Collaboration with Regulators to Support Quality and Accountability Following Medical Errors: The Communication and Resolution Program Certification Pilot

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Objective. Communication and resolution programs (CRPs) involve institutions responding to adverse events using transparency with patients, event analysis, recurrence prevention, and compensation. Collaboration with regulators around CRPs could enhance health care quality.

Setting and Participants. Health care institutions, liability insurers, and the Medical Quality Assurance Commission (MQAC, board of medicine) in Washington State.

Study Design. MQAC has collaborated with the Foundation for Health Care Quality (FHCQ) on the CRP Certification pilot. A panel of physicians, risk managers, and patient advocates at FHCQ will review cases for use of the CRP key elements. Cases meeting this standard will be “CRP Certified.” If MQAC determines that the CRP enhanced patient safety comparable or better than board action, the Commission may close the case.

Principal Findings. Developing this process identified the following issues: (1) protecting information submitted for CRP Certification; (2) determining what information the Commission needs to assess whether additional investigation is warranted; (3) preserving the Commission’s responsibility to protect the public while working with health care organizations; and (4) addressing concerns that CRP Certification not shield incompetent providers.

Conclusions. The CRP Certification program is a promising example of collaboration among institutions, insurers, and regulators to promote patient-centered accountability and learning following adverse events.

Key Words. Regulation, legal liability, quality assurance, disclosure, medical errors

From the public's perspective, among the most important entities overseeing the quality of health care are state medical boards. The public acts through elected officials to create state medical boards and develop the rules governing their operation. State medical boards are professional self-regulatory bodies that have the legal status of a state agency and a statutory obligation to protect the public by licensing physicians and monitoring those it has licensed. In addition, state medical boards have rule making authority, and they can articulate binding expectations for professional education and practice.

State medical boards provide the public with a potent mechanism for addressing problems with health care quality and safety (Lens and van der Wal 1997; Gibson and Singh 2003; Wachter and Shojania 2005; Makary 2012). Boards can objectively investigate what happened and take action ranging from issuing letters of concern, requiring physicians to undertake educational activities, mandating proctoring/oversight, and restricting or revoking a provider's license. Boards as public entities must emphasize transparency, and in contrast to the secrecy often surrounding quality improvement or peer review at the institutional level, any significant action that boards take is generally publicly reported.

Yet several factors can limit the ability of state medical boards to improve health care quality and safety. Most boards consider malpractice payments to represent a potential marker of a quality and safety problem and require that these payments be reported to the board. However, in conventional malpractice litigation there can be long lags between when an adverse event occurs and when a payment is made, hampering the board's ability to intervene in a timely fashion (Studdert et al. 2006). In addition, safety experts emphasize that system breakdowns rather than provider incompetence are important root causes of most adverse events, yet traditional board action does not adequately address system failures (Institute of Medicine [U.S.] Committee on Quality of Health Care in America 2000). Finally, although state board actions are publicly reported, state boards can be limited in the extent

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to which they can share lessons learned and disseminate best practices to assist their licensees.

The development of communication and resolution programs (CRPs), which promote accountability with institutions, providers, and patients, and disseminate learning following adverse events, provides an interesting opportunity to address some of these limitations (Gallagher 2009). CRPs are based on transparency and disclosure of adverse events to patients. CRPs also encourage making proactive offers of compensation when the adverse event was due to unreasonable care, rather than forcing the patient to seek compensation through the tort system (Mello et al. 2014a). CRPs have their origins partly in principles of Just Culture, which recognize that the prominent role of system failures in contributing to medical errors creates responsibilities on the part of institutions to hold themselves accountable and to identify and implement improvements (Marx 2001; Dekker 2012).

Only a fraction of CRP cases would ever come to the attention of a state board. Many CRP cases involve adverse events not due to errors or do not otherwise generate a payment to a patient. State boards would be unaware of these cases unless a separate complaint was submitted to the board. Nonetheless, research on early adopters of CRPs, including participants in the AHRQ Demonstration Projects, documented that requirements that medical professional liability payments made on behalf of a physician be reported to state medical boards (and to the National Practitioner Data Bank) were important barriers to physician participation in CRPs. Some physicians perceive state medical board action and NPDB reports as an onerous “black mark” requiring justification whenever they apply for hospital privileges or liability insurance, and find them especially problematic where CRP payments are made in cases where system failures rather than physician incompetence caused harm, or where the care did not meet the institution’s high internal standards yet could be defended in court (Mello et al. 2014a,b).

