



Special Report: CANDOR

Partnership for Patients Hospital Improvement Innovation Network
Iowa Healthcare Collaborative

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CANDOR in Iowa

Abstract

Much has been done to improve healthcare quality and safety in the United States (U.S.). Still, there are times when patients experience an unanticipated health outcome. The Communication and Optimal Resolution (CANDOR¹) process is one that healthcare institutions and practitioners can use to respond in a timely, thorough and just way when unexpected events cause patient harm. Although evidence is growing that supports the CANDOR approach, there remains a strong element of fear by various stakeholders regarding the level of transparency it requires. Despite state legislation, CANDOR is not well known, understood or exercised in the state of Iowa. More concrete research clearly demonstrating the relationship between CANDOR, malpractice claims and liability expenses is needed to create a business case that CANDOR is not only “the right thing to do,” but also contributes to improvements that will make care safer, improve outcomes and save money. Through a robust, engaging, interactive and experiential four-part, in-person workshop series, hospital audiences learned key elements of the CANDOR approach utilizing the AHRQ CANDOR toolkit as a guide. As the workshop series matured, participants were able to demonstrate a significantly improved confidence and knowledge level related to CANDOR skills, accompanied by visible commitment towards CANDOR and post-workshop action that demonstrates successful uptake among Iowa hospitals. Many healthcare professionals entered the field, hearing the call to help patients. CANDOR provides a way to fulfill this call when unanticipated harm occurs. To effectively spread CANDOR we must be mindful that the paradigm shift in behaviors and response to harm may require more innovative and customized training and support to transform traditional behaviors and normalize compassionate honesty. This project demonstrates a promising model.

¹ In the Iowa statute, the term “*Candor*” is used instead of the all caps acronym “CANDOR” used in the AHRQ toolkit. In this report, we use the acronym CANDOR for consistency except when referring explicitly to the implementation of *Candor* in Iowa or state of Iowa legislation.

INTRODUCTION

Problem Description

Preventing harm caused by unsafe healthcare is a global, national and local priority. Despite widespread recognition of patient safety as a public health issue since at least 1999, preventable patient harm still occurs in alarming numbers. For years it has been recognized that medical error in United States (U.S.) hospitals was leading to patient deaths. In 1984, the landmark Harvard Medical Practice Study estimated there were 180,000 patient deaths annually (1). New research in 2016 suggests that U.S. hospital deaths attributed to medical error have reached 250,000, making it the 3rd largest cause of preventable death (2). Even newer research in 2018 found that for the first time more people in the world die from poor quality care than from lack of access to care (3). Existing research or public health data still lacks the ability to reliably estimate preventable harm due to missed, wrong or miscommunicated diagnoses (4).

In 2002, the World Health Organization (WHO) recognized patient safety as a global imperative. That year the Fifty-Fifth World Health Assembly called upon all member nations to take action (5). In response, WHO launched the World Alliance for Patient Safety in 2004, acknowledging that to tackle patient safety effectively, a campaign involving cultural change and systems-based safety science was necessary. These actions set forward a plan to facilitate learning about why preventable harm events occur and to find solutions that will prevent them in the future (6).

Collaborative efforts and partnerships have strengthened among healthcare organizations, clinicians, thought leaders, policymaking bodies and payors that are positioned to incentivize achievement of expected outcomes. Their efforts have been matched by the pioneering spirit of dedicated innovators and researchers, educators, nonprofit/non-governmental advocacy groups, product makers and activated healthcare consumers. The sum of their efforts has generated substantial evidence that when forces align the collective impact can truly make a difference. Through focused attention and aligned efforts in the U.S. driven by the Centers for Medicare and Medicaid Services (CMS), measurable patient harm was reduced by 21% between 2010 and 2015, resulting in 125,000 fewer deaths, 3 million fewer injuries and \$28 billion in saved costs (7). A centerpiece of this work is the CMS Partnership for Patients (PfP) campaign, launched in 2011. PfP is a nationwide campaign with the goal of engaging all of the nation's acute care medical centers in making hospital care safer, more reliable, and less costly through the achievement of two goals: (1) decrease all-cause patient harm by 20% percent and (2) reduce all 30-day hospital readmissions by 12%. The PfP is driven by CMS support for the Hospital Improvement Innovation Networks (HIIN), including the Iowa Healthcare Collaborative's (IHC) Compass HIIN (8).

Despite the significant progress, there are still hurdles that have proven to be difficult to jump on the journey to achieving the bold aim of zero harm. Perhaps one of the tallest hurdles is a culturally embedded “deny and defend” paradigm that manifests as a pervasive “wall of silence” following unexpected patient harm (9). Achieving PfP aims and sustaining the improvement CMS is driving in the U.S. hinges largely on a successful shift to a culture of safety in healthcare dedicated to continuous learning and its spread through collaboration across local, national and international communities.

The CANDOR toolkit is an evidence-based state of the art toolkit for driving and sustaining individual behavior and organizational culture change that optimizes continuous improvement in reducing preventable harm (10). Developed by innovators with support from CMS federal partner, the Agency for Healthcare Research and Quality (AHRQ), the CANDOR toolkit is designed as a tool that can be used to embed a comprehensive, principled and systematic approach to responding when unexpected outcomes occur.

Key Components of the CANDOR approach include:

- Rapid reporting and response to unexpected patient harm,
- Early and ongoing, open and honest communication with patients and their loved ones,
- Emotional support for provider staff as well as patients and family members,
- Event review using human factors theory to maximize understanding and identification of contributory causes and strong solutions to improve processes,
- Fair and timely financial and non-financial resolution with apology when the harm is caused by inappropriate care, and
- Continuous learning and improvement that serves to prevent future harm.

In 2015, the State of Iowa enacted innovative legislation designed to advance the uptake of *Candor* by Iowa hospitals (11). The law encourages open and honest conversation between patients and providers by limiting the use of statements shared by anyone in subsequent litigation, provided patients and families give consent. Successful implementation of *Candor* programs in Iowa depends on buy-in and behavior change by physicians and other healthcare leaders, as well as training that challenges and overcomes the normalized paradigm of defensiveness. The advance of CANDOR also depends on upskilling

the healthcare workforce in several areas, notably communication during and after unexpected events, as well as event analysis using human factors and cognitive interviewing approaches. Implementation of CANDOR in Iowa and lessons learned along the way will serve as an important resource for all HIINs, as well as policymakers, educators and patient safety advocates in other U.S. States as well as other countries.

Available Knowledge

The case for CANDOR began in the Veterans Health Administration (VHA) with Dr. Steven Kraman who in 1999 published an early report of the importance of open and honest communication and early financial resolution in healthcare (12). Kraman described his positive experience of being extremely honest with his VHA patients. Subsequently the University of Michigan implemented a “Michigan Model” of a principled approach to disclosure and resolution that included early, open, and honest communication, and studied its financial viability (13). Inspired by the Michigan Model, the University of Illinois Hospital & Health Sciences System in Chicago built their patient safety program on the Michigan principles. In addition to communication and resolution, this University of Illinois approach focused on event reporting, event analysis, peer support, and process improvement aimed at harm prevention (14, 15). Other innovators have begun to design, launch and publish their own versions of communication and resolution programs (CRP). To date, no CRP program has reported a negative financial impact (16, 17).

Encouraged by reports of the positive impact of CRPs in liability cost reduction, as well as improvement in patient safety metrics, AHRQ funded a series of demonstration and planning grants to learn more about the interface between patient safety and medical liability, and tort reform. The goal of these grants was to accelerate innovations that had the potential to reduce both preventable patient harm and medical liability costs (18). Based on data from these grants, AHRQ next funded the creation of the CANDOR toolkit focused on the implementation of CRP domains as a comprehensive response to patient harm (10).

Evidence supporting the case for CANDOR or other CRP programs continues to accumulate. Learning to date is summarized below:

Improved Patient Safety Processes and Outcomes

- A. Statistically significant increase in the reporting of near misses, unsafe conditions, and unexpected harm events to patients and staff (15).
- B. Substantial increase in inter-professional event analyses with associated process improvements and redesign (15).
- C. Significant reduction in serious safety events (19).
- D. Financial benefits exceeding \$1,000,000 per hospital in a 10-hospital system (MedStar Health) that includes a major academic medical center (Georgetown) (19).

Patient Engagement and Satisfaction

- A. Improved Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHP) scores (19).
- B. Patient perceptions of courtesy and respect.
- C. Nursing and Physician Listening.
- D. Physician Explanation.

Physician and Staff Engagement and Well Being

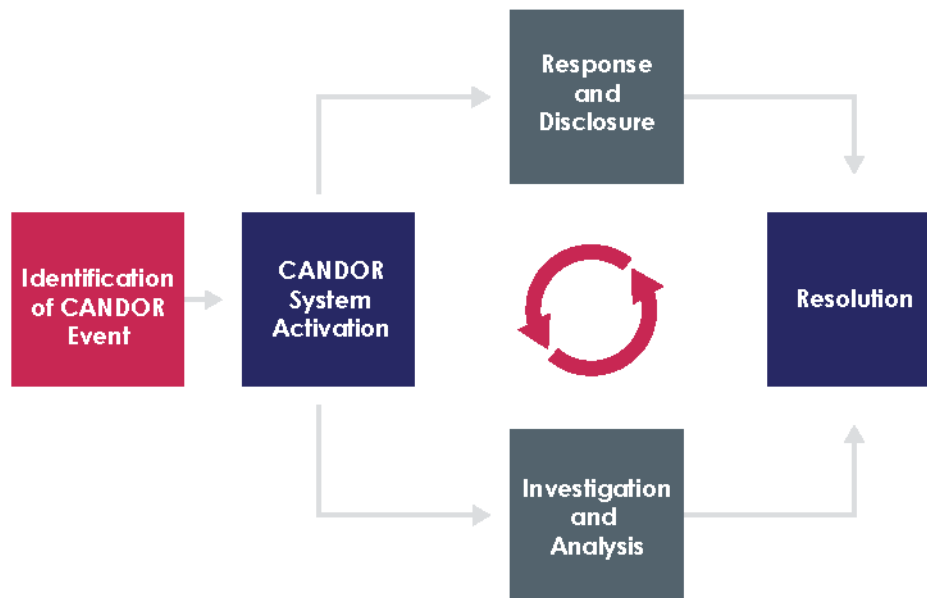
- A. Care for the caregiver component increases sense of well-being.
- B. Assists with suicide prevention.
- C. Fosters less burnout.
- D. Decreases nursing turnover.
- E. For an academic medical center - >\$1,800,000 saving per year with reduction in nurse turnover and decrease in nursing vacancy (20).
- F. Time from event to final resolution reduced from mean of 5 years to 1 year – 4 fewer years of emotional stress during legal discovery period (13,15,21).
- G. Statistically significantly decreases the practice of “defensive medicine” with substantial cost savings to organizations – for patients with diagnosis of chest pain the savings in fewer laboratory tests and radiographic studies resulted in a mean savings of approximately \$200 per discharge (22).

Liability Metrics

- A. Substantial decrease in Claims/Lawsuits with \$25-50,000 savings per claim prevented (13,15,21).
- B. For lawsuits filed - >\$100,000 reduction in liability expenses per case (12,14,20).
- C. Average annual reduction of \$3-5,000,000 in actual payouts versus predicted after first two years of program (15,19).

