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Ensuring successful implementation of communication-and-resolution programmes

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ABSTRACT

Background Communication-and-resolution programmes (CRP) aim to increase transparency surrounding adverse events, improve patient safety and promote reconciliation by proactively meeting injured patients' needs. Although early adopters of CRP models reported relatively smooth implementation, other organisations have struggled to achieve the same. However, two Massachusetts hospital systems implementing a CRP demonstrated high fidelity to protocol without raising liability costs.

Study question What factors may account for the Massachusetts hospitals' ability to implement their CRP successfully?

Setting The CRP was collaboratively designed by two academic medical centres, four of their community hospitals and a multistakeholder coalition.

Data and methods Data were synthesised from (1) key informant interviews around the time of implementation and 2 years later with individuals important to the CRP's success and (2) notes from 89 teleconferences between hospitals' CRP implementation teams and study staff to discuss implementation progress. Interview transcripts and teleconference notes were analysed using standard methods of thematic content analysis. A total of 45 individuals participated in interviews (n=24 persons in 38 interviews), teleconferences (n=32) or both (n=11).

Results Participants identified facilitators of the hospitals' success as: (1) the support of top institutional leaders, (2) heavy investments in educating physicians about the programme, (3) active cultivation of the relationship between hospital risk managers and representatives from the liability insurer, (4) the use of formal decision protocols, (5) effective oversight by full-time project managers, (6) collaborative group implementation, and (7) small institutional size.

Conclusion Although not necessarily causal, several distinctive factors appear to be associated with successful CRP implementation.

INTRODUCTION

Medical errors remain a leading cause of injury and death in the USA despite two decades of intensive focus on prevention.[1] Ensuring that healthcare facilities respond to adverse events in a compassionate way therefore remains a key priority. Communication-and-resolution programmes (CRP) have emerged as a leading approach. Through CRPs, healthcare facilities and liability insurers discuss adverse events with patients and families; provide psychosocial support to caregivers involved in the event; investigate; explain what happened; apologise; and where substandard care caused harm, disclose the error and proactively offer compensation.[2]

Interest in the CRP approach has spread rapidly.[3] From its origins in the Lexington, Kentucky Veterans Affairs Hospital and the University of Michigan Health System, the model spread to an initial handful of early adopters, all academic medical centres (AMC).[4] From there, demonstration projects supported by the Agency for Healthcare Research and Quality (AHRQ) tested it in new settings, including free-standing hospitals and multispecialty clinics.[5] With AHRQ funding, an implementation toolkit (called Communication and Optimal Resolution, or CANDOR) was developed to scale the approach nationally.[6] Today, more than 200 hospitals have commenced CRP implementation.[7]

Positive results reported by early adopters inspired optimism about the benefits of CRPs[4 8–10]; however, the experiences of several other organisations have been sobering.[7 11–13] Despite best efforts, some were unable to overcome barriers to implementing CRPs as envisioned, at least in the short term.[3] A summary of implementation experiences in 200 hospitals concluded that there was 'significant variability in the degree to which organizations have implemented the components of a comprehensive CRP'.[7] Among five New York City hospitals, for example, all reported improvements in adverse event reporting and communications with patients but none consistently

provided compensation proactively.[11 12] Compensation was offered in only one in six CRP cases judged to involve a standard-of-care violation that caused harm, because the CRP did not change compensation practices except by strengthening efforts to settle 'slam-dunk' cases involving clear error, serious harm and a complaining family.[12] In Washington State, six facilities implementing CRPs 'experienced small victories in resolving particular cases' but 'were unable to successfully implement a collaborative CRP'.[13] They demonstrated considerable hesitancy to actually apply the approach, putting only 30 events into the CRP process over 20 months.[13] Only one hospital reported that its compensation practices changed.

In contrast, two hospital systems in Massachusetts had positive experiences implementing a CRP known as Communication, Apology and Resolution (CARe).[14] As previously reported,[2 15] they implemented the CRP with high fidelity, with positive results on key success measures (details in online supplementary appendix sections A1 and A2). What factors may account for the Massachusetts hospitals' ability to surmount obstacles to successful CRP implementation when other institutions have struggled? Drawing on key informant interviews and documentation from structured meetings over 2 years, we identify factors that facilitated implementation.

METHODS

The CARe programme

The aims of CARe are to enhance communication surrounding adverse events, improve patient safety, support clinicians in disclosing adverse events, and reduce lawsuits and promote reconciliation by proactively meeting injured patients' needs.[2] The programme was implemented at two large, urban AMCs in Massachusetts, Beth Israel Deaconess Medical Center and Baystate Medical Center, and two of each centre's community hospitals (table 1; online supplementary appendix sections A3).[2]

The day-to-day operations of CARe were carried out by the hospitals' risk management departments, which were supported by a full-time, on-site project manager at each hospital system. The programme's creation and implementation were led by the chief quality officers at the AMCs and a former president of the state medical society. These physicians founded and received ongoing assistance from a coalition of stakeholders known as the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI).[16] CARe was evaluated by a team led by academic researchers.[2]

CARe's key elements were incorporated into a formal protocol including decision criteria and pathways (table 2; online supplementary appendix section A4). Following an internal investigation, the hospital decides whether or not to refer the event to the liability insurer or self-insured claims unit (both of which we call the 'insurer' for simplicity) for possible compensation. Risk managers and designated clinicians make the referral determination based on prespecified criteria—either the investigation indicated that a standard-of-care violation may have caused significant harm or the event entered CARe as a statutorily required prelitigation notice.[2] Following insurer review, a meeting is convened with the patient/family (and both parties' attorneys, if desired) to discuss a resolution.

