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By Michelle M. Mello, Allen Kachalia, Stephanie Roche, Melinda Van Niel, Lisa Buchsbaum, Suzanne Dodson, Patricia Folcarelli, Evan M. Benjamin, and Kenneth E. Sands

# Outcomes In Two Massachusetts Hospital Systems Give Reason For Optimism About Communication-And-Resolution Programs

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ABSTRACT Through communication-and-resolution programs, hospitals and liability insurers communicate with patients when adverse events occur; investigate and explain what happened; and, where appropriate, apologize and proactively offer compensation. Using data recorded by program staff members and from surveys of involved clinicians, we examined case outcomes of a program used by two academic medical centers and two of their community hospitals in Massachusetts in the period 2013-15. The hospitals demonstrated good adherence to the program protocol. Ninety-one percent of the program events did not meet compensation eligibility criteria, and those events that did were not costly to resolve (the median payment was \$75,000). Only 5 percent of events led to malpractice claims or lawsuits. Clinicians were supportive of the program but desired better communication about it from staff members. Our findings suggest that communication-and-resolution programs will not lead to higher liability costs when hospitals adhere to their commitment to offer compensation proactively.

espite widespread adoption of tort reforms in the United States, concerns persist about the liability system's effects on the cost of health care and on patients and physicians involved in adverse events. In response, there has been increasing experimentation with approaches that channel disputes away from the tort system—most prominently, communication-and-resolution programs (CRPs). In these programs, hospitals and liability insurers disclose adverse events to patients; investigate; explain what happened; apologize; and in cases where substandard care caused harm, proactively offer compensation.

The CRP model received attention because early adopters reported large reductions in the volume and cost of malpractice claims.<sup>3</sup> Policy makers' interest led the Agency for Healthcare Research and Quality (AHRQ) to fund CRP dem-

onstration projects and develop an implementation tool kit.<sup>4</sup>

Enthusiasm for CRPs has been tempered in some quarters by concerns about how they may operate in practice. Some hospitals worry that routine disclosures to patients will trigger an avalanche of new malpractice claims and that insurers will struggle with the consequences.<sup>5</sup> The potential for higher costs has raised concerns that hospitals with CRPs might not adhere to their commitments to consistently deliver fair and proactive compensation offers.<sup>6,7</sup>

We implemented and evaluated a CRP known as CARe (Communication, Apology, and Resolution) in six Massachusetts hospitals. Our evaluation aimed to answer three questions: Did the institutions adhere to the CRP protocol? If so, did the program lead to high compensation costs? Finally, what did clinicians involved with the program think of it? After describing the setting

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and the program, in this article we present some of the findings of this evaluation.

#### The Setting

CARe was implemented at two large, urban academic medical centers, Beth Israel Deaconess Medical Center and Baystate Medical Center, and at two of each center's community hospitals. Beth Israel Deaconess is a 672-bed, Level I trauma center that is insured through a risk retention group. Baystate is a 716-bed, Level I trauma center that is self-insured. Baystate's two community hospitals (one with 90 beds and one with 25) and Beth Israel Deaconess's two community hospitals (one with 88 beds and one with 58) also participated. Beth Israel Deaconess and Baystate had preexisting disclosure and apology policies. All hospitals that implemented CARe participated in the evaluation, except the Beth Israel Deaconess community hospitals-which did not contribute data because no Institutional Review Board review was available.

CARe implementation benefited from the 2012 adoption of a Massachusetts statute that combined an adverse event disclosure requirement for health care providers and facilities with legal protection for them if they made statements of apology. The law also required malpractice plaintiffs to give defendants written prelitigation notice (PLN) 180 days before filing suit, to create an opportunity to resolve the dispute.

# The CARe Program

CARe was developed following an exploratory process in which clinical quality leaders and academic researchers studied stakeholders' perceptions of obstacles to implementing CRPs in Massachusetts. Interviews revealed high support for the CRP concept and actionable steps that could help overcome barriers to CRP implementation <sup>9</sup>

The program evaluated in this article was led by the chief quality officers at Beth Israel Deaconess and Baystate and a former president of the state medical society. They founded and received ongoing assistance from the Massachusetts Alliance for Communication and Resolution Following Medical Injury, a coalition of stakeholders and academic researchers.<sup>10</sup>

CARe was operated by the hospitals' risk-management departments, which were supported in that operation by one project manager at each academic medical center and an evaluation team led by academic researchers. Biweekly conference calls were held to address challenges and standardize practices across hospitals. For

further program details, see the online Appendix.11

CARe's objectives were to improve communication and transparency surrounding adverse events, improve patient safety, reduce lawsuits and promote reconciliation by proactively meeting injured patients' needs, and support clinicians in disclosing medical injuries. The program was designed through a collaborative process that involved the hospitals, their insurers, and members of the Massachusetts Alliance for Communication and Resolution Following Medical Injury.

Implementation of the program required institutions to use the CARe model in all clinical settings for all adverse events. Events were included in the CARe evaluation if they met (or if the patient alleged that they met) a severity threshold (they caused either permanent harm or temporary harm that led to or extended a hospitalization, required an invasive procedure, or resulted in at least three outpatient visits), they triggered state agency reporting requirements, a provider requested the use of the CARe process, or a PLN was received.

The key elements of CARe were incorporated into a written protocol for managing CARe events that included decision pathways and decision criteria (for details, see Appendix A4).<sup>11</sup> The protocol called for compensation offers when violations of the standard of care caused significant harm. The hospital conducted an internal investigation and then decided whether to refer the event to the liability insurer for possible compensation (for details on the decision criteria, see Appendix A4).11 Risk managers and designated clinicians made this decision based on prespecified criteria (either the investigation indicated that a standard-of-care violation might have caused significant harm, or the event entered CARe because of a PLN). The insurer then completed its review after obtaining medical and CARe records with the patient's permission and talking with the risk manager. A meeting was held between insurer and hospital representatives and the patient and family (and the parties' attorneys, if desired) to relay findings and seek a resolution.

#### **Study Data And Methods**

The CARe evaluation followed the same methods as those in other CRP demonstration projects. <sup>12,13</sup> Outcome measures included the proportion of CARe events that resulted in legal action, dollar amounts paid to patients, hospitals' adherence to the CARe protocol, and clinicians' satisfaction with the program.

