surprise:** Rounding a dose to the nearest unit or standard dose amount could have unique unintended clinical consequences for low-weight pediatric patients.

The physician then returns to assess the patient and informs the mother that antibiotics have been ordered. He learns that the patient's twin is at home with the father and queries the mother for the first name as a safety check. When he looks at the EHR again, he now realizes that he had ordered the medications for the "wrong" twin. He informs the mother that because this is an emergency situation, he will not correct the mistake now but will make a note in both charts. He writes in the progress note that because of an error in patient identification, the order for the sepsis medication was made for the wrong twin, even if the "right" twin received the administered medication. He includes a note in the right twin's chart that he has discussed this with the mother and that he will add the correct information to both twins' charts.

#### Human Factors Concepts Identified

- **Potential for work-flow mismatch:** Difficult for subsequent providers, such as the nurse documenting medication administration, to document actions in the proper location.
- Difficult to change inaccuracies in documentation after the event, even when documentation is often delayed until after care is provided.

The physician then observes an acute change in the neurological status of the infant and orders a computed tomography (CT) scan in the EHR. There are 24 available options for CT scans, taking into account the potential implications of size-based parameters and sedation techniques. Choosing the appropriate test would be difficult for a less experienced physician without consulting with a radiologist. Because the radiologist does not have access to the EHR or the EHR's data until the morning of the procedure, it is not possible for the radiologist to audit and correct orders in advance.

#### Human Factors Concepts Identified

- **Potential for responsibility-authority double bind:** Although physicians are responsible for ordering CT scans, radiology expertise is often needed to know exactly which CT scan is best to order.

\* The scenario is fictional. Adapted from Lowry SZ, et al. *NISTIR 7865. A Human Factors Guide to Enhance EHR Usability of Critical Care Interactions When Supporting Pediatric Patient Care*. Gaithersburg, MD: National Institute of Standards and Technology, 2012. Accessed Jan 30, 2013. <http://www.nist.gov/healthcare/usability/upload/NIST-IR-7865.pdf>.

## Return on Investment for Vendor Computerized Physician Order Entry in Four Community Hospitals: The Importance of Decision Support

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In-hospital adverse events have long been established as a major cause of morbidity and mortality for hospitalized patients and represent a major cost burden to health care systems.<sup>1</sup> In the Harvard Medical Practice Study, adverse drug events (ADEs) were the leading cause of hospital-acquired harm, accounting for 19.4% of all adverse events.<sup>2</sup> Indeed, an Institute of Medicine report estimated that in the United States, approximately 450,000 preventable ADEs occur annually, accounting for \$3.5 billion of excess costs for the health care system nationwide annually.<sup>3</sup>

Health information technology (IT) is regarded as one of the tools that has the greatest potential to substantially improve quality in general and patient safety specifically.<sup>4</sup> For preventing medication errors and ADEs, computerized physician order entry (also known as computerized provider order entry) (CPOE) systems have emerged as a leading strategy, particularly if coupled with electronic decision support systems (DSSs).<sup>5,6</sup> However, despite the evidence, adoption of these systems has been slow across the United States.<sup>7</sup> One of the reasons for this has been the lack of evidence on CPOE effectiveness in community hospitals, which make up the vast majority of acute care hospitals in the United States; lack of evidence based on vendor-developed, as opposed to internally developed, systems; and, finally, an uncertain return on investment (ROI) associated with CPOE implementation. Although a study done in a large academic medical center with a homegrown CPOE system identified substantial cost savings and a positive ROI,<sup>8</sup> no such evidence exists for community hospitals using vendor-developed systems.

We performed a prospective before-and-after study conducted in five Massachusetts community hospitals that have implemented vendor CPOE systems. An initial pre-implementation study quantified the incidence of ADEs in six community hospitals,<sup>9</sup> while in a post-implementation follow-up study in five of those hospitals, we found a decrease of 34% in the preventable ADE rate following the adoption of CPOE.<sup>10</sup> Focusing on the cost savings achieved through prevention of ADEs, we then performed a study to assess the ROI for vendor-related

\* Drs. Cadet, Coffey, and Kaufman served as study coordinators at their respective sites. To preserve site anonymity, the authors' physician organizations are named but not their hospitals or job titles.

### Article-at-a-Glance

**Background:** In-hospital adverse events are a major cause of morbidity and mortality and represent a major cost burden to health care systems. A study was conducted to evaluate the return on investment (ROI) for the adoption of vendor-developed computerized physician order entry (CPOE) systems in four community hospitals in Massachusetts.

**Methods:** Of the four hospitals, two were under one management structure and implemented the same vendor-developed CPOE system (Hospital Group A), while the other two were under a second management structure and implemented another vendor-developed CPOE system (Hospital Group B). Cost savings were calculated on the basis of reduction in preventable adverse drug event (ADE) rates as measured previously. ROI, net cash flow, and the breakeven point during a 10-year cost-and-benefit model were calculated. At the time of the study, none of the participating hospitals had implemented more than a rudimentary decision support system together with CPOE.

**Results:** Implementation costs were lower for Hospital Group A than B (\$7,130,894 total or \$83/admission versus \$19,293,379 total or \$113/admission, respectively), as were preventable ADE-related avoided costs (\$7,937,651 and \$16,557,056, respectively). A cost-benefit analysis demonstrated that Hospital Group A had an ROI of 11.3%, breaking even on the investment eight years following implementation. Hospital Group B showed a negative return, with an ROI of -3.1%.

**Conclusions:** Adoption of vendor CPOE systems in community hospitals was associated with a modest ROI at best when applying cost savings attributable to prevention of ADEs only. The modest financial returns can be attributed to the lack of clinical decision support tools.

CPOE systems deployed in these community hospitals, as we describe in this article.

### Methods

The study protocol was approved by the Partners Healthcare Human Research Committee and by the study site committees.

## PARTICIPATING HOSPITALS

In 2011-2012 we performed a financial evaluation assessing the ROI of vendor-developed CPOE systems in four of the five hospitals that participated in the earlier study.<sup>10</sup> The remaining hospital (Site 3) could not provide the needed granularity of cost data to perform an accurate analysis and was therefore excluded from further analysis.

The four hospitals were small-to-medium-size community hospitals, each with 100 to 300 inpatient beds. At each hospital, admitting services were using CPOE, with the exception of the psychiatric and neonatal services, which were excluded from analysis. Two sites belonged to what we designated as Hospital Group A, and two to Hospital Group B, as follows:

- Hospital Group A: Sites 1 and 2 were hospitals that were under one management structure and implemented the same vendor-developed CPOE system.
- Hospital Group B: Sites 4 and 5, also under one management structure, implemented another CPOE system.

None of the participating sites had implemented any medication-related DSS along with their CPOE systems at the time that this study was performed.

## COST DATA

Costs associated with implementing, running, and maintaining the CPOE systems, which were received from the hospitals' financial units, were kept de-identified throughout the analysis and subsequent publications. We included capital costs and one-time non-capital costs for implementation and ongoing annual operational costs. Capital implementation costs included items such as hardware and software (servers and operating systems, CPOE license, workstations, and programming), network-associated costs, and implementation costs (payments to vendor, project management and team, consultants, and other technical support). One-time non-capital costs included implementation support (such as training for nurses and pharmacy and physician site champions) and information system staff-related costs (training for physicians was not associated with additional costs to the hospital). Distinguishing between capital and one-time non-capital costs was performed by the sites' financial teams. Annual ongoing costs included hardware/software maintenance (including help desk), non-IT resources (ongoing training, physician champion), and supply. Costs not directly attributable to the CPOE system, such as costs attributable to implementation of other IT systems that served the CPOE adoption as well, were excluded from the models. As an example, Hospital

Group B paid bundled licensing for CPOE and for other IT systems. We did not include these costs because the hospitals would have paid the same license fees whether they implemented CPOE or not.

## BENEFIT DATA

The main financial benefit attributable to CPOE systems that we assessed in this analysis was the decrease of preventable ADEs associated with implementation of the system. To calculate these cost savings, we applied the ADE rate decrease for the four sites that we calculated in our analysis<sup>10</sup> and the actual number of annual patient admissions for the sites to our estimate of cost per ADE. In our original study, we included patients age 18 years or older who were admitted to any of the participating hospitals during the study period (pre-CPOE implementation during a 20-month period from January 1, 2005, to August 31, 2006, and post-CPOE implementation, which began 6 months post-implementation at each study site and lasted 6 to 12 months, from October 1, 2008, to September 30, 2010).<sup>10</sup> We randomly selected 200 patient records from each site for both the pre- and post-implementation periods, for which we extracted and classified incidents as ADEs, potential ADEs (both rated for severity), or medication errors with no potential for injury. The investigators were blinded to hospital site and prescribing physician.

