RESEARCH ARTICLE

Successful System Implementation of a Communication and Resolution Program

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1. Abstract

Communication and Resolution Programs (CRP) are becoming more commonplace in the United States. ChristianaCare adopted this approach after participating in a demonstration project through the US Agency for Healthcare Research and Quality in 2014-5. This paper documents our successful implementation of our CRP and the first five years of our results. Our organization saw increased reporting of medical events, improved patient safety, mitigation of medico-legal risks and improved patient and caregiver experience. The path to implementation is challenging and represents a major shift in how organizations deal with unexpected medical outcomes. The process is complex involving individuals from patient relations, risk management and patient safety. But the benefits are satisfying. Keys to success include strong leadership support and engagement of a multidisciplinary team.

2. Introduction

The earliest published report of a program to disclose medical errors and provide compensation to the affected patients dates to 1987 at the Veterans Affairs Hospital in Lexington, Kentucky.[1] After two lawsuit judgments costing over $1.5 million, they adopted a more proactive approach to event identification and analysis, and transparently disclosing what they had learned. This approach ultimately resulted in a reduced cost per claim, shorter time for cases to be resolved, and fewer legal expenses. Research at the University of Michigan showed similar outcomes in 2002, with their disclosure program resulting in more than 50% reduction in the number of claims and time to resolution, as well as a 67% reduction in legal costs.[2] In 2010, Boothman's group at the University of Michigan published comparative results pre- vs. post-disclosure and compensation program. Their striking results further demonstrated decreases in claims, lawsuits, time to resolution, and legal costs.[3]

Research demonstrates that the concern for disclosure programs resulting in increased legal risk may be unfounded. Mello reported on the implementation of a communication and resolution program at two academic medical centers and two affiliated community hospitals, showing that 91% of events reviewed did not meet their internal criteria for compensation, those that did had a median payment of $75000, and only 5% of cases resulted in claims or lawsuits.[4] A group from the University of Illinois Hospital added to the body of knowledge showing that a disclosure program resulted in an increase in event reporting, decreased claims, reduced legal fees and costs per claim over the period from 2002 to 2014.[5]

The medicolegal benefits of these programs are patently clear, with several large insurance carriers helping to make disclosure practices more universally employed by actively encouraging, supporting, and even incentivizing their members to adopt standardized methods. For example, COPIC Financial Service Group in Colorado offers CANDOR forms and resources freely on their website,[6] while BETA Insurance Group, the largest professional liability insurer of hospitals on the West Coast, offers renewal premium credits for members meeting key benchmarks as part of their HEART program (Healing, Empathy, Accountability, Resolution, Trust).[7]

Citing these results in a 2006 New England Journal of Medicine perspective piece, Senators Hillary Rodham Clinton and Barack Obama proposed the National Medical Error Disclosure and Compensation (MEDiC) Bill.[8] While previous publications had highlighted the medico-legal benefits of disclosure programs, Clinton and Obama's editorial emphasized their potential to improve patient safety and reduce preventable harm. The bill, had it passed, would have created an Office of Patient Safety and Health Care Quality within the Department of Health and Human Services (DHHS), and provided grant money for healthcare systems to develop communication and resolution programs (CRP).

Disclosure program advocacy gained further momentum with private sector groups. The Sorry Works! Coalition, and group of lawyers, doctors, patient advocates, and insurers promotes disclosure as a potential solution to our medical malpractice crisis.[9] Others believe that disclosure is more closely aligned with improving patient safety.[10] From the patient perspective, these programs offer transparency and solace knowing that steps are being taken to avoid similar future events.[11] Disclosure programs allow clinicians to discuss these events more openly, helping to diminish the emotional impact of being involved in these cases.[12] Regardless of the motivation, disclosure of medical errors is a complex concept that involves an organizational culture shift and the need for education.

Gallagher and colleagues reviewed the adoption of disclosure policies and legislation, noting the lack of guidance for implementing disclosure practices, as well as variation in how caregivers are

trained in disclosure messaging.[13] The authors describe the promotion of disclosure programs when the National Quality Forum (NQF) developed a Safe Practice in 2006 recognizing disclosure as a key component to safe healthcare, while also acknowledging that the complex nature of disclosure discussions makes it challenging to monitor with metrics. This would later become important as pay-for-performance initiatives gained prominence, relying on quality consortiums such as The Leapfrog Group to report on healthcare systems' use of NQF Safe Practice measures. The state of the art of disclosure in 2007 pointed to the need for more comprehensive education of clinicians to develop the skills necessary to have these conversations.