Table 1 Participating hospitals, insurers and individuals*

Identifier	Description	Participating individuals, n		
		Baseline interviews	Final interviews	Conference calls
Insurer	A risk retention group that insures a group of academic medical centres for professional liability.	2	1	0
BIDMC	A not-for-profit academic medical centre system in eastern Massachusetts. BIDMC's liability insurance carrier is Insurer. Insurer also provides insurance for most of the physicians who practise in BIDMC hospitals.			
BIDMC-1	A 672-bed, level I trauma centre in an urban area.	2	2	11
BIDMC-2	An 88-bed, acute care general hospital in a suburban area.	3	3	3
BIDMC-3	A 58-bed, acute care general hospital in a suburban area.	2	2	6
Baystate	A not-for-profit academic medical centre system in central and western Massachusetts. Baystate self-insures its hospitals and employees and offers optional insurance to affiliated community physicians and practices. Risk management functions are carried out at the hospital level, but central administration plays a major role in claims management.	1	2	2
Baystate-1	A 716-bed, level I trauma centre in an urban area.	6	5	3
Baystate-2	A 90-bed, acute care general hospital in a suburban area.	2	2	5
Baystate-3	A 25-bed, acute care general hospital in a suburban area.	2	1	2
Total		20	18	32

Participants in the row for 'Baystate' worked across all three Baystate hospitals. Two participants shown in the row for Baystate-2 also performed work for Baystate-1. Two participants from the Insurer were interviewed together at their request.
*Hospital characteristics are reported as of the time the study was completed.
BIDMC, Beth Israel Deaconess Medical Center.

Table 2 Description of the CARe process

CARe process element	Key steps in CARe protocol
1. Communicate with the patient* when an adverse event occurs.	▶ Clinicians, patients or attorneys alert the risk management office when an adverse event occurs. ▶ Risk management activates support services for the involved clinician(s) (offer of communication coaching and peer support). ▶ Communication with the patient about the event takes place and is documented in the medical record.
2. Investigate why the event occurred.	▶ The hospital, led by risk management or patient safety, conducts an internal investigation, which may involve multiple departments and external review. ▶ The hospital reaches a determination about whether the event satisfies the CARe compensation criteria: temporary-severe harm or greater; causally related to medical care; and attributable to a deviation from the standard of care. ▶ If the criteria are met, or if the event came to the hospital's attention as a prelitigation notice, the event is referred to the hospital's insurer. ▶ The insurer conducts its own review of whether CARe compensation criteria are satisfied, incorporating information from hospital's review, medical record and (as needed) other external reviews. ▶ Hospital and insurer identify patient safety lessons. ▶ Hospital and insurer discuss the approach to resolving the event with the patient.
3 Communicate investigation findings to the patient, apologise and, where appropriate, offer fair financial compensation without the patient having to file a claim.	▶ Hospital and insurer representatives communicate investigation findings to the patient, ordinarily in a face-to-face meeting, after advising him/her that they may involve legal counsel. ▶ Patient is offered an empathetic apology appropriate to the situation. ▶ Patient is asked what his/her needs and concerns are. ▶ Patient is offered compensation if criteria were met. In addition, or as an alternative where compensation criteria were not met, 'service recovery items' (eg, meal vouchers, medical bill waivers) may be offered as gestures of goodwill. ▶ Multiple meetings may be held as needed to work towards resolution.
4. Implement measures to avoid recurrences of the event.	▶ Hospital feeds patient safety lessons identified in the investigation into its quality and safety improvement system for further action.

*Communications may also include the patient's family, as appropriate to the situation.
CARe, Communication, Apology and Resolution.

Data

The academic research team synthesised data from two sources. First, key informant interviews were conducted in the first 2–6 months after CARe implementation and at project's end. CARe leaders at each site were asked to suggest up to four individuals who played (or were likely to play, for baseline interviews) an important role in the implementation or administration of CARe. Two to four interview participants from these lists were recruited by email from each hospital and the liability insurance organisations. Semi-structured interviews were conducted by one of three interviewers (MMM, AK and YG) (one female investigator, one male investigator and one female research assistant, all of whom were unacquainted with most participants at the time of the baseline interviews). Interviewers followed an interview guide (provided in online supplementary appendix sections A5 and A6) that contained open-ended questions concerning the hospital's policies and procedures regarding adverse event response and claims management, participants' expectations or experiences concerning CARe implementation, perceptions of how successful or unsuccessful implementation had been and factors that participants believed had facilitated and jeopardised successful implementation. These questions (and more specific probes) were informed by the academic researchers' prior interview studies of CRP implementation efforts at several other organisations. Interviewers calibrated their styles by listening during one another's early interviews. Interviews were conducted by telephone, lasted 30–45 min and were transcribed.

The second data source was detailed notes on implementation progress taken during 89 conference calls held approximately monthly among study team members, risk managers, quality managers and project managers for each hospital. The purpose of the calls was to share information about implementation challenges and brainstorm solutions. One academic investigator with experience leading hospital quality improvement initiatives (AK) led the calls and research assistants (YG and SR) took notes.

Interview transcripts and call notes were coded and analysed by one investigator (MMM) using standard methods of thematic content analysis.[17 18] The initial coding guide was based on the interview guide and codes used in two prior studies of CRP implementation,[12 13] and refined following analysis of the first five interview transcripts.