We used the cost per preventable ADE estimate—\$3,511—from our previous analysis, which we performed using data from the same Massachusetts community hospitals that participated in the current study.<sup>11</sup> We did not include a breakdown analysis by severity of ADE because the number of ADEs in each severity category was relatively small, so that a small variance in these numbers would have had an inordinate impact on the model results. However, we did include this breakdown in the sensitivity analysis. We adjusted for the prospective reimbursement rate because if a patient's care is not prospectively reimbursed, then savings do not necessarily accrue to the hospital from an avoided ADE. We estimated a prospective reimbursement rate of 80% for the time the study was performed on the basis of discussions with the hospitals about their payer mix.

To establish cost savings due to reduced use of unnecessary expensive medications, we compared use for the 10 most expensive medications for each study period (pre and post) in an attempt to compare between similar drugs in both periods. However, we found that for some hospitals, only 1 drug was considered expensive for both periods. With the rationale that comparing use of a single drug would not provide an accurate assessment, we excluded unnecessary use of expensive medications from this analysis.

## RETURN ON INVESTMENT MODEL

We applied the costs and benefits values in an ROI model that was distributed over time for the full period of the model. We selected a model period of 10 years because results from a previous study showed the breakeven point to be 6 years post-implementation.<sup>8</sup> Each model period was set to be 6 months, the time of implementation for Hospital group A, to allow for easier comparisons between hospital groups. Cost savings from preventable ADEs that were avoided were realized only after the system was operational.

We discounted all costs and benefits at a 7% annual percentage rate according to the US Office of Management and Budget recommendations.<sup>12</sup> This represents a societal discount rate that allows also adjusting for opportunity costs for the hospitals within the time frame of the model. Discounted cash flows were calculated by subtracting total implementation costs during the period of analysis from total cost savings over the same period. If discounted cash flow is positive at the end of the period of analysis, the project is financially viable for that period. Discounted ROI is calculated by subtracting total implementation costs during the period of analysis from total cost savings in the same period, then dividing the result by total costs. A positive ROI means the project was a good investment for the hospital. For the breakeven point, we subtracted discounted cumulative costs from discounted cumulative cost savings on a period-by-period basis; the first period in which those cumulative savings turn positive is when the hospital groups reach the breakeven point. All costs and cost savings were inflated to 2011 US dollars using the Bureau of Labor Statistics Producer Price Index time series for General Medical and Surgical Hospitals.<sup>13</sup>

## SENSITIVITY ANALYSIS

To reach a best-case scenario and a worst-case scenario for the ROI analysis, we performed a sensitivity analysis to adjust for some of the estimations we made. First, for the rate of avoided ADEs, we used a range of 20% of our observed avoided ADE rate as a lower boundary and 40% above our observed avoided-ADE rate as an upper boundary (assuming that under robust DSS, the avoided-ADE rate could be increased substantially). Second, for the costs per ADE, we also calculated cost savings, taking into account the breakdown by severity of ADE. We used costs by ADE severity from the previous analysis performed at these hospitals (life-threatening, \$5,788; serious, \$2,694; and significant, \$1,642—all in 2006 US dollars).<sup>11</sup> The incidence of potential ADEs by severity per site was calculated from recently published data.<sup>10</sup> Finally, we also adjusted for a range of prospective

reimbursement rates that would cover most community hospitals in the United States (60%–100%) and allowed for a range of discount rates, from 3% to 10%.

## Results

### IMPLEMENTATION COSTS

Because the two sites within each group shared the same accounting system, and implementation was a two-site joint project, we performed the ROI analysis per hospital group. Hospital Group A implemented the CPOE system in six months, Hospital Group B in one year. Table 1 (page 22) summarizes the capital, onetime non-capital, and annual ongoing costs for both hospital groups. Initial implementation and ongoing cost data adjusted for number of admissions show the hospital groups to have comparable implementation costs (\$83 per admission for Hospital Group A and \$113 per admission for Hospital Group B). The difference in implementation costs was mostly due to the higher fees for IT consultants and building a clinical support team (train-the-trainer) at Hospital Group B.

### AVOIDED COSTS AND RETURN ON INVESTMENT

Avoided costs associated with CPOE implementation are displayed in Table 2 (page 22). Reduction in ADE rates varied across the sites, ranging from 71% in Site 5 to 14% in Site 4. When applying the average cost per preventable ADE, Hospital Group B achieved higher cost savings (\$16,557,056 versus \$7,937,651), mainly because of the higher volume of patients.

Modeling monetary costs and benefits for 10 years post-CPOE adoption at both hospital groups identified a modest positive ROI for Hospital Group A, with an ROI of 11.3% (discounted over 10 years), with the hospital breaking even on the investment after 8 years. For Hospital Group B, our models showed a negative ROI of -14.2% (discounted over 10 years), with the hospital group never breaking even on its investment within the 10-year time frame of the model (Table 3, page 23).

### SENSITIVITY ANALYSIS

For the sensitivity analysis, applying a range for avoided ADEs, real annual interest rates, prospective payment ratio, and estimation for cost of ADE broken down by severity showed a wide range in the total avoided costs attributed to ADE prevention, which, of course, translated to a wide range in net cash flow and ROI (Table 3). We used an estimation of a 40% increase in avoided ADEs, an interest rate of 3%, and a prospective payment ratio of 100% to represent the best-case scenario; an estimation of a 20% decrease in avoided ADEs, an interest rate of 7%, and a prospective payment ratio of 60% represented the worst-case scenario. When calculating avoided costs by

| <b>Table 1. Costs Associated with Implementation and Maintenance of Computerized Physician Order Entry Systems at Two Hospital Groups (Four Hospitals)*</b> |   |   |
|---|---|---|
|   | <b>Hospital Group A (Sites 1 and 2)</b> | <b>Hospital Group B (Sites 4 and 5)</b> |
| <b>Capital (\$)</b>   |   |   |
| Hardware/Software   | 897,610                                 | 652,990                                 |
| Network/Integration   | 299,2031                                | 260,39                                  |
| Implementation/Consultants  | 1,770,341                               | 5,688,907                               |
| Total (discounted over 10 years)  | 2,967,154                               | 6,492,480                               |
| <b>Onetime Non-capital (\$)</b>   |   |   |
| Implementation Support/Training   | 319,178                                 | 2,288,298                               |
| IS Department Staff   | 62,431                                  | 6,604                                   |
| Total (discounted over 10 years)  | 381,609                                 | 2,256,734                               |
| <b>Ongoing (\$)</b>   |   |   |
| Hardware/Software (annual)  | 178,325                                 | 532,582                                 |
| Non-IT Resources (annual)   | 149,602                                 | 440,427                                 |
| IT Maintenance (annual)   | 220,984                                 | 672,749                                 |
| Total (discounted over 10 years)  | 3,782,131                               | 10,544,165                              |
| <b>Total</b>  | <b>\$7,130,894</b>                      | <b>\$19,293,379</b>                     |
| <b>Cost per Admission<sup>†</sup></b>   | <b>\$83</b>                             | <b>\$113</b>                            |

\* All costs are represented in 2011 US dollars. Total costs and cost per admission are discounted totals for 10 years and take into account a real annual interest rate of 7.0%. IS, information systems, IT, information technology.  
<sup>†</sup> Patient admission numbers are provided in Table 2.

| <b>Table 2. Avoided Costs Due to Avoidance of Preventable Adverse Drug Events for the Four Community Hospitals*</b> |                         |               |                         |               |
|---|-------------------------|---------------|-------------------------|---------------|
|   | <b>Hospital Group A</b> |               | <b>Hospital Group B</b> |               |
|   | <b>Site 1</b>           | <b>Site 2</b> | <b>Site 4</b>           | <b>Site 5</b> |
| <b>Preventable ADE rates (%)</b>  |                         |               |                         |               |
| Pre-CPOE  | 14.0                    | 9.0           | 10.5                    | 8.5           |
| Post-CPOE   | 11.5                    | 4.0           | 9.0                     | 2.5           |
| Difference  | 2.5                     | 5.0           | 1.5                     | 6.0           |
| Admissions/Year   | 2,826                   | 5,730         | 4,992                   | 12,105        |
| Total Avoided ADEs/Year   | 71                      | 287           | 75                      | 726           |
| <b>Total Avoided Costs Over 10 Years (Discounted)</b>   | <b>\$7,937,651</b>      |               | <b>\$16,557,056</b>     |               |

\* Data on preventable ADE rates from Leung AA, et al. Impact of vendor computerized physician order entry in community hospitals. *J Gen Intern Med.* 2012;27(7):801–807. The total avoided costs uses a cost of \$3,511 per preventable ADE (Hug BL, et al. The costs of adverse drug events in community hospitals. *Jt Comm J Qual Patient Saf.* 2012;38(3):120–126) and takes into account a prospective payment ratio of 80%. Total avoided costs are in 2011 US dollars. ADE, adverse drug event; CPOE, computerized physician order entry.

by specific ADE severity (life-threatening, serious, and significant) and running the cost-effectiveness models, Hospital Group A improved its cost-effectiveness, with a net cash flow of \$5,375,609 and an ROI of 75.4% discounted over 10 years, reaching a breakeven point on the investment after 3.5 years. Hospital group B, however, showed worse financial results, with a net cash flow of -\$6,332,329 and an ROI of -37.0%, without reaching a breakeven on the investment within the 10 years of the model. These differences were attributable to the larger

relative reduction in the more costly life-threatening ADEs at the two hospitals in Hospital Group A, where the system prevented overall 300 such ADEs, while in the two sites at Hospital Group B, only 14 such ADEs were prevented.