Gallagher published a paper with recommendations for embedding communication and resolution programs as a 'mission critical' organizational priority.[10] These suggestions focused on compelling organizational leaders to recognize the importance of these programs, to ground them in the clinical mission, and to ensure appropriate investment in the resources necessary to implement an effective program.

One group of early adopters took a more qualitative approach by performing structured interviews with leaders about disclosure preconceptions.[14] While they found most were quite supportive of the concept, they identified several barriers to implementation including clinician discomfort with having disclosure conversations with patients, attorneys interested in maintaining the status quo, concerns around increased liability risk, general inertia, and concerns that disclosure programs might be viewed as a way of coercing patients not to sue. In fact, another study identified that higher compensation offers decreased the likelihood that patients would seek legal advice and increased the perception that the motivation for disclosure was to avoid litigation.[15] Their recommendation for reducing the perception of ulterior motives was to separate the disclosure discussion about the medical event from communications focused on compensation.

While the MEDiC Bill was never enacted into law, it served as the impetus for President Obama in 2009 to direct the DHHS to investigate ways to improve medical liability while increasing patient safety. As a result, the Medical Liability Reform & Patient Safety Initiative was established by the Agency for Healthcare Research and Quality (AHRQ) for funding planning and demonstration grants. Our organization participated in an AHRQ sponsored demonstration project known as Communication and Optimal Resolution (CANDOR). This pilot resulted in the creation of an implementation guide to be used by other hospital systems.[16] This article will share ChristianaCare's implementation process, learnings, and the first 5 years (2015-2020) of results to assist other organizations planning to adopt a similar approach.

ChristianaCare is a multicenter teaching health system that serves a diverse patient population in communities across four states with its 4 clinical campuses, 5 urgent care centers, 120 practice locations, a Level I trauma center, a level III neonatal intensive care unit, and a virtual care platform.

3. Methods

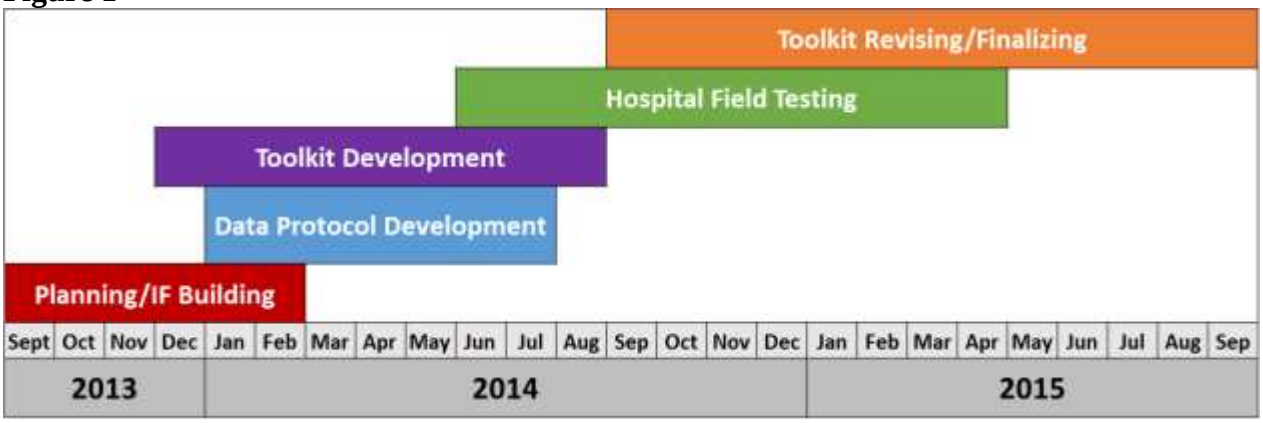
AHRQ defines communication and optimal resolution (CANDOR) as a process that hospitals and practitioners can use to respond in a timely, thorough, and just way when unexpected events cause patient harm.[16] The CANDOR program includes the following components:

1. Event Reporting and Analysis – Identification, reporting, review, analysis, and process improvement following safety events
2. Communication - Guiding initial disclosure, ongoing feedback discussions, and final disclosure.
3. Care for the Caregiver - Providing peer support to caregivers needing emotional care.

