Online Supplement:
Ensuring Successful Implementation of Communication-and-Resolution Programs

Contents

A1. Indicators that the Massachusetts CRP Was Successfully Implemented

We characterize the Massachusetts hospitals as having implementing their CRP successfully based on several indicia reported in previous publications.(1, 2) First, data prospectively collected on 989 adverse events showed that the hospitals demonstrated good adherence to the key elements of the CRP protocol: disclosure and apology, timely investigation, feedback of investigation findings to patients, and offers of compensation where substandard care caused serious harm.(1) Ongoing, consensus-driven work by leaders in the field of CRPs has identified consistent application of these key elements as a core metric for gauging CRP performance.(3)

Second, the CARe program yielded favorable financial results notwithstanding the hospitals' principled commitment to offering compensation where substandard care caused harm. CARe events were not costly to resolve (the median payment was $75,000) and rarely (5%) led to malpractice claims or lawsuits.(1) After CARe implementation, there was a significant decrease in the rate of new claims at the implementing hospitals, a change not seen at comparison hospitals that did not implement a CRP.(2) Additionally, both of the academic medical centers implementing CARe experienced a significant decrease for defense costs (though the community hospitals did not).

Third, a survey of 162 clinical staff who were involved in a CARe event were very supportive of the program. Although many felt unfamiliar with the program, among those who felt informed enough to opine about it 69% gave a strongly positive rating for their overall support for using the CARe process to resolve adverse events, 20% gave a moderately positive rating, and 10% gave a negative rating.(1)

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A2. Interview and Conference Call Participants' Perceptions of the Success of CARe Implementation

In our key informant interviews at the end of the project, respondents uniformly reported that implementation of CARe had gone well. They expressed sentiments such as "it's been very successful", "it feels really good," "I'm very proud of it," "it's been a great experience," "a fairly transformational change," and "it's embedded in the management, the directors at the hospital, like everybody". One of the community hospitals reported that implementation got off to a rocky start due to poor communication from the academic medical center leading the implementation within that system, but reported that "it has been a positive" at the end of the study. Asked whether CARe would be continued after the study was over, no respondents expressed any doubt that it would.

Buttressing these overall perceptions of successful implementation were reports in interviews and conference calls of improvements in 4 key areas: adverse event reporting, patient communication, event investigation, and compensation practices. All but one hospital reported that reporting had increased, although one attributed this to implementation of a new reporting system in addition to CARe. There was strong agreement that CARe had spurred improvements in the quality of communications with patients and families about adverse events, and some hospitals also reported an uptick in the frequency of disclosure conversations. CARe provided training and supports to assist clinicians in communicating effectively about adverse events, and communicated a clear expectation from management that "This is what we do and we will support you through that process". It also provided for more tracking of communications to make sure that they occurred and promised follow-up was delivered.

Respondents reported improvements to their event investigation process in terms of speed, thoroughness, inclusiveness, and accountability. Some reported concluding their investigations more quickly under CARe while others perceived the time to be unchanged but the depth of investigation to have increased. All reported that they were investigating event reports they used to simply file away because a patient had not complained, and that investigations now followed consistent, defined steps. Under CARe, investigations were more likely to directly involve the family and all the involved providers, and results were more consistently communicated to both.

In terms of compensation decisions, hospitals reported following a more systematic, algorithmic approach, as opposed to "sitting back and waiting for the patient" to ask or sue, or "sort of selectively" offering compensation. Through the conference calls, they discussed and agreed on how and when to bring the topic of compensation up with families. This involved making a compensation offer before patients asked, and using the word "compensation" rather than only making open-ended queries such as, "What are you looking for?" They also reported that they no longer took into account "totally irrelevant" factors such as whether "the mother would make a really lousy witness" in making compensation decisions. Finally, they reported making compensation offers more commonly for injuries of low or moderate severity than in the past.

A3. Details of CARe Program Design and Implementation

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The following text was adapted from the online appendix to: Mello MM, Kachalia A, Roche S, Van Niel M, Buchsbaum L, Dodson S, Folcarelli P, Benjamin EM, Sands KE. Outcomes in two Massachusetts hospital systems give reason for optimism about communication-and-resolution programs. Health Affairs 2017;36(10):1795-1803.