As mentioned before, because the number of ADEs in each severity category was relatively small, we decided to use the average cost per ADE for our base model and include this breakdown on the sensitivity analysis only. Overall, for Hospital Group A, the sensitivity analysis was found to be most sensitive to cost by ADE severity and next most

**Table 3. Return on Investment of Implementing Computerized Physician Order Entry at Two Hospital Groups (Four Hospitals) Calculated for a 10-Year Period\***

|  | Hospital Group A |                         | Hospital Group B |                          |
|--|------------------|-------------------------|------------------|--------------------------|
|  | Base Case        | Sensitivity Analysis    | Base Case        | Sensitivity Analysis     |
| Total Costs (\$)   | 7,130,894        | 6,698,083–7,861,725     | 19,293,379       | 17,947,586–21,551,985    |
| Total Avoided Costs (\$)   | 7,937,651        | 3,374,063–36,561,760    | 16,557,056       | 4,534,304–48,935,737     |
| <b>Cost-Effectiveness</b>  |                  |                         |                  |                          |
| Cost per Avoided ADE (\$)  | 2,627            | 1,182– 5,141            | 3,345            | 1,525–6,482              |
| Net Cash Flow (\$)   | 806,757          | (-3,324,020)–28,700,035 | (-2,736,323)     | (-13,413,283)–27,383,752 |
| Return on Investment (%)   | 11.3             | (-49.6)–365.1           | (-14.2)          | (-74.7)–127.1            |
| Breakeven Point (years)  | 8.0              | NA–1.5                  | NA               | NA–3                     |
| * Costs and net cash flow represent discounted values over a 10-year model adjusted to 2011 US dollar year. Sensitivity analysis includes rate of avoided adverse drug events, real annual interest rates, prospective payment ratio, and estimation for cost of ADE (broken down by severity of ADE; see Methods section for details). ADE, adverse drug event; NA, not applicable. |                  |                         |                  |                          |

sensitive to the avoided-ADE rate. For Hospital Group B, the avoided-ADE rate was ranked first, with cost by ADE severity ranked as the second most sensitive factor.

For both hospital groups, the prospective payment ratio and interest rates followed as the third and fourth factors, respectively. Table 4 (page 24) shows the sensitivity analysis, in which one of the four variables is varied one at a time, while the other three variables are constant.

**Discussion**

We evaluated the financial ROI of vendor-based CPOE systems associated with prevention of ADEs at four community hospitals and found at best a modest ROI. We also found variability in costs associated with implementation of CPOE systems, as well as in attributed cost savings, with a 10-year ROI ranging from 11.3% to a negative return of -3.1%. It is important to note that all four institutions for which cost analyses had been done had implemented very modest levels of decision support.

Although there is growing evidence to demonstrate the effectiveness of CPOE in reducing rates of both medication errors and preventable ADEs<sup>5,6,14–16</sup> and even suggesting associated decreased mortality rates,<sup>17</sup> the literature also suggests great variability in measured benefits among sites.<sup>18,19</sup> Metzger et al., drawing on actual errors that had resulted in harm, used a CPOE “flight simulator” to assess the medication-related decision support in CPOE systems in a sample of 62 hospitals. Although some systems intercepted as many as 82% of the orders that would cause serious ADEs, others did so for as few as 10%. The ability of CPOE systems to intercept and prevent ADEs can be attributed to several factors, including integration into the clinician work flow, synergy with other electronic systems (such as bar coding),<sup>20</sup> and above all, as shown by

Metzger et al., the level and type of decision support.<sup>19</sup> Similarly, one would also expect variation in the cost savings associated with implementing CPOE. Kaushal et al., who investigated the ROI of CPOE in an academic medical center, showed that the level and type of decision support was directly related to the amount of savings the hospital achieved.<sup>8</sup> Renal-dosing guidance, expensive-drug guidance, and ADE prevention through drug dose, allergy, and drug interactions were found to be the most financially beneficial interventions.

In the current study, all four sites had implemented very limited decision support with their CPOE. Without DSS, CPOE eliminates most of the prescribing errors associated with illegible writing and unstructured orders, as well as dosing variability. Still, the main potential for cost savings remains untapped in the absence of accompanying DSS. As an example, if the four sites had eliminated at least 50% of their potential ADEs, the ROI would have been considerably higher (50.9% for Hospital Group A versus the current 11.3%, and 5.9% for Hospital Group B versus the current -3.1%). However, for greater financial returns, further savings would need to be achieved through the implementation of other DSS components aimed at minimizing unnecessary use of expensive medications and redundant laboratory tests or imaging, and promoting standardization of care through guidelines and care pathways.

The variability between hospitals in terms of CPOE implementation and ongoing costs may be due to a variety of factors other than differences in size of the hospitals and hospital groups. Existing IT infrastructure in terms of hardware (such as workstations), staff resources, and pharmacy resources, for example, is an important determinant of initial costs. Choice of system vendor or

**Table 4. Sensitivity Analysis of Cost-Effectiveness Parameters: Sensitivity Analysis Variables Are Varied One at a Time, While the Other Three Variables Are Constant\***

|   | Cost per Avoided ADE (\$) | Net Cash Flow (\$)        | Return on Investment (%) | Breakeven Point (Years) |
|---|---------------------------|---------------------------|--------------------------|-------------------------|
| <b>Hospital Group A</b>   |                           |                           |                          |                         |
| Real Interest Rate (3%–10%)   | 2,468–2,896               | 331,216–1,609,738         | 4.9–20.5                 | 7.0– 9.0                |
| PPS (60%–100%)  | 2,102–3,503               | (-1,177,656)–2,791,169    | (-16.5)–39.1             | 5.0–NA                  |
| ADE Prevention Rate (-20% to +40%)  | 1,340–4,105               | (-2,050,798)–8,426,901    | (-28.8)–118.2            | 3.0–NA                  |
| Average Avoided Cost per ADE*   | Unchanged                 | 806,757–5,375,609         | 11.3–75.4                | 3.5–8.0                 |
| <b>Hospital Group B</b>   |                           |                           |                          |                         |
| Real Interest Rate (3%–10%)   | 3,111–3,736               | (-3,411,048)–(-1,578,215) | (-19.0)–(-7.3)           | NA                      |
| PPS (60%–100%)  | 2,676–4,459               | (-6,875,587)–1,402,941    | (-35.6)–7.3              | 8.5–NA                  |
| ADE Prevention Rate (-20% to +40%)  | 1,706–5,226               | (-8,696,863)–13,158,450   | (-45.1)–68.2             | 4.0–NA                  |
| Average Avoided Cost per ADE†   | Unchanged                 | (-8,533,894)–(-2,736,323) | (-44.2)–(-14.2)          | NA                      |
| * Costs and net cash flow represent discounted values over a 10-year model adjusted to 2011 US dollars. ADE, adverse drug event; PPS, Prospective Payment System; NA, not applicable. |                           |                           |                          |                         |
| † Estimation for cost of ADE is broken down by severity of ADE (see Methods section for detail).  |                           |                           |                          |                         |

or decision to develop internally would have a significant effect on costs. Furthermore, implementation strategy might affect costs. For example, as our case illustrates, hospitals might decide to develop internally a CPOE clinical support team (as did Hospital Group B) instead of contracting with the vendor for ongoing support (as did Hospital group A). Because we expect there to be no direct correlation between system costs and achieved cost savings, further studies regarding the identification of the key success factors in implementation are necessary for hospitals to control implementation costs and maximize ROI.

The importance of local hospital configuration and customization of CPOE and DSS, as mentioned elsewhere,<sup>8,19,21</sup> cannot be overstated. As expected, internally developed systems with custom-built DSS appear to show a higher benefit<sup>19</sup> and thus a greater ROI,<sup>8</sup> although it should be noted that these ROI evaluations were done in mature implementations. The risk for community hospitals is that they will “stall” post-implementation and not add sufficient clinical decision support. That is precisely what happened to the four hospitals included in this study, even though they are a part of a multihospital state collaborative that has shared approaches to success in this area.