4. Resolution - Determining gaps in care, causation, and developing a plan for early resolution and compensation.

The AHRQ demonstration project timeline is depicted in Figure 1. ChristianaCare joined the project in early 2014.

Figure 1



The CANDOR toolkit was organized in the 8 modules listed below comprised of slide presentations, lecture materials, checklists, and videos.[16]

Module 1: An Overview of the CANDOR Process
Module 2: Obtaining Organizational Buy-in and Support
Module 3: Preparing for Implementation: Gap Analysis
Module 4: Event Reporting, Event Investigation and Analysis
Module 5: Response and Disclosure
Module 6: Care for the Caregiver
Module 7: Resolution
Module 8: Organizational Learning and Sustainability

An Implementation Guide is available for organizations that are committed to improving their response to unanticipated patient harm events.[16]

The following activities guide implementation of the CANDOR process:

- Form a multidisciplinary project team including clinicians, support staff, patient, and family advisors
- Conduct training sessions for all project team members
- Conduct ongoing communications and education with staff, patients, and families about the organization's commitment
- Engage staff, patients, and families in the planning, implementation, and evaluation

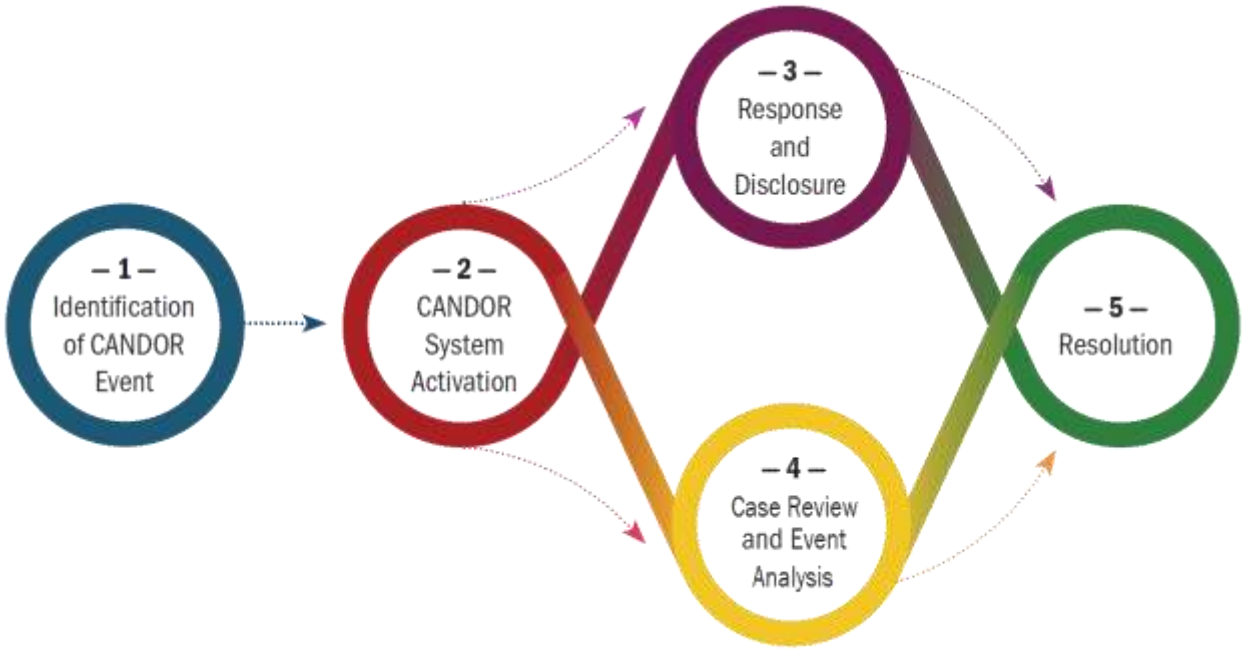
ChristianaCare joined the AHRQ demonstration project in 2014. Our participation was supported by a strong commitment from senior leadership and aligned with our strategic priority of patient-centered care. The Chief Medical Officer (CMO), Chief Legal Officer and Senior Vice President for Quality and Safety served as our executive sponsors. We formed a multidisciplinary CANDOR

Implementation Team, with membership from patient safety, risk management, patient relations, care for the caregiver, physician liaisons, nurses, and other clinical leaders. This team was responsible for project management of the demonstration project, directing CANDOR implementation and serving as master trainers in our organization.