Limitations

The number of interviews conducted within each hospital was small, though it included a large proportion of the key personnel responsible for CARe implementation. The academic researchers did not directly observe CARe implementation within the hospitals, and interview responses could reflect self-serving bias, conscious or unconscious. Information from conference calls, a less formal setting in which candid discussion flowed freely, provides some check against such bias. Finally, though they did not work at the CARe implementation sites, the academic researchers were not fully independent of MACRMI.

Table 3 Roles of interview and conference call participants

Role	Participating individuals, n		
	Baseline interviews	Final interviews	Conference calls
Hospital leader (eg, chief medical officer, chief operating officer, senior vice president for quality)	10	7	5
Risk manager	5	6	20
Patient relations leader	1	1	2
Project manager	1	2	3
Insurer representative	3	2	0
Quality representative	0	0	2
Total	20	18	32

RESULTS

Participants

Forty-five individuals participated in interviews (24 persons in 38 interviews), conference calls (32 persons) or both (11 persons) (table 1). The interview completion rate was 88% (38 of 43 interview invitations issued). Among the 24 persons interviewed, 14 completed two interviews and 10 completed one (nine of these joined or left the hospital staff during the project and one did not respond to an invitation). Participants' roles are detailed in table 3.

Factors facilitating successful implementation

Participants identified seven factors that facilitated successful implementation of CARe (table 4).

Support from top institutional leaders and risk managers

Clinical and non-clinical leaders at the highest levels of each hospital made their support for and commitment to the CARe programme clear from the outset and sustained it throughout implementation. In particular, participants emphasised the importance of leadership by two highly regarded physicians with leading quality roles in the hospital systems. These physicians championed the programme, spearheaded implementation and made its success a personal priority. They cultivated the support of the hospitals and insurers' chief executive officers and boards of directors, as well as chairs and quality improvement leaders of large clinical departments. Those individuals' support for CARe reportedly strengthened over time, particularly that of powerful department chairs, who became more active champions after an adverse event in their department got their 'tires into the grit'.

In all but one hospital, these two champions also obtained risk managers' firm commitment to CARe early on. In one system, implementation was reportedly 'adrift' until a newly hired risk management director took 'very seriously' the message from a senior leader that 'he wants this to work'.

Heavy investments in engaging physicians

Engaging clinical staff, especially physicians who are 'not part of the infrastructure' because they are not hospital employees, was perceived as an important precondition for success. CRP teams treated clinical staff education as a continuing responsibility. 'It seems to need to be constantly reinforced,' a leader at a large hospital remarked. At the large hospitals, teams were 'relentless' about going department to department to present the programme and answer physicians' questions. Even with extensive effort, some respondents reported that physicians' awareness of CARe remained suboptimal.

Outreach efforts were important to make physicians aware of what the programme had to offer and to allay anxieties about the potential consequences of disclosure and compensation offers. A chief concern was having a settlement reported to the National Practitioner Data Bank (NPDB), a national repository of paid malpractice claims. 'You've got folks who are still older-school: "Don't share stuff, because that's when bad things happen",' a leader of a large hospital commented, 'So we're constantly talking about the evidence' regarding the effects of CRPs on malpractice risk. According to a leader of a small hospital, over time, physicians who had gone through the CARe process began to share their positive experiences during educational sessions and 'sell it with their own stories … that's where the buy-in from the medical staff has been'. By project's end, respondents consistently reported that physicians' anxieties about CARe had decreased as comfort with the process had grown.

Active cultivation of relationship with insurer

Hospitals in both systems faced the challenge of fully engaging their insurers in the CARe approach. CARe represented a 'huge culture change for claims people', 'flipping on their heads everything they learned through their careers'. Claims staff who were 'used to defending a doctor' now had 'to be thinking about this from a system perspective and patient and family perspective'. In one system, insurer personnel initially projected an attitude of 'nervousness' and 'skepticism'. However, over time they embraced the approach as hospital staff actively worked to cultivate their relationship with insurer staff and the two groups made efforts to see things from one another's perspectives and bridge differences in their approaches to adverse event response.

As claims managers' collaboration with risk managers and trust in one another strengthened, insurers shifted their frame 'beautifully'. Also influencing insurer representatives' perspective were a growing sense that 'clinicians seem to want to move in this direction' and dissipating concerns that 'the financial sky is going to fall'. CRP teams viewed the insurer's attitudinal shift as critical because proactive compensation cannot be delivered without the insurer's agreement.