DATA Following Institutional Review Board

approval, hospital risk managers and project managers recorded data about each case. Beth Israel Deaconess and Baystate began collecting data in February and March 2013, respectively, and Baystate's community hospitals began doing so in May and August of the same year. Data collection ended in October 2015, for an observation period of 32–33 months at the academic medical centers and 27–29 months at the community hospitals. Updated information on additional settlements, claims, PLNs, and lawsuits was obtained in August 2016.

Data were collected and managed using RED-Cap electronic data capture tools. Because previous CRP evaluations identified implementation fidelity as a problem for new adopters, <sup>12-14</sup> data collection included detailed documentation of reasons for not following the CARe protocol.

A satisfaction survey was administered via REDCap to one or two clinicians identified by risk managers as being the most involved in CARe's handling of each of the 270 events in the third year of the program at the academic medical centers. Structured questions asked about clinicians' familiarity with and perceptions of CARe (for the full text of the survey, see Appendix A2).<sup>11</sup>

Data were collected on 989 CARe events. Two hundred and seventy invitations to participate in the survey were sent to 225 clinicians involved in CARe events in the third year (some clinicians were involved in more than one event). The survey completion rate was 68.1 percent (184 responses to 270 invitations).

**LIMITATIONS** This study had a number of limitations. First, the Massachusetts hospitals' CRP experiences might not be broadly generalizable. Research suggests that organizational characteristics affect CRP implementation fidelity and outcomes. <sup>2,12,14</sup> Furthermore, the presence of project managers might have heightened our hospitals' adherence to CRP protocol, and Massachusetts's PLN law might have helped avert lawsuits.

Second, as discussed below, our analysis might underreport the numbers of claims and lawsuits that ultimately occurred for CARe events. Finally, although our survey response rate was high, nonresponse bias cannot be ruled out.

#### **Study Results**

The four hospitals we studied (identified as hospitals A–D in Exhibit 1) applied the CARe process to a diverse set of events across all clinical departments. Of the 989 total events we studied, 60 of them (6.1 percent) entered CARe because a PLN or claim was received, while 929 (88.9 percent) entered the program because an adverse event

that allegedly exceeded the severity threshold was reported, the event met other criteria, or both (see Appendix Figure A4).<sup>11</sup>

**COMMUNICATION WITH PATIENTS AND FAMI- LIES** Adherence to the communication element of the CRP protocol was high. Where communication did not occur, it was usually for a valid reason, as described below.

An initial communication with the patient or family discussing the harm event was documented for 760 of the 929 (81.8 percent) events that did not enter the CARe process because of a PLN (see Appendix Figure A4). Where no conversation occurred, leading reasons included that the hospital was unaware of the event until a patient complained (18 cases), the hospital initiated an investigation through other quality-review mechanisms in response to a staff member's report of a possible adverse event but found no problem to disclose to the patient (27 cases), and the patient or family did not respond to multiple contact attempts (12 cases) (data not shown).

An oral or written resolution communication that provided feedback to the patient or family on the investigation findings was documented in 573 of 944 (60.7 percent) of cases in which the CARe process had been completed by the close of data collection (see Appendix Figure A4). 11 In 80 cases, no such communication was deemed necessary because all pertinent information had already been conveyed to the patient, family, or both (data not shown). Other leading reasons for not having such a communication were that the investigation revealed no concerns about the care or was inconclusive, and the patient or family was not expecting further communication (69 cases); the patient or family did not respond to outreach attempts or was unwilling to engage (57 cases); and no initial disclosure conversation had been held (25 cases). No reason was documented in 109 cases.

entered the CARe process met the criteria for compensation. After investigating, hospitals found that the standard of care had been met in 675 of 916 (73.7 percent) of cases where a determination could be reached, and that the standard had been violated in 241 cases (26.3 percent) (Appendix Figure A3). Of the remaining 73 (out of 989) cases, no determination could be reached in 59 cases, 9 cases were pending at the close of data collection, and 5 were referred directly to the insurer (see the Notes to Appendix Figure A3).<sup>11</sup>

Of the 241 cases involving standard-of-care violations, 133 (55.4 percent) were potentially eligible for compensation because they involved significant harm (see Appendix Figure A3).<sup>11</sup>

#### EXHIBIT 1

#### Characteristics of CARe events in four Massachusetts hospitals

	No.	Percen
HOSPITAL		
A B C D	474 449 36 30	47.9 45.4 3.6 3.0
PATIENT CHARACTERISTICS		
Female Mean age (years) <sup>a</sup> White Black Asian Native Hawaiian or Pacific Islander Hispanic	519 53.1 667 72 33 1 91	56.2 — <sup>b</sup> 86.3 9.3 4.3 0.1 11.1
PRIMARY INVOLVED CLINICIAN TYPE		
Attending or ED physician Registered nurse Resident or fellow Anesthesiologist Radiologist Other	632 164 48 34 29 78	64.2 16.6 4.9 3.4 2.9 7.9
FIRST REPORTED TO RISK MANAGEMENT BY:		
Internal facility reporter Patient or family member Attorney for patient or family member Patient's insurer State department of public health	705 247 32 4 1	71.3 25.0 3.2 0.4 0.1
ADVERSE EVENT TYPE		
Surgical or procedural complication <sup>c</sup> Medical management Diagnostic error or delay Fall Obstetrical or neonatal complication Medication related Cardiac or respiratory arrest Infection Other Unable to determine	341 219 154 98 64 63 58 52 64	34.5 22.1 15.6 9.9 6.5 6.4 5.9 5.3 6.5 1.2
INJURY SEVERITY		
Death Permanent harm Temporary harm requiring:   Life-sustaining intervention   Hospitalization or extended hospital stay   Invasive medical procedure, at least 3 outpatient visits, or both	169 70 72 236 143	17.2 7.1 7.3 24.1 14.6
Other treatment or intervention	156	15.9

**SOURCE** Authors' analysis of data from four hospitals that are part of Beth Israel Deaconess Medical Center and Baystate Medical Center. **NOTES** N=989 events. The exhibit shows percentages of nonmissing responses. Percentages might not sum to 100 because of rounding or because categories are not mutually exclusive. Additional details on event characteristics are available in Appendix A3 (see Note 11 in text). CARe is Communication, Apology, and Resolution. ED is emergency department. "Standard deviation: 23.9. "Not applicable. 'Includes complications from diagnostic and bedside procedures. "National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) score, which ranges from A (circumstances or events that have the capacity to cause error) to I (an error occurred that may have contributed to or resulted in the patient's death).