In collaboration with the AHRQ grant researchers and faculty, change readiness and gap analyses were performed regarding key National Quality Forum (NQF) practices. Members of the team attended training and simulation sessions on all eight modules. This assessment and training were instrumental in guiding and developing capacity for the following implementation activities:

- Established an Event Management Team which determined the impact on workflow, roles, and event management infrastructure. Key efforts included revision of our event management checklist to include role delineation and timeframes.
- Created a CANDOR Response Team to huddle rapidly following the identification of a severe patient harm event, including key stakeholders from Care for the Caregiver, CANDOR Physician advisor, Patient Safety, Patient Relation, Risk Management, Event Review Team, and leadership from the involved patient care area.
- Developed a conference call checklist to guide the initial management of a patient safety event (see supplemental material).
- A CANDOR brochure was developed to describe the process, encourage prompt reporting, and recommend immediate interventions following a patient safety event (see supplemental material).
- Convened a data work team to define key data elements to be captured for each event and embedded them into our electronic event reporting system.
- Built capability of Patient Relations representatives to better seek the patient's and family's perspective.
- Enhanced existing pre-family meeting and family meeting guidelines (see supplemental materials).
- Collaborated with Care for the Caregiver Team to develop a diverse group of peer supporters available 24/7, as well as job aid for guiding conversations with staff after an event has occurred (see supplemental materials).
- Established a Communication Team responsible for implementing a Communication Coach/Consult Service which included training sessions with instructional videos and standardized patients. Developed Communication Tip Cards to standardize disclosure conversations (see supplemental material).
- Convened a Resolution Team responsible for standardizing the process for holding and waiving bills and having CANDOR training sessions with external legal counsel and insurance carriers. This team established a CANDOR Review Panel, a multidisciplinary forum to review the facts from the patient safety case analysis and assess the quality of the care.
- Held multiple sessions with caregivers across the organization including the Medical-Dental staff to introduce the CANDOR process (Figure 2) and build engagement.

Figure 2



ChristianaCare's CANDOR process is further described below.

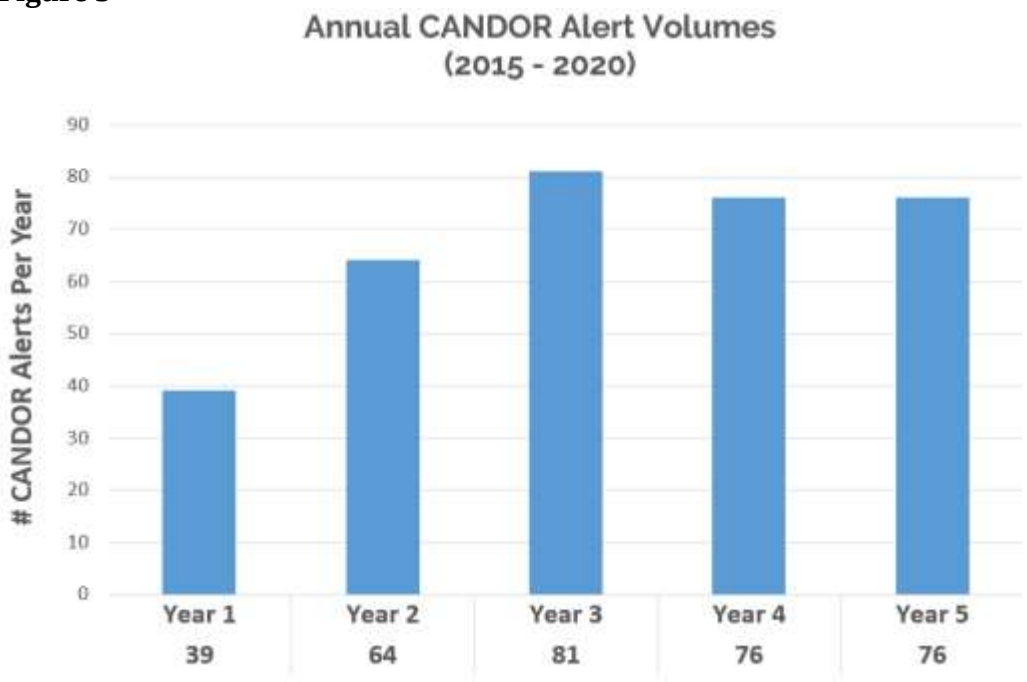
It was critically important that our organization developed standard terminology when managing CANDOR cases. A **CANDOR Event** was defined as an event involving an unexpected patient death or permanent harm, and in which there is potential for care to have contributed to the outcome. CANDOR Event determinations are collaboratively managed between the CANDOR physician liaison and the lead physician from the clinical department's event review team. A **CANDOR Alert** is formal notification to the CANDOR Response Team and key stakeholders that a new CANDOR event has been identified.