Rationale

The CANDOR toolkit facilitates change depicted by this change model:



Fundamentally CANDOR seeks to normalize compassionate honesty as a transformation goal in the organizations that implement. CANDOR, as with all CRPs, represents a paradigm shift from a traditional, defensive posture to a more timely, open and honest response to patient harm as depicted in Table 1.

Table 1. The Paradigm Shift

Variance Reporting	From delayed or not at all to immediate
Communication Following Harm	From delay, deny and defend to immediate, ongoing and transparent
Event Review	From shame, blame, and train to human factors-based analysis and process redesign
Care for the Caregiver	From suffering in isolation to immediate and ongoing support
Resolution	From making them fight for it to early offer in cases of inappropriate care

Specific Aims

The Compass HIIN will develop a project to spread CANDOR in a subset of hospitals and identify effective strategies for uptake.

Interested communities include:

- Patient receiving care and their family members (22)
- Iowa hospitals, key personnel including executive leadership, medical staff, risk management, legal
- Iowa Hospital Association
- Iowa Medical Society and its membership
- Liability insurers in Iowa
- Nationwide: all HIINs, CMS
- Globally: Patient safety and healthcare transformation advocates in other nations

METHODS

Training methods include:

- Interactive face-to-face experiential learning with these components:
 - case-based didactic knowledge transfer,
 - table-top group communication exercises,
 - realistic communication practice with actors playing roles of aggrieved patients, their loved ones, and members of the care team, and
 - cases based on actual de-identified patient harm events, supplemented by mock medical records.
- Through the sequential structure of four workshops, training tracked cases from moment of unexpected event through initial and ongoing communication, event review, care for care givers, and financial and non-financial resolution. Engagement of patient advocates throughout each aspect of training.
- Human factors approach to event analysis using actual cases.
- Training in cognitive interviewing techniques proven to optimize fact finding and causal analysis in event review processes.
- Continuous improvement, data driven through use of evaluations after each workshop event.
- Identification of threats to culture change, including organizational personnel who act as Assassins, Posers or Saboteurs of CANDOR.
- Engagement as faculty of patients and family members who experienced a harm event, including those who were treated with CANDOR and those who wished they had been so treated.
- Assessing and scoring the communication skills of participants during workshop 1 and measuring growth of those skills over the entirety of the four-workshop series.

Context and Interventions

The CANDOR approach is a comprehensive, principled, and systematic approach to the prevention of patient harm and response when it occurs. It is especially meaningful to patients and patient advocates because of its emphasis on learning from harm events and prevention of future harm. (23, 24, 25) It also is important to federal payers for health care, a stakeholder motivated to reduce health system costs associated with healthcare acquired conditions (HACs) and extended hospital stays or avoidable readmissions. (8) The CANDOR toolkit also maps to numerous National Quality Forum (NQF) Safe Practices for Better Healthcare (26), a guide to healthcare transformation in the U.S., and to core competency requirements embedded in physician residency programs by the Accreditation Council for Graduate Medical Education (27).

Emotional support for healthcare staff involved in patient safety events has emerged in both the literature and feedback from hospital and health system implementation sites as a powerful motivator for the uptake of CANDOR. This aligns with increasing interest in organizational strategies to prevent clinician burnout and promote well-being (28).

In Iowa, there is local interest in assisting provider organizations to successfully implement state legislation enacted to facilitate *Candor*. Specifically, there is concern over how and when to discuss patient consent to engage in a *Candor* process in a manner that complies with the law's requirement of a signed consent form as prerequisite. During the workshop interventions described below, Iowa hospital and physician leaders described their commitment to the *Candor* approach as a thoughtful "leap of faith" designed to support both users and providers of care after the trauma of an unexpected harm event, as well as a pathway for behavior change, accelerating learning and prevention.

Implementation of *Candor* in Iowa also will be shaped by the specific issues and resource challenges of hospitals serving rural communities. Several rural critical access hospitals participated in the workshop series, which provided a forum for discussing cooperative approaches to sharing personnel trained and available to rapidly implement a *Candor* response in rural hospital settings.

Study of the Interventions

The interventions used were the CANDOR toolkit and a series of four in-person workshops designed to interactively train Iowa hospital personnel to implement the toolkit. The workshops were conducted in Des Moines Iowa, starting in June and concluding in September 2018. The overall objectives of the workshops were to motivate behavior change and transfer both knowledge and skills. The four workshops were:

1. Communication and Care for the Caregiver (June 2018)
2. Event Reporting and Review (July 2018)

3. Resolution (August 2018)
4. Putting it all Together (September 2018)

Each workshop was built around a curriculum structure that included the following core components:

- Agendas with specified objectives, that also can be used in replicated events;
- PowerPoint slide decks, that also can be used in replicated events;
- Continuing education credits for physicians, nurses, risk managers and lawyers, the applications for which can be used in replicated events;
- Patient or patient advocate presenters who motivated learning by sharing the impact of preventable harm in their lives, connecting the participants hearts with their heads, and stressing the importance of CANDOR-related behaviors;
- Expert faculty used to teach core content such as communications skills, human factors approaches to event cause analysis, and financial resolution;
- Skill-building simulation in the form of role play, in which workshop participants practiced interaction with actors playing a variety of patient, family member and provider personnel roles;
- Role play scenarios built out from real cases of unexpected harm events, that are embedded in a curriculum for use in subsequent educational events;
- Facilitated discussion designed to engage participants in coaching and learning from one another after each patient story, expert presentation or role play exercise;
- Key stakeholders such as lawyers and liability insurers who brought additional subject matter expertise and perspective to each facilitated discussion;
- Professional filming each workshop, to enable capture of patient story, expert presentation and role play content in video clips that can be used in curricula for subsequent educational events;
- Workshop evaluations that were reviewed after each of the four workshops to measure impact and refine curricula for subsequent workshops in the series and future follow-up offerings.

The *Candor* Workshop Series brochure including agendas for each of the four workshops, video and resource library links are attached as Appendices 1, 6 and 7.

In the final workshop, a detailed and publication-worthy *Fire in the Operating Room* case study was developed that can be used itself in future trainings, and as a model for other case studies to be developed. It includes detailed learning goals, framing, situational facts, graphic learning aids and instructions for role play, and is attached as Appendix 8.

Workshop Evaluations are collected in Appendices 2-5.

The project was managed by Kate Carpenter, BHA, CPHQ, RT(R)(M) (CT), Program Manager, Compass HIIN.

Compass HIIN entered into two subcontracts to support the successful implementation the project. The project management team, which met weekly, was comprised of designated leads from each subcontractor. Subcontractors, their roles and lead personnel are described below:

<p>Transparent Healthcare Consulting, LLC on behalf of MedStar Institute for Quality and Safety (MIQS)</p>	<p>Lead personnel:</p> <ul style="list-style-type: none"> • Timothy B. McDonald, MD JD, President of the Center for Open and Honest Communication at MIQS and principal, Transparent Healthcare Consulting, LLC • Martin J. Hatlie, JD, Co-Director of MIQS 	<p>Role:</p> <p>MIQS leads developed curriculum, including workshop objectives, agendas, faculty and content. Content included PowerPoint slide decks and case studies used in role play simulations. Under Dr. McDonald's leadership, MIQS also recruited and prepared workshop faculty, worked cooperatively on workshop logistics, assisted in editing film footage, and contributed to the development of project marketing materials and this report.</p>
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Iowa Medical Society

Lead personnel:

- Dennis Tibben, Director, Government Affairs
- Kate Strickler, General Counsel and Policy Advisor
- Becca Kritenbrink, MPA, Manager of Major Initiative and Foundation Relationships

Role:

Developed curriculum specifically related to the Iowa Candor Statute, worked cooperatively on workshop logistics, helped secure venues, coordinated with CLE Productions to organize professional videography services for each workshop, promotion of the workshop series to Iowa Physicians and provide hospitals technical assistance related to the Iowa Candor statute.

Measures

Measures for this project included both quantitative and qualitative data. Measurements were selected that could inform the study of our processes and outcomes of the interventions. The primary data sources for this study include:

1. Baseline communication skills assessment
2. Qualitative skills assessment through review of enactment video recordings
3. Participant pre and post self-assessments on both knowledge and confidence
4. Post-workshop evaluations
5. Post workshop series hospital questionnaire

To assist with ongoing assessment, participants were given an evaluation survey following each workshop. Compass HIIN included questions to measure the impact of contextual elements, such as engagement of patients or family caregivers as faculty, value of role-play to awareness raising and skill building use of experienced actors who bring role plays to life authentically, and relevance of training to the day to day work of participants. Comments from participants in open fields on the evaluation surveys after each workshop were carefully reviewed, and feedback was incorporated into planning for future workshops in the series to be responsive.

To ensure data completeness and accuracy, instructions were provided on how to complete pre and post assessments. This activity was distributed and completed during the workshop. Evaluations following each workshop event were delivered electronically to each confirmed attendee via a second party. Completion was required to receive documentation of continuing education credit. Communication skills assessment was delivered to registered participants using a SurveyMonkey collector, results were provided back to each participant in a sealed envelope at the first workshop. Qualitative skills were assessed through review of recorded enactments following each workshop. The post workshop series questionnaire was also disseminated to each hospital team leader. Communication skills assessment methodology to assess improvement in communication as the workshop series advanced.

Analysis

Five analysis methods used are described below:

One: Baseline Communication Skills Assessment

Baseline communication skills were measured prior to the commencement of the Candor training workshops. This included a task for the participant to describe exactly what they would say to parents of their daughter who had just experienced an unexpected cardiac arrest. These responses were scored using the Communication Skills Assessment Tool in the **CANDOR toolkit**.

Two: Qualitative Skills Assessment through Review of Enactment Video Recordings

Observations of change in the quality of empathic communication from first enactment in workshop one thru the final enactment in workshop four were conducted by subject matter experts. This included a review of the video clips from all the workshops. A qualitative approach was used for determining the degree of empathy employed and effectiveness of the communication. Evidence of:

- A. preparatory remarks, known as the 'shot across the bow' prior to the delivery of the medical error disclosure,
- B. focusing on the feelings of the patient/loved one during the conversation,
- C. an apology,
- D. offer of follow-up,
- E. non-verbal cues and
- F. feedback from the actors on the degree to which they felt trust, support, and the degree to which the participants listened.

Three: Participant Pre- and Post-Self-Assessments on Both Knowledge and Confidence

Pre- and post-workshop self-assessment of the participant's knowledge in the following domains:

- A. communication following harm,
- B. how to learn and improve following unexpected harm,
- C. providing emotional first aid to peers and
- D. approaching families about financial resolution following harm events.

Events and post workshop self-assessment of the participant's confidence in the engagement of the following situations:

- A. communicating with patients and families after harm,
- B. providing emotional support to peers,
- C. engaging in learning and improving following harm events and
- D. approaching patients and families about financial resolution following unexpected harm.

Four: Post-Workshop Evaluations

Following each workshop aggregate evaluation results were carefully reviewed and analyzed for results and comments about the usefulness of the trainings and the training methods used.