Setting

CARe Pilot sites consisted of 2 urban academic medical centers, Beth Israel Deaconess Medical Center (BIDMC), and Baystate Medical Center (BMC), and 4 of their affiliated community hospitals. BIDMC is a level 1 trauma center and Harvard Medical School teaching hospital in Boston, Massachusetts. At the conclusion of the study, it had 672 licensed beds and approximately 5,000 births per year. BIDMC is insured through a risk retention group, CRICO RMF, an outside organization that insures all the Harvard teaching hospitals. Beth Israel Deaconess Milton (BIDM), an 88-bed community hospital in Milton, MA, and Beth Israel Deaconess Needham (BIDN), a 58-bed community hospital in Needham, MA, also participated.

BMC is a level 1 trauma center with a pediatric designation and a Tufts University School of Medicine teaching hospital in Springfield, Massachusetts. At the end of the study, it had 716 licensed beds and approximately 4,000 births a year. BMC is self-insured through the entity Baystate Health Insurance Company. Baystate Franklin Medical Center (BF), a 90-bed community hospital in Greenfield, MA, and Baystate Mary Lane Hospital (BML), a 25-bed community hospital in Ware, MA, also participated in the study.

The physicians at the Beth Israel Deaconess hospitals are covered by the same insurer as their hospitals, as are the physicians at the Baystate hospitals. Under Massachusetts law, the total liability of not-for-profit hospitals is capped at $100,000, but that of physicians at these hospitals is not. The cap applies to all hospitals in our CARe and comparison groups, all of which are not-for-profit entities.

Insurers' usual practice when settling claims is to allocate some percentage responsibility to the hospital if the underlying clinical problem involved systems issues that transcended the named physician(s). Hospitals can voluntarily waive the statutory cap on their damages when entering into settlements, and sometimes do so where such a result seems equitable.

Project Genesis and Leadership

CARe was developed following an exploratory process funded by a planning grant from the Agency for Healthcare Research and Quality. Clinical quality leaders partnered with academic researchers to conduct a key informant interview study of stakeholders' perceptions of obstacles to implementing CRPs in Massachusetts. That project revealed high support for the CRP concept and several actionable steps that could help overcome barriers.(4)

The CARe project was initiated and led by the chief quality officers at BIDMC and BMC and the former president of the state medical society.(5) They founded and received ongoing guidance from a coalition of stakeholders, the Massachusetts Alliance for Communication and Resolution

following Medical Injury (MACRMI), described further below. Several of the MACRMI member institutions contributed funding for the project. The CARe founders again collaborated with academic researchers at the Harvard School of Public Health to build an evaluation of CARe into the design of the program.

CARe was conceived with several objectives: to improve communication and transparency about adverse outcomes; provide an alternative to lawsuits and their unnecessary costs by meeting patients' and families' financial needs; improve patient safety; support patients and families by providing a fair, timely, and healing resolution to medical harm incidents; and support clinicians in disclosing medical injuries and addressing their aftermath.

Program Design and Implementation Process

Statewide Resources

MACRMI is an alliance of major stakeholders in the medical liability system who work together to make Communication, Apology, and Resolution (CARe) the status quo response to medical harm events. Members include Massachusetts malpractice insurers, patient advocacy groups, the state's bar association and medical society, healthcare facilities, and others. They meet to develop resources to lower the barriers for other healthcare facilities to use the CARe approach and work through challenges in implementation and spread. MACRMI hosts a website (www.macrmi.info) that houses its print and video resources as well as a blog, and the group holds an Annual Forum on the latest CARe topics.

MACRMI laid the groundwork for the project hospitals to begin their CARe programs. First, MACRMI members determined what tools would be necessary to create a uniform program across institutions and what would help persons on the front lines make the process work within their existing structures. The group worked collaboratively to develop and review drafts of these resources so that input from all stakeholders was reflected. This process resulted in policy recommendations, checklists, marketing materials, and, importantly, CARe process algorithms. The algorithms outline roles and actions to be taken after an adverse event meeting a threshold level of severity occurs, and the decision points that determine what communication steps are taken and whether a financial offer is made.

After the pilots were launched, MACRMI continued to develop resources addressing specific issues that arose (i.e. Best Practices for Attorneys participating in CARe Resolutions), and tools for new sites to start their own programs (i.e. Implementation Guide), while continuing to provide a discussion forum for those piloting the program to work through challenges.

In July 2012, around the time of MACRMI's founding, the Massachusetts legislature passed a new law (M.G.L. Ch. 224 §§ 220-223) for the purpose of facilitating the growth of CRPs in the state. The law (1) requires the disclosure of known, significant adverse events to patients; (2) protects apologies of responsibility and statements of regret against use as evidence in court unless a direct contradiction of fact is made; and (3) imposes a mandatory pre-litigation notice period. The last provision requires a potential plaintiff to give the parties they intend to sue for

malpractice 182 days written notice, during which time the parties may work toward a resolution. The CARe program handled events that the hospital first learned about through a pre-litigation notice, as well as events detected earlier.