Hospitals judged 82 of the 124 (66.1 percent) cases to be causally related to medical care. Overall, the hospitals determined that 9.0 percent of the events that involved significant harm were caused by substandard care (data not shown).

**INSURER DECISIONS AND RESOLUTION EFFORTS** Fidelity to the CRP protocol was strong for compensation processes, although barriers were sometimes encountered. CRP events were not costly to resolve.

Of the 980 events for which hospitals reached a decision about whether to refer the case to the insurer for possible compensation, 140 (14.3 percent) met the referral criteria (Exhibit 2). Seventeen of these cases were not actually referred to the insurer because the patient declined or did not respond to the offer of insurer review (9 cases); risk managers judged the family to be satisfied with the explanation, apology, or other items (such as bill waivers) given (7 cases); or the patient alleged that an event had occurred that was absent from the medical record (1 case) (data not shown). Another 15 cases were referred to the insurer but not reviewed because the patient did not release medical records, declined the review, or experienced harm that was later determined to be below the severity threshold (data not shown).

Insurers reviewed the remaining files. Of these, 28 were still pending at the close of data collection. Insurers also reviewed 37 files at a hospital's request although the criteria for review were not met (Exhibit 2)—for example, because an upset family demanded a review. As of August 2016, among cases for which the insurer review had been completed, insurers found that the standard of care had been violated in 46 of 111 (41.4 percent) cases and had not been violated in 52.3 percent of cases (in 7 cases, the insurer could not reach a determination) (data not shown).

Exhibit 2 and Appendix Figure A4<sup>11</sup> show what was offered to patients as of October 2015. Overall, there was substantial compliance with the CARe protocol, and most discrepancies had reasonable explanations. For example, in fifteen cases, compensation was not offered despite a standard-of-care violation. Of these, twelve had justifications (the harm was below the minimum severity threshold, ongoing discussions later resulted in a compensation offer, or patients did not desire compensation or would not engage). In the other three, risk managers decided that the patient seemed satisfied with service recovery items (such as medical bill waivers, meal vouchers, parking reimbursement, and gift cards) or denied the claim because the plaintiff's counsel did not furnish expert support for it. In

#### Flow and resolution of events in the CARe program as of October 2015

	Number
Hospital investigation completed	980 (out of 989 reported events) <sup>a</sup>
CRITERIA FOR INSURER REFERRAL MET	
Number of events Not referred to insurer Referred to insurer Standard of care met Still pending, not reviewed, or not determined Standard of care violated Compensation offered Apology made Explanation provided	140 17 123 35 49 39 24 (out of 35 cases where deemed appropriate) <sup>b</sup> 33 (out of 32 cases where deemed appropriate) <sup>c</sup> 34 (out of 30 cases where deemed appropriate)
Number of events  Not referred to insurer Referred to insurer Standard of care met Still pending, not reviewed, or not determined Standard of care violated Compensation offered Apology made Explanation provided	840 803 37 22 8 7 6 (out of 6 cases where deemed appropriate) 7 (out of 5 cases where deemed appropriate) <sup>c</sup> 5 (out of 4 cases where deemed appropriate) <sup>c</sup>

**SOURCE** Authors' analysis of data from four hospitals that are part of Beth Israel Deaconess Medical Center and Baystate Medical Center. **NOTE** Appendix A4 provides a more detailed graphical presentation (see Note 11 in text). <sup>a</sup>The 989 reported events exclude forty-five in which the Communication, Apology, and Resolution (CARe) process had not yet been completed by close of our data collection period, in October 2015. Feedback communication may have occurred subsequently. <sup>b</sup>The numerator excludes four cases in which compensation was offered after October 2015. <sup>c</sup>The numerator includes some apologies and explanations that were communicated before the case was referred to the insurer.

the thirty-one cases where no apology was offered, leading reasons were patient unresponsiveness to outreach and situations in which the case had entered the CARe process because of a PLN or claim, it was found to lack merit, and a denial letter was issued without an apology.

Monetary compensation had been offered in 43 cases and paid in 40 cases by August 2016 (median payment: \$75,000; interquartile range: \$22,500, \$250,000; maximum payment: \$2 million) (data not shown). Additionally, service recovery items were offered in 181 cases (18.5 percent) (Appendix Figure A5). Of these cases, 71.2 percent did not meet criteria for compensation, 12.2 percent received both a bill waiver and compensation, and all but 2 of the remaining cases had justifications for the lack of a compensation offer (for example, the family declined the offer of an insurer review) (data not shown).

**LIABILITY OUTCOMES** Few CARe events escalated to legal action. As of August 2016, 47 of the 929 (5.1 percent) events that did not enter the CARe process because of a PLN or claim had led to claims, PLNs, or lawsuits (for details, see Appendix Figure A5). Among all 989 events, 40 (4.0 percent) were settled with a release of claims signed.

During the CARe process, insurers deemed

fourteen of the forty-seven events that ultimately resulted in legal action ineligible for compensation due to lack of negligence or (in one case) lack of harm. They deemed twenty-two of the cases compensable, offered compensation in all of them, and had settled twenty of them by August 2016. Determinations had not been reached in the other eleven cases by the end of the study period (data not shown).