Five: Post-Workshop Series Hospital Questionnaire

Following the completion of the four-part workshop series an electronic questionnaire was distributed to each participating hospital to evaluate and measure their organizational commitment towards Candor and if the workshop series had motivated follow-up action at the organization level. Individual responses were captured using SurveyMonkey. The questionnaire assessed the following questions:

- Is your organization having discussions at the executive level about implementing Candor in your facility? If so, is the hospital legal department/representation engaged in those discussions?
- What follow-up offering would best support their organization in their future direction/plans for Candor?
- Steps that have taken or plan to take as result of the workshop series.

Together, the qualitative and quantitative data were used to:

- Understand the impact the interventions had on skills and confidence on key domains of the CANDOR process.
- Identify the specific interventions that contributed to uptake of commitment to CANDOR

Ethical Considerations

All workshop faculty disclosed real or potential conflicts of interest in accordance with CEU provider requirements. In development of the case studies, details were changed to prevent and disclosure of patient information or the identities and locations of all people and organizations involved in the underlying events.

RESULTS

Series Results

The CANDOR toolkit is in the public domain, and therefore was available to the project team and participants from the inception of the project. In proposal development and initial planning, use of virtual training vehicles were anticipated, not in person events. The shift to in person workshops was driven by the goal of transferring skills to change behaviors. Experiential learning methods are the most effective for skill building among adults. This understanding prompted the project team to develop and market a workshop series that could be delivered within the project timeframe and budget. The shift to interactive learning via role play with actors opened the opportunity to develop more complex cases for teaching and transferring communication skills.

In total, 27 organizations were represented at the Candor workshop series. Of these, 20 were hospitals. The number of confirmed attendees per workshop is listed in the table below:

Workshop One	Workshop Two	Workshop Three	Workshop Four
44	26	42	48

As described above, several methodologies were used to assess the effectiveness of the CANDOR Training. The results were:

One: Baseline Communication Skills Assessment

Results: At baseline, only two of the 26 persons who completed the communication skills assessment demonstrated a high level of empathic communication during the task completion. This is similar to other data McDonald and Lambert have accumulated in over 1,200 prior communication assessments from more than 200 hospitals and physician group practices.

Two: Qualitative Skills Assessment through Review of Enactment Video Recordings

Results: A review of notes taken during the workshops and reviews of all the videos of the enactments the participants demonstrated a progressive increase in the degree to which they empathically communicated to the patients and loved ones. Some participants engaged in communication scenarios at each workshop and each of those showed a significant increase in the six elements of empathic communication listed above.

Three: Participant Pre- and Post-Self-Assessments on Both Knowledge and Confidence

Results (25 assessments submitted):

	Mean Pre	Mean Post	Change	Paired T-Test
Knowledge change related to communication following harm using a 4-16 scale used in previous analyses of CRP programs such as CANDOR (27).	7.95 SD 2.45	13.0 SD 1.88	5.05 p < .0001	p < .00001
Knowledge related to how to learn and improve following unexpected harm	8.45 SD 2.8	13.1 SD 2.21	4.65 p < .0001	p < .00001
Knowledge related to providing emotional first aid to peers	8.78 SD 2.1	13.8 SD	5.02 p < .0001	p < .00001
Knowledge related to approaching families about financial resolution following harm events	6 SD 1.6	11.36 SD 2.79	5.36 p < .0001	p < .00001

Results (25 assessments submitted): Confidence change was also measured using a 4-16 scale (27).

	Mean Pre	Mean Post	Change	Paired T-Test
Confidence change related to communicating with patients and families following harm	8.1 SD 2.29	13 SD 1.7	4.9 p < .0001	p < .00001
Confidence change related to providing emotional first aid to peers	9.3 SD 2.4	13.65 SD 1.4	4.35 p < .0001	p < .00001
Confidence change in engaging in learning and improving following harm events	9.42 SD 2.45	13.63 SD 1.98	4.21 p < .0001	p < .00001
Confidence in approaching patients and families about financial resolution following unexpected harm events	5.95 SD 1.8	11.3. SD 2.7	5.35 p < .0001	p < .00001

Note that the knowledge and confidence was lowest AND changed the most in the domain of approaching families about financial issues.

Four: Post-Workshop Evaluations

Results: Each workshop received consistently high scores with little variation. Participants reported highest level of change in the areas of: knowledge, competence, performance and patient outcomes. The overall average response to the question, “How well did the program meet your objectives for attending?” demonstrated 92.72% of participants rated it as excellent. There were recurring themes in the comments section about the value of the face-to-face workshops and the skill-building power of the enactments with well-trained actors.

Examples of attendee comments captured in post workshop evaluations include:

- “I attend many educational sessions as part of my role. This is by far the best series I have attended in a very long time (and I am a harsh critic!) Can't wait for the last two sessions!”
- “I love observing the role playing as I feel that is beneficial to see how the patients and their families could potentially respond. The emotion involved is overwhelming at times, but it is certainly appropriate and makes you feel like you are observing a real time conversation.”
- “Having individuals who have been harmed by medical errors is very powerful--sets the stage for the rest of the day, drives home the reason for the program.”
- “It's always good to have guest speakers that have been personally effected by healthcare. It saddens me that we fail patients but makes me hopeful by them sharing their story and us working on process improvements; we can make healthcare a better, and safer place.”
- “I like how you would review just a little of each session as we progressed through each class. It was a good reminder and helped the main topics to really sink in.”
- “This conference was one of the best I have been to in my professional career.”
- “Hearing from those who have been harmed by medical mistakes really reinforced the need for change in the approach and response by healthcare entities and those who can influence change.”
- “The practice sessions and the actors really make this a great training experience. The immediate feedback was very helpful.”
- “I hope this is offered again in Iowa so more of my colleagues can attend and get this very important training. No one ever wants to have these conversations, but it is really to ours and the patients and families to have been trained on how we can make this a better experience for everyone. Unfortunately, accidents and errors occur, more importantly how we handle them after is even more important and this training series was priceless in preparing us for them if they should need to happen.”

- “This by far was the best series of training I have been to in my career (10 years). I wish other facilities would do this same work!”

Five: Post-Workshop Series Hospital Questionnaire

Results: 92.31% of hospitals who completed the series reported that they are or are planning to have discussion at the executive level about implementing CANDOR in their facility. Of those, 85% are including their hospital legal representation in those conversations. Within 30 days following the completion of the workshop series, 77% of respondents were able to list steps their organization has taken regarding Candor as a result of this workshop series. Examples of hospital activity post workshop series from the cohort include:

- Scheduling CANDOR presentations for their organizational senior team and leadership.
- Organizational meetings to strategize an implementation plan.
- Development of a CANDOR committee.
- Identification of a “Go Team”
- Formalize a root cause analysis process
- Planning of “Just Culture” training
- Collaboration at the network level
- Work on organizational implementation of a Care for the Caregiver program

The importance of open and honest communication to patients and family members was underscored by inclusion of persons who experienced preventable harm in healthcare as faculty in each workshop. The project team recruited patient/family faculty who had both experienced a CANDOR-like process, as well as those who did not and considered the failure to communicate to be an additional devastating harm. Welcoming patients and family members as faculty also created an environment where empathy thrived. In the context of medical liability and liability reform, it disruptively changed who talks to who about what. Workshop participants who work in healthcare heard in a non-defensive environment what it is like to be harmed as a patient as well as family members who experienced a “collateral harm” to their loved one’s harm. Patient/family faculty were able to understand the complexity of concerns and feelings providers weigh when their performance may have contributed to harm.

The sequence of the workshops mirrored the evolution of how a provider organization and its personnel are called upon to respond when an unexpected event occurs – initial communication, event review with cognitive interviewing and human factors analysis, follow up communication and resolution, with care for the caregiver at every stage in the CANDOR process. It also fostered an understanding of how the Iowa legislation shaped *Candor*-like communication and the obtaining of patient consent, as well as challenges faced by providers in getting a signed consent form at the beginning of the *Candor* process as set forth in Iowa law.

Concluding the series with a workshop that takes participants through the entire process using a deeply developed case study based on real events served to reinforce understanding of the CANDOR process and confidence that implementation in their home organizations was feasible. The final workshop also provided the opportunity to assess growth in skills among participants, key factors in embedding behavior change for both individuals and in organizational culture.

Finally, it should be noted that nearly all hospitals participating in the workshop series are located in rural Iowa communities. IHC and its workshop partners are now fostering a dialogue about collaboration among rural hospitals to cooperatively structure availability of personnel trained in *Candor* that can rapidly respond when unexpected harm occurs in rural Iowa hospital settings.

The use of trained actors in role play scenarios also had important contextual impact that should be noted. The actors were skilled, knew the cases well and were well-rehearsed, creating the opportunity for them to make challenging statements and adopt behaviors of grief, fear, anger and confusion that felt quite authentic to workshop series participants. The combination of patient and family engagement as faculty and actors trained to express or evoke deep emotion created an intense and powerful connection to feeling in this workshop series.

Including patients and family members as faculty created meaningful opportunities for health care provider participants to hear from and get to talk to persons who both experienced CANDOR-like processes after a harm event and those that did not. Modeling open and honest communication, participants used the workshop settings to practice shattering the “wall of silence” that has historically been erected after unexpected harm event. Attendees put “feelings first” as participants planned and practiced communication overtures. These settings put providers in the shoes of those on the patient side – and vice versa -- the workshop advanced the growth of empathic attitudes and feelings, as well as improved communication skills with increased empathy.

Many participants commented in their evaluations about the significance of having patients and family members present. Several evaluations included comments to the effect that they had not been to trainings like this before, or that this was the best training they had been to for a long time, or ever. It is reasonable to infer from these evaluations that the integration of patient and family interaction added to the memorability of the experience and the retention of new knowledge, attitudes and skills.

The inclusion of patients, family members and actors in this series was a departure from the original plan to deliver CANDOR content virtually. The venue and travel costs of convening in person events were an adjustment. Based on evaluations, they produced the expected benefit of a more meaningful and effective training.

Budget, time and convening logistics constraints prevented the project team from doing CANDOR-readiness gap analyses in the organizations who participated in the series. Based on the experience of the project team in working with over 200 hospitals, gap analyses produce crucial data that are predictors of readiness, successful implementation and sustainability of CANDOR (17). The project team believes that this workshop series was a necessary precursor to gap analyses for the participant organizations involved, helping organizational leaders understand the importance of this data.

DISCUSSION

Summary

Desired knowledge and skills transfer were achieved and all 16 of the stated pre-workshop objectives were measured throughout the workshop and post-workshop evaluations. Detailed aims/objectives of each of the workshops were as follows:

Workshop One

Communication and Caring for Caregivers After Unexpected Harm Communication Domain

Specific Active Learning Objectives: Upon completion of this activity, participant should be able to:

1. Coach a healthcare team through the critical phases of the open communication process.
2. Assess whether the healthcare team is ready to conduct the communication effectively.
3. Activate institutional leadership to formulate a communication plan.

Care for the Caregiver Domain

Active Learning Objectives: Upon completion of this activity, participant should be able to:

1. State how the communication consultation and coaching process interfaces with the care-for-the-caregiver program.
2. Provide initial emotional first aid to clinicians following an adverse medical event.
3. Establish a comprehensive approach to patient harm that includes care for the caregiver.

Workshop Two

Event Reporting and Review

Following the workshop, the attendees will be able to:

1. Describe the fair and accountable approach to the review of unexpected harm events in healthcare.
2. Understand the need to apply human factors engineering concepts to event review.
3. Conduct basic cognitive interviews of staff involved in unexpected events.
4. Identify sustainable process re-designs and improvements with a high likelihood of being effective and sustainable.