As part of their statutory obligation to protect the public, state medical boards often seek out new learning about how professionals practice and how care can be improved. CRPs, with their combination of a prompt, compassionate patient response to adverse events coupled with thorough event analysis, verified correction of observed deficiencies in care, and disseminated learning, represent a prime example of an innovation worthy of state board collaboration. Considerable CRP work has occurred in Washington State, where the state medical board (the Washington Medical Quality Assurance Commission or MQAC) has a long and distinguished history of innovative programs to promote patient safety. MQAC, founded 8 years before

Washington became a state, received the 2012 Administrators in Medicine Best in Boards award. MQAC has also been recognized for its innovative work on opioid prescribing, ambulatory surgery, and cosmetic surgery.

MQAC agreed to collaborate with the Washington State Foundation for Health Care Quality (FHCQ) to pilot a novel approach to quality regulation dubbed “CRP Certification.” Under this approach, if a health care institution (and involved physicians) can demonstrate it has adequately addressed a harm event, medical boards may allow the CRP process to play an important role in the mutual goal of improving not just physician care, but that of institutions and all medical personnel.

More concretely, CRP Certification allows a physician and institution who use the CRP in response to medical errors to seek review of the case from a neutral committee at FHCQ composed of patient advocates, physicians, and CRP experts from risk management and quality improvement. This review will determine if the key elements of CRPs (early event reporting, open communication with the patient, event analysis, and identification of gaps that contributed to the event, demonstrated learning to close these gaps, and proactive resolution with the patient) were employed. Cases that demonstrate the presence of these key elements to the satisfaction of the CRP Certification Review Committee will be marked as “CRP Certified.” While retaining all its authority, MQAC may choose to close eligible CRP Certified cases as satisfactorily resolved, reasoning that this demonstrated accountability and learning has addressed the safety of the public and therefore further board action is unnecessary.

In this article, we describe the concept of CRP Certification, explain how it will be evaluated, and discuss challenges and policy issues confronted to date.

What Are CRPs?

CRPs are a principled, systematic, and comprehensive approach for responding to patients who have been harmed by their health care. They are an integral component of a larger commitment to patient quality and safety, and they are implemented for the benefit of both patients and the professionals who deliver care (Mello et al. 2014a) (Table 1). When executed well, CRPs promote quality improvement, patient safety, and patient-centered accountability.

CRPs are based on a Just Culture approach that distinguishes among “human error” (an inadvertent act by a caregiver, such as a slip or

Table 1: Key Steps in the CRP Process

Initial response: following recognition of an unsafe condition/practice or an adverse event, the key steps in the CRP process include:

1. Immediate reporting of the adverse event to the institution or organization by the involved health care providers (within 30 minutes of the event's discovery).
2. Ensuring the patient's immediate clinical needs related to the risk or adverse event are addressed.
3. Ensuring the staff's immediate needs are addressed.
4. Engaging the patient and family as soon as possible after the event's discovery in establishing priorities and expectations, including listening to and communicating with the patient and family about what happened, how the patient's immediate needs are being addressed, what the patient should expect from the CRP process going forward, and unqualified expressions of empathy. Monitor and respond to the patient's and family needs, questions, and concerns and to share factual (as differentiated from speculative) information about the event as it becomes available.
5. Holding the patient's bills, pending outcome of the event analysis.

Engaging Patient Safety and Quality Improvement Activities

1. Undertaking a rigorous, human factors-based event analysis, including information and perspective from the patient and family.
2. Developing and implementing plans for preventing recurrences, based on human factors and Just Culture principles.

Continuing patient engagement and moving toward resolution

1. Holding a resolution discussion with the patient and family and sharing the final results of the event analysis and prevention plans.
2. For adverse events determined to be caused by unreasonable care, a proactive and fair offer of financial or nonfinancial compensation provided to the patient and family.

Educate patients or their families about their right to seek legal representation at any time. (Note: In the case of mentally incapacitated patients without a legal guardian or minors, follow state law regarding legal representation requirements.)

Postevent dissemination of patient safety and quality improvement lessons learned

1. Anonymize the lessons learned and disseminate intraorganizationally.
 2. Communicate anonymized lessons learned to extraorganizational entity for dissemination to relevant health care stakeholder groups statewide and beyond.
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lapse), “at-risk behavior” (taking shortcuts, violating a safety rule without perceiving it as likely to cause harm), and “reckless behavior” (conscious choices by caregivers to engage in behavior they know poses a significant risk, such as ignoring required safety steps) (Dekker 2012). These models also employ a “substitution test”—would three other caregivers with similar skills and knowledge do the same in similar circumstances?—to identify situations in which system flaws have developed that create predisposing conditions for an error to occur. Finally, knowledge of whether the caregiver has a history of

repeatedly making similar mistakes is considered in formulating an appropriate response (Marx 2009).