CARe Event Criteria

The project hospitals and academic research team collaboratively decided what criteria would define eligibility for the CARe study: all clinical areas would be eligible, but only events reported as exceeding or believed to exceed a particular severity threshold would be included. The chosen threshold was "Level E – Significant" from the NCC-MMERP Index (6), which corresponds to harm that was temporary but severe enough to require at least an invasive medical procedure or 3 outpatient visits.

Preparation for CARe Launch

Preparation for CARe program launch took 6-9 months at each participating hospital. Full-time project managers were hired at BIDMC and BMC to ensure that CARe was rolled out consistently and that there was a high level of awareness of the program among clinical staff. Because CARe was led by senior hospital executives at these institutions, buy-in from top leadership was present from program inception. Obtaining the support of frontline risk management and patient safety staff, who would have substantial responsibility for overseeing the CARe process, was a top priority leading up to the launch of the program. CARe algorithms, policies, and Best Practices were reviewed by the risk management teams before being ratified as official practice, and expectations were set regarding disclosure coaching responsibilities and data collection. At BIDMC, the hospital's adverse event reporting system was modified to capture essential elements of the CARe process (for example, a field was added for "Was this event communicated to patient/family?")

The CARe project managers were given access to all adverse event files and were responsible for tracking case progress along the algorithms at weekly meetings with the risk management team. Discussions with the hospitals' malpractice insurers were also held and strategies were developed to coordinate the actions of hospital and insurer staff and define roles. Additionally, project managers conducted outreach to clinical staff within their respective institutions, creating educational presentations, posters, intranet pages, and badge cards for clinicians with a 24/7 coaching/questions pager number.

The founding quality officers and members of the quality team gave presentations at departmental leadership meetings over the course of a year to explain the reasoning for moving to a CARe approach, show data supporting the approach, and describe the changes in practice that would affect them. Badge cards were handed out at each session. Questions and concerns about the program were addressed—for example, many clinicians raised concerns about reporting of malpractice settlements to the National Practitioner Data Bank. Content regarding the resolution of adverse events through CARe was also incorporated into new physician and resident orientation curriculum.

CARe Program Operation

The teams that oversaw and implemented CARe in both hospital systems were comprised of leaders in health care quality and safety departments (such as Chief Medical and Chief Quality Officers and/or Senior Vice Presidents), risk managers, and a project manager. The team members were selected so that the team could motivate from both above and within, and to give the team the logistical support needed to implement each necessary piece of the program throughout the entire medical center. Risk managers that were part of the teams had preexisting relationships with quality leaders in specific departments, which allowed them to use that trust to help create a culture shift within the departments themselves, not only in the risk and safety offices.

The daily work of running the program was handled by the project managers, each hospital's Director of Patient Safety/Risk Management, and the risk management/patient safety teams. Each week during regularly scheduled team meetings, in-progress cases that met the study event criteria were read aloud with the last known status and whether the next step in the algorithm had been completed. If a step was skipped or the algorithm not followed, the case was reopened and steps retraced. Because data collection was monitored by project managers in real time, if the algorithm was not followed, there were rapid opportunities to raise the anomaly with the RM team. Typically, there was a valid explanation for the deviation (for example, the patient did not wish to engage in discussions about the event after repeated outreach attempts). Project managers also readied cases for monthly conversations between the Director of Patient Safety and the malpractice insurer to ensure that the CARe process proceeded expeditiously and that everyone on the team was kept informed.

A4. Additional Detail on CARe Process

The following text appears in the online appendix to: Mello MM, Kachalia A, Roche S, Van Niel M, Buchsbaum L, Dodson S, Folcarelli P, Benjamin EM, Sands KE. Outcomes in two Massachusetts hospital systems give reason for optimism about communication-and-resolution programs. Health Aff 2017;36(10):1795-1803.

The CARe program is similar to the model implemented by the University of Michigan Health System. It enshrines that program's key elements: (1) communicate with patients and families when adverse outcomes occur; (2) investigate and explain what happened; (3) implement systems to avoid recurrences; and (4) where appropriate, apologize and offer fair financial compensation without the patient having to file a lawsuit.