The Health Information Technology for Economic and Clinical Health (HITECH) Act and the meaningful use incentives emphasize the use of both CPOE and basic DSS (drug-drug and drug-allergy interaction checks) in the Stage 1 core set objectives,<sup>22</sup> although hospitals need to go beyond meeting the basic criteria to realize substantial

benefit. The findings of this study suggest that the meaningful use criteria alone may not be sufficient to motivate community hospitals to put key decision support in place. Hospitals might wish to conduct post-implementation tests of clinical decision support to determine functionality and make appropriate adjustments that would improve patient safety.<sup>23</sup>

**LIMITATIONS**

Our analysis has several limitations. First, we included only cost savings attributable to the reduction of preventable ADEs and did not factor in changes in nonpreventable ADEs or other elements that could affect costs, such as reductions in use of expensive medications and changes in administration route (for example, intravenous to oral) and laboratory or imaging orders, and work flow-related issues. Thus, these results are likely conservative. Furthermore, we chose not to include nonpreventable ADEs, which could not be prevented by any patient safety application known today. We also chose not to include work flow-related cost implications, in part because the extent to which cost savings are actually accrued by the hospital is controversial. We chose to run the ROI model for a 10-year period, with the understanding that projecting forward for such a length of time is problematic, particularly with regard to IT solutions. However, because the hospitals had a borderline or negative ROI, we allowed a longer time frame to try to capture the breakeven point.

Another weakness is in the ability to generalize our conclusions to other community hospitals. Although the study was done on four hospitals, the costs were based

on the CPOE approach of two hospital systems. Given that hospitals will have a variable level of information technology infrastructure at baseline, and that philosophy of implementation (for example, consultant versus internal staff) would differ across hospitals, our results would likely vary accordingly.

## Conclusions

Adoption of a vendor CPOE system without accompanying DSS at four community hospitals was associated with a very modestly positive ROI for one hospital group implementing one vendor system and a negative ROI for a second hospital group implementing another vendor system, when applying cost savings attributable to prevention of ADEs. We relate these low financial returns to the lack of linked decision support systems at these hospitals. For CPOE systems to provide a positive ROI paying back their implementation and ongoing costs, hospitals need to realize cost savings related directly and indirectly to these systems. Key sources of these savings include reducing ADEs (which are associated with attributed excess costs), unnecessary use of expensive medications, redundant laboratory tests or imaging, and promoting standardization of care through guidelines and care pathways. A test to assess the adequacy of medication-related decision support in place, which would be taken periodically, could help hospitals ensure that they have such decision support in place and functioning, which could prevent ADEs and perhaps could address other domains also.

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Dr. Bates is a co-inventor on Patent No 6029138 held by Brigham and Women's Hospital on the use of decision support software for medical management, licensed to the privately held company Medicalis Corporation, in which he holds a minority equity

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## Standard IC.02.02.01 (Hospital Accreditation Program)

The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.

### *Standard Introduction and Rationale*

#### **Introduction to Standards IC.02.01.01 through IC.02.03.01 – Implementation**

The activities of infection prevention and control should be practical and involve collaboration between departments and staff. Everyone who works in the hospital should have a role and hold each other accountable. Important infection prevention and control information should be available to both staff and patients. Standard and transmission-based precautions should be used, and any outbreak of infection within the hospital should be investigated.

#### **Rationale for IC.02.02.01**

The Centers for Disease Control and Prevention (CDC) estimate that 46.5 million surgical procedures are performed in hospitals and ambulatory settings each year; this includes approximately 5 million gastrointestinal endoscopies.\* Each of these procedures involves contact with a medical device or surgical instrument. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Additionally, many more people are at risk of developing an infection from contact with medical equipment, devices, or supplies while seeking other health services. Failure to properly clean, disinfect, or sterilize, and use or store medical equipment, devices, and supplies, not only poses risks for the person seeking health services, but also carries the risk for person-to-person transmission of infections.

There are numerous steps involved in the cleaning, disinfecting, and sterilizing of medical equipment, devices, and supplies. It is critical that health care workers follow standardized practices to minimize infection risks related to medical equipment, devices, and supplies. In order to maintain a reliable system for controlling this process, organizations pay attention to the following:

- Orientation, training, and competency of health care workers who are processing medical equipment, devices, and supplies
- Levels of staffing and supervision of the health care workers who are processing medical equipment, devices, and supplies
- Standardization of process regardless of whether it is centralized or decentralized
- Reinforcing the process (for example, the use of placards which list the steps to be followed, according to manufacturer's guidelines)
- Ongoing quality monitoring

\*: [http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf).

### *Elements of Performance*

1. The hospital implements infection prevention and control activities when doing the following: Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.\*

Note: Low-level disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions.

\*: For further information regarding cleaning and performing low-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at [http://www.cdc.gov/hicpac/Disinfection\\_Sterilization/acknowledg.html](http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html).

2. The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.\* (See also EC.02.04.03, EP 4)

Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes.

\*: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at [http://www.cdc.gov/hicpac/Disinfection\\_Sterilization/acknowledg.html](http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html) (Sterilization and Disinfection in Healthcare Settings).

3. The hospital implements infection prevention and control activities when doing the following: Disposing of medical equipment, devices, and supplies.
4. The hospital implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies.
5. When reprocessing single-use devices, the hospital implements infection prevention and control activities that are consistent with regulatory and professional standards.

## Infection Control Standards FAQ

### *Endotracheal Tubes – How to Clean, Disinfect, and Store this Device*

New – October 11, 2013

Devices such as endotracheal tubes (ETT's) may be exposed to potentially infectious material during indicated use, and can become contaminated through direct contact with the patient's skin, mucous membranes, secretions and blood. An ETT interferes with normal patient defenses allowing pathogens direct access to the lung.

To reduce the risk of infection, the importance of standardizing the process of reprocessing as indicated, with a minimum high level disinfection or sterilization (if a single use device is not used and manufacturer's instructions for use is adhered to), and storage is emphasized.

#### **Cleaning and Disinfecting**

ETT's are most commonly obtained as sterile single use devices. As defined, single use devices are intended for one time use, on a single patient, during a single procedure.

If an ETT is not labeled as a single use device, it is considered a semi-critical item and therefore would require using the process for disinfection and sterilization of semi-critical items as designated by the CDC as "high-level" disinfection. Please refer to the CDC and HICPAC document entitled Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. In addition, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) states ETT's are "semicritical" items. Please refer to the CDC and HICPAC's document entitled Guidelines for Preventing Healthcare-Associated Pneumonia, 2003. The last page of the guideline lists ETT's as semicritical items. Recommendation IIIA1b states how semicritical items must be processed and packaged:

"Whenever possible, use steam sterilization (by autoclaving) or high-level disinfection by wet heat pasteurization at >158°F (>70°C) for 30 minutes for reprocessing semicritical equipment or devices (i.e., items that come into direct or indirect contact with mucous membranes of the lower respiratory tract) that are not sensitive to heat and moisture (see examples in Appendix). Use low-temperature sterilization methods (as approved by the Office of Device Evaluation, Center for Devices and Radiologic Health, FDA) for equipment or devices that are heat- or moisture-sensitive (307;309;310;314;315). After disinfection, proceed with appropriate rinsing, drying, and packaging, taking care not to contaminate the disinfected items in the process (308;310). CATEGORY IA"

#### **Storage**

- ETT's should be kept free from contamination until the time of use. Once opened, there is potential for microorganisms to settle on the device the longer it remains open and unused.
- Increased handling of the opened unused device increases the chances of contamination.
- Ensure that the storage area provides protection from dust, moisture, temperature and humidity extremes.
- Refer to the CDC and HICPAC document entitled Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

#### **Pre-opening of Endotracheal tubes (ETT)**

- Currently available evidence-based guidelines do not include recommendations for or against the pre-opening of ETT's prior to use for any length of time.
- Related scientific articles to date that address pre-opening ETT's and the risk of contamination with potentially harmful organisms while left opened for days, are limited.

- Until evidence exists that is supported by well-designed clinical studies, an organization may:
  - conduct a risk assessment, and refer to appropriate professional organizations that address this issue in their position statements,
  - weigh the risk versus the benefits of having pre-opened ETT's given the absence of firm evidence that pre-opened ETT's are advantageous or best practice,
  - utilize a consistent process throughout their organization based on expert clinical consensus that is documented in policy and procedure.