1. Identification - Cases are commonly identified by an event report or direct contact from staff members. Less frequently, events may be recognized from a patient grievance or from an autopsy that reveals a cause of death not previously identified and treated.
2. CANDOR System Activation - A Candor Response Team, as previously described, holds a conference call following a checklist (see supplemental material) developed to create standard work to guide the initial management of the event. Steps include:
   a. Contact caregivers for fact-finding and emotional support
   b. Hold bills pending the review
   c. Request an autopsy as appropriate
   d. Sequester any equipment as needed
   e. Identify other departments that need to review the care
   f. Establish a plan for initial disclosure
   g. Set a debrief time
3. Response and Disclosure - Explain to patient and/or family the unexpected nature of the outcome and express regret, provide an overview of the event review process, and express a commitment to meet when the review is complete.
4. Case Review and Event Analysis - A timeline of the case is prepared by patient safety staff from the medical record. A post-event debrief occurs following the Just Culture algorithm to

uncover the root cause and contributing factors, identify system opportunities and to develop and implement strategies to mitigate the risk of future harm. Peer Review may be indicated but is a separate and distinct process from the event review. Additional information may be gathered through risk management individual interviews, morbidity and mortality conferences and external review where appropriate.

5. Resolution - After completion of the review process, the CANDOR Review Panel convenes to review and assess the quality of the care. Once that determination is made, involved clinicians meet to ensure agreement about the message to the family. The next step is a family meeting attended by clinicians, the CANDOR physician advisor, and the patient relations liaison. In cases where the determination is that our care was responsible for the patient harm, a separate meeting with the patient/family, risk management and the insurance carrier is held.

Figure 3



4. Results

From September 2015 until December 2020, we have identified 355 CANDOR Alerts. The first 3 years saw a steady increase in the number of alerts, leveling off in years 4 and 5 (Figure 3).

Candor Alerts occurred across all clinical services with the preponderance seen in acute medicine, surgery, and heart and vascular (Figure 4). The various categories of events are listed in Table 1. Sixty-two percent of the CANDOR cases were unexpected deaths and 38% were permanent harm. Of the 355 CANDOR cases between September 2015 and December 2020, 218 cases were evaluated by the CANDOR panel. Many of the other 137 cases did not reach the panel because either no system issues could be identified, the harm to the patient was determined to not be permanent, or the outcome was clearly related to the patient's underlying medical condition. Additionally, some cases did not proceed to a CANDOR panel discussion because they underwent further analysis in other forums including root cause analysis, morbidity and mortality conference,

peer review committee, or review by an external medical expert. Six cases were not handled by the panel due to early notification of attorney representation.

Since the inception of our CANDOR program, there has been a 28% increase in reporting of patient safety events. Through the review of these cases, numerous patient safety improvements have been made. Some notable examples include:

- Failure Modes and Effects Analysis on new telemonitoring system to proactively identify potential failure modes, their causes and effects
- Removal of barcodes from IV medications to prevent inadvertent scanning of the incorrect barcode label
- Revision of the Dobhoff tube insertion process as a staged process to confirm tube placement and avoid intrapulmonary placement
- Elimination of the use of chest tubes with trocars to prevent puncture injuries when performing chest tube placement
- Enhanced process to share pathology reports with patients to ensure patients receive the correct interpretation of the results