These basic principles were operationalized in two CARe algorithms. The first, "Defining a CARe Case" (**Exhibit A1**) describes initial steps that should be taken for every adverse event and a decision tree for moving events along to later steps in the process. Generally, when an adverse event occurs, risk management is alerted and support services for the involved clinician(s) are activated, consisting of an offer of communication coaching and peer support. Communication with the patient about the event takes place and is documented in the medical

record. An internal investigation follows, during which internal and external experts may be consulted.

At the conclusion of the investigation, two questions laid out in the algorithm are answered by clinicians with departmental leadership roles in quality improvement, in concert with risk managers: Was the legal standard of care (i.e., negligence) violated? If so, did the deviation cause the patient significant harm? If the standard of care was met, or a lapse in standard of care did not cause significant harm, the algorithm calls for communication with the patient about the investigation results and safety improvements to be made, and allows for an offer of service recovery (for example, reimbursing parking expenses or waiving medical bills). If the standard of care was not met (or the investigation team is unsure), and the care caused the patient significant harm, then the case becomes a CARe Insurer Case, meaning that the insurer will become involved as it is likely a case for compensation.

The alternative pathway in this first algorithm applies to an event that comes to the institution's attention through receipt of a pre-litigation notice. For example, these could be events that occurred before CARe was launched and have been investigated by a plaintiff's attorney. All such events are sent to the insurer, because the patient is represented by an attorney and attorney-to-attorney communication is ethically required. In other words, these cases automatically proceed as a CARe Insurer Case whether or not an internal investigation team believes the standard of care was violated.

The second algorithm, "CARe Insurer Case Protocol" (**Exhibit A2**), outlines the steps for insurer review and resolution of a case. First, CARe representatives explain the investigation findings to the patient/family and inform them that the hospital would like to send the case to the insurer to review for possible compensation. If the hospital is not self-insured, the patient must consent to release their medical records to the insurer. The insurer then reviews the documentary record and discusses the event with the hospital risk manager. It may commission additional expert reviews. The insurer reaches its own determination about whether the legal standard of care (i.e., negligence) was violated, allocates the percentage of fault in the case to the system or provider (or both), and schedules a resolution meeting with the patient/family and their attorney, if applicable, to offer compensation (or to discuss the reasons for not offering compensation). During this time, lessons learned from the insurer investigation are fed back to the hospital and improvements may be made. Improvements are also relayed to the patient during the resolution meeting.

Cases that come in as pre-litigation notices take a different path in the algorithm. If the insurer determines that the standard of care was met, or the lapse did not significantly harm the patient, it sends a letter to the patient's attorney detailing its findings. There is also the option to extend the 180-day period if both parties agree that more time is needed to conduct an investigation and resolve the case. If the insurer finds that a standard-of-care violation caused significant harm, it encourages the patient to seek legal counsel. The appointed attorney for the hospital and the plaintiff's attorney then negotiate fair compensation.

Resolution meetings may result in a settlement offer being accepted and a release of claims signed, or a service recovery offer being accepted without a release of claims. They may lead to a longer process of negotiation, or to an outright rejection of the offer. It may or may not be apparent at this time whether the patient/family intends to pursue litigation. Plaintiffs in Massachusetts have three years to file a malpractice claim.

The CARe process is formally closed when risk managers judge that no further outreach to the patient/family is necessary, appropriate, or likely to be fruitful. For instance, risk managers may terminate the process after the family requests that the hospital stop contacting them, or after several unanswered phone calls.

Illustrative examples of the CARe process are provided below in **Exhibit A3**. Clinical details from these CARe cases have been altered to protect the anonymity of the involved patient and providers.