Workshop Three

Resolution

Following the workshop, the attendees will be able to:

1. Describe the approach to determining appropriateness of care following patient harm events.
2. Understand the Iowa Candor legislation and how it used during the process of resolving patient harm events.
3. Employ empathic communication skills during financial resolution conversations.

Workshop Four

Pulling It All Together

Following the workshop, the attendees will be able to:

1. Describe the comprehensive, principled and systematic approach to harm from event thru resolution.
2. Understand the interconnectedness of all the domains of the response to harm.
3. Employ empathic communication skills at all points of contact.

Overall, this project was able to successfully spread CANDOR in a subset of hospitals and identify effective strategies for uptake as summarized in this final report.

Strengths of the project included:

- In-person training,
- Communication assessment methods,
- Participation of patients and family members in the learning process,
- Extensive use of interactive role play,
- Experienced actors, well versed in the facts of and communication challenges inherent in cases used in role play scenarios,
- Actual case-based experiential learning,
- Connected heart to head and hand at each step along the way,
- Video capture of experiential scenarios with learning, and
- Detailed built out Fire in the OR Case Study, used in workshop 4 and included here as in Appendix 8 for use in subsequent educational events.

Interpretation

The interventions, specifically interactive experiential domain specific workshops, were designed to increase knowledge and skills of all participants associated with empathic communication in all health care situations. In addition, by using real cases we could simulate other organizational responses associated with unexpected patient harm. Put together, the outcomes measured by observations of communications behaviors and post-workshop self-evaluations demonstrate the effectiveness of the interventions and achieving the objectives of each workshop. Compass HIIN results were similar to those found during the development of the AHRQ CANDOR toolkit (9) and previous studies of the impact of CRP Programs (29).

Post work shop surveys show that many of the hospitals engaged in the workshop are moving forward with ongoing CANDOR implementation within Iowa. Furthermore, the post workshop surveys show a substantial impact on the individuals who participated in the workshops in all the domains – including communication following unexpected harm, engaging in learning and improving following harm, providing emotional first aid to peers and approaching patients and loved ones following harm. The inclusion of harmed patients and families in each work shop also positively affected hearts and minds of the participants. No unanticipated outcomes were observed.

Early in the process, the project team concluded that virtual delivery of content as originally planned would not be sufficient to transfer the skills needed to successfully implement CANDOR. A strategic trade-off was to deliver the training in person at a central location in Des Moines. This may have had the effect of limiting participation by requiring participants to invest in time and travel costs. The project team notes, however, that this investment of time and travel also is an indicator of commitment demonstrated by those who attended. This is reflected in comments in evaluations from multiple participants to the effect that this workshop series was among the best they have attended, as well as comments stating that skills and confidence had grown as a result of the workshop series.

Budget constraints also prevented the project team from doing a gap assessment of readiness to implement CANDOR with participating hospitals, an opportunity cost. The project team notes, however, that the workshop series conveyed a deeper understanding of the importance of readiness assessment among hospital stakeholders, which better prepared participating hospitals to successfully deploy the gap assessment tool in the CANDOR toolkit (9).

Limitations

Training that relies on face-to-face experiential training is resource intensive and may limit the ability to take to scale with an exclusive face-to-face approach. A portion of this training was specific to the implementation under the Iowa Candor legislation.

The recording of all the workshops including the experiential scenarios creates the opportunity for an on-line curriculum that could be delivered with an adult learning approach that would be capable of broad spread of the concepts and skills and confidence transfer thru an on-line medium.

Conclusions

These workshops were quite useful for delivering the content and meeting the objectives for a comprehensive, principled and systematic approach to patient harm that includes empathic communication, human factors-based event review with learning and improving and reaching financial and non-financial resolution following harm. Implementation of CANDOR programs by Iowa hospitals, particularly in the context of the Iowa Candor legislation, also has potential to advance the evidence base for the impact of such programs. While data on the impact of CANDOR type programs on liability claims and costs is increasingly encouraging, more needs to be learned on the value of such approach to meeting patient and family needs after a harm event, and the impact of CANDOR on prevention of future harm (30). Use of patient narratives along with periodic use of a video-based curriculum can be used to sustain the progress made during the workshops. An online resource library that supports the curriculum of each workshop event may also be utilized for future spread to additional audiences. Workshop content and experiential learning can be delivered in any healthcare setting including the outpatient, rural and critical access areas.

Further assistance to organizations seeking to implement all the CANDOR components, including guidance in performing a local needs assessment/gap analysis with provision of currently known best practices associated with CANDOR implementation may be available. This will include topic-specific webinars and on-site engagements with leadership from hospitals interested in further implementation.

Other next steps could potentially include the development of a library of harm events cases with associated interactive curriculum capable of being delivered face-to-face or on-line and in collaboration with patient and family advocates.

OTHER INFORMATION

Funding

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References

1. Leape LL, Error in Medicine, *JAMA*. 1994;272(23):1851-1857.
2. Makary MA, Daniel M. Medical error-the third leading cause of death in the US, *BMJ*. 2016; 353: i2139.
3. Kruk ME et al, MDOI: [10.1016/S0140-6736\(18\)31668-4](https://doi.org/10.1016/S0140-6736(18)31668-4), accessible at <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2818%2931668-4>
4. National Academies of Sciences, Engineering, and Medicine; Committee on Diagnostic Error in Health Care, Board on Health Care Services; Institute of Medicine. *Improving Diagnosis in Health Care*. Washington, DC: National Academies Press; 2015.
5. World Health Organization. Resolution WHA55.18. Quality of care: patient safety. In: Fifty-Fifth World Health Assembly, Geneva, 13–18 May 2002. Volume 1. Resolutions and decisions. Geneva: World Health Organization; 2002. WHO document WHA55/2002/REC/1.
6. World Health Organization. World Alliance for Patient Safety: forward programme. Geneva: World Health Organization; 2004. Available at <http://apps.who.int/iris/handle/10665/43072>
7. Agency for Healthcare Research and Quality. National Patient Safety Efforts Save 125,000 Lives and Nearly \$28 Billion in Cost. Available at https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html?utm_source=AHRO&utm_medium=PR&utm_term=&utm_content=6&utm_campaign=AHRO_NSO_HAC_2016.
8. Centers for Medicare and Medicaid Services Partnership for Patients Campaign. Available at <https://partnershipforpatients.cms.gov/about-the-partnership/what-is-the-partnership-about/lpwhat-the-partnership-is-about.html>.
9. Gibson, R., & Singh, J.P. (2003). Wall of silence: The untold story of the medical mistakes that kill and injure millions of Americans. Jackson, TN: Perseus Distribution Services.
10. AHRQ. <https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/introduction.html>.
11. Iowa Code, Ch. 135P, Adverse Health Care Incidents, Communications, Confidentiality. See, Iowa Medical Society, [https://www.iowamedical.org/iowa/Iowa Public/Resources/Center for Physician Advocacy/Candor/Iowa Public/Issues/Candor/Candor.aspx](https://www.iowamedical.org/iowa/Iowa%20Public/Resources/Center%20for%20Physician%20Advocacy/Candor/Iowa%20Public/Issues/Candor/Candor.aspx)
12. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med*. 1999;131(12):963-967.
13. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. *Ann Intern Med*. 153(4):213-221.
14. McDonald TB, Helmchen LA, Smith KM, et al. Responding to patient safety incidents: the "seven pillars". *Qual Saf Health Care*. 19(6):e11.
15. Lambert BL, Centomani NM, Smith KM, et al. The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes. *Health Serv Res*. 2016;51 Suppl 3:2491-2515.
16. Mello MM, Kachalia A, Roche S, et al. Outcomes In Two Massachusetts Hospital Systems Give Reason For Optimism About Communication-And-Resolution Programs. *Health Aff (Millwood)*. 2017;36(10):1795-1803.
17. McDonald TB et al. Implementing communication and resolution programs: Lessons learned from the first 200 hospitals, *Journal of Patient Safety and Risk Management* 2018, 23(2):73–78.
18. AHRQ. 2010. <https://archive.ahrq.gov/news/newsroom/press-releases/2010/hhsliabaw.html>.
19. *Modern Healthcare*. <http://www.modernhealthcare.com/article/20160813/MAGAZINE/308139997>
20. Armstrong Institute. <https://armstronginstitute.blogs.hopkinsmedicine.org/2017/06/27/supporting-second-victims-also-helps-hospital-budgets/>
21. Adams MA, Elmunzer BJ, Scheiman JM. *Am J Gastroenterol*. 2014 Apr;109(4):460-4. doi: 10.1038/ajg.2013.375. Effect of a health system's medical error disclosure program on gastroenterology-related claims rates and costs.
22. Helmchen LA, Lambert BL, McDonald TB. *Health Serv Res*. 2016 Dec;51 Suppl 3:2516-2536. doi:

- 10.1111/1475-6773.12610. Changes in Physician Practice Patterns after Implementation of a Communication-and-Resolution Program.
23. Mazor KM, Simon SR, Gurwitz JH. Communicating with patients about medical errors: A review of the literature. *Arch Intern Med.* 2004;164:1690-1697.
 24. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA.* 2003;289(8):1001-1007.
 25. Hemmelgarn C, Seeking answers, hearing silence, *Health Affairs* 2018, DOI: 10.1377/HLTHAFF.2017.1535, accessible at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1535>.
 26. National Quality Forum. Safe practices for better healthcare. Available at http://www.qualityforum.org/news_and_resources/press_kits/safe_practices_for_better_healthcare.aspx.
 27. Accreditation Council for Graduate Medical Education. Implementing milestones and clinical competency committees. Available at: <http://www.acgme.org/acgmeweb/Portals/0/PDFs/ACGMEMilestones-CCC-AssesmentWebinar.pdf>.
 28. Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. *Ann Fam Med.* 2014;12(6):573-576.
 29. Gunderson AJ et al, Teaching medical students the art of medical error full disclosure: evaluation of a new curriculum, *Teaching and Learning in Medicine* 2009, 21(3), 229 – 232.
 30. Gallagher TH et al, Can communication and resolution programs achieve their potential? Five key questions, *Health Affairs* 2018, 37(11): 1845–1852.

Attachments

[Appendix 1: Candor Workshop Series Brochure](#)

[Appendix 6: Candor Workshop Series Video Library](#) (Link)

[Appendix 7: Candor Workshop Series Resource Library](#) (Link)

[Appendix 8: Fire in the Operating Room Case Study](#)

For access to appendices 2 – 5 (workshop evaluations), please contact Kate Carpenter, director, hospital services, at carpenterk@ihconline.org.

Appendix 1: Candor Workshop Series Brochure



1

**Communication and
Care for the Caregiver**
June 13, 2018

3

Resolution
August 16, 2018

2

**Event Reporting
and Review**
July 19, 2018

4

**Putting It All
Together**
September 13, 2018

Appendix 1: Candor Workshop Series Brochure



Candor Training Series

Program Overview

The intent of the summer *Candor* training series is to familiarize network hospitals with the early disclosure process, Communication and Optimal Resolution (*Candor*). *Candor* is a powerful tool that works to maintain relationships with patients and families after an adverse event through immediate and frequent communication. It provides care for the caregiver and creates a culture of learning and process improvement throughout the facility. Through this training series Iowa Healthcare Collaborative, Iowa Medical Society, Iowa Hospital Association and MedStar Institute for Quality and Safety will guide hospitals through the various elements of the *Candor* process and provide the tools needed for effective implementation at their facility.