Table 4 Factors facilitating successful implementation of CARe programme

Facilitator	Illustrative quotations from interviews and conference call notes
Support from top institutional leaders and risk managers	► 'I think that there's a very strong commitment in this institution to the CARe programme and to the process and to doing the right thing for our patients and our providers. I don't question that at all. The commitment is clear.' (Baseline interview, small hospital) ► 'You've got to have somebody who's got boots on the ground …. who's going to direct this and take ownership and make sure that it's going to happen. … If you look at [senior clinical leader], he *clearly* takes ownership of this for this hospital. … People have to *own* the challenge to make it happen or it's just going to fizzle away.' (End-of-project interview, large hospital)
Heavy investments in engaging physicians	► '[Project staff member] kept a list of every single clinical department and *was relentless* about asking us, "Did we get to that clinical department?" …[Y]ou really need that. It's like a political campaign.' (End-of-project interview, large hospital) ► 'Extensive education throughout organization for medical staff—during CME and medical committee meetings, as well as communication to those who could not attend these. Several sessions for non-medical staff; approximately 90% are apprised of program. Greatest concerns [are] from medical staff and what it would mean for them.' (Conference call notes, small hospital) ► 'It seems to need to be constantly reinforced. … We have posters. We have cards that go on people's badges. … It's part of the orientation of every new provider and certainly of our residents … So the education piece is ongoing and very necessary to keep the awareness on the front burner….' (End-of-project interview, large hospital)
Active cultivation of the relationship between hospital risk managers and insurer representatives	► 'That "Yes, we really are potentially going to pay a lot of money in a situation where we have no letter from an attorney," that's a *big* cultural change. … It has to have the insurance company standing right by your side.' (End-of-project interview, small hospital) ► '[Hospital representatives] have a very, very good relationship with the claims reps and they trust each other. I feel like without that, it would be really hard to do this. The relationships have a lot to do with it.' (End-of-project interview, large hospital) ► 'It's more of a collaborative relationship that only works I think because there's mutual respect for our assessments and for their assessments. We can have what I consider to be sometimes heated but scholarly discussions about each particular case.' (End-of-project interview, large hospital)
Use of formal decision protocols and structures	► 'I think the objective classification of harm was very helpful. …That NCC MERP scale has just been adopted across the organization. … You've got to be objective. … The algorithms are important. It's nice to be able to go back and have this not be "Because A said so" that this is the case, but it's like, the algorithm. … "this happened and it is this harm severity".' (End-of-project interview, small hospital) ► 'There's a weekly huddle that happens between the quality, [insurer], and risk folks so in a sense they can run their cases: "What do you know? What do I know?"' (End-of-project interview, small hospital)
Oversight and assistance from project managers	► 'They are keeping my staff … to task with the communications. They'll say, "Do you think we've met the standard of care on that one?" And they're just riding, they're riding them.' (End-of-project interview, large hospital) ► 'Like so many things in healthcare, you spend your day dealing with the firefighting and the tyranny of the urgent. Unfortunately this [CARe] requires some maintenance and a steady rhythm … [project manager was instrumental in] sustaining that commitment to us all getting together to talk … And pushing out and writing the brochures and writing up the best practices. … If we'd had to write them or pull ourselves together to create it, it wouldn't have happened.' (End-of-project interview, small hospital) ► 'I don't think we can just leave it up to the risk managers and claims [managers]. We're going to need somebody that sort of is the glue between them.' (End-of-project interview, large hospital)
Group implementation	► 'It has been helpful to be doing this alongside other institutions. The shared learning and the ability to discuss situations with other institutions was very helpful, especially other local institutions who understand the state systems and the other state entities. … I would encourage others to think strongly about that model just because there's a lot of times when it's not in the manual what you should do next or what's the right way to approach a case." (End-of-project interview, large hospital) ► 'I think a whole group of people that really believe in it, I think that's what carries us on.' (End-of-project interview, small hospital) ► 'The [hospital] system, CARe and the MACRMI initiative coming together, other facilities and learning from them in terms of how CARe approached various events that might occur, that was helpful. That was supportive.' (End-of-project interview, small hospital)
Small hospital size	► 'I think if you were in a big 180-bed hospital and people don't know each other by their first names and it hasn't got that sort of small-family feel, I think in fact it would be tougher and you would need a larger army of disciples.' (End-of-project interview, small hospital) ► 'We all really know each other well. …To do something it doesn't take up and down the chain of command like it would at a larger organization sometimes. Just our smaller size where folks are seen, we're visible, we're out there. … But that said, we have the incredible support of [the hospital system and AMC].' (End-of-project interview, small hospital) ► 'The benefit of [small size] is that it is a core group of individuals … It also allows us to move cases much more quickly. … The benefit as well is that when you have a contact person from the patient to the hospital, they [patients] become familiar with that person. They have a connectedness to that person. They learn to trust you.' (End-of-project interview, small hospital)

AMC, academic medical centre; CARe, Communication, Apology and Resolution; CME, continuing medical education; MACRMI, Massachusetts Alliance for Communication and Resolution following Medical Injury; NCC MERP
, National Coordinating Council for Medication Error Reporting and Prevention.

One initial difference in philosophy related to the handling of 'grey cases'—those where the hospital's liability was unclear. Hospital representatives reportedly took the view that for minor injuries, 'they should just compensate quickly' to 'make it right', while insurers felt more obligated to balance the patient's needs against those of the clinicians and hospital. Respondents consistently conveyed, however, that once they had completed their review, disagreement about whether compensation was appropriate rarely persisted.

Another difference related to the speed of decision-making. Conference calls in the first year of implementation evince repeated discussion of delays while the insurer reviewed a case. Through group discussion, risk managers developed solutions for improving communication with the insurer and conducting better 'co-management of cases'. Insurer representatives were reportedly 'responsive', leading to 'a big shift' and 'increase in trust' over time. Although the slow pace of insurer review remained frustrating to some hospital personnel at project's end, most felt it had

improved, and the insurer felt hospital staff had better 'appreciation of how complex it can be'.

Use of formal decision protocols and structures

Along with the MACRMI coalition, the implementing teams created formal processes and structures that facilitated the smooth operation of CARe. These included two flow charts: one defining which types of events should be handled through CARe and outlining response steps, and a second describing steps when the hospital determines compensation may be appropriate (online supplementary appendix section A4). 'The algorithms are important,' one leader of a small hospital commented, because they make the process of deciding what resolution to offer more 'objective', with less room to wiggle out of determinations unfavourable to the hospital. Throughout the project, hospitals and project staff produced a range of other documents to strengthen CARe's protocol, such as timelines for each step and guidelines on how frequently to contact families and how to tell families their case would be considered for compensation.