Figure 4

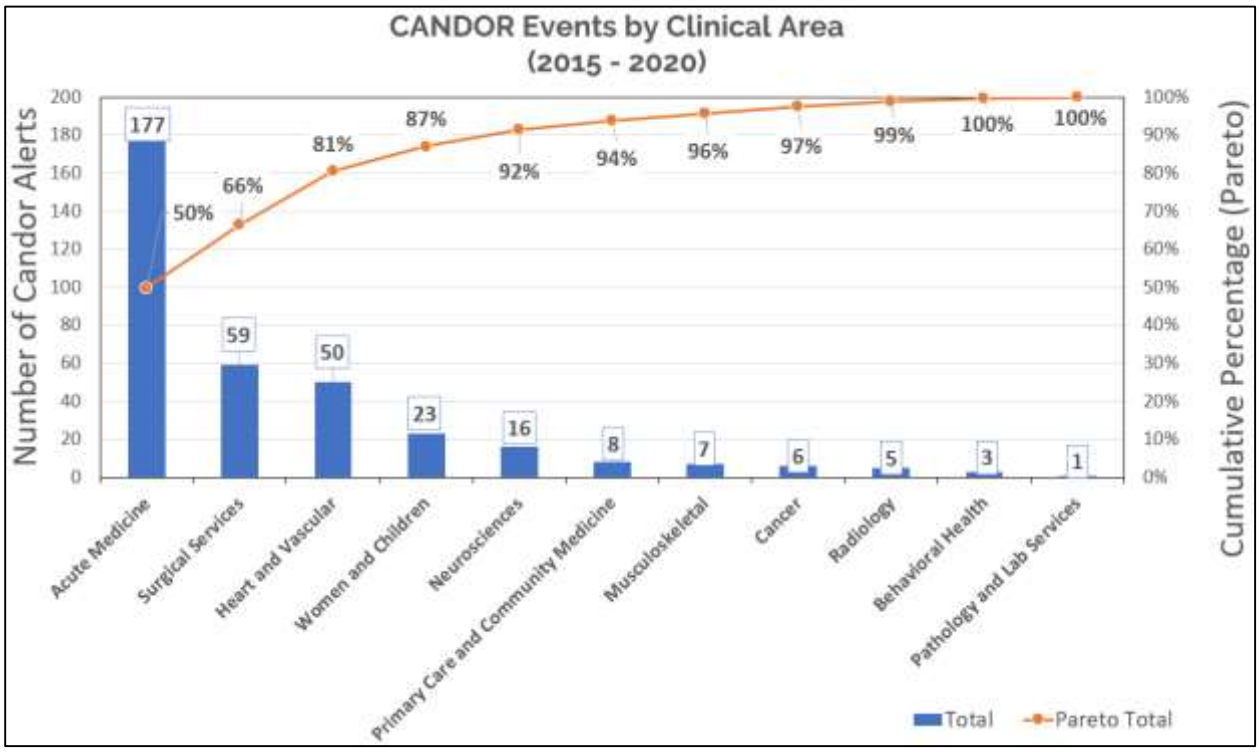
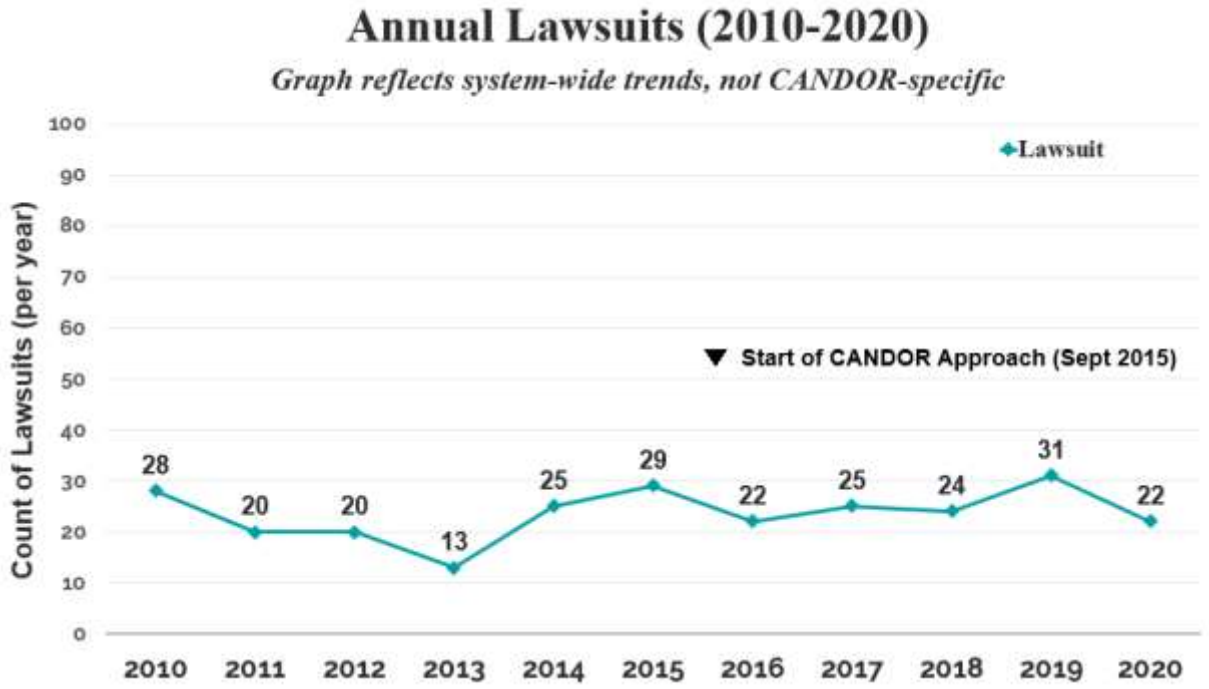