PATIENT SAFETY OUTCOMES Patient safety improvements were frequently identified during the CARe process. For cases reviewed by the insurer, patient safety improvements that had been or were likely to be implemented by the hospital because of the incident were recorded. Of the 132 cases in which review had progressed far enough for the patient safety question to have been answered by October 2015, 54 (40.9 percent) gave rise to a safety improvement action. These included sharing investigation findings with clinical staff members (27.3 percent), clinical staff educational efforts (25.8 percent), policy changes (15.9 percent), safety alerts sent to staff members (10.6 percent), input into the quality improvement system for further analysis (7.6 percent), new process flow diagrams (7.6 percent), human factor engineering analysis (4.5 percent), and other steps (6.8 percent)

(some events resulted in more than one safety improvement action). The safety interventions implemented were diverse—for example, new labeling for high-risk medications, color-coded socks for patients at risk for falls, radio frequency identification tags for surgical sponges, improved interpreter services, process improvements for managing the selection of implantables in surgery, and a multidisciplinary checklist for breech deliveries.

**PROVIDERS' PERCEPTIONS** Providers who were familiar with CARe had favorable perceptions of it (Exhibit 3). We received 184 surveys from 162 different providers—including 124 physicians and physician trainees (76.5 percent), 34 nurses (21.0 percent), and 4 others (2.5 percent). Of the respondents, 57.3 percent were male, and 87.9 percent were white.

Two findings emerged from the survey responses. First, many clinicians were unfamiliar with the CARe program in general or with what had occurred in the handling of the event they were involved in. Nearly 40 percent of the responses indicated that the clinician was either not very or not at all familiar with the program (Exhibit 3).

Second, most clinicians who felt informed enough to provide satisfaction ratings expressed positive views. Only 10.2 percent gave a negative rating of the program overall, while 69.4 percent

gave strongly positive ratings. Ratings were similar concerning how fairly CARe representatives treated the patient or family. Dissatisfaction was somewhat more prevalent concerning how the clinicians were treated in the CARe process (17.9 percent were dissatisfied), how well CARe representatives communicated with them (23.1 percent), and how long it took to resolve the event with the patient or family (23.0 percent); however, strong majorities still expressed positive views. The most commonly suggested improvement to CARe was to improve communication with involved clinicians (data not shown).

#### **Discussion**

This study provides insights into whether institutions operating communication-andresolution programs maintain their commitments once financial consequences emerge. In the first three years of their use of one of these programs, Communication, Apology, and Resolution (CARe), the hospitals had good adherence to the key elements of its protocols and found that only 5 percent of CARe events led to claims. However, the hospitals' experience does highlight some of the barriers to executing a CRP.

HOSPITALS ADHERED TO PROTOCOLS BUT ENCOUNTERED BARRIERS In adopting CARe, hos-

#### EXHIBIT 3

#### Satisfaction with CARe program reported on 184 surveys from clinicians involved in CARe events

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niliar

**SOURCE** Authors' analysis of data from four hospitals that are part of Beth Israel Deaconess Medical Center and Baystate Medical Center. **NOTES** The percentages for "able to answer" are of respondents who did not say they didn't know enough to answer. Percentages might not sum to 100 because of rounding. Appendix A2 includes the full survey questionnaire (see Note 11 in text). CARe is Communication, Apology, and Resolution. 'Asked only of the 118 clinicians who reported having been involved in the disclosure conversation. <sup>4</sup>Not applicable.

pitals committed to delivering several key elements: an initial disclosure, investigation, referral to insurers when certain criteria were met, and feedback communication that provided the investigation findings and resolution elements determined to be appropriate.

An initial disclosure conversation was held about 80 percent of the time (excluding cases that entered the CARe process because of a PLN), and there were reasonable explanations for not having one in most of the remaining cases. Resolution elements determined to be appropriate were usually delivered and usually consistent with compensation criteria. Consistency in delivering feedback was somewhat lower, with communication occurring in about 60 percent of the events.

The leading reason for not having a feedback communication was that all key information was known at the time of the initial conversation. However, patient-related factors sometimes presented barriers—for example, some patients did not wish to talk. In meetings between CARe program staff and the evaluation team, risk managers expressed uncertainty about how vigorously to pursue patients who did not seem to want to engage.

Despite the good overall adherence to the CARe protocol, some deviations were not fully explained. With regard to delivering compensation where criteria were met, there were a handful of cases in which patients seemed satisfied with something else, such as an apology and service recovery items. Although some families do not desire compensation, mistakes can easily be made in drawing this conclusion without explicitly asking. Service recovery items should not be offered as a substitute for full compensation in cases where compensation criteria are met.

The Massachusetts hospitals were able to adhere to their CRP commitments more consistently than hospitals in an earlier demonstration project in New York. There, compensation offers were made in only one in six CRP events judged to be due to a standard-of-care violation. <sup>13,14</sup> The New York hospitals cited resistance by insurers and physicians as factors preventing them from making offers—a problem not reported in Massachusetts.

CRITERIA Although public discussion of CRPs focuses on their role in compensating victims of medical error, most CARe events did not involve errors. In the Massachusetts hospitals' judgment, only about 9 percent of events met compensation criteria. When an event was ineligible for insurer referral, CARe's role was to deliver a meaningful disclosure, explanation, and sympathetic apology. The data indicate that

hospitals did this consistently.

A key takeaway lesson is that most often, CRPs' work involves communicating with patients about adverse outcomes that are not due to substandard care—providing the information and empathy that patients need to be able to process the event<sup>15</sup> and understand that it does not merit legal redress.

The compensation criteria in CRPs usually mirror those of the tort system, in which liability requires evidence of both causation and breach of the standard of care and in which most paid claims involve events that caused serious harm.<sup>16</sup> In our analysis, the leading reason for ineligibility for compensation was that the standard of care had been met. The proportion of cases in which that standard had been met-about threequarters—is consistent with that reported in the New York CRP project.<sup>13</sup> Among CARe events in which the standard of care had been violated, about half involved significant harm, and twothirds of those injuries were caused by medical care. An example of a standard-of-care violation with no causation is a patient who contracted a hospital-acquired infection and later died, but not because of the infection.

Rational observers may question whether these figures indicate bias in hospitals' evaluations, but findings from other studies suggest that this is not the case. The findings that three-quarters of adverse events did not involve substandard care and that the majority did not involve significant harm accord with the results of two large studies that reviewed data from hospital charts. 17,18 It is difficult to find comparable data on causation of events, but CARe hospitals judged harm to have been caused by medical care most of the time. The low proportion of compensable events suggests that the CARe hospitals applied the process to a broad swath of reported incidents, not merely those they expected to generate litigation.