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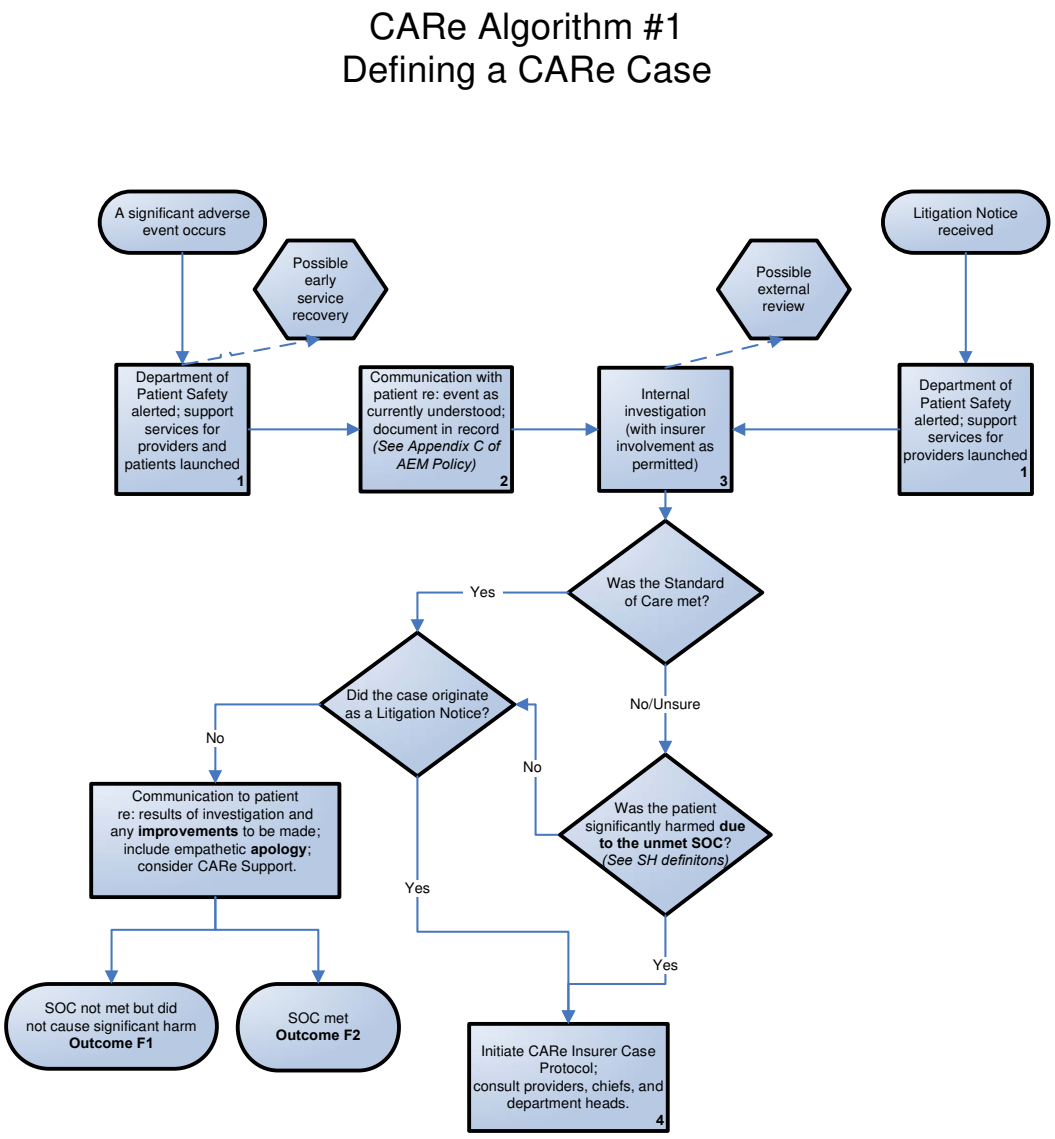
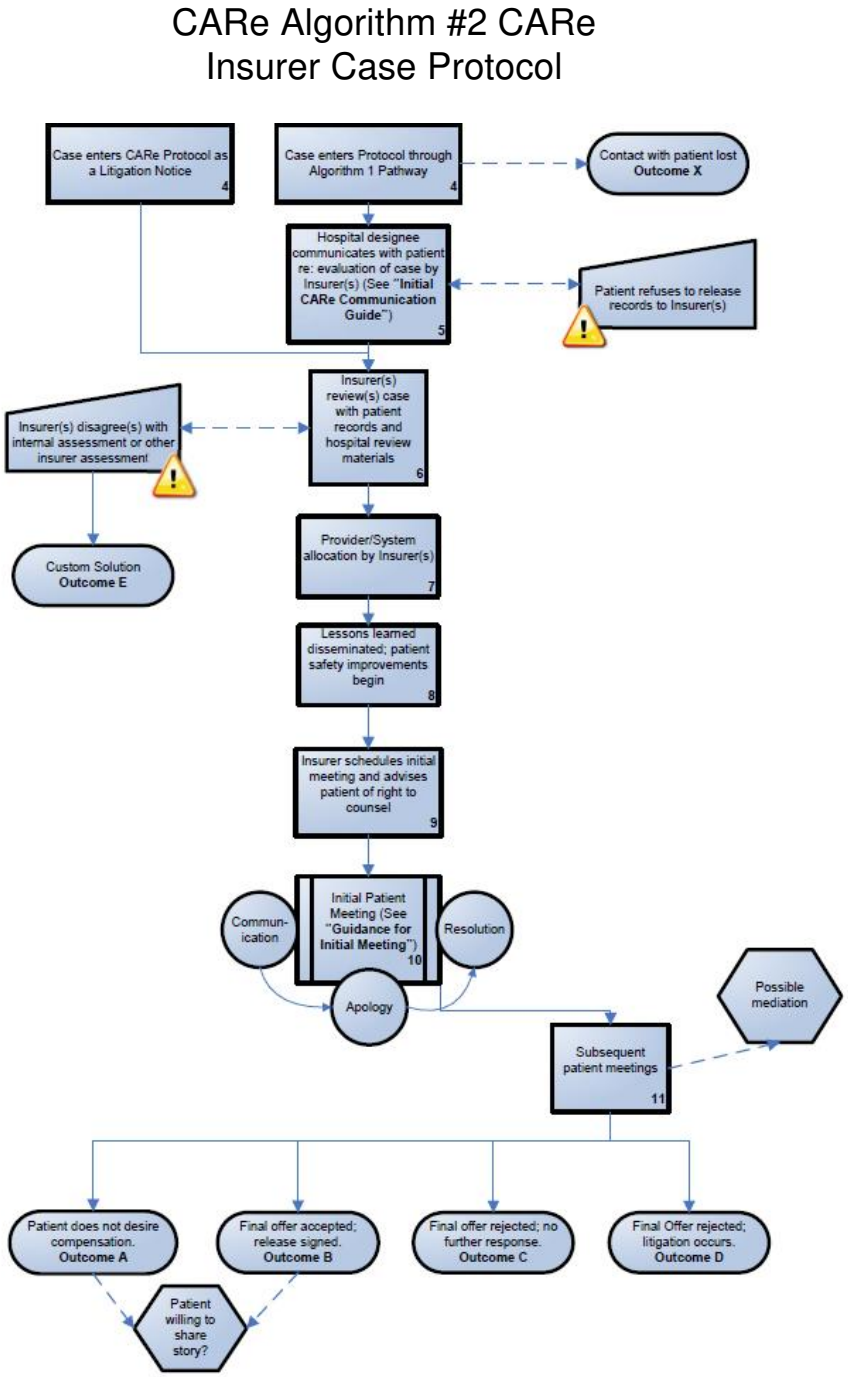
Exhibit A1. CARe Process Algorithm: Referral of Cases to Insurer for Possible Compensation†