Another innovation was the creation of standing meetings where individuals from different offices (eg, risk management, patient safety and the insurer) came together to 'run the list' of active CARe cases, share information and make decisions. This 'weekly huddle' helped ensure that cases moved along and steps were not missed, while also fostering closer relationships.

Oversight and assistance from project managers

Respondents repeatedly credited the study's two on-site project managers—who had business management training and were funded by the project grant—with ensuring that CARe was carried out as intended and helping the implementing teams integrate CARe into their routine workflow. Because CARe was their full-time responsibility, the project managers contributed 'a steady rhythm' that kept the programme on track while risk managers were pulled in many directions by urgent events. In conference calls, they provided guidance to risk managers (particularly at small hospitals) about how to operationalise steps in the CARe process.

Within hospitals, project managers participated in the meetings in which risk managers reviewed the status of cases and kept 'riding them' about whether decisions had been reached: 'What was the latest communication? Is there an update on Mr. Smith?' Rather than finding this intervention intrusive, risk managers appreciated the extra help to 'mak[e] sure we're not letting things fall through the cracks'. Many were surprised by how much their workload expanded under CARe, which occurred because they were reviewing events that they previously would not have and because their reviews were more extensive and involved more communication with providers and families. Some reported feeling 'overwhelmed' at times and 'running pretty much at much speed to keep up'; project managers were 'the glue' that brought them together and kept them focused on CARe's goals.

Group implementation

Respondents frequently mentioned that the experience of implementing CARe alongside other institutions in a collaborative environment had been helpful. Their comments centred on three aspects of the group experience: implementing the programme as a hospital system, implementing with another hospital system and working through the MACRMI coalition.

The most commonly cited benefit of group implementation was having a structure for shared learning. Conference calls gave participants a forum to discuss thorny problems presented by CARe cases for which 'it's not in the manual what you should do'. For example, when a patient has not responded to an invitation to meet, how persistently should risk managers try to reach her? Further, challenging situations were shared and solutions generated at regularly convened meetings of the hospitals, insurers and MACRMI leaders. For instance, the group discussed what to do if the hospital and insurer disagreed about compensability.

A second benefit of group implementation was creating an environment in which successes could be celebrated. Respondents noted that CARe implementation is 'a tough journey to travel on your own'; these conversations nurtured their sense that they were 'making a difference' and provided 'validation that you're doing the right thing'.

Third, group implementation was perceived to cultivate a shared culture of commitment to CARe and a sense of accountability. On conference calls, for example, discussions often centred on what patients want after medical injury and how the institutions' response could be patient centred. Documents developed by MACRMI and the hospitals reaffirmed the core principles of CARe. To enhance accountability, data from each hospital on the volume and outcomes of CARe events were shared at MACRMI meetings.

Small hospital size

A final facilitator cited by many community hospital participants was their small institutional size. Notwithstanding early concerns that small institutions might not have the resources to shoulder the workload of CARe, the small hospitals perceived their size as an advantage, while also acknowledging that they were able to draw on the 'bench strength' and 'incredible support' of larger institutions involved in group implementation of CARe, including the AMC in their system and MACRMI.

The key perceived benefit of small size was that a 'core group of experienced people' responded to adverse events. Because the number of adverse events was low, the small hospitals' top leaders, who had

deep knowledge of CARe, could be directly involved in responding to each and shepherding cases through the process. 'Usually when something happens, people know in seconds,' one leader said, and can 'get right to the bedside and start having conversations.' Making that connection quickly and providing a single point of contact reportedly facilitated the resolution conversations to take place down the line. Patients 'have a connectedness with that person,' another leader commented, so 'they learn to trust you.' Having a small cadre of people in charge also made it easier to implement new programmes and conduct event reviews swiftly without taking it 'up and down the chain of command', observed a risk manager.

Some respondents pointed out one other advantage: having fewer clinicians to educate about CARe made it easier to win their trust. Although they faced challenges in reaching physicians who were not hospital employees, risk managers 'got to know the leaders of the different departments pretty quickly' and physicians 'got to know their face'. Word of mouth also travelled quickly, and physicians who had had a positive experience with CARe helped win others over. A leader of a small hospital remarked that at a bigger facility 'you would need a larger army of disciples'. Although respondents from the bigger hospitals did not identify their large size as a barrier to CARe implementation in general, some did comment that extending educational outreach to all their clinicians was very challenging.

DISCUSSION

Implementing CRPs involves significant challenges, which healthcare organisations have had uneven success in surmounting.[3 7] Our evaluation of a successful CRP initiative in six Massachusetts hospitals identified seven factors that may enhance the likelihood that CRP implementation efforts will be effective: (1) support from top institutional leaders and risk management, (2) heavy investments in educating physicians, (3) active cultivation of the relationship between the hospital and the liability insurer, (4) use of formal decision protocols, (5) oversight and assistance from project managers, (6) implementation as part of a collaborating group, and (7) small institutional size.