Given the rarity with which CRP events result in settlements, it is reasonable to wonder whether the programs are worth the time they require, but risk managers in our study thought they were (see Appendix A8 for details).11 By providing explanations and expressions of sympathy for harms not arising from negligence, CRPs may avert lawsuits springing from misunderstanding. Malpractice claims frequently involve injuries not caused by substandard care,16 and plaintiffs are often motivated by perceptions that providers communicated poorly or attempted to cover up negligence.19 CRPs also encourage systematic evaluation of whether each adverse event suggests patient safety lessons. Finally, CRPs can help hospitals foster a culture of transparency by supporting clinicians in making disclosures.

**EVENTS WERE NOT COSTLY TO RESOLVE AND RARELY LED TO CLAIMS** The CARe program did not trigger a barrage of new litigation or costs. Only 5.1 percent of events that did not enter the program because of a claim or PLN resulted in a claim by August 2016. The compensation paid for CARe events was fairly modest (median: \$75,000).

Additional legal actions may yet occur in our sample. For 705 events, the statute of limitations had not run out as of August 2016 (meaning that the patient still had time to file a claim). However, among the events for which the statute of limitations had expired, the proportion that resulted in legal action was not much higher than that among events for which it had not (6.7 percent versus 4.5 percent). Even for the most recent events, nearly a year had elapsed between the event and the end of our observation period.

Two factors may explain the paucity of claims that emerged from this group of over 900 harm events. Patients may have emerged from CARe discussions with an understanding that the injury had not been caused by substandard care. Alternatively, they may have disagreed with the hospital's characterization but felt pessimistic that they could prevail in litigation. Getting an attorney to take a case is difficult when one must explain that the hospital has investigated and explained that no settlement offer is warranted. This makes it all the more important that hospitals' CRP evaluations be made in good faith after diligent investigation.

**PROGRAMS MUST COMMUNICATE EFFECTIVELY WITH CLINICIANS, NOT JUST PATIENTS** Clinicians familiar with CARe strongly supported it, but many clinicians had little awareness of the program. As one survey respondent commented, "Great idea, too bad it's kept a secret."

All hospitals presented the CARe program for approval to hospital and medical staff governance groups and described it at multiple educational sessions and departmental visits at launch and over the next three years. However, survey data from both the Massachusetts and New York projects<sup>13</sup> indicate that such outreach alone

# The CARe program did not trigger a barrage of new litigation or costs.

may be insufficient. There must also be robust communication with involved clinicians about individual cases, since information about CRPs might not seem salient to clinicians until they are involved in an event.

The most likely explanation for clinicians' low familiarity with the CARe program is that risk managers often did not label patient-reported events "CARe events" when discussing events with them. They typically used the program's name only if a case was being referred to the insurer. More consistent branding can reinforce program identity and demonstrate that CRPs do important work even in cases that do not involve errors.

Strong communication with providers serves other purposes as well: providing "care for the caregivers" following traumatic events, signaling that the hospital's caring relationship with the patient continues after an injury occurs, and reassuring clinicians that unfair blame is not being placed. Institutions in which CRPs have become deeply culturally engrained report that enormous effort in communicating with clinicians is required.<sup>2</sup>

#### Conclusion

Although there are clear opportunities to strengthen communication-and-resolution programs going forward, the Massachusetts experience is cause for optimism about the prospects for this approach to medical injury resolution.

Some of the results presented in this article were previously presented at the faculty workshop of the Washington University School of Law, St. Louis, Missouri, February 8, 2017. The project sponsors (Baystate Health Insurance Company, Blue Cross Blue Shield of

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#### NOTES

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### **Appendix**

#### **Contents:**

- Appendix A1. Additional detail on clinician survey methods
- Appendix A2. Full text of the clinician survey questionnaire
- Appendix A3. Additional detail on CARe program design and implementation
- Appendix A4. Additional detail on CARe process
- Appendix A5. Graphical presentation of hospitals' determinations in CARE cases
- Appendix A6. Graphical presentation of the flow and resolution of events in the CARe program
- Appendix A7. Details of liability outcomes and other characteristics of CARe events
- Appendix A8. Risk managers' perceptions of the CARe process

### Appendix A1. Additional detail on clinician survey methods

<u>CARe events included in the survey</u>. For each Year 3 CARe event, surveys were sent to 1-2 clinicians identified by risk managers as having been involved in the CARe process. However, in some cases, risk managers reported difficulty identifying a provider to survey. The project team gathered details on each such case and discussed whether to ask the risk manager to make additional efforts (for example, an internet search to locate a provider who had left the hospital) or to exclude the case. In the end, we decided to exclude 28 events from the survey. The reasons for exclusion were as follows:

- 16 were excluded because there was no communication with the patient. In 5 of these cases, the hospital tried to engage the patient in conversation but the patient refused or stopped responding to the hospital's invitations to talk. The remaining cases were mostly events that were flagged internally and reviewed to see if there was a problem with the care. When internal review revealed no problems, the case was closed. One case involved a psychiatric patient who engaged in self-harm. The hospital and the patient's care team decided not to communicate with the patient about the event in order to avert further harm. Although not all elements of the CARe process were delivered, these cases were retained in the sample of CARe cases because some elements were applied (i.e., the event was investigated and evaluated for possible compensation)
- 5 were excluded because no clinician participated in any communication with the patient. All communication was handled by Quality, Risk Management or Patient Relations.
- 5 were excluded because there was no involved provider available to survey. One of these cases involved an injury when a patient stepped on broken glass on the floor; two involved providers who had left the project hospitals and could not be located; and two involved care by providers who were not employed by the project hospitals (i.e., outside ambulance service, visiting nurse).
- 2 were excluded because the hospital could not identify the involved provider. These were patient falls in which the involved nurses were not identified. Ordinarily, nurse managers were able to supply that information, but the managers happened to have left the institution before we could ask.

Number of clinicians surveyed per CARe event. Our protocol allowed for the survey to be sent to up to 2 clinicians per CARe event, if risk managers felt more than one person had been closely involved with the case. This is why the total number of surveys sent, 270, exceeds the total number of events for which surveys were sent, 229.