† Exhibit presents CARe Algorithm #1 as it stood at the time the study was conducted. The current version, reflecting minor modifications, is available at https://www.macrmi.info/resource_library/?cat=33#jump.

Exhibit A2. CARe Process Algorithm: Insurer Review and Follow Up†



† Exhibit presents CARe Algorithm #2 as it stood at the time the study was conducted. The current version, reflecting minor modifications, is available at https://www.macrmi.info/resource_library/?cat=33#jump.

Exhibit A3. Illustrative Case Examples of How CARe Works (some clinical details have been altered to protect patient privacy)

Example 1: Patient Death from Infection Following Appropriate Care

A relatively healthy patient was admitted to the hospital with an infection. The infection was serious and could not be successfully treated, and the patient died. The death was investigated and the hospital found the standard of care was met. The family, however, was quite upset and concerned that something might have been missed. Hospital leadership, including the involved clinicians, met with the family to explain what happened. The hospital representatives expressed empathy, but explained that the standard of care was met. At the end of the conversation, the hospital representatives communicated that they welcomed more questions at any time. The family eventually returned with a number of questions that were answered by hospital representatives in person and in writing. The family was still unhappy with the outcome, but expressed appreciation for the communication, empathy, and transparency from the hospital. The family did not file a malpractice claim.

Example 2: Error in Following Up on Lab Test Results

A patient called the hospital's patient and family relations office to voice concern over a relatively routine lab result that was missed in follow up. This miss led to a prolonged hospital stay with several weeks of missed work and avoidable health complications for the patient. In calling to voice concern about the care, the patient expressed that his primary motivation was to make sure the problem was fixed and that he was not seeking compensation. When the hospital investigated, it concluded that the standard of care had not been met. The hospital apologized and outlined what would be done to fix the problem. Since the patient had not indicated that he would find a compensation offer offensive, it also worked with the insurer to proactively offer the patient compensation.

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A5. Interview Guide for Baseline Interviews

The IRB-approved interview guide is set forth below. Bullet points below numbered questions are follow-up probes that may or may not have been asked, depending on whether the participant's response to the numbered question covered those issues and on time constraints.