These findings add to the growing literature on CRP implementation, which to date has focused more on identifying barriers than on how to realise the full benefits of CRPs.[4 7 12 13 19] Though our analysis does not definitively establish that the identified elements are necessary or sufficient for effective implementation, many of them directly address barriers identified in prior work on CRPs—such as lack of engagement of top leaders, minimal physician involvement and lack of a clear implementation plan. In addition, the factors identified were not present for hospitals that struggled with CRP implementation (eg, in demonstration projects in Washington State and New York City) but were for others that had a smoother experience (eg, University of Michigan). Also salient is that many of the identified themes are in line with quality improvement requirements in other domains of care.

For example, an oft-cited principle in leadership and change management is that success requires leadership engagement.[20] The Massachusetts hospitals, much like pioneer organisations such as University of Michigan, had strong support and engagement from top organisational leadership. Interview participants emphasised that it was important that the physician champions who spearheaded CARe's creation and adoption were highly respected clinical leaders who devoted substantial energy over a sustained period of time to ensuring the programme's success. In contrast, in the New York hospitals, some risk management and quality leaders vigorously championed the CRP but most top leaders were disengaged or openly unsupportive.[12] Whereas the CRP in Massachusetts was created at the initiative of the chief quality officers of the two hospital systems, in New York the CRP was designed and spearheaded by outsiders from the New York State Department of Health, and some hospital leaders had tepid enthusiasm for adopting it. In Washington, participants consistently described the top leaders at all six facilities as firmly supportive—but not active champions of the programme.[13] They were reportedly overburdened with responsibilities, including major organisational initiatives such as a new electronic health record, budget cuts and practice acquisitions—competing priorities that siphoned leadership attention. Collectively, these findings suggest that CRPs require unequivocal support and engagement from the highest levels of leadership.

In addition to leadership, ensuring key stakeholders are on board for any new effort is indispensable. In this evaluation, buy-in from liability insurers and physicians stood out as particularly critical. Because the insurer holds the purse strings, if it does not believe that proactive compensation is the right way to proceed, a CRP becomes impracticable. Recently, MedStar, a large hospital system, reported that it had actively worked to nurture its hospitals' relationship with their insurance carrier and 'formulate a more amiable relationship' in working CRP cases, with some success.[21] In contrast, a lack of insurer buy-in persisted in both the New York and Washington demonstration projects. In New York, insurers preferred to wait for a formal demand for compensation except in 'slam dunk cases' where liability was clear.[12] In Washington, one hospital worked diligently with its insurer to improve their relationship but the others could not move beyond past disputes. They reported that insurer representatives never embraced the CRP philosophy, which impeded alignment of compensation practices with CRP principles.[13]

Physicians are important stakeholders for CRPs because they are typically the ones who must have

difficult conversations with patients and are at risk of being sued and reported to the NPDB. At institutions that pioneered CRPs, extensive clinical staff education was viewed as a crucial and ongoing commitment over at least several years.[4 22] CRP leaders gave presentations about the programme at meetings of department chairs, quality officers and every department; education about the CRP was also included in the onboarding process for all residents and fellows and the programme was publicised using posters and brochures on the clinical floors, a website and employee badge cards. In contrast, during the Washington study, educational outreach was perceived as difficult or impossible because of risk managers' workloads, though work on this objective continues in the state.[13] In New York, hospitals did work to educate surgical departments about the CRP but regretted that they had done it too late.[12] Putting these experiences together, devoting significant resources to physician education and engagement appears to be a necessary component for successful implementation.

In a variety of quality improvement domains (eg, use of intravenous heparin, early recovery after surgery protocols), standardisation via protocol is a well-known tactic for reducing variability and improving outcomes.[23 24] Given the challenging steps involved in the CRP process—such as acknowledging liability for error—the risk for deviation from desired practice is high. To guard against this, the Massachusetts hospitals used a detailed algorithm to hold themselves accountable to the process and identify when they deviated. They reported that this practice substantially contributed to their success.

Pioneer institutions such as University of Michigan and University of Illinois at Chicago did not report that the use of formal decision protocols was essential to their success, but two created a new structure—multidisciplinary committees—to make decisions about compensation, and one developed flow charts to govern case management.[4 22] The New York and Washington hospitals used checklists to help ensure that the key elements of the CRP were applied to each eligible event, but did not go much beyond this.[12 13] New York risk managers resisted the idea that decision-making about adverse events was amenable to being guided by a protocol, maintaining that 'every case is individual'. In Washington, one facility quickly developed concrete protocols for implementing the CRP, but the others did so slowly or not at all. At project's end, multiple facilities in Washington advised others to develop detailed CRP protocols.

Developing protocols gave the Massachusetts hospitals a means of executing the programme and fostered collaboration. Group implementation was also employed in the New York and Washington projects, and large hospital systems that have adopted CRPs can also be characterised as using this approach.[7 21] The New York and Washington sites all reported benefits from group implementation,[12 13] but the Massachusetts hospitals appeared to develop a stronger *esprit de corps* than their forbears and received additional support from MACRMI.

Any institutional programme has a greater chance of success where a skilled manager provides strong oversight of its day-to-day operations, and the CRPs in Massachusetts were no exception. In addition to committed risk management leaders, the presence of dedicated, full-time project managers reportedly facilitated CARe's success. Three earlier CRP adopters did not arrange for comparable staffing and nevertheless reported successful implementation, but at two of them, risk management leaders devoted a significant portion of their time to serving as CRP coordinator, and all sites noted that the CRP involved increased workload.[4] The New York and Washington projects both provided project managers to assist the implementing hospitals, but unlike the project managers in Massachusetts, they were not embedded within the hospitals. Rather, they were employed by the Department of Health and a university, respectively. Despite extensive effort, as outsiders they experienced constraints on their ability to influence hospitals to change their practices.[12 13] Risk managers in the New York and Washington projects reported substantial increases in their workloads and recommended allocating 0.5–1.0 FTE of dedicated staff time to running the CRP.