<u>Clinicians involved in multiple CARe events</u>. Some clinicians were surveyed multiple times for different CARe events in which they were involved. Hence, the number of unique clinicians sent a survey (225) is less than the number of events for which surveys were sent (229); and the number of unique clinicians who completed a survey (162) is less than the total number of surveys completed (184).

# Appendix A2. Full text of the clinician survey questionnaire

 $\square$  No  $\rightarrow$  SKIP TO QUESTION 4.

2) Please indicate your agreement or disagreement with the following statements:

you described the unexpected care outcome?

□ Yes

# Communication, Apology and Resolution Program Provider Satisfaction Survey

In the Communication, Apology and Resolution Program (also known as "CARe"), risk managers, facility leaders, and insurance company representatives work with clinical staff to communicate with patients and families about unexpected care outcomes, rapidly investigate what happened and, in appropriate cases, offer compensation without waiting for a lawsuit to be filed.

In answering the questions that follow, please think about the most recent unexpected outcome in which you were involved that was handled by CARe.

1) Did you personally participate in a discussion with the patient or the patient's family members in which

During the discussion(s) I had with the patient and/or family about the unexpected care outcome, I or

	other representatives from my facility:					
		Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
a.	asked the patient/family what questions they had.					
b.	asked the patient/family what needs they had.					
c.	provided a sincere statement of regret (such as, "I am sorry this happened").					
d.	provided an apology of responsibility (such as, "I am sorry for the error").					
f.	explained our role in the event.					
g.	set expectations with patient/family about what would happen next.					
h.	explained what would be done to prevent the event from recurring.  Note: If the event wasn't preventable, check this box and go to the next question:  Not Applicable					

3)	outcome?	from 1 to	10 below	, where 1		` '	-			anexpected care atisfied," please
	Extremely dissatisfied									Extremely satisfied
	1	2	3	4	5	6	7	8	9	10
hel	☐ Not vo ☐ Some ☐ Very i	all familia ery familian what familian familian ow, the term CARe pro	r. c. ar. m <b>Progra</b> gram (for	ım repre	sentative(s					teracted with that patient
5)	How satisfied the discussion								tatives ii	n preparing for
	☐ I did no	ot receive a	ny assista	ince.						
	Extremely dissatisfied		-							Extremely satisfied
	1				5				9	10
	OI	otional: W	hy?							
6)	Overall, how s	satisfied wo	ere you v	vith your	interactio	ons with P	rogram r	epresenta	tives?	
	☐ I did no	ot have any	direct in	teractions	with Prog	ram repres	sentatives.			
	Extremely dissatisfied									Extremely satisfied
	1	2	3	4	5	6	7	8	9	10
	O <sub>l</sub>	otional: W	hy?							
7)	How satisfied	were you v	with <u>how</u>	long it to	ook to reso	olve the ev	ent with	the patien	t/family	?
	☐ I don't	know how	long it to	ok to reso	olve.					
	Extremely dissatisfied									Extremely satisfied
	1	2	3	4	5	6	7	8	9	10
	OI	otional: W	hy?							
8)	Overall, how f	airly did P	rogram	represen	tatives tre	at <u>the pat</u>	ient/famil	<u>y</u> ?		
	☐ I don't	know enou	gh about	it to ansv	ver.					
	Extremely unfairly									Extremely fairly
	1	2	3	4	5	6	7	8	9	10
	Or	otional: W	hv?							

outcomes	2 Optional: Vow supportive				6	7	8	9	<b>fairly</b> 10
O) Overall, h outcomes  I d  Extremel unsupport	Optional: V	Why?			V	,	_		
outcomes  I d  Extremel unsupport	ow supportiv								
outcomes  I d  Extremel unsupport		70 0 PO 37011							
Extremel unsupport		e are you	of using t	the CARe	process to	try to re	solve una	nticipate	d care
unsupport	on't know end	ough about	t it to answ	ver.					
1	ve								Extremely supportive
1	2	3	4	5	6	7	8	9	10
	Optional: V	Why?							
help us un	derstand the	experienc	ees of diffe	erent grou	ips of pro	viders, ple	ease provi	de some	information
		mal magitic	9						
□ Ph	<b>our professio</b> ysician	-							
	ysician traine ident (medica			fellow)					
☐ Nu	rse (RN, LPN	I/LVN, nu		etist, nurse	practition	er, or nurs	e midwife	·)	
	ysician assista de (nursing or								
□ Те	chnician (labo		R, radiolog	gy, or other	r)				
	erapist armacist								
☐ Ot	her, please sp	ecify:			_				
-1 ***									
3) What is y □ M									
☐ Ot	her, please spo	ecify:			_				

15)	What i	is your race? (Check all that apply.)
		American Indian or Alaskan Native
		Asian
		Black or African American
		Native Hawaiian or Other Pacific Islander
		White
16)	To wh	ich age group do you belong?
		Under 35
		35-44
		45-54
		55-64
		65 or higher
17)	What i	is your clinical specialty? (Please write in.)

THANK YOU for your response.

### Appendix A3. Additional detail on CARe program design and implementation

# **Setting**

CARe Pilot sites consisted of two urban academic medical centers, Beth Israel Deaconess Medical Center (BIDMC), and Baystate Medical Center (BMC), and four of their affiliated community hospitals. BIDMC is a level 1 trauma center and Harvard Medical School teaching hospital in Boston, Massachusetts with 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. It has 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.

Table A1 displays the study components in which each site participated. For each study event, BIDMC and BMC contributed case-level information in a detailed form in REDCap (the "Long Form"). BF and BML completed a pared-down version ("Short Form") to protect their risk managers' time. BIDM and BIDN did not contribute case-level data because institutional review board review was unavailable there. All sites participated in monthly implementation check-in calls and key informant interviews.

Table A1. Study Components in Which CARe Sites Participated

Site	REDCap Data	Cases Entered	Implementation	Interviews
	Collection	into REDCap	Check-In Calls	
BIDMC	Long Form	451	Yes	Yes
BIDM	None	0	Yes	Yes
BIDN	None	0	Yes	Yes
BMC	Long Form	474	Yes	Yes
BF	Short Form	30	Yes	Yes
BML	Short Form	36	Yes	Yes

# **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. <sup>1</sup>

The CARe project was initiated and led by the chief quality officers at BIDMC and BMC and the former president of the state medical association.<sup>2</sup> 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 (<a href="www.macrmi.info">www.macrmi.info</a>) 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 180 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," meaning 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 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.