Leadership Interview Guide: Baseline Interview

Introductory comments:

- Introduction of interviewers and thank you for participating
- Interview will take about 30 minutes
- Goal of the interview is to help us understand how implementing the CARe program affects your organization
- There are no right or wrong answers; we hope you will feel free to be candid
- Your answers will not be shared with others at your organization, other participants in the project, or anyone else outside the research team, except in aggregated and deidentified form
- Do you have any questions?
- Is it OK if we tape record the interview? (If not: OK, we will just take notes then.)

1. Could you walk me through what happens immediately after an adverse event is detected?
   - What steps are taken, and what are the immediate priorities?
   - Who is involved?
   - What is the timeframe for the various immediate response steps?
   - How do you decide whether a detected incident should be reported to the adverse event reporting system? Whether it should be reported to your insurer?
   - How do you decide whether a reported event should be investigated?
   - Are these steps formalized in a written policy on adverse event reporting?
   - How do you measure compliance with your policy (or shared understanding) concerning what should occur after an adverse event is detected?

2. Could you describe how you go about investigating a reported adverse event?
   - Who is consulted? Who is involved as an investigator? How and when are standing committees involved?
   - What determinations do you make?
   - How long does an investigation typically take in a simple case? A complex case?

3. What barriers, if any, do you think may keep your clinical staff from reporting 100% of the adverse events they should be reporting to risk management?

4. How strong a "culture of disclosure" do you think there currently is in the facility? Do you think clinical staff perceive facility leadership as strongly championing full, routine disclosure? Why or why not?
   - What barriers, if any, are there to full, routine disclosure?

5. What types of events, if any, are routinely disclosed? What types would sometimes be disclosed, and how would you make that decision? Who would be involved? Are there some types of events that are not appropriate to disclose?
   - Are these conventions formalized in a written policy on disclosure?

6. When, if ever, is an apology of responsibility offered as part of a disclosure? By "apology of responsibility," I mean a statement of apology that includes an acceptance of responsibility for what happened, like, "I'm sorry we did this to you."
   - How about an apology of sympathy—a statement of regret for the harm the patient suffered, like, "I'm sorry this happened to you"?

7. Could you describe how a decision is made about whether or not to offer compensation or some other remedial gesture to the patient/family after an adverse event occurs? Who is involved? What do they do to reach a decision?
   - How often would you offer compensation in a case where you did not think there was a violation of the standard of care?
   - How often would you offer compensation *before* a claim was received?
   - How do you decide how much compensation to offer?
   - How are compensation offers conveyed to patients/families?
   - Are these practices formalized in a written policy or set of operating procedures?

8. How different does the CARe process seem from the process you have been using so far? Probe: What will you be changing?

9. Could you describe any steps you take to determine if clinical care improvements are needed as a result of things you learn about in adverse event reports and claims?
   - Do you keep records of safety improvements you have made as a direct result of information from AE reports and claims?
   - After a quality review or RCA, are recommended improvements shared with your staff who are handling claims investigations?
   - Are recommended improvements shared with the patient or family? Why/why not?
   - Do patients or families participate in you facility's quality review or RCA process?

10. What are your expectations about how the CARe process might affect …
    - Patient safety at your facility?
    - Liability costs? Frequency of claims?
    - Patients' experiences following an adverse event?
    - Clinicians' experiences following an adverse event?

11. Overall, how successful do you think the CARe program will be in improving processes of adverse event response at your facility, including transparency with patients?
    - What do you think will be the most helpful part of the program?
    - Are there elements of the program that you think will be unhelpful, or even harmful?

12. What do you think will be the major challenges associated with implementing the CARe program at your facility?
    - Are there aspects of the liability environment in Massachusetts that you think will be helpful or unhelpful in implementing the CARe program?

- How supportive do you think the top leadership at your organization is of implementing the CARe program?
- Is there a strong "champion" of the CARe program in your organization?
- Do you feel like there are people you can consult informally within your facility about challenges you might encounter implementing the CARe program?
- Overall, do you feel well supported in your efforts to implement it?

13. What features of your organization, if any, do you think will be most helpful in ensuring that the CARe program is launched and operated successfully?

16. Aside from this project, has your facility previously made efforts to change the way you approach medical injury response or malpractice claims?
    - If so: What did you do, and how did it go? What components did you find useful or not useful? What would you say were the takeaway lessons from that experience?

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A6. Interview Guide for End-of-Project Interviews

The IRB-approved interview guide is set forth below. Bullet points below numbered questions are follow-up probes that may or may not have been asked, depending on whether the participant's response to the numbered question covered those issues and on time constraints.