Table 1

Harm Categories* Identified
▪ Cardiac/Respiratory Arrest ▪ Diagnostic Related ▪ Surgical/Procedural Complications ▪ Medical Management ▪ Medication Error/Adverse Drug Event ▪ OB/Neonatal Complication ▪ Infection ▪ Failure to Rescue
* Categories from Data Protocol Development during pilot

Data from our legal department has been gathered. One must consider that the statute of limitations in the State of Delaware is 2 years and hence the most recent data should be considered preliminary. The overall number of lawsuits per year for the organization has remained unchanged (Figure 5). The number of lawsuits resulting from CANDOR cases has remained stable between 5 and 7 per year. The rate of lawsuits from CANDOR cases has declined from 20% in 2015 to 10% in 2018 (2019-2020 data excluded for reason noted above). In 2018, the number of claims per 100,000 patient days is 16 times higher for non-CANDOR cases than for CANDOR cases. The cost per claim has also declined for closed CANDOR cases from $18,643 in 2015 to $2,375 in 2018. In addition, the cost per claim for non-CANDOR cases has also declined from $6,724 in 2015 to $2817 in 2018. Of the 355 CANDOR events included in this analysis, 18 (5.1%) have resulted in a claim and 30 (8.5%) have resulted in a lawsuit.

Figure 5



Between 2015 and 2020 there have been over 1600 peer support encounters, with an average annual increase of 45%. Based on a survey provided to caregivers and clinicians who attend post-

event debriefs, 97% of attendees express that they felt psychologically safe during these discussions.

From our experience, there are many factors that were critical to the successful implementation of our CANDOR program (Table 2). The involvement of senior leadership achieved alignment with our strategic priority of patient-centered care, allocation of resources and assistance to help remove any barriers to implementation. CANDOR aligns with ChristianaCare's core values and behaviors as follows, 'we tell the truth with courage and empathy', 'we accept responsibility for our attitudes and actions', and 'we commit to being exceptional today and even better tomorrow'. Creation of a peer support network and the embedding of Just Culture principles were amongst the strategies that ensured the psychological safety of staff involved in these event reviews.

Table 2. Factors Critical to Successful Disclosure Program Implementation

1. Leadership Support
    - Engage Board of Directors, Senior Leadership
    - Resource Allocation
    - Barrier Removal
2. Alignment with Organization Priorities
    - Tailor messaging to organization-specific goals
3. Alignment with Mission, Vision, Values, Behaviors
4. Psychological Safety, Assuming Good Intentions
5. Just Culture Principles for Event Management
6. Multiple education modalities for clinicians to learn/practice disclosure discussions (simulation, didactic, self-learning module)
7. Just-in-Time Coaching available as needed
8. Performance Improvement for disclosure tracking
9. Robust emotional support for involved caregivers