### Appendix A4. Additional detail on CARe Process

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" (Figure 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 standard of care met? If not, 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" (Figure 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 standard of care was met, 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

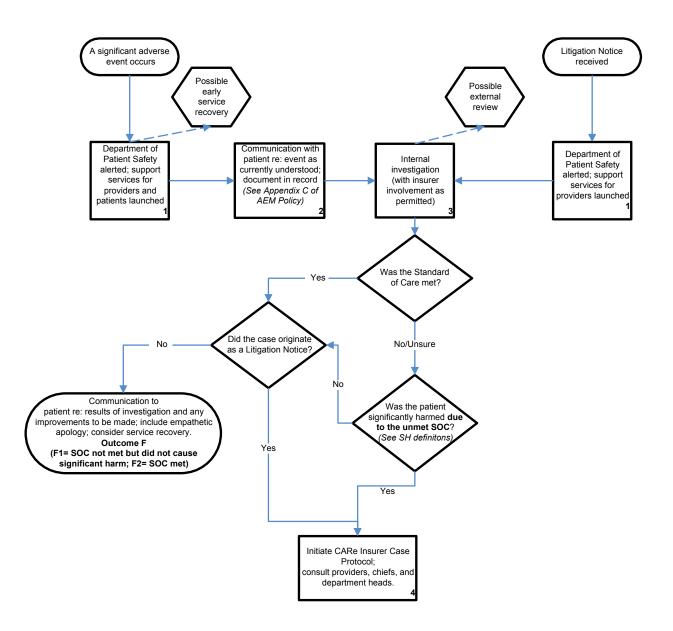
are also relayed to the patient during the resolution meeting.

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.

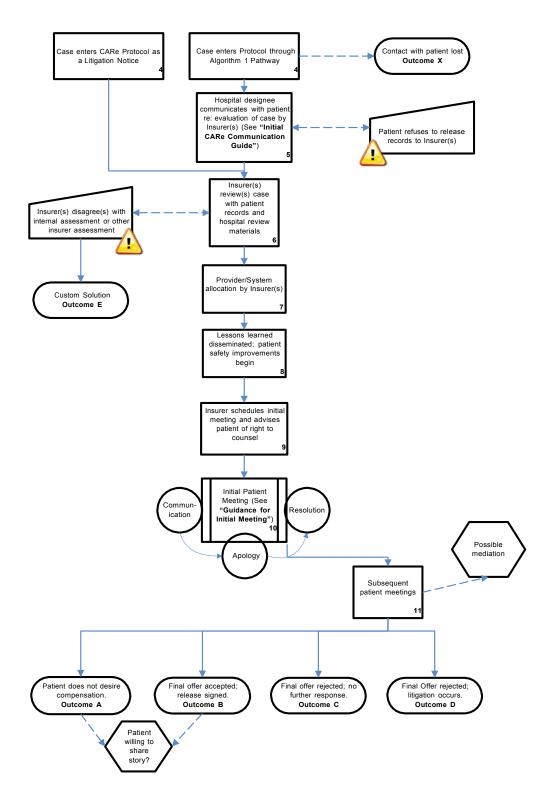
The CARe process is formally closed when risk managers judge that no further outreach to the patient/family is necessary, appropriate, or likely to be fruitful. For instance, risk managers may terminate the process after the family requests that the hospital stop contacting them, or after several unanswered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

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



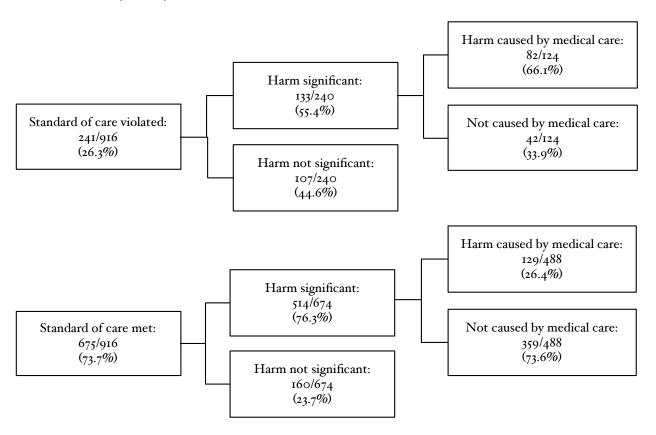
© 2013 Massachusetts Alliance for Communication and Resolution following Medical Injury

Figure A2. CARe Process Algorithm: Insurer Review and Follow Up



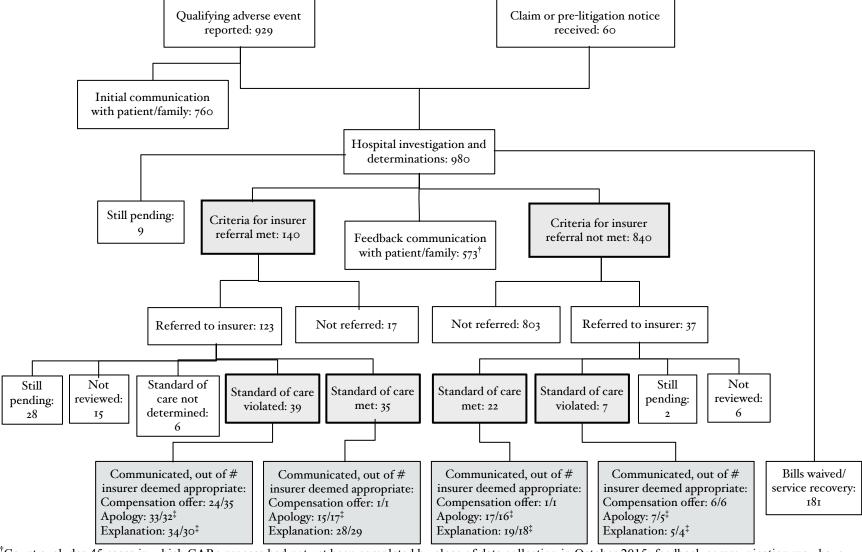
# Appendix A5. Graphical presentation of hospitals' determinations in CARe cases

Figure A3. Hospitals' Determinations About Standard-of-Care Violations, Harm Severity, and Causation (n=916)<sup>†</sup>



<sup>&</sup>lt;sup>†</sup>Sample size is 916 rather than 989 because exhibit excludes 14 cases not reviewed by the hospitals (9 still pending review, 5 referred directly to insurer because they entered the study as pre-litigation notices) and 59 cases for which the hospital could not reach a standard-of-care determination. Among the 916 cases shown are 2 cases in which hospitals could not reach a determination about harm severity and 35 cases in which they could not reach a causation determination. Causation judgments were not made for cases below the significant-harm severity threshold for compensation.