Although they did not emerge as themes in our analysis of interview and call notes, three environmental or contextual factors may help explain the relative success with implementation in Massachusetts. First, because the hospitals did not rely heavily on staffing models using independent physician groups, most CARe cases were handled by a single insurer. The hospitals in Washington State, in contrast, routinely had to navigate collaborations across insurers, and found that in some cases the facility's insurer was committed to the CRP process but the insurer for an involved physician was not.[13]

Second, compared with earlier adopters, the Massachusetts hospitals had more information available when they launched their programmes. Reports of the experiences of more than a dozen organisations adopting CRPs were published and MACRMI performed a pilot study exploring stakeholders' views of potential barriers to CRP implementation in Massachusetts and addressed these barriers in preparing for implementation.[19]

One element of MACRMI's effort involved spearheading a successful initiative to get state legislation passed to require adverse event disclosure, protect statements of apology and impose a 180-day 'cooling-off' or prelitigation notice period before malpractice claims could be formally filed.[25 26] This legislation constitutes the third factor that may have facilitated the successful effort in Massachusetts. In general, CRP

participants in Massachusetts, New York and Washington had mixed views about whether and how the state's liability environment affected the prospects for successful CRP implementation: some felt that a volatile environment made physicians too frightened of the potential consequences of disclosure and proactive compensation offers, while others believed it generated a hunger for alternatives to litigation. But there was no disagreement that a prelitigation notice law was helpful in creating the space for CRPs to do their work.[3] CRPs in California and Massachusetts benefited from such laws, while those in Illinois, Washington and elsewhere did not.

Despite diligent and energetic efforts, organisations seeking to implement CRPs have not uniformly had smooth implementation experiences. Consistent success becomes more likely, however, as new entrants to the field glean more and more from the experiences of earlier adopters. Useful tools now exist to help organisations interested in implementing CRPs assess gaps in their policies, processes and culture that may jeopardise successful implementation if not addressed.[3 6 7 27 28] An initiative underway to develop metrics for gauging CRPs' performance[3] should further assist new adopters as they work to ensure careful attention to implementation fidelity. The Massachusetts hospitals' experience expands this bank of knowledge, highlighting tangible actions for organisations to consider taking to successfully deliver on the promise of CRPs. Collectively, these learnings provide both concrete lessons and general cause for optimism about the prospects for CRPs to transform healthcare organisations' response to medical injury on a broad scale.

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

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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.

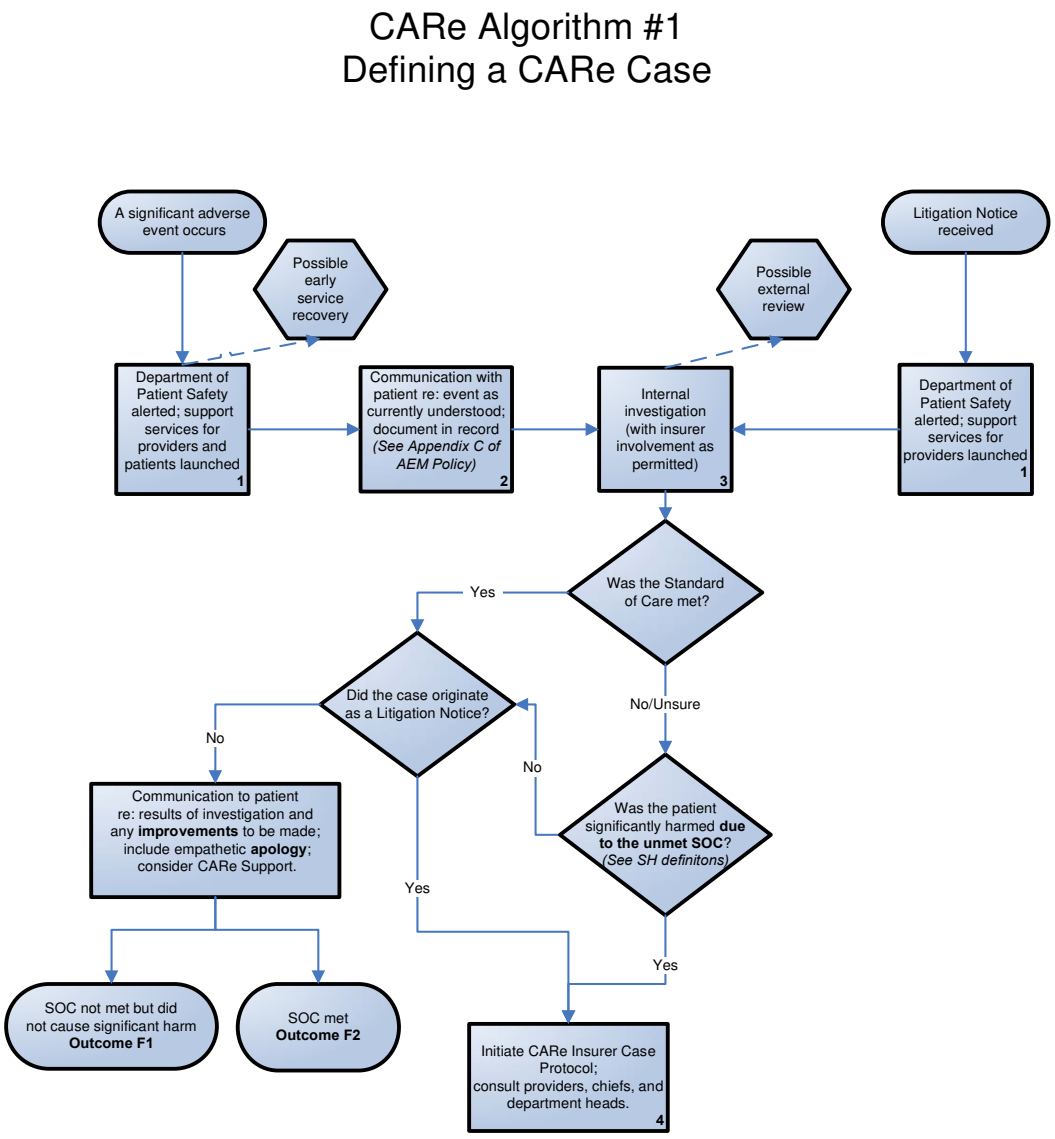
Resolution meetings may result in a settlement offer being accepted and a release of claims signed, or a service recovery offer being accepted without a release of claims. They may lead to a longer process of negotiation, or to an outright rejection of the offer. It may or may not be apparent at this 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.