MECHANICS OF THE CRP CERTIFICATION PROGRAM

CRP Certification is a formalized application of CRP and Just Culture principles (see Figure 1). When an unanticipated outcome of health care occurs, a provider or risk manager initiates the CRP process. For a subset of CRP cases, the involved provider, institution, or liability insurer may feel that submitting a CRP certification application is appropriate. Once the CRP process is complete, a CRP Certification application is submitted through the FHCQ website (Appendix SA2). The application asks the submitter to outline the institution's response to the adverse event. The information collected includes how quickly the provider reported the adverse event, how the immediate health care needs of the patient were addressed, how information about the adverse event was shared with the patient and family, what recommendations for performance improvement at the provider and institution levels were made, and whether a proactive offer of compensation was extended. Cases involving providers who pose a significant risk of harm to patients through gross incompetence, recklessness, boundary violations, provider impairment, or intentional misconduct are ineligible for CRP Certification.

A review panel at FHCQ of 15 physicians, risk and claims managers, and patient advocates determines whether the provider, institution, or insurer fulfilled the key CRP elements. The diversity of the Review Panel helps ensure

Figure 1: Summary of CRP Certification Process

that key stakeholder perspectives on patient harm and adverse event response are taken into account. Identifying information about the patient, physician, and institution is removed from the application prior to it being sent to the review panel. Members of the panel are not allowed to review cases from institutions or providers with which they are affiliated. If insufficient information is provided, reviewers can request supplemental material. Certification is only granted if review panel members unanimously agree, ensuring appropriate valuation of the opinions of the patient advocates.

If certified, the submitting provider, institution, or insurer will receive a CRP Certification report outlining the event and the CRP response (Appendix SA3). The applicant can submit the CRP Certification report to MQAC, demonstrating that the patient's needs were met and that safety gaps have been closed. MQAC may elect to close a CRP Certified case as satisfactorily resolved, although it retains the authority to conduct an independent investigation and take action.

A central goal of the CRP process is promoting learning following adverse events at the individual provider and health care system level. The CRP Certification process requires applicants to identify improvements and lessons learned that have occurred at both of these levels. For patient safety to truly improve, however, it is essential that these lessons not be confined to the health care organization where the event occurred. To this end, FHCQ will disseminate de-identified lessons learned in collaboration with the Washington State Medical Association and Washington State Hospital Association.

Launching the CRP Certification Pilot

The CRP Certification process was designed through a 2-year, multistakeholder process. During the planning process, this consortium completed the basic program design and materials (Appendices SA2 and SA3); executed a Statement of Understanding around CRP Certification between the FHCQ and MQAC; recruited a review panel; and created a CRP Certification education curriculum for physicians, patients, and institutions. The first 18 months after the CRP Certification program went live on December 1, 2015 will constitute the pilot period, during which we anticipate a minimum of 40 cases will be submitted for CRP Certification review.

Data Sources for Program Evaluation

During the pilot period, the CRP Certification program will be evaluated to gauge its performance using a variety of data sources (Table 2). Some

Table 2: CRP Certification Pilot Program Evaluation Data Sources

<i>Key Constructs</i>	<i>Measures</i>
<ul style="list-style-type: none">● Physician engagement in the CRP process● Uptake of certification process● Fidelity to CRP key elements● Frequency with which CRP is used to resolve events● Efficiency of process● Frequency of certification● Stakeholder satisfaction● Positive balance of benefits over risks/harms● Potential for overcoming problems/shortcomings	<ul style="list-style-type: none">● Frequency with which physicians decline to participate in CRP● Frequency with which physicians resist early settlement● Perceived importance of certification in winning physicians' participation in CRP● Number of certification applications● Diversity of sources of CRP applications● Proportion of key CRP elements determined to be present in submitted cases● Proportion of applications certified● Reported frequency of use of CRP● Reasons for submitting applications● Number of quality/safety lessons identified● Time between initial submission and return of decision report● Proportion of applications certified● Proportion of certified cases closed by MQAC as satisfactorily resolved● MQAC rationales for decisions● Number of quality/safety lessons shared statewide● Stakeholder perceptions of certification process and prospects for continuation/expansion● Stakeholder support and objections● Nature of normative concerns arising from implementation of certification