Appendix A6. Graphical presentation of the flow and resolution of events in the CARe program Figure A4

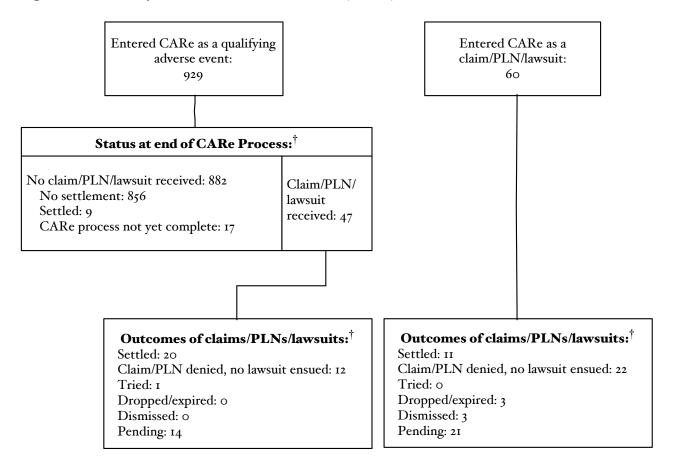


<sup>&</sup>lt;sup>†</sup>Count excludes  $\overline{45}$  cases in which CARe process had not yet been completed by close of data collection in October 2015; feedback communication may have occurred subsequently.

<sup>&</sup>lt;sup>‡</sup>Numerator includes some apologies and explanations that were communicated before the case was referred to the insurer.

# Appendix A7. Details of liability outcomes and other characteristics of CARe events

Figure A5. Liability Outcomes of CARe Events (n=989)



<sup>&</sup>lt;sup>†</sup>As of August 2016.

Table A3. Additional Details of CARe Event Characteristics (n=989)

	n	%		n	%
Hospital:			Adverse event type(s):		
A	474	47.9	Surgical/procedural complication <sup>b</sup>	341	34.5
В	449	45.4	Medical management	219	22.1
С	36	3.6	Diagnostic error/delay	154	15.6
D	30	3.0	Fall	98	9.9
Patient:			Obstetrical/neonatal complication	64	6.5
Female	519	56.2	Medication related	63	6.4
Age (mean, s.d.)	53.1	(23.9)	Cardiac/respiratory arrest	58	5.9
Race			Infection	52	5.3
White	667	86.3	Skin injury	35	3.5
Black	72	9.3	Self-harm/suicide/attempted suicide	13	1.3
Asian	33	4.3	Medical equipment/device malfunction	4	0.4
Native Hawaiian/Pacific Islander	1	0.1	Other	12	1.2
Hispanic ethnicity	91	11.1	Unable to determine	12	1.2
Primary involved clinician:			Injury severity (NCC-MERP score):		
Attending/emergency room physician	632	64.2	Death	169	17.2
Registered nurse	164	16.6	Permanent harm	70	7.1
Resident or fellow	48	4.9	Temporary harm requiring life-sustaining intervention	72	7.3
Anesthesiologist	34	3.4	Temporary harm requiring initial or prolonged hospitalization	236	24.1
Radiologist	29	2.9	Temporary harm requiring invasive medical procedure and/or	143	14.6
			$\geq$ 3 visits		
Other	78	7.9	Temporary harm requiring treatment or intervention,	156	15.9
			excluding those in the category above		
First reported to risk management by:			No physical harm <sup>c</sup>	135	13.8
Internal facility reporter	705	71.3	Depth of hospital investigation		
Patient/family	247	25.0	Extensive	389	39.8
Attorney for patient/family	32	3.2	Modest	563	57.6
Patient's insurer	4	0.4	None	25	2.6
State department of public health	1	0.1			

# Appendix A8. Risk managers' perceptions of the CARe process

Risk managers' impressions of the CARe process were elicited for each event at the academic medical centers. For most events, they disagreed with the statement that CARe required a lot of resources and time that the event didn't merit (mean rating 21.4 on 0-100 scale, where 100="totally agree"; s.d. 22.9). On the other hand, they did not consistently report that CARe sped time to resolution of the event (mean 43.7, s.d. 29.1), better enabled the hospital to preserve relations with the patient (mean 50.2, s.d. 28.6), spurred safety improvements that wouldn't otherwise have occurred (mean 36.1, s.d. 29.8), or avoided higher event-related costs (mean 26.5, s.d. 22.6). These impressions likely reflect the fact that most CARe events did not involve standard-of-care violations.

Asked to identify barriers to carrying out the CARe process, risk managers cited patient/family unwillingness to engage, unresponsiveness, or unavailability in 36 cases. Physician or insurer unwillingness to take necessary actions were named in only 3 cases. In 7 cases, free-text comments indicated that the family became angry when told there was no standard-of-care violation. In 14, risk managers commented on the difficulty of applying CARe to cases that began as PLNs or turned into PLNs midway through CARe. The hospital could no longer communicate directly with patients in such cases and attorneys were either unwilling to engage or slow to provide information. In 8 cases, early missteps in communication occurred (for instance, physicians wrongly stating that an error occurred), from which it was difficult to recover.

#### References

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- 2. Peto RR, Tenerowicz LM, Benjamin EM, Morsi DS, Burger PK. One System's Journey in Creating a Disclosure and Apology Program. Joint Commission Journal and Quality and Safety 2009;35:487-96.