Joint Commission surveyors will evaluate processes related to ETT's to ensure that they are safe for patient use. They will check that ETT's are:

- A single use device, or if not a single use device, are processed via either high-level disinfection or sterilization, according to manufacturer's instructions for use (IFU's).
- Packaged as a sterile single use device. If the ETT is not a single use device, CDC and HICPAC guidelines do not specify one method in which ETT's should be packaged. An example of an acceptable packaging method would be a peel pack post steam sterilization.
- Stored in a way that would prevent recontamination. Examples of noncompliant storage would include unwrapped or opened ETT's in an anesthesia drawer, as well as unwrapped or opened ETT's on top of or within a code cart.
- If the organization pre-opens ETT's (refer to the above section on pre-opening of ETT's) a consistent process is demonstrated and is reflected by policy and procedure.

### ***Laryngoscopes – Blades and Handles: How to Clean, Disinfect, and Store These Devices***

Revised – October 11, 2013

Devices such as laryngoscope blades and handles, may be exposed to potentially infectious material during indicated use, and can become contaminated through direct contact with the patient's skin, mucous membranes, secretions and blood. To reduce the risk of infection, the importance of standardizing the reprocessing and storage of the laryngoscope's blade and handle is emphasized (for non-disposable laryngoscopes).

#### **Cleaning – Laryngoscope Blades**

Equipment used for intubation such as laryngoscope blades should be properly cleaned using the process for disinfection and sterilization of semi-critical items as designated by the CDC as "high-level" disinfection. Please refer to the CDC and HICPAC document entitled Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

In addition, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) states laryngoscope blades are "semicritical" items, which should be sterilized or subjected to high-level disinfection before reuse." Read CDC and HICPAC's document entitled Guidelines for Preventing Healthcare-Associated Pneumonia, 2003. The last page of the guideline lists laryngoscope blades as semicritical items. Recommendation IIIA1b (pages 57-58) states how semi-critical items must be processed and packaged:

"Whenever possible, use steam sterilization (by autoclaving) or high-level disinfection by wet heat pasteurization at >158°F (>70°C) for 30 minutes for reprocessing semi-critical equipment or devices (i.e., items that come into direct or indirect contact with mucous membranes of the lower respiratory tract) that are not sensitive to heat and moisture (see examples in Appendix). Use low-temperature sterilization methods (as approved by the Office of Device Evaluation, Center for Devices and Radiologic Health, FDA) for equipment or devices that are heat- or moisture-sensitive (307;309;310;314;315). After disinfection, proceed with appropriate rinsing, drying, and packaging, taking care not to contaminate the disinfected items in the process (308;310). CATEGORY IA"

## Cleaning – Laryngoscope Handles

Laryngoscope handles are considered contaminated after use and must be processed prior to use with the next patient. Some manufacturers suggest a low-level surface disinfectant be utilized on the surface of the handle, while others may recommend high level disinfection or sterilization. As is the case with all medical devices, the manufacturer's indications for use (IFU) must be followed. Also check with your state for additional law or regulation; we are aware of at least one state that requires additional processing.

## Storage

Laryngoscopes should be kept free from contamination until the time of use. Once opened, there is potential for microorganisms to settle on the equipment the longer it remains open and unused. In addition, increased handling of the opened unused blade increases the probability of contamination. Ensure that the storage area provides protection against dust, moisture, temperature and humidity extremes.

Please refer to the CDC and HICPAC document entitled Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

- Storing laryngoscope blades individually eliminates the potential for contaminating multiple blades if packaged together, and therefore having to reprocess several unused blades as opposed to the one that was used.
  - An option would be to contain the individual blade in a closed plastic bag, placed in a clean storage location.
  - If steam sterilized, a peel-pack may be used.
- When testing the light source and blade use:
  - proper hand hygiene
  - partially remove the blade from the package, attach to the light source, and test.
- Following testing, insert the blade back into the package and return to a clean storage location (manipulation of the blade onto the light source/handle can be tested without actually removing the blade from the bag or pack without touching the blade itself).
- Institute this practice to all areas where laryngoscopes are used. Examples are: code carts, anesthesia carts, and difficult airway boxes or carts.

Joint Commission surveyors will evaluate processes related to laryngoscope blades/handles to ensure that they are safe for use on the next patient. They will check that laryngoscope blades/handles are:

- For laryngoscope blades - processed via either high-level disinfection or sterilization.
- For laryngoscope handles – following manufacturer's instructions-for-use for cleaning/disinfection guidance.
- Packaged in some way. CDC and HICPAC guidelines do not specify the manner in which laryngoscope blades should be packaged.
- Stored in a way that would prevent contamination. Examples of compliant storage include, but are not limited to, a peel pack post steam sterilization, or containment within a closed plastic bag.

Examples of noncompliant storage would include unwrapped blades in an anesthesia drawer, as well as unwrapped blades on top of or within a code cart.

- The organization demonstrates a consistent process applied to all appropriate areas as reflected by organization policy and procedure.

## *Laundering of Surgical Scrubs and Other Surgical Attire*

### **Does The Joint Commission require employers to commercially launder surgical scrubs and other surgical attire?**

New – October 22, 2013

For surgical scrubs or other surgical attire not visibly contaminated, organizations can choose between home laundering (acceptable per CDC/HICPAC) or a healthcare-accredited laundry facility (recommended per AORN). For all visibly contaminated clothing, the employer must be responsible for laundering per OSHA standards. Your organization should develop a policy addressing how they will manage this process and what guidelines they are following which will drive our survey process.

- IC.01.05.01 EP 1 requires organizations to follow evidence-based national guidelines. The two main guidelines regarding this topic do not agree, therefore an organization may choose one or the other:
  - CDC/HICPAC Recommendations – Laundry and Bedding I. Employer Responsibilities A. Employers must launder workers' personal protective garments that are contaminated with blood or other potentially infectious materials. (OSHA: 29 CFR 1910.1030). There is no stated guidance on garments that are not contaminated with blood or other potentially infectious materials.
  - AORN's most recent Recommended Practices - Recommendation V states, "Surgical attire should be laundered in a health care-accredited laundry facility."
- LD.04.01.01 EP 2 requires compliance with law and regulation. The OSHA Bloodborne Pathogen Act requires all visibly contaminated clothing, including scrubs or personally owned items, be laundered by the employer at no cost to the employee. See section 1910.1030(d)(3)(iv).

## *Use of Self-Contained High Level Disinfection Units for Semi-Critical Devices*

New – October 22, 2013

**What are the Joint Commission recommendations regarding Gluteraldehyde User Station's (GUS), disinfection soak station's (or similar self-contained high level disinfection units which often use 0.55% ortho-phthalaldehyde) for disinfecting devices (such as vaginal probes and other endocavity probes) utilized in various settings (such as radiology, outpatient procedure rooms in hospital, and ambulatory care settings). Specifically, are there any specific requirements for ventilation, use and processing locations (shared or separate) and can the unit share space with a sterilizer?**

This response is specific to the use of self-contained high level disinfection (HLD) units and does not apply to reprocessing of instruments, such as endoscopes, bronchoscopes or TEE probes. In addition, the Joint Commission does not endorse or promote any specific brand, product, process or device for performing HLD or sterilization. Such decisions are the responsibility of the organization's leadership, giving consideration to the scope of services provided, patient population served and accepted evidence-based guidelines, law and regulation.

Disinfection strategies vary widely for semi-critical devices (such as vaginal probes, endocavity probes). Based on the device and product(s) used for reprocessing, it would be expected that organizations follow the manufacturer's recommendations to ensure safe, effective use.

This response addresses the environment where Gluteraldehyde User Station's (GUS) disinfection soak stations (or similar self-contained high level disinfection units, such as those using 0.55% orthophthalaldehyde) are used. The primary intent is that the 'process' for cleaning and disinfection of probes is consistent with current evidence-based practices (that is recommended by AAMI, CDC, etc.) for such devices as well as following recommendations from the product's manufacturer for both the device used for reprocessing as well as the device being reprocessed.

The Joint Commission and OSHA require that health care facilities protect workers and patients from known risks. Since all high-level disinfectants by definition are toxic, and their fumes are known irritants, workers and patients need protection from exposure. Proper handling and use of high-level disinfectants falls under The Joint Commission's Environment of Care Standard 02.02.01 EP 9 which states "The organization minimizes risks associated with selecting, handling storing, transporting, using and disposing hazardous gases and vapors."

The Joint Commission Infection Control Standard IC.02.02.01 EP2 may be scored if the high level disinfectant is not being properly used, including improper efficacy testing, frequency for changing the solutions in the unit not following policy, or dilution ratio requirements not being followed.