5. Discussion

The development of a communication and resolution program has led to a more integrated approach to managing patient safety events with unanticipated outcomes by creating a partnership between patient safety, risk management and patient relations. Our review and analysis of patient safety events has been more coordinated and expeditious. This is consistent with the process described by Gallagher et al., in which they advocated that "by presenting disclosure as a patient-safety challenge rather than a risk-management problem, the safe practice emphasizes that effective disclosure is a component of broad system improvement. It also encourages hospitals to integrate their risk-management, patient-safety, and quality programs.".[13] Our process is like the one used by the Massachusetts Alliance for Communication and Resolution After Medical Injury (MACRMI), in that we review unexpected medical outcomes that we have deemed eligible for a communication and resolution approach.[17]

Our CANDOR program has created a shift in our culture of safety and gained acceptance across our organization, as evidenced by its consistent growth over the first three years. This is consistent with other studies that demonstrate improvements in patient safety.[3,4,5,18] Most cases came from high-risk clinical services, but as expected, many cases involved multiple clinical services and almost every clinical area has identified CANDOR eligible cases. Further evidence for an improved safety culture is the increase we witnessed in event reporting and the specific safety

improvements made across our system. Lambert and colleagues at the University of Illinois at Chicago found similar increases in reporting of safety events.[5]

Our program has not captured the patient experience in a systematic way. Anecdotally, most family meetings have been cordial, with family members expressing their appreciation of the process. The patient relations team plays a critical role in soliciting feedback and clinical concerns from patients/families. Our experience is that patients and families often raise concerns about how we made them feel rather than specific medical management concerns. Patient focus groups studied at Washington University found that patients wanted disclosure of all events that resulted in harm, expected full disclosure of all information in a truthful and compassionate manner and desired an apology.[19]

Being involved in a medical event that led to patient harm has a serious emotional impact on caregivers.[12,19] Our Care for the Caregiver program provided peer support to many caregivers. Ensuring the psychological well-being of all staff is an essential component of any compensation and resolution program. Additionally, most caregivers felt psychologically safe during our review process. Evidence suggests that physicians involved in harmful errors were able to cope better if they were able to talk about the event and if given the support and training to disclose and apologize.[12] Having disclosure conversations is challenging, especially when considering one study found that less than 10% receive training in disclosure.[12] We provided education to teach clinicians how to lead these discussions using a self-learning module, in-time coaching and simulation with confederates.

The risk management and legal benefits of communication and resolution have been well described in the literature.[1-4] We encountered initial resistance to our program from some clinicians concerned about the possible increased risk of litigation. These fears have diminished over time as our actual results did not validate their concerns. We found no increase in the number of lawsuits against our organization since the implementation of our program. These data need to be interpreted with some caution since the statute of limitations for filing a lawsuit varies in different jurisdictions. Thus far very few of our CANDOR cases have resulted in legal action which is especially meaningful considering our definition of a CANDOR event is limited to those involving patient death or permanent harm. Our results showing a stable number of lawsuits, a decreased number of claims per 100,000 patient days and a reduction in the cost per claim is consistent with other published studies.[2-5]

There were important lessons learned during the implementation of our CANDOR program. We learned that culture change is challenging and doesn't develop rapidly. Another lesson learned is that patient safety professionals, risk managers, patient relations advocates and clinicians all bring different but equally important perspectives to the management of these events. It was helpful to recognize this and to take steps to ensure collaboration. We have seen value in the CANDOR program in patient safety, risk management, patient, and caregiver experience. We have found benefits in engaging with motivated, safety-minded clinicians throughout the health system as partners in case review, disclosure training and support, peer support and volunteering their time and expertise for our CANDOR review panel.

Our efforts to improve our CANDOR program continue. To facilitate improvement, we held a retreat with key stakeholders. As a result, we have refined our process of onboarding of new clinicians to the CANDOR program, developed a 'Go Team' concept when there is a need to immediately debrief an event, and we are exploring ways in which to offer clinicians time off after being involved in a safety event.

6. Conclusion

Developing a communication and optimal resolution is a complex yet worthwhile endeavor. Taking this approach to patient safety events and unanticipated outcomes is a patient safety improvement strategy that promotes transparent patient-centered care and the psychological well-being of clinicians involved in these events. Successful implementation requires strong leadership support and the active engagement of a multidisciplinary team. Our healthcare system and our patients continue to reap the benefits of our program. Incorporation of a communication and resolution program is a significant step in the journey toward high reliability.

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