Registration

There is no registration fee to attend the *Candor* Workshop. Please fill out the registration form located at <https://www.ihconline.org/additional-tools/events/candor-training-series-registration/> and email it to Megan Wilshusen at wilshusenm@ihconline.org.

Program Location

Workshop 1	Workshops 2 and 3	Workshop 4
Iowa Medical Society Boardroom 515 E Locust St. #400 Des Moines, IA 50309	Courtyard by Marriott Ankeny 2405 SE Creekview Drive Ankeny, IA 50021	IHA Conference Center 100 E Grand Avenue #100 Des Moines, IA 50309

Lodging

Workshops 1 and 4: A discounted rate is being offered at the following hotels to IHC event attendees on a “non-last room” availability, meaning that there are times when this rate will not be available to book due to high demand in the area so it is important to book early if you think you may need arrangements. When calling, please ask for the Iowa Hospital Association (IHA) rate and reference the corporate ID.

Staybridge Suites Des Moines Downtown

Corporate Rate: \$129 per night + taxes
Telephone: 1-877-238-8889
Corporate ID #: 786828419

Embassy Suites Des Moines Downtown

Corporate Rate: \$139 per night + taxes
Telephone: 515-244-1700
Corporate ID #: 560001333

Workshop 2: A discounted guest room rate has been secured at the Courtyard Marriott in Ankeny for \$119.00 plus tax for night of July 18. Reservations can be made by calling 515-422-5555 and referencing the Iowa Healthcare Collaborative room block. To receive the discounted rate reservations must be made before July 5, 2018.

Workshop 3: A discounted guest room rate has been secured at the Courtyard Marriott in Ankeny for \$119.00 plus tax for night of August 15. Reservations can be made by calling 515-422-5555 and referencing the Iowa Healthcare Collaborative room block. To receive the discounted rate reservations must be made before August 1, 2018.

Program Notes

Dress for the workshops is business casual. Layered clothing is recommended for your comfort.

Appendix 1: Candor Workshop Series Brochure

Workshop 1

Communication and Care for the Caregiver

Intended Audience

C-Suite, physicians, nurses, patient safety leads, risk management leads

Description

During this interactive and highly experiential training, attendees will learn about the evolution of approaches to the response to patient harm. Empathic and honest communication including the disclosure of mistakes or errors if they have occurred, specifically in the context of Iowa's *Candor* legislation will be discussed. Attendees will also gain a clearer understanding of issues surrounding the emotional angst for members of the care team through case study enactments. Experiential learning will involve group and individual exercises practicing these communication objectives.

Learning Objectives

- Outline ways to coach a healthcare team through the critical phases of the open communication process.
- Assess whether the healthcare team is ready to conduct the communication effectively.
- Organize institutional leadership to formulate a communication plan.
- State how the communication consultation and coaching process interfaces with the care-for-the-caregiver program.
- Discuss how to provide initial emotional first aid to clinicians following an adverse medical event.
- Develop a comprehensive approach to patient harm that includes care for the caregiver.

Speakers

Bruce Lambert, PhD
 Kristina (Krissy) Chavez
 Timothy McDonald, MD, JD

June 13, 2018

8:00 AM	Welcome, Introduction and Reflection
8:15 AM	Background on Communication and Disclosure
8:30 AM	The Context of <i>Candor</i> in Iowa
9:00 AM	Communication Skills Assessment and Feedback
9:30 AM	Communication and Disclosure
10:00 AM	Break
10:15 AM	Experiential Communication Learning Case Study 1 Case Study 2
12:00 PM	Lunch
12:30 PM	Disclosure 101/Spectrum Cases
1:00 PM	Just Culture, Care for the Caregiver Background
1:45 PM	Enactments – Care for the Caregiver Experiential Learning Case Study 1 Case Study 2
3:15 PM	Operational Questions and Lessons Learned
4:00 PM	Adjourn

Appendix 1: Candor Workshop Series Brochure

Workshop 2

Event Reporting and Review

July 19, 2018

Intended Audience

CMOs, CNOs, key people involved in root cause analysis (RCAs) or event reviews

Description

During this interactive and experiential workshop attendees will use actual de-identified cases of medical harm to work through the processes of event reporting and event review in a way that is consistent with the principled, comprehensive and systematic approach to patient harm. This will include the application of human-factored engineering concepts and the process of cognitive interviewing. Finally, all of the information learned from the review will serve as the basis for the development of sustainable change and prevention of future harm.

Learning Objectives

- Describe the fair and accountable approach to the review of unexpected harm events in healthcare.
- Explain the need to apply human-factored engineering concepts to event review.
- Discuss ways to conduct basic cognitive interviews of staff involved in unexpected events.
- Identify sustainable process re-designs and improvements with a high likelihood of being effective and sustainable.

Speakers

Timothy McDonald, MD, JD
Kelley Baker, MA
Lt Col Steven L. Coffee

8:00 AM	Welcome, Introduction and Reflection
8:15 AM	Background on Traditional Root Cause Analyses (RCA) and the Need to Improve
8:45 AM	Introduction to RCA Squared Concepts, Including Cognitive Interviewing and Patient Involvement
9:30 AM	Review of the MegaCase with Mock Medical Records
10:00 AM	Break
10:15 AM	Experiential Cognitive Interview and Learning Physician Nurse
12:00 PM	Lunch
12:30 PM	Putting Pieces of the Event Review Together
1:00 PM	Just Culture in the Context of Event Review
1:45 PM	The Solutions Meeting – Identifying Sustainable Changes and Plan for Patient and Family Discussion
2:45 PM	Break
3:00 PM	Operational Questions and Lessons Learned
4:00 PM	Adjourn

Appendix 1: Candor Workshop Series Brochure

Workshop Resolution **3**

August 16, 2018

Intended Audience

Physicians, Patient safety leads, risk management leads, claims staff, legal counsel, clinical leads

Description

During this interactive and experiential workshop attendees will use de-identified cases of medical harm to work through the processes of using the results of event investigation to determine whether care was appropriate in a way that is consistent with the principled, comprehensive and systematic approach to patient harm. In addition, cases of inappropriate care will be taken through the Iowa *Candor* statutory methodology with full application of the processes. Financial and non-financial options for resolution will be described and applied with the use of enactments involving trained actors.

Learning Objectives

- Describe the approach to determining appropriateness of care following patient harm events.
- Outline the Iowa *Candor* legislation and how it is used during the process of resolving patient harm events.
- Use empathic communication skills during financial resolution conversations.

Speakers

Jack Gentry
Teresa Gentry
Jennifer Gonsalves
Timothy McDonald, MD, JD
Michael McCoy, MD
Kate Strickler, JD

8:00 AM	Welcome, Introduction and Reflection
8:15 AM	Background on the Full <i>Candor</i> Approach
8:45 AM	Introduction and Explanation of the Iowa <i>Candor</i> Legislation
9:30 AM	Review of the MegaCase with Mock Medical Records
10:00 AM	Break
10:15 AM	Processes for Determining Appropriateness of Care with Enactments
12:00 PM	Lunch
1:00 PM	Arriving at Fair Financial Compensation Following Harm
2:00 PM	Patient and Family Perspective on Resolution, Including Non-Financial Options
2:30 PM	Break
2:45 PM	Enacting the Resolution Conversation
3:30 PM	Operational Questions and Lessons Learned
4:00 PM	Adjourn

Appendix 1: Candor Workshop Series Brochure

Workshop 4

Putting It All Together

September 13, 2018

Intended Audience

Participants from the first three trainings

Description

During this interactive and experiential workshop the attendees will use actual de-identified cases of medical harm to work through all of the processes associated with the principled approach to patient harm. This will include event reporting, system activation, immediate and ongoing communication with patients, families, loved ones and the care team, event review and resolution.

Learning Objectives

- Describe the comprehensive, principled and systematic approach to harm from event through resolution.
- Explain the interconnectedness of all of the domains of the response to harm.
- Use empathic communication skills at all points of contact.

Speakers

Bruce Lambert, PhD
Carole Hemmelgarn, MS
Timothy McDonald, MD, JD

8:00 AM	Welcome, Introduction and Reflection
8:15 AM	Background on the Full <i>Candor</i> Approach from Patient and Family Perspective
8:45 AM	Review of a MegaCase and Sharing of Processes for System Activation Following Harm
9:00 AM	Enactment of Initial Communication with Patient and Family
10:00 AM	Break
10:15 AM	Review of Event in the Context of Just Culture
11:15 AM	Enactment of Caring for Affected Members of the Care Team After Unexpected Harm
12:00 PM	Lunch
1:00 PM	Identification of Sustainable Process Improvements
2:00 PM	Resolution Financial and Non-Financial Options
2:30 PM	Break
2:45 PM	Enacting the Resolution Conversation
3:30 PM	Operational Questions and Lessons Learned
4:00 PM	Adjourn

Appendix 1: Candor Workshop Series Brochure

Continuing Education

Nursing: 7.25 Nursing Contact Hours will be awarded workshop 1, 7.0 for workshop 2 and 6.5 for workshops 3 and 4 by IHA Iowa Board of Nursing provider #4. Iowa Nursing Contact Hours will not be issued unless your Iowa license number is provided on the certificate completed the day of the conference.

Note: To receive Nursing Contact Hours or a certificate of attendance, you must attend the entire conference. No partial credit will be granted.

DO: Des Moines University (DMU) is accredited by the American Osteopathic Association (AOA) to provide osteopathic continuing medical education for physicians. DMU designates this program for a maximum of 6.25 AOA Category 2-A credits and will report CME and specialty credits commensurate with the extent of the physician's participation in this activity.

MD: This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Iowa Medical Society (IMS) through the joint providership of Des Moines University (DMU) and the Iowa Healthcare Collaborative. DMU is accredited by IMS to provide continuing medical education for physicians. DMU designates this live activity for a maximum of 6.25 *AMA PRA Category 1 Credit(s)*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Other Health Professionals: This live activity is designated for 6.25 *AMA PRA Category 1 Credit(s)*[™].

Educational Grants: No commercial interest company provided financial support for this continuing education activity.

Disclaimer: Everyone in a position to control the content of this educational activity will disclose to the CME provider and to attendees all relevant financial relationships with any commercial interest. They will also disclose if any pharmaceuticals or medical procedures and devices discussed are investigational or unapproved for use by the U.S. Food and Drug Administration (FDA). Determination of educational content and the selection of speakers is the responsibility of the activity director. Firms providing financial support did not have input in these areas. The information provided at this CME activity is for continuing education purposes only and is not meant to substitute for the independent medical judgment of a healthcare provider relative to diagnostic and treatment options of a specific patient's medical condition. The content of each presentation does not necessarily reflect the views of Des Moines University.



CLE: Candor Workshop 3, scheduled for August 16, has been approved for 6.25 hours of Continuing Legal Education.