The Joint Commission expects organizations to use evidence-based national guidelines, such as the ANSI/AAMI ST58:2013 "Chemical Sterilization and High-level Disinfection in Health Care Facilities." This document includes the following requirements:

- Chemical sterilants should be used in an area that is properly ventilated.
- When general room ventilation is not adequate, a self-contained, freestanding system\* or a local exhaust hood should be installed to capture chemical vapor during processing.
- When an outside exhaust system is not available, a ductless fume hood\* can be used to deliver vapor to a filter system that chemically inactivates the vapor; then clean, filtered air is returned to the room.
- Filters for these systems should be replaced in accordance with the manufacturer's recommendations.
- \*A ductless fume hood is simply a freestanding system that captures the toxic fumes and vapors and returns clean air to the room. Other names for ductless fume hoods are vapor control systems and disinfection soak stations.

Practitioners should consult the labels of proprietary products for specific instructions. They should also consult instrument manufacturers regarding compatibility of these agents with probes. Many of the chemical disinfectants are potentially toxic and many require adequate precautions such as proper ventilation, personal protective devices (gloves, face/eye protection, etc.) and thorough rinsing before reuse of the probe. Specific questions pertaining to device cleaning and the self contained high level disinfection units:

1. What is the normal sequence of operations regarding device processing, including room environments?
  - After the patient is removed from the room the device is either processed in the room or removed from the room in a covered container and brought to a separate room where the GUS (Gluteraldehyde User Station) disinfection soak station (or similar self-contained high level disinfection unit, such as those using 0.55% ortho-phthalaldehyde) is located. The processing procedure does not determine the pressure differentials of the room (i.e. negative pressure), but the pressure differentials are established by The Facility Guidelines Institute (FGI) 2010 Guidelines for Design & Construction of Health Care Facilities and the identified use of the room. For example, a soiled utility room is required to be maintained under negative pressure, whether or not the GUS is in the room. A clean utility room is required to be maintained under positive pressure, whether or not the GUS is in the room.
  - The cleaning and disinfecting process should follow national guidelines (such as CDC guidelines) where staff should wear appropriate Personal Protective Equipment (PPE) and follow manufacturers' recommendations to process the device.
  - Store the device in a manner that will protect from damage or contamination and that is consistent with national guidelines and manufacturers' recommendations such as hanging vertically in a cabinet and storing in a clean environment
2. Is it acceptable to rinse the probes under tap water after Cidex disinfection OR should sterile water be used?
  - There is no current recommendation to use sterile or filtered water rather than tap water for rinsing semi-critical equipment that contact mucous membranes. The Joint Commission would expect the organization to conduct a risk assessment to determine the quality of their rinse media.

## High-Level Disinfection and Sterilization: Know Your Process

The Joint Commission's standards compliance data for the first half of 2013 showed that 37% of **ambulatory care organizations**, 43% of **critical access hospitals**, 47% of hospitals, and 26% of **office based-surgery practices** were found out of compliance with Infection Prevention and Control (IC) Standard IC.02.02.01: "The [organization] reduces the risk of infections associated with medical equipment, devices, and supplies" (see September 2013 *Perspectives*, pages 1, 6–11). Reducing the risk of infections associated with medical equipment, devices, and supplies—in particular, the risk related to breaches in high-level disinfection or sterilization processes\*—continues to be a challenge in hospital, ambulatory care, and surgery settings.

The areas of leadership, infection prevention and control, surgical services, central sterile processing, environmental services, and engineering all play a critical role in reducing risk and harm to patients who receive procedures involving the use of reprocessed equipment, devices, and supplies. Standardizing the use of high-level disinfectants and sterilization practices is critical for ensuring that medical equipment, devices, and supplies do not transmit infectious agents to patients. This is true whether an organization has one centralized sterile processing department or several smaller decentralized locations.

Organizations can begin to address potential and actual process vulnerabilities by conducting a risk assessment and taking a closer look at high-level disinfection and sterilization as a potential high-risk area and process. What follows are the five most frequently noted areas for improvement (identified from Joint Commission-conducted surveys) in high-level disinfection and sterilization. These are provided to present organizations with a proactive opportunity to identify similar areas of improvement within their own processes.

### Evidence-based Guidelines

Lack of having—and/or lack of using—current evidence-based guidelines for cleaning, disinfection, high-level disinfection, and sterilization practices is a frequently identified issue as required under Standard IC.01.05.01, EP 1. This includes knowledge of guideline content and accessibility of guidelines (electronic or manual) for staff use. See the sidebar on page 35 for a list

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\* See Standard IC.02.02.01, Element of Performance 2: "The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies."

of sources that provide current standards, evidence-based guidelines, and recommended practices for high-level disinfection and sterilization.

### Orientation, Training, and Competency

Another issue (see Standard IC.02.02.01) is the lack of orientation, training, and competency (initial and ongoing) of all staff involved in processing or handling semicritical and critical devices that require high-level disinfection or sterilization. This includes providing complete documentation of employee orientation, training, and competencies. The complex processes of high-level disinfection and sterilization require that competent personnel, who are trained in sterilization and high-level disinfection, perform these tasks. In addition, orientation, training, and competency should be conducted by personnel who are competently trained on recent evidence-based guidelines and manufacturer's instructions to ensure that accurate information is being shared.

Note that an organization's policies must specify whether to use high-level disinfection or sterilization based on the intended use of the device or piece of equipment. Critical items (such as surgical instruments, which contact sterile tissue or the vascular system) require sterilization. Semicritical items (such as endoscopes, which contact mucous membranes) require high-level disinfection. Organizations are advised to follow manufacturer's instructions, however, as some devices that would typically be considered semicritical may require sterilization based on intended use by the organization.

### Quality Control and Quality Monitoring

A third issue is divided between the lack of quality control for high-level disinfection and the lack of quality monitoring for sterilization, which speaks to requirements under EP 2.

#### Quality control for high-level disinfection.

Processing medical equipment, devices, and supplies under non-validated conditions may jeopardize patient safety. For example, using a high-level disinfectant concentration lower than that recommended by the manufacturer (when estimating how much of it to use) could result in process failures. Users must ensure that the concentration, exposure time, and exposure temperature for each cycle are accurate and documented/logged. In addition, all solution test strips and chemical monitoring devices should be used according to manufacturers' written instructions. Be sure to use the correct test strip for testing solutions, and monitor the concentration of the active ingredient in solutions before each use.

**Quality monitoring for sterilization.** Quality monitoring tools include physical monitors, chemical indicators, and biological indicators that help expose sterilization process failures. Noted as posing a particular challenge to organizations, biological indicators demonstrate whether conditions were adequate for achieving sterilization and are the only monitoring tool that provides a direct measure of a process's lethality.

Users must ensure that the biological indicator selected for use is the correct one for the sterilization cycle being tested, and they must check the sterilization cycle and the manufacturer's instructions-for-use to confirm appropriateness.

Biological indicator lot numbers and control lot numbers must be from the same lot (that is, they should match). Biological indicators should be used for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use. In addition, biological indicators should be used to monitor every load containing implants. The usage and results of biological indicators should be documented.

### Supervisory and Infection Prevention and Control Staff

The fourth most frequently identified issue involves the participation and collaboration of staff in monitoring high-level disinfection and sterilization processes.

**Ongoing monitoring/supervision by qualified supervisory staff.** According to Standard IC.02.02.01, competent, qualified personnel must supervise high-level disinfection and sterilization processes, which include decontamination, inspection, preparation, packaging (for terminal sterilization), storage, and distribution. Personnel assigned to supervisory functions or managerial oversight should have education, training, and experience with these critical tasks in order to be prepared for this responsibility. Organizations should document the achievement and maintenance of this orientation, competency, and training.

**Working with infection prevention and control staff.** High-level disinfection and sterilization are critical components of infection prevention and control. Infection prevention and control practitioners may work closely with surgical services and central sterile processing staff, directly observing and evaluating practices, to safeguard the cleaning, disinfection, and sterilization of medical equipment, devices, and supplies. In addition, infection prevention and control staff monitor patient outcomes in order to identify failures in process and practice. The Centers for Disease Control and Prevention's "Patient Notification Toolkit" and the Association for Professionals

in Infection Control and Epidemiology's "Protocol for Exposure Investigation After the Failure to Follow Disinfection and Sterilization Principles" (*see* references at the end of this article) both provide guidance on the evaluation of potential disinfection and sterilization failures.

### Record Keeping

The fifth most frequently noted issue involves documentation. Lapses in record keeping and incomprehensible, nonstandardized logs diminish the validation, monitoring, and accountability of a process. Proper documentation, required under EP 2, ensures that high-level disinfection processes and sterilization cycles are monitored in real time, that parameters have been met, and that accountability is established. Documentation also helps staff determine—based on a positive biological indicator or non-responsive chemical indicator (suggesting sterility problems)—whether a recall of a specific lot containing instruments is indicated. And finally, supporting documentation provides a traceable path to the patient and product identification in the event of a recall.