Leadership Interview Guide: End of Project Period Interview

Introductory comments:

- Introduction of interviewers and thank you for participating
- Interview will take about 30 minutes
- Goal of the interview is to help us understand how implementing the CARe program affected your facility
- There are no right or wrong answers; we hope you will feel free to be candid
- Your answers will not be shared with others at your facility, other participants in the project, or anyone else outside the research team, except in aggregated and de-identified form
- Do you have any questions?
- Is it OK if we tape-record the interview? (If not: OK, we will just take notes then.)

1. Could you walk me through your CARe program process here at the facility? Suppose an adverse event is reported by a clinical care provider to risk management. What happens next? And then? (Probe for: immediate response; initial disclosure; support for clinicians making disclosures; initial investigation; referral to CARe; feedback to families for cases not referred to insurer; insurer review)
    - Do the initial stages of this process vary depending on whether the event is serious or less serious? Clearly due to error vs. not evidently due to error?
    - How do you measure compliance with your policy (or shared understanding) concerning what should occur in the CARe program?
    - Overall, what if anything has changed about the way you respond to adverse events since you implemented the CARe program? Probe: Obtain detail on specific processes around reporting, disclosure, investigation, and settlement.

2. How strong a "culture of disclosure" do you think there currently is in the facility? Do you think clinical staff perceive facility leadership as strongly championing full, routine disclosure?
    - What barriers, if any, are there to full, routine disclosure?

3. What types of events, if any, are routinely disclosed? What types would sometimes be disclosed, and how would you make that decision? Who would be involved? Are there some types of events that are not appropriate to disclose?
    - Has anything changed here since you implemented the CARe program? If so: Do you attribute that change to the CARe program, or something else?

4. When, if ever, is an apology of responsibility offered as part of a disclosure? By "apology of responsibility," I mean a statement of apology that includes an acceptance of responsibility for what happened, like, "I'm sorry we did this to you."
    - How about an apology of sympathy—a statement of regret for the harm the patient suffered, like, "I'm sorry this happened to you"?

5. Could you describe how a decision is made about whether or not to offer compensation or some other remedial gesture to the patient/family after an adverse event occurs? Who is involved? What do they do to reach a decision?
    - How often would you offer compensation in a case where you did not think there was a violation of the standard of care?
    - How often would you offer compensation before a patient/family signals interest in receiving it?
    - How do you decide how much compensation to offer?
    - How are compensation offers conveyed to patients/families?

6. Could you describe any steps you take to determine if clinical care improvements are needed as a result of things you learn about in adverse event reports and claims?
    a. Do you keep records of safety improvements you have made as a direct result of information from AE reports and claims?
    b. After a quality review or RCA, are recommended improvements shared with your staff who are handling claims investigations?
    c. Are recommended improvements shared with the patient or family? Why/why not?
    d. Do patients or families participate in you facility's quality review or RCA process?

7. What are your perceptions of how the CARe program may have affected…
    - The culture of disclosure at your facility?
    - Patient safety improvement efforts at your facility? Probe: Can you identify any specific patient safety improvements made as a result of things learned in the CARe program?
    - Clinicians' reporting of adverse events to risk management?
    - The frequency and quality of disclosure conversations?
    - Liability costs? Frequency of claims?
    - Patients' experiences following an adverse event?
    - Clinicians' experiences following an adverse event?

8. What have been the major challenges associated with implementing the CARe program at your facility?
    - Are there aspects of the liability environment in Massachusetts that you think have been helpful or unhelpful in implementing the CARe program?
    - How supportive do you think the top leadership at your organization has been of the CARe program?
    - Has there been a strong "champion" of the CARe program in your organization?
    - Did you feel like there were people you were able to consult informally within your facility about challenges you encountered implementing the CARe program?
    - Overall, did you feel well supported in your efforts to implement the CARe program?

9. What features of your organization, if any, do you think have been most helpful in ensuring that the CARe program was launched and operated successfully?

10. Did your facility encounter problems in implementing the original plan for the CARe program? Were there things you thought you would do at the outset that you ended up deciding to change later on? (Probe on: disclosure training, incident investigation, resolution decision making, patient safety learning processes)

- Overall, how completely do you think the CARe program, as originally envisioned in your work plan, was implemented?

11. Overall, how successful do you think the CARe program has been in improving processes of adverse event response at your facility, including transparency with patients?
    - What do you think the most helpful part of the CARe program has been?
    - Are there elements of the CARe program that you think have been unhelpful, or even harmful?
    - Is your facility going to continue the CARe program?

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A7. References

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