Certificate of Attendance: Continuing Education Certificates for proof of attendance can be printed after completion of the evaluation that will be emailed after the conference. Some national, state and local licensing boards and professional organizations will grant continuing education credits for attendance when you submit the course outline and your certificate of attendance. IHC recommends you keep a copy of the onsite agenda and contact your own board or certification organization to find out what is required.

Handout Information

These are paperless workshops. You will be notified via email when the handouts are available online, with a direct link to access the files. Paper copies of handouts will not be available onsite at the conference.

ADA Policy

IHC does not discriminate in its educational programs on the basis of race, religion, color, sex or handicap. IHC wishes to ensure no individual with a disability is excluded, denied services or segregated or otherwise treated differently than other individuals because of the absence of auxiliary aids and services. If you need any of the auxiliary aids or services identified in the Americans with Disabilities Act in order to attend this conference, please call 515-283-9383 or write to the Department of Education at IHC.

Registration

Download the fillable PDF form available at
<https://www.ihconline.org/additional-tools/events/candor-training-series-registration/>
 or contact Megan Wilshusen at wilshusenm@ihconline.org to register your hospital now.

Appendix 1: Candor Workshop Series Brochure

Speaker Biographies

Kelley M. Baker, MA, is program director for quality and safety research in the MedStar Institute for Quality & Safety. She is a human-factors engineer with significant experience leading human-factors reviews of serious safety events, hazards and near misses in MedStar Health's ten hospitals and ambulatory care facilities. These reviews include observations and interviews to identify human-factors issues and develop actionable recommendations for effective, sustainable solutions to reduce medical error and improve patient safety. Her work focuses on patient safety, her experience includes patient safety and patient engagement research, as well as medical device usability evaluations. Baker is currently the program director for MedStar's task order with the Agency for Healthcare Research and Quality to develop a Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families.

Kristina (Krissy) Malizzo Chavez is a patient safety advocate who lives in Hobart, Indiana. She graduated from Purdue University and works as a teacher in the Hobart school system. Fluent in Spanish, her advocacy work extends to coaching on how to communicate with people who do not speak English or for whom English is a second language. She became involved in CANDOR work after the death of her sister Michelle in 2008, caused by an anesthesia event and other failures during the course of her care while undergoing a surgical procedure. Chavez and her parents, Bob and Barb Malizzo, are involved nationally in healthcare transformation work and often speak about their decision to honor her sister by working together with providers to make healthcare safer, more transparent and trustworthy.

Lt Col Steven L. Coffee is joint manpower analyst, Directorate of Manpower and Personnel, Office of the Chairman Joint Chiefs of Staff in the United States Air Force. In this capacity, Colonel Coffee advises the Director, Manpower and Personnel Directorate on all joint manpower requirements determination matters supporting nine United Combatant Command Commanders and the Chairman of the Joint Chiefs of Staff. Colonel Coffee graduated from Morehouse College in Atlanta, GA and George Washington University in Washington, DC. He entered the Air Force in 2001 through the Tennessee State University Reserve Officer Training Corps. Colonel Coffee is a charter member and first community chair of the Medstar Georgetown Patient and Family Advisory Council for Quality and Safety and assists in patient advocacy for the Medstar Health System and the Partnership for Patients.

Jack Gentry graduated from Loyola University with bachelor's degrees in political science and American history. He spent 37 years as a Baltimore City police officer, he was also a member of the SWAT team and a hostage negotiator. While looking forward to an active retirement he was seriously injured as a result of a medical error during an elective surgery to repair two bulging discs in his neck and is paralyzed from the neck down. His story exemplifies how a determined patient working together with a dedicated physician and a health system that live their values of caring and transparency can move forward and make the best of a tragic, life-altering situation. The hospital involved immediately disclosed what had occurred during surgery and then stayed in communication with Gentry and his family to ensure their needs were being met during months of rehabilitation and adjustment to the new realities of their life. Gentry and his wife, Teresa, have become vocal advocates for MedStar's approach and the larger movement across the country in the way healthcare providers respond to unintended medical harm.

Teresa Gentry received a bachelor's degree in nursing from the University of Delaware. She has worked in healthcare systems and schools in the Baltimore region. She began her nursing career at Johns Hopkins Hospital, caring for general surgery, cardiac, orthopedic and neurosurgery patients. She was also the coordinator and instructor in their Nurse Internship Program. Later she worked in staff development, utilization review and quality assurance at other Maryland hospitals. In 2015, after spending 16 years as a school nurse at Calvert Hall High School, she retired to be more available to care for her husband. She has joined him as a patient safety advocate with an interest in full disclosure and apology when medical harm occurs.

Appendix 1: Candor Workshop Series Brochure

Jennifer Gonsalves is a claims manager in the corporate risk management department of MedStar Health, managing professional and general liability claims across the system. She obtained a bachelor's degree in psychology from Hollins University and a bachelor's degree in nursing from the University of Maryland. She worked as a registered nurse in the Arlington Hospital Emergency Department until 2000. While working as a nurse Gonsalves earned her Juris Doctor degree from the University of Baltimore. Before joining MedStar Health's corporate risk management team as a claims manager in September 2014, Gonsalves worked as a clinical risk manager at the MedStar Washington Hospital Center and as a director of risk management at MedStar Georgetown University Hospital.

Carole Hemmelgarn, MS, has worked in healthcare for 30 years. She holds a master's degree in healthcare ethics from Creighton University and a master's degree in the field of patient safety leadership from the University of Illinois Chicago where she is an adjunct professor teaching in the master's program. She is on the Patient and Family Engagement committee for Solutions for Patient Safety and the Patient and Family Advisory Council for Quality and Safety at MedStar Health. Hemmelgarn is involved in patient safety work across the country. Her passion resides in the area of communication and resolution programs, health care communication, storytelling in healthcare and the aftermath endured by providers, patients and families when medical harm transpires.

Michael McCoy, MD, is a board-certified obstetrics and gynecology physician from West Burlington who serves as CMO at Great River Health System. In 2013, he chaired the Iowa Medical Society Task Force that first identified the early disclosure concept. He has fought tirelessly ever since to help educate his peers around the state to change the culture in Iowa from deny and defend to a more patient-focused approach of disclosure and continued engagement following an unanticipated outcome. Great River Health System has been leading Iowa's first Candor pilot site. Dr. McCoy and his facility has seen several instances of unanticipated patient outcomes resolved in a manner that satisfied their facility, providers, as well as the patient, without the need for legal action.

Bruce Lambert, PhD, received his doctorate in speech communication from the University of Illinois at Urbana-Champaign. He is professor in the Department of Communication Studies and director of the Center for Communication and Health at Northwestern University. His research focuses on health communication, patient safety and medical liability reform. Lambert is the principal investigator on a five-year grant, funded by the Agency for Healthcare Research and Quality, to study techniques for preventing wrong-drug and wrong-patient errors. He is president of BLL Consulting and Pharm IR, firms that solve problems involving health, communication and technology. He blogs about communication at howcommunicationworks.com.

Timothy McDonald, MD, JD, is president for the Center for Open and Honest Communication at the MedStar Institute for Quality and Safety and a professor of law at Loyola University – Chicago. Dr. McDonald is a physician-attorney whose research has focused on the principled approach to patient harm with an emphasis on reporting of patient safety events, the use of simulation and human-factors analysis and providing open and honest communication following harm events. His federally funded research has focused on these domains and their impact on improving the quality of care while mitigating medical liability and other legal-related issues.

Kate Strickler, JD, graduated from Drake University in 2010. She has been working for the Iowa Medical Society since 2014, first as a staff attorney and now as general counsel. She advises lobbyists on the impact proposed legislation will have on physicians, evaluates compliance with state and federal regulations and is working to implement medical early disclosure program across the state of Iowa. In addition to her work as general counsel, she has a private practice in Chicago, Illinois.

Appendix 8: Fire in the Operating Room Case Study

FIRE IN THE OPERATING ROOM MEGACASE

APPLICABLE DIDACTIC/POWERPOINT

CANDOR – the comprehensive, principled and systematic approach to the prevention and response to patient harm.

CASE-BASED LEARNING

Facts that will be presented to the participants:

- Elderly gentleman with dementia and severe aortic stenosis [A.S.] falls at home
- Develops a subdural hematoma
- Taken to the operating room for burr hole placement
- Patient is prepped and draped
- Moderate sedation is given due to severe A.S.
- Incision is made
- Ten minutes in to procedure patient sits up
- Smoke escapes from under the drapes
- Flames are extinguished
- What next?

Enactments

Enactment #1 will involve the need for person[s] in the operating room to immediately meet with the children of the gentleman who has been burned in the operating room to explain what they know, what they don't know, and what they are going to do to find out what they do not know.

Enactment #2 will be the Cognitive Interview of the neurosurgeon.

Enactment #3 will be cognitive interview of the OR Nurse

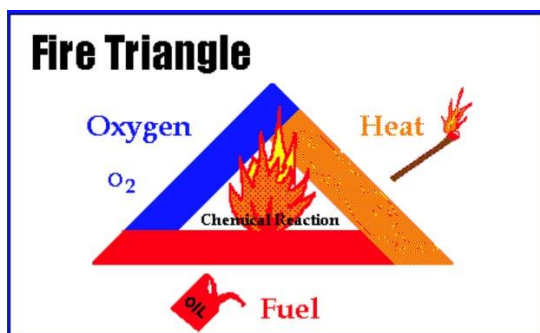
Enactment #3 will play out the Care for the Caregiver scene during which the neurosurgeon receives emotional first aid from a peer.

Enactment #4 will involve the follow up conversation with the children of the burned patient to share what has been learned about the cause of the fire, the plan for financial compensation [for all burn related medical care (past and future), and future preventative measures including an offer to include the family in the process improvement efforts.

What should be discovered during the event review

APPLICABLE DIDACTIC/POWERPOINT

The Fire Triangle



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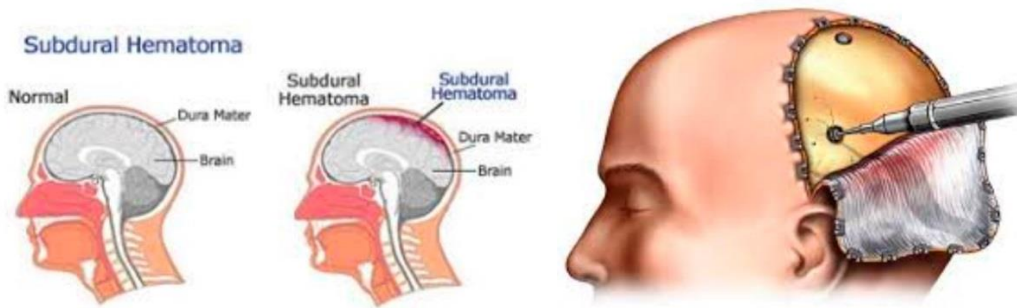
APPLICABLE DIDACTIC/POWERPOINT

HUMAN FACTORS BASED EVENT REVIEW:

LEARNER NEEDS TO DISCOVER ALL OF THE INFORMATION BELOW:

Basic Medical Background: In this case, the patient has a serious co-morbidity of severe aortic stenosis [AS]. This means there is a very small opening in aortic valve that blood must be pumped through to get to the rest of the body – i.e. up thru the carotid artery to the brain. When the aortic valve opening is super small, patients are at risk of syncope or “passing out”. That is what happened to this patient. He passed out and hit his head and that caused the subdural hematoma or collection of blood that was putting pressure on his brain. Blood in that location needs to be removed. Neurosurgeons remove subdural hematoma’s by making an incision in the scalp, obtaining access to the skull at the area over the collection of blood, and then drill a hole in the skull [a burr hole] until the collection of blood is located and then drained. Sometimes a plastic catheter is left in place to allow for ongoing draining of blood from that space if there is a risk of blood re-accumulating.