#### Resources for High-level Disinfection and Sterilization Practices

- American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 <https://www.aami.org/publications/standards/st79.html>
- ANSI/AAMI ST58:2013 (<https://www.aami.org/publications/standards/st58.html>)
- Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 ([http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf))
- Association for Professionals in Infection Control and Epidemiology (<http://www.apic.org>)
- Association of PeriOperative Registered Nurses (<http://www.aorn.org>)
- Occupational Safety and Health Administration (<http://www.osha.gov>)
- Society for Gastroenterology Nurses and Associates (<http://www.sgna.org>)

## Making the Process Safer

Breaching the complex processes of high-level disinfection and sterilization of reusable medical devices poses a potentially significant risk to patient safety. The effectiveness of high-level disinfection and sterilization processes depends on the correct performance of every step, and a breakdown in the process can impact the outcome of high-level disinfection or sterilization.

Consistent results for high-level disinfection and sterilization require continuous attention to quality control and monitoring as well as to staff and supervisor training. While actual and potential variability in high-level disinfection and sterilization practices occurs in health care settings every day, organizations can make medical equipment, devices, and supplies safer for patient use by standardizing and accurately conducting processes.

## References

- ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. American National Standards Institute/Association for the Advancement of Medical Instrumentation. Oct 14, 2013.
- ANSI/AAMI ST58:2013: Chemical sterilization and high-level disinfection in health care facilities. American National Standards Institute/Association for the Advancement of Medical Instrumentation. Aug 21, 2013.
- Carrico R, et al (editors). *APIC Text of Infection Control and Epidemiology*, 3rd ed. Washington, DC: Association for Professionals in Infection Control and Epidemiology, 2009. (See Chapter 21: “Cleaning, Disinfection, and Sterilization”)
- Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infection Control and Hospital Epidemiology*. 2007 Feb;28(2):146–155.
- Centers for Disease Control and Prevention. Patient Notification Toolkit: A Guide to Assist Health Departments and Healthcare Facilities with Conducting a Patient Notification Following Identification of an Infection Control Lapse or Disease Transmission. (Updated: Jun 6, 2013.) Accessed Dec 5, 2013. <http://www.cdc.gov/injectionsafety/pntoolkit/>
- Association for Professionals in Infection Control and Epidemiology. Protocol for Exposure Investigation After the Failure to Follow Disinfection and Sterilization Principles. [http://apicchicago.org/pdf/2010/Dr.Rutala\\_dsfailureChiaco2010.pdf](http://apicchicago.org/pdf/2010/Dr.Rutala_dsfailureChiaco2010.pdf)

## Appendix A: Additional Resources

### *Print Resources*

JCR periodical articles can be purchased on PubMed via Ingenta (<http://www.ingentaconnect.com/>).

### *Electronic Resources*

The Joint Commission: <http://www.jointcommission.org>

Joint Commission Resources: <http://www.jcrinc.com/>

Centers for Disease Control and Prevention (CDC) – Cleaning and Performing Low-Level Disinfection of Medical Equipment, Devices, and Supplies:

[http://www.cdc.gov/hicpac/Disinfection\\_Sterilization/acknowledg.html](http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html)

Centers for Disease Control and Prevention (CDC) – Sterilization and Disinfection in Health Care Settings:

[http://www.cdc.gov/hicpac/Disinfection\\_Sterilization/acknowledg.html](http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html)

Institute of Medicine – Health IT and Patient Safety: Building Safer Systems for Better Care:

<http://iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx>

National Institute of Standards and Technology (NIST) – A Human Factors Guide to Enhance EHR Usability of Critical Care Interactions When Supporting Pediatric Patient Care:

<http://www.nist.gov/healthcare/usability/upload/NIST-IR-7865.pdf>

The Joint Commission – Health Care-Associated Infections Portal:

<http://www.jointcommission.org/hai.aspx>

The Joint Commission – Topics: Infection Control:

[http://www.jointcommission.org/infection\\_control.aspx](http://www.jointcommission.org/infection_control.aspx)

**NOTE:** The Internet is an ever-evolving environment and links are subject to change without notice.

## Appendix B: Faculty Biographies

*NOTE: These presenters do not have any financial arrangements or affiliations with corporate organizations that either provide educational grants to this program or may be referenced in this activity. These presenters have also attested that their discussion will not include any unapproved or off-label use of products.*

### **Libby Brown, RHIA, CPHQ, CJCP**

Lead CSR Consultant

Joint Commission Resources, Inc.

Libby Brown has extensive healthcare management experience in acute care settings, as well as experience in ambulatory healthcare, behavioral healthcare, and long-term care. She has expertise in healthcare administration, quality management, case management, accreditation, and health information management. She has been a Continuous Service Readiness consultant for Joint Commission Resources for hospitals in Tennessee, Mississippi, and Kentucky since September 2005.

Ms. Brown brings demonstrated experience as a healthcare executive, quality management professional, and a health information management professional to her role for Joint Commission Resources. Her past experience includes serving as an Assistant Administrator at Baptist Memorial Hospital – Memphis in Memphis, Tennessee and Baptist Memorial Hospital – North Mississippi in Oxford, Mississippi. She has provided consultative services to the Baptist Memorial Health Care Corporation system hospitals located in Mississippi, Tennessee, and Arkansas. In addition, she has held director-level management positions for Health First Medical Group, a multi-specialty physician practice group in Memphis, Tennessee; Parkwood Hospital, a behavioral health hospital in Olive Branch, Mississippi; and Humana Hospitals in Natchez, Mississippi and Memphis, Tennessee.

Ms. Brown has served as a clinical instructor for the University of Mississippi, School of Health Related Professions and provided annual lectures for the undergraduate Health Information Management program at the University of Tennessee and the graduate program in Health Care Administration at the University of Memphis. She also has served as a quality examiner for the state of Mississippi utilizing the Malcolm Baldrige criteria.

Ms. Brown earned her bachelor's of science degree in Health Information Management at the University of Mississippi in Oxford, Mississippi. She is a Certified Professional in Health Care Quality (CPHQ), National Association Healthcare Quality, 1998; and a Registered Health Information Administrator (RHIA), American Health Information Management Association, 1980. Her professional affiliations include Tennessee Association for Health Care Quality and the Tennessee Hospital Association. She is also a Joint Commission-certified Yellow Belt.

### **Lisa A. Waldowski, MS, APRN, CIC**

Infection Control Specialist

Standards Interpretation Group

The Joint Commission

Lisa Waldowski is the Infection Control Specialist for The Joint Commission Enterprise, under the Standards Interpretation Group (SIG) at The Joint Commission. In her role, Ms. Waldowski advises surveyors with interpretations and education of infection control findings and responds to challenging questions, complaints, and potential threat to life/patient safety infection control related events.

Ms. Waldowski has been with The Joint Commission since January 2013. Prior to joining The Joint Commission, Ms. Waldowski worked with Shriners' Hospitals for Children – Honolulu, the State of Hawaii Department of Health, and Hawaii Pacific Health in paradise, otherwise known as Honolulu, Hawaii.

Ms. Waldowski earned her MSN and PNP from The University of Hawaii – Manoa. She is certified as a PNP and as an Infection Control Practitioner.

## Appendix C: Continuing Education (CE) Accrediting Bodies

To be eligible for CE credit from any of the following accrediting bodies, you **MUST** view the video presentation and read the Resource Guide first. Then, complete the post test at <http://twnlms.com/> by the due date listed online. See Appendix E.

### Accreditation Council for Continuing Medical Education

Joint Commission Resources (JCR) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. JCR takes responsibility for the content, quality, and scientific integrity of this CME activity. JCR designates this educational activity for the listed contact hours of AMA PRA Category 1 Credit(s)<sup>TM</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

### American Nurses Credentialing Center's Commission on Accreditation

JCR is also accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. JCR designates this continuing nursing education activity for the listed contact hours.

JCR is a provider approved by the California Board of Registered Nursing, provider number CEP 6381 for the listed contact hours.

### American College of Healthcare Executives

Joint Commission Resources is authorized to award the listed contact hours of pre-approved ACHE Qualified Education credit for this program toward advancement, or re-certification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward ACHE Qualified Education credit should indicate their attendance when submitting application to the American College of Healthcare Executives for advancement or re-certification.

### National Association for Healthcare Quality

This activity has been approved by the National Association for Healthcare Quality (NAHQ) for 1.0 Certified Professional Healthcare Quality (CPHQ) CE credit.

Successful completion of this CE activity includes the following:

- View the presentation and read the accompanying Resource Guide.
- Complete the online Evaluation Form and Post Test.
- A CE certificate/statement of credit can be printed online following successful completion of the Post Test and the Evaluation Form.