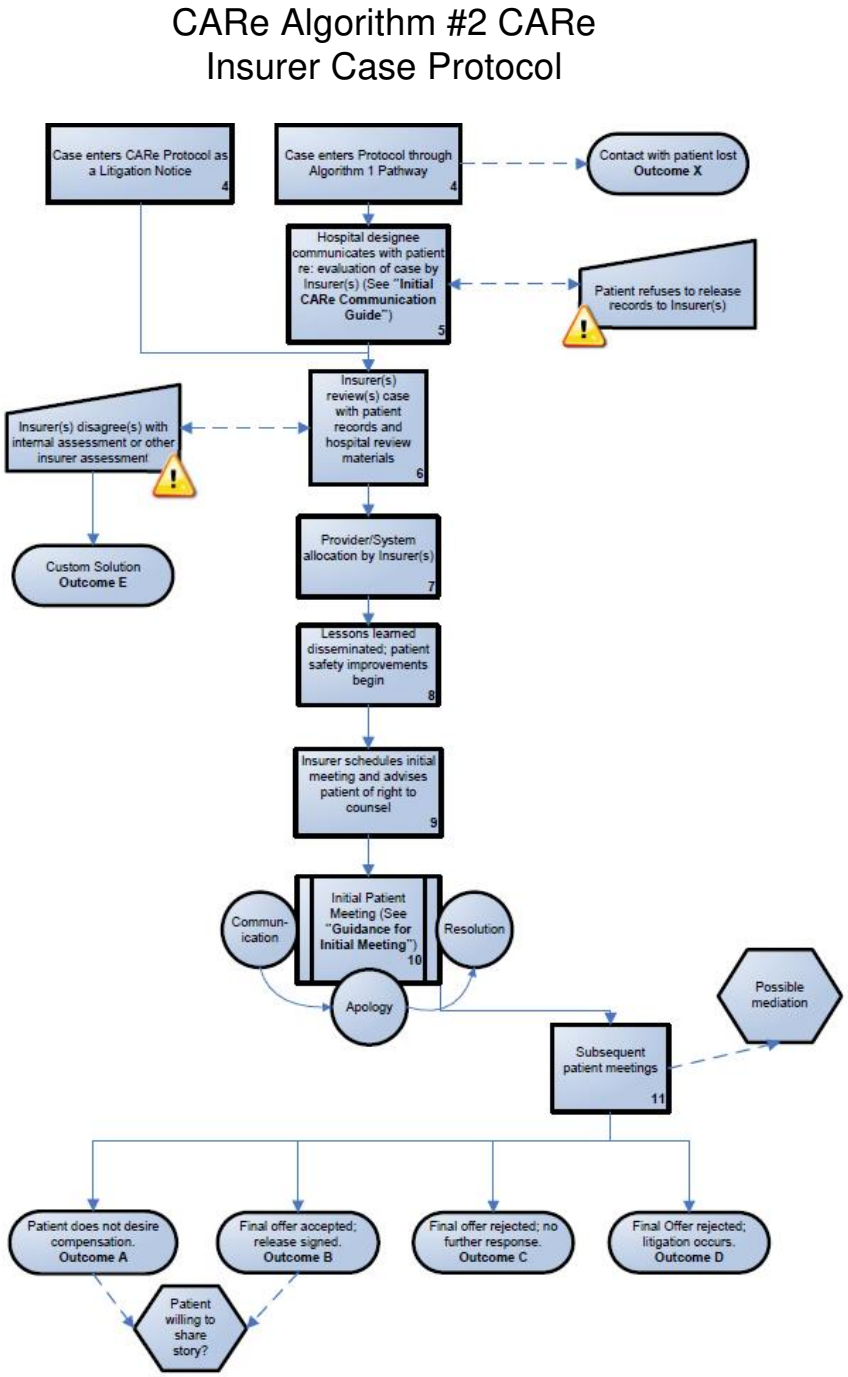
Mello MM, *et al. BMJ Qual Saf* 2020;0:1–10. doi: 10.1136/bmjqs-2019-010296

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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