Picture of subdural hematoma and where/how burr holes are made.



Oxygen issues:

Normally, a patient undergoing the placement of burr holes would be intubated [a breathing tube placed in his wind pipe] and receive general anesthesia. For this patient, the administration of general anesthesia in the presence of aortic stenosis poses a serious risk for cardiac arrest and death. Because of the high risk of general anesthesia the anesthesiologist decided to give intravenous sedation instead of general anesthesia thru a breathing tube. Due to the potential of the sedation suppressing respiration, anesthesiologists will often provide supplemental oxygen thru a nasal cannula that is plastic tubing with two prongs that insert in

Appendix 8: Fire in the Operating Room Case Study

each nostril and connect to an oxygen source on the anesthesia machine. The oxygen tubing runs across the patient's face and behind the ears and along the chest.

Picture of nasal cannula and oxygen tubing



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Importantly, in this scenario, the anesthesiologist did not communicate to the neurosurgeon the plan for sedation instead of general anesthesia. Therefore, the 2 liters per minute of oxygen thru the nasal cannula became the first element of the fire triangle.

Of note, the administration of oxygen in this scenario is “routine” but was not necessary.

Fuel:

The second element that is need to support combustion [a fire] is fuel – something to burn. In this case, the neurosurgeon used “Duraprep®” to wash the skin prior to making the incision and drilling the holes. In recent years, it has been recommended to use “isopropyl alcohol-based” cleaning solutions for surgery as that seems to prevent postoperative infections of the surgical site. Prior to the introduction of these alcohol based solutions in the operating room, there was nothing highly flammable in the OR. Previous flammable anesthetic gases had been banned from ORs for decades. One of the unintended consequences of trying to eliminate surgical site infections was the introduction of something highly flammable back in to the OR. Of critical importance in this case, all of the surgeons were using an abundant amount of the solution thinking more must be better. They were not mindful of the risk and, in fact, none had read the label on the applicator package in which the solution was stored stating that the larger applicator [containing many milliliters of solution] should NOT be used on the head or neck as was done in this case [see applicator and labels below]. This patient was cleansed with 9 X more solution that recommended – two of the large applicators were used [52 ccs] instead one small applicator [6 ccs]. In addition, with so much used, some of the solution seeped under the neck and back of the patient and soaked the sheet and the foam mattress on the OR table. The surgeon had inadvertently and essentially created “Sterno®” on the OR table. One final, important fact that should be learned is that the sales representative for Duraprep® had not advised anyone of the recommendation to use the smaller applicator on head and neck cases. The sales representative received a greater commission on selling the larger applicators and that is all he recommended purchasing so the OR never had the smaller ones in stock!!! Hence, an abundance of the second of the three fire triangle elements was present.

Pictures of the DuraPrep Applicator and how it us used to prepare the skin prior to surgery



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Picture of label for the 26 cc applicator

[Note statement just under red box “Keep Away from fire or flame. To reduce the risk of fire, PREP CAREFULLY: Do not use use 26-mL applicator for head and neck surgery or on an area smaller than 8 in. x 10 in.”]



Picture of label for the 6 cc applicator

Note statement “for head, neck, and small prep areas” [red arrow]

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8635 REF 0.2 fl oz • 6 mL
34-8703-8000-2



Heat or “spark”

When the surgeon made the incision in the scalp that is highly vascular normal bleeding occurred. It is common and appropriate practice for the surgeon to use electrocautery on the tiny blood vessels to cause them to coagulate and stop bleeding. Electrocautery provides intense “heat” or the spark to start a fire if the other elements are present.

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Picture of electrocautery device



Picture of "hot" cautery tip



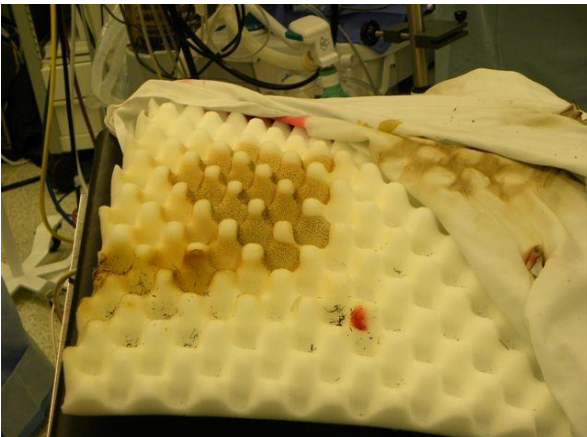
So, in this case, we have all three of the elements in substantial quantities – oxygen [thru the nasal cannula], fuel [isopropyl alcohol in the DurePrep], and heat [spark from the cautery].

LEARNER ALSO NEEDS TO DISCOVER Other important facts

There was no effective communication related to fire risk between the neurosurgeon, anesthesiologist and OR nurse. A "time out" was performed but the check list [**AT THAT TIME** in 2007] did not include fire risk assessment [it does now].



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WHO Safe Surgery Checklist in 2009 – note that there is no assessment of fire risk on this checklist.

Surgical Safety Checklist
World Health Organization
Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

Before skin incision

Before patient leaves operating room

(with at least nurse and anaesthetist)

(with nurse, anaesthetist and surgeon)

(with nurse, anaesthetist and surgeon)

Has the patient confirmed his/her identity, site, procedure, and consent?

 Yes

Is the site marked?

 Yes
 Not applicable

Is the anaesthesia machine and medication check complete?

 Yes

Is the pulse oximeter on the patient and functioning?

 Yes

Does the patient have a:

Known allergy?

 No
 Yes

Difficult airway or aspiration risk?

 No
 Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

 No
 Yes, and two IVs/central access and fluids planned

Confirm all team members have introduced themselves by name and role.

Confirm the patient's name, procedure, and where the incision will be made.

Has antibiotic prophylaxis been given within the last 60 minutes?

 Yes
 Not applicable

Anticipated Critical Events

To Surgeon:

 What are the critical or non-routine steps?
 How long will the case take?
 What is the anticipated blood loss?

To Anaesthetist:

 Are there any patient-specific concerns?

To Nursing Team:

 Has sterility (including indicator results) been confirmed?
 Are there equipment issues or any concerns?

Is essential imaging displayed?

 Yes
 Not applicable

Nurse Verbally Confirms:

 The name of the procedure
 Completion of instrument, sponge and needle counts
 Specimen labelling (read specimen labels aloud, including patient name)
 Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:

 What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

© WHO, 2009

AORN Surgery Checklist – note the “Fire Risk Assessment...” in the third column under “Time Out”

COMPREHENSIVE SURGICAL CHECKLIST			
PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
<p>In Preoperative Ready Area</p>	<p>Before Induction of Anesthesia</p>	<p>Before Skin Incision</p>	<p>Before the Patient Leaves the Operating Room</p>
<p>Patient or patient representative actively confirms with registered nurse (RN):</p> <p>Identity <input type="checkbox"/> Yes Procedure and procedure site <input type="checkbox"/> Yes Consent(s) <input type="checkbox"/> Yes Site marked <input type="checkbox"/> Yes <input type="checkbox"/> N/A by the person performing the procedure</p> <p>RN confirms presence of: History and physical <input type="checkbox"/> Yes Preanesthesia assessment <input type="checkbox"/> Yes Nursing assessment <input type="checkbox"/> Yes Diagnostic and radiologic test results <input type="checkbox"/> Yes <input type="checkbox"/> N/A Blood products <input type="checkbox"/> Yes <input type="checkbox"/> N/A Any special equipment, devices, implants <input type="checkbox"/> Yes <input type="checkbox"/> N/A</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px; font-size: 8px;"> Include in Preprocedure check-in as per institutional custom: Beta blocker medication given <input type="checkbox"/> Yes <input type="checkbox"/> N/A Venous thromboembolism prophylaxis ordered <input type="checkbox"/> Yes <input type="checkbox"/> N/A Normothermia measures <input type="checkbox"/> Yes <input type="checkbox"/> N/A </div>	<p>RN and anesthesia professional confirm:</p> <p>Confirmation of the following: identity, procedure, procedure site, and consent(s) <input type="checkbox"/> Yes Site marked <input type="checkbox"/> Yes <input type="checkbox"/> N/A by person performing the procedure Patient allergies <input type="checkbox"/> Yes <input type="checkbox"/> N/A Pulse oximeter on patient <input type="checkbox"/> Yes Difficult airway or aspiration risk <input type="checkbox"/> No <input type="checkbox"/> Yes (preparation confirmed) Risk of blood loss (> 500 mL) <input type="checkbox"/> Yes <input type="checkbox"/> N/A # of units available _____ Anesthesia safety check completed <input type="checkbox"/> Yes</p> <p>Briefing: All members of the team have discussed care plan and addressed concerns <input type="checkbox"/> Yes</p>	<p>Initiated by designated team member: All other activities to be suspended (except in case of life-threatening emergency)</p> <p>Introduction of team members <input type="checkbox"/> Yes All: Confirmation of the following: identity, procedure, incision site, consent(s) <input type="checkbox"/> Yes Site is marked and visible <input type="checkbox"/> Yes <input type="checkbox"/> N/A Fire Risk Assessment and Discussion <input type="checkbox"/> Yes (prevention methods implemented) <input type="checkbox"/> N/A Relevant images properly labeled and displayed <input type="checkbox"/> Yes <input type="checkbox"/> N/A Any equipment concerns <input type="checkbox"/> Yes <input type="checkbox"/> N/A</p> <p>Anticipated Critical Events Surgeon: States the following: <input type="checkbox"/> Critical or nonroutine steps <input type="checkbox"/> Case duration <input type="checkbox"/> Anticipated blood loss</p> <p>Anesthesia professional: Antibiotic prophylaxis within 1 hour before incision <input type="checkbox"/> Yes <input type="checkbox"/> N/A Additional concerns <input type="checkbox"/> Yes <input type="checkbox"/> N/A</p> <p>Scrub person and RN circulator: Sterilization indicators confirmed <input type="checkbox"/> Yes Additional concerns <input type="checkbox"/> Yes <input type="checkbox"/> N/A</p> <p>RN: Documented completion of time out: <input type="checkbox"/> Yes</p>	<p>RN confirms:</p> <p>Name of operative procedure: _____</p> <p>Completion of sponge, sharp, and instrument counts <input type="checkbox"/> Yes <input type="checkbox"/> N/A Specimens identified and labeled <input type="checkbox"/> Yes <input type="checkbox"/> N/A Equipment problems to be addressed <input type="checkbox"/> Yes <input type="checkbox"/> N/A Discussion of Wound Classification <input type="checkbox"/> Yes</p> <p>To all team members: What are the key concerns for recovery and management of this patient? _____ _____</p> <p>Debriefing with all team members: Opportunity for discussion of – team performance – key events – any permanent changes in the preference card</p> <p style="text-align: right; font-size: 8px;">June 2016</p>

The Joint Commission does not stipulate which team member initiates any section of the checklist except for site marking. The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements.