**NOTE:** This information applies to The Joint Commission Resources Quality & Safety Network program titled, Solutions Part 2: How to Meet the Most Challenging Medical Records and Infection Control Standards, originally presented on Thursday, April 24, 2014 from 2:00 - 3:00 p.m. ET.  
There is no individual participant fee for this educational activity.

## Appendix D: Discipline Codes Instructions

Some of our programs are accredited for more than one discipline. To ensure that we issue each participant a certificate by the appropriate accrediting body, we ask that you supply us with the following information: 1) two-digit discipline code. 2) followed by the position code (example: for a medical doctor, use 10 MD).

| Discipline           | Discipline Code | Position Code | Position                              |
|----------------------|-----------------|---------------|---------------------------------------|
| Physician (CME)      | 10              | MD            | Medical Doctor                        |
|                      |                 | MDFP          | MD-Family Practice                    |
|                      |                 | MDPS          | MD-Psychiatrist                       |
|                      |                 | MDPH          | MD-Public Health Certificate          |
|                      |                 | MDPP          | MD-Public Psychiatry Certificate      |
|                      |                 | MDAC          | MD-Area Clinical Needs                |
|                      |                 | MDMF          | MD-Medical Faculty Certificate        |
|                      |                 | MSP           | MD-Medical Staff Physician            |
|                      |                 | MDLL          | MD-Limited License                    |
|                      |                 | 40            | PHA                                   |
|                      |                 | DDS           | Doctor of Dental Science              |
|                      |                 | OP            | Other Medical Professional            |
| Administration       | 12              | HA            | Hospital Administrator                |
|                      |                 | ADM           | LTC Administrator                     |
|                      |                 | OA            | Other Administrator                   |
| Pharmacy             | 13              | PH            | Pharmacist (PharmD)                   |
|                      |                 | PHN           | Pharmacist, Nuclear                   |
|                      |                 | PHC           | Pharmacist, Consultant                |
|                      |                 | PA            | Pharmacy Technician                   |
| Dietary              | 14              | RD            | Registered Dietitian/Nutritionist     |
|                      |                 | NC            | Nutrition Counselor                   |
|                      |                 | DTR           | Dietetic Technician                   |
| Dietary Manager      | 15              | DOD           | Dietary Manager                       |
| Counseling           | 16              | MHC           | Mental Health Counselor, Licensed     |
|                      |                 | SW            | Social Worker, Licensed               |
|                      |                 | OCT           | Other Counselor/Therapist             |
|                      |                 | MFT           | Marriage/Family Therapist, Licensed   |
| Laboratory           | 17              | LTG           | Laboratory Technologist/ Professional |
|                      |                 | LT            | Laboratory Technician                 |
|                      |                 | LS            | Laboratory Supervisor                 |
|                      |                 | LD            | Laboratory Director                   |
| Physical Therapy     | 18              | PT            | Physical Therapist                    |
|                      |                 | PTA           | Physical Therapy Assistant            |
| Occupational Therapy | 19              | OT            | Occupational Therapist                |
|                      |                 | OTA           | Occupational Therapy Assistant        |

| Discipline                 | Discipline Code | Position Code | Position                              |
|----------------------------|-----------------|---------------|---------------------------------------|
| Respiratory Therapy        | 20              | RT            | Respiratory Therapist, Registered     |
|                            |                 | RTC           | Respiratory Therapist, Certified      |
|                            |                 | RPNC          | Resp. Practitioner, Non-Critical Care |
|                            |                 | RPCC          | Resp. Practitioner, Critical Care     |
| Medical Records            | 21              | RHA           | Health Information Administrator      |
|                            |                 | RHT           | Health Information Technician         |
|                            |                 | CCS           | Coding Specialist                     |
|                            |                 | CCP           | Coding Specialist, Physician-Based    |
| Radiology                  | 22              | RAD           | Radiologic Technologist               |
| Sonography                 | 23              | MS            | Medical Sonographer                   |
| Athletic Training          | 24              | AT            | Athletic Trainer                      |
| HC Quality                 | 25              | HQP           | Healthcare Quality Professional       |
| Activity Professional      | 26              | ADP           | Profession Activity Director          |
|                            |                 | ADC           | Activity Director                     |
|                            |                 | AAC           | Activity Assistant                    |
|                            |                 | ACC           | Activity Consultant                   |
| Nurse (CNE)                | 30              | RN            | Registered Nurse                      |
|                            |                 | ARNP          | Advanced RN Practitioner              |
|                            |                 | NP            | Nurse Practitioner                    |
|                            |                 | LPN           | Licensed Practical Nurse (or LVN)     |
|                            |                 | ON            | Other Nursing Professional            |
| Psychology                 | 33              | PSY           | Psychologist (non-MD)                 |
|                            |                 | PSYL          | Psychologist, Limited License         |
| Case Mgmt                  | 35              | CCM           | Certified Case Manager                |
| Nursing Assistant          | 45              | C N A         | Certified Nursing Assistant           |
|                            |                 | RA            | Restorative Care Aide                 |
|                            |                 | H S A         | Health Support Aide                   |
|                            |                 | NA            | Nurse Aide, Non-certified             |
|                            |                 | NT            | Nursing Technician                    |
| Emergency Medical Services | 46              | CFR           | First Responder                       |
|                            |                 | EMTB          | EMT, Basic Level/EMT1                 |
|                            |                 | EMTI          | EMT, Intermediate Level/EMT2/EMT3     |
|                            |                 | EMTP          | EMT, Paramedic Level/EMT4             |
|                            |                 | OTH           | Other                                 |
| Health Unit Coor           | 55              | CHUC          | Health Unit Coordinator, Certified    |
| Other                      | 27              | OTH           | Other                                 |

## Appendix E: Post-Test

To be eligible for CE credit, you MUST view the video presentation and read the Resource Guide first. Then complete the post-test at <http://twinklms.com/> by the due date listed online.

1. Which Joint Commission standard requires the hospital to maintain complete and accurate records for each individual patient?
  - a. PC.01.01.01
  - b. RC.02.02.02
  - c. RC.01.01.01
  - d. IM.02.02.03
2. Any methodology used to transmit medical record information within and between care settings should \_\_\_\_\_.
  - a. provide safer patient care
  - b. improve provider coordination
  - c. increase consistency of communications
  - d. All of the above.
3. Which Element of Performance for RC.01.01.01 requires that the medical record contains information about the patient's care, treatment, or services that promotes continuity of care among providers?
  - a. EP 1
  - b. EP 8
  - c. EP 11
  - d. EP 13
4. Which of the following steps can help improve the accuracy and completeness of an organization's medical records?
  - a. Involving the staff when medical record compliance issues are discussed.
  - b. Providing physician education on medical records.
  - c. Conducting chart audits.
  - d. All of the above.
5. RC.01.01.01, EP 19, stating that all entries in the medical record, including all orders, are timed, applies to \_\_\_\_\_.
  - a. hospitals that use Joint Commission accreditation for deemed status purposes
  - b. critical access hospitals only
  - c. only hospitals applying for their initial Joint Commission accreditation
  - d. hospitals that do not use Joint Commission accreditation for deemed status purposes
6. Which Joint Commission standard requires the hospital to reduce the risk of infections associated with medical equipment, devices, and supplies?
  - a. IC.01.01.01
  - b. RC.01.01.01
  - c. IC.02.02.01
  - d. PC.02.02.01

7. If an endotracheal tube (ETT) is not labeled as a single use device, it is considered a semi-critical item and therefore would require using the process designated by the CDC as low-level disinfection.
  - a. True
  - b. False
8. Issues in hospitals that have contributed to non-compliance with IC.02.02.01 include \_\_\_\_\_.
  - a. lack of staff training and competence assessment
  - b. failure to update and follow the hospital's own policies and procedures
  - c. inadequate supervision
  - d. All of the above.
9. Equipment used for intubation such as laryngoscope blades should be properly cleaned using the process for disinfection and sterilization of semi-critical items as designated by the CDC as high-level disinfection.
  - a. True
  - b. False
10. Which Element of Performance for IC.02.02.01 requires that hospitals implement infection prevention and control activities when performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies?
  - a. EP 1
  - b. EP 2
  - c. EP 3
  - d. EP 4

## Appendix F: JCRQSN Contact Information

### General information, customer service issues, or program reception issues

JCRQSN Customer Service Team

[support@jcrqsn.com](mailto:support@jcrqsn.com)

toll-free 1-888-219-4678

### Questions or comments about JCRQSN educational programming

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### Questions about standards

Joint Commission Standards Interpretation Group

1-630-792-5900

### Questions about JCR education or other resources

JCR Customer Service Center

1-877-223-6866