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THROUGH THE INTERVIEWS AND EVENT ANALYSIS THE LEARNER SHOULD DISCOVER:

The neurosurgeon was not aware of the nasal cannula oxygen and was not mindful of the amount of solution being used. He also did not know there were two sizes of DuraPrep™ applicators. He had never read the label on the applicator and had never had an “in-service” or training session on the special precautions of using DuraPrep™.

The anesthesiologist was unaware and not mindful of the amount of alcohol-based solution.

It was not standard practice for the nurse to be documenting or assessing the presence of the fire triangle elements at that time.

After the cautery was used the patient began to move due to the pain from the fire. Thinking he needed more sedation, the anesthesiologist gave more intravenously. Shortly thereafter, the patient “sat up” at which time smoke came billowing out from under him, flames were noted and towels were used to put out the fire. A plastic surgeon was called immediately to help treat the burns. The crisis management activation phone number was called.

The patient ultimately had the necessary burr holes placed, he required multiple clinic visits and several operations to treat the burns that eventually healed but with residual scars on the back and posterior part of his neck.

The presence of dementia is important as that means it is appropriate for the communications to include the children.

Appendix 8: Fire in the Operating Room Case Study

What should have happened

1. The small applicators of Duraprep® should have been purchased and stocked in materials management.
2. Only the small applicators of Duraprep® should have been made available on the “case carts” for head and neck cases.
3. The applicators should have much more obvious and prominent warnings about limiting the volume to be used.
4. A reliable process should have been used to prevent any pooling of the prep solution under the patient
5. Adequate time for prep solution to dry completely should have been forced to occur
6. Supplemental oxygen should not have been used but, if necessary, should have been discontinued at the moment of the use of electrocautery.
7. Prior to the incision, there should have been a conversation with surgeon, anesthesiologist, and nurse to discuss minimization of any fire risk – use of a comprehensive checklist
8. These issues, specifically fire assessment and prevention, should have been included in the orientation and yearly teaching for all personnel working in the OR.

APPLICABLE DIDACTIC/POWERPOINT

Empathic Communication and the comprehensive and systematic inter-professional approach to communication after harm including the communication with patients and loved ones, providing emotional first aid to peers, conducting cognitive interviews, and empathically providing financial and non-financial resolution options.

Appendix 8: Fire in the Operating Room Case Study

ENACTMENT CONSIDERATIONS from which the learner will gain additional critical information

Scene 1: Initial communication with family about fire in the OR

Participants: Children of patient, volunteers from audience

There will be the need for you to be told about the fire in the operating room at a time when you are both in a waiting room outside the operating room. You should assume those who plan to speak with you will take you to a private room next to the general waiting room.

Mental model: Burr holes to not take long to create, so when you are approached you will assume they are coming to tell you that the surgery is over and went fine. You will both be worried about your dad because of his worsening dementia, his bad aortic heart valve, his recent fall, and the subdural hematoma. When you are told of a “fire” in the OR, depending upon what you are told, one of your first questions may be “who was smoking in the OR” because the thought of a fire is so inconceivable. Other reactions will be of shock, dismay, bewilderment, and fear that he is in pain. You will also be afraid that this event may cause his heart to completely fail. You will also have lots of questions about what next? When will they be able to drain the subdural blood? Can his heart handle to surgery need to do that and repair the damage done by the fire?

Appendix 8: Fire in the Operating Room Case Study

Learner Objectives:

- 1.) Communicate honestly and openly what is known, not known, and what is going to be done to learn more
- 2.) Empathic communication and active listening with good non-verbal cues
- 3.) Promise of good ongoing care of patient, non-abandonment, frequent follow-up

Scene 2A: Cognitive interview of Neurosurgeon two days after the fire

Participants: Neurosurgeon and volunteer from audience

The goal of this enactment is to learn as much as possible from the neurosurgeon about the fire and how it happened. The surgeon is knowledgeable about the Fire Triangle.

It will be critical to learn many of the facts provided above – specifically, the surgeon uses a large amount of DurePrep™ thinking more is better. He does know that it contains alcohol but, until this case, was unaware of the amount of alcohol or the need to limit the amount for head and neck surgery. He had never had any training in the applicator, had never read the package insert, and had never engaged in a fire assessment prior to a surgery. Had he known about the nasal cannula oxygen he would have had a discussion about the risk of fire and discussed with the anesthesiologist to stop the flow of oxygen when he was using the cautery. But the patient’s face and the nasal cannula were covered with a towel when he was applying the DurePrep™ to the scalp prior to the incision. The towel obscured his view of the face. He had not had a conversation with the anesthesiologist about the plan to use sedation with supplemental oxygen. This surgeon was NOT present during the “time out” – **the junior partner was in the room for the initial timeout and steps 1 -5 below. He was trying to move things along since they had so many cases that day.**

Steps followed during the prep and draping of the patient

- 1) Face covered with 2 towels
- 2) Head shaved with clippers
- 3) 70% alcohol poured on 4X4's to wipe head
- 4) 4 steri-drape 1000's used

Appendix 8: Fire in the Operating Room Case Study

- 5) Incision site is marked
- 6) Head prepped with 26 ml of Duraprep

Upon entrance of the primary surgeon, first junior surgeon leaves to go prepare next patient, and after scrubbing his hands, patient is prepped in a sterile fashion with an additional

- 7.) 26 ml of Duraprep
- 8.) 4 additional towels used to drape head
- 9.) Ioban applied
- 10) Spilt sheet applied
- 11.) Injection of lidocaine with epi to limit bleeding during incision.

The neurosurgeon fully recalls this scene in the OR: Prior to making the incision in the patient's scalp he injected local anesthetic with epinephrine to decrease the amount of bleeding with the incision. After he made the incision there was some bleeding from the scalp blood vessels and he used electrocautery to stop that bleeding. After the cautery was used the patient began to move due to the pain from the fire.

Appendix 8: Fire in the Operating Room Case Study

Thinking he needed more sedation, the anesthesiologist gave more intravenously. Shortly thereafter, the patient "sat up" at which time smoke came billowing out from under him, flames were noted and towels were used to put out the fire. A plastic surgeon was called immediately to help treat the burns. The crisis management activation phone number was called.

He will be able to describe he was able to drain the subdural hematoma the day after the fire.

Learner Objectives:

- 1.) Create rapport with interviewee
- 2.) Make good use of open ended questions without interrupting
- 3.) Restate the flow of events from very beginning to end.

Scene 2B: Cognitive Interview of nurse.

Participants: OR Nurse and volunteer from audience

OR Nurse is same position and same mental model as the neurosurgeon. They did run through the Safe Surgery Checklist but the nurse remembers it was a junior surgeon who was present for the "time out" and does not think that the surgeon who did the case was present for the timeout. Unaware of the DuraPrep™ dangers but has an understanding of the fire triangle. Like the neurosurgeon, has never seen a fire in the OR before. Had never had formal training or in-service on the use of DuraPrep or any other alcohol based prep solution.

Mental model: The neurosurgeon feels embarrassed, humiliated, and angry. Angry that there was not a process to limit the amount of DuraPrep™ or training to avoid a fire. The nurse feels similarly.

Learner Objectives:

- 1.) Create rapport with interviewee
- 2.) Make good use of open ended questions without interrupting
- 3.) Restate the flow of events from very beginning to end.

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Scene 3A: Neurosurgeon receives emotional first aid five days after the fire – a weekend has passed.

Participants: Neurosurgeon and volunteer from audience

Mental model:

For the reasons mentioned above the neurosurgeon is in dire need of emotional first aid. He has learned of all of the other information in this document and realizes that it is only by luck that a fire has not occurred before in one of his operating rooms. He is very appreciative that the hospital team that responded immediately and ongoing has been supportive of him, the patient, and their family. He feels guilty that his plastic surgeon colleague has provided so much care for his patient. He has not been sleeping well and keeps flashing back to seeing the flames and smoke. He has not been drinking or otherwise medicating himself to ease his pain. He has no one else at home for support.

Learner Objectives

1. Deal with feelings first
2. Curiosity

Appendix 8: Fire in the Operating Room Case Study

3. Non-judgmental over of support
4. Reflective Listening
5. Follow-up

Scene 3B: OR Nurse receives emotional first aid five days after the fire.

Participants: Nurse and volunteer from the audience

Nurse has same feelings as neurosurgeon but is particularly worried about no longer being a trusted member of the team.

Learner Objectives

1. Deal with feelings first
2. Curiosity
3. Non-judgmental over of support
4. Reflective Listening
5. Follow-up

Scene 4:

Participants: Children of patient, their lawyer, and volunteers from audience

This will take place in a private room in or near the hospital. Many months will have passed since the fire. Your dad will have had the subdural blood drained and will have had many plastic surgeries and visits to the plastic surgeon office for burn treatment. His dementia is stable and he seems to have made a reasonable recovery and for that you are grateful. I would like for Marty to play the role of your lawyer for this visit.

Mental model: You are relieved but still upset and confused about what happened. You appreciate the “Patient Safety Compensation Card” you will have been given at the end of the first visit. You have used this as his “insurance card” at each follow up care appointment. You are willing to sign the consent for the Iowa Candor conversation. In this meeting, you are very interested in learning what happened with the event review and what has been done to make sure this does not happen again. You may also want to raise the issue of how much pain and discomfort he has experienced even though your dad does not remember the fire – he does remember that pain afterwards and you are sad about that. The lawyer for the family will want to stress the need for compensation for the pain and suffering as well as reassurances of future prevention. The children will, with some hesitation, be interested in helping train in the importance of fire risk assessment and prevention whilst using their dad’s experience to connect the heart with the head. SEE BELOW FOR SOLUTION CONSIDERATIONS.

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Learner Objectives:

- 1.) Communicate honestly and openly what is now known, what may not be known, and what is going to be done to improve and provide solutions [see below].
- 2.) Empathic communication and active listening with good non-verbal cues
- 3.) Promise of good ongoing care of patient, non-abandonment, frequent follow-up
- 4.) Offer of engaging family in solutions
- 5.) Transition to the handling of financial support and resolution.

SOLUTIONS CONSIDERATIONS:

Appendix 8: Fire in the Operating Room Case Study

STRONG ACTIONS:

- Architectural/physical plant changes **only 6 cc applicators stocked in ORs that do head & neck sx**
- New device with usability testing – **ensure procurement of small, 6 cc applicators**
- Engineering control (forcing functions)
- Simplified process
- Standardized equipment or process – **eliminate 26 cc prep solution from head & neck case carts**
- Tangible involvement by leadership – **engage PFACQS in solution roll-out**

Intermediate Actions

- Increase staffing/decrease workload
- Software enhancements/modifications – **modify case cart software to reflect change in applicators**
- Eliminate/reduce distractions
- Checklists/cognitive aids – **modify safe surgery check list to include fire risk**
- Eliminate look- and sound-alikes
- Standardized communication tools (e.g., read back) – **see checklist change**
- Enhanced documentation/communication
- Redundancy

Weak Actions

- Double checks
- Warnings, labels, and signs – **increase size of font/label for “DO NOT USE ON HEAD & NECK”**
- New procedure/memorandum/policy
- Training – **fire scenario simulations conducted in all areas that use alcohol prep**
- Additional study/analysis
- Discipline