data sources relate to the short-term goal of encouraging greater physician participation in CRPs. Others aim at assessing the general question of whether invigorated facility-based quality regulation can serve as a robust, beneficial substitute for state board regulation. We will extract information submitted in CRP Certification applications, such as date of submission, safety lessons identified, and key elements of the CRP that the institution claims it has executed. We will also examine the records of the review panel and MQAC relating to these applications, along with communications MQAC makes to health care providers relating to safety lessons learned (e.g., alerts, reports, presentations). These data will be triangulated with key informant interviews of a range of important stakeholders to

understand the strengths and weaknesses of the CRP Certification program from multiple perspectives.

Challenges Encountered to Date

Perhaps the most difficult challenge in designing the CRP Certification process has been addressing the tension between the desire of health care organizations and liability insurers to protect information submitted to the CRP Certification process from public dissemination resulting from MQAC's legislatively mandated requirement to disclose information about the actions it takes. On the surface, there is some irony in this tension, given that the CRP process embraces transparency with patients about adverse events. However, public disclosure laws in Washington State are such that essentially the entire MQAC file related to a complaint, with narrow exceptions such as patient-identifying information, is available to the public (and the media and plaintiff attorneys) upon request. This is a different kind of transparency from that which motivated CRP adopters—the desire for greater candor with affected patients and families and more robust internal discussion of opportunities for safety improvement (Mello and Catalano 2015).

In Washington State, concerns about broad public disclosure of CRP cases have arisen against a backdrop of successful efforts by plaintiff's attorneys to narrow the state's legal protections for information generated in quality improvement and peer-review processes [See *Lowry v. PeaceHealth*, 280 P.3d 1078 (Wash. 2012); *Fellows v. Moynihan*, 285 P.3d 864 (Wash. 2012); *Cornu-Labat v. Hospital District No. 2*, 298 P.3d 741 (Wash. 2013)]. The shifting terrain has put providers, insurers, and their defense attorneys on edge and elevated concerns about whether participating in CRP Certification would lead to further reduction in their legal umbrella. Without confidence in these protections, health care practitioners' willingness to participate in event reviews could decline precipitously, with deleterious consequences for the ability to learn from and prevent adverse events.

Yet for MQAC, disclosing information about the CRP Certification process is a requirement of being a public agency. MQAC is scrutinized closely by the legislature, the media, professional health care organizations, and patient advocates. CRP Certification involves reviewing the determinations of health care organizations, which are not disinterested parties when it comes to policing quality problems within their walls. It is thus unsurprising that

MQAC has insisted it must maintain full transparency with the public about its decisions in the CRP Certification pilot. This tension could be especially acute if a CRP Certified case which is closed by MQAC as satisfactorily resolved involved a medical error leading to a patient death, which could trigger public concern that for the most serious errors punishment of the involved providers is prerequisite to an adequate regulatory response. Public education about CRP Certification and Just Culture will be important going forward to mitigate this possibility.

Ultimately, the balance that has been struck involved securing formal designation of the CRP Certification process as a Washington State Department of Health–approved coordinated quality improvement program (CQIP). CQIP designation allows protected sharing of quality improvement information among CQIP plans, and there allows health care institutions with a CQIP plan to share quality improvement information in the CRP Certification application (Appendix SA2). The decisions of the review committee and supporting rationale will then be summarized in the CRP Certification report (Appendix SA3) that is returned to the submitting institution or liability insurer. It is this CRP Certification report that the institution or liability insurer can choose to submit to MQAC for review. We expect continued adjustments will be required of the balance between how much information about a case MQAC must disclose statutorily and how much information institutions or insurers are willing to submit as the Certification pilot gets underway.

The compromise described above may help address a second, related challenge: proactively addressing anticipated public concern that the CRP Certification process might be used to shield incompetent providers. The CRP Certification process is designed for cases involving medical errors made by competent providers. Health care institutions and insurers submitting cases are asked to attest to the fact that they have no concerns about provider competence as part of the application process. Yet we anticipate that persuading the public that CRP Certification will not somehow allow incompetent providers to continue harming patients will be an ongoing challenge that can only be resolved as cases accumulate.

Building confidence among the stakeholders involved in CRP certification, too, is an enduring issue that requires time and experience to address. The progress achieved to date demonstrates the goodwill and commitment to the CRP Certification program among the key stakeholders, but additional trust building will be required for the process to

succeed. This will only occur as cases progress through certification and health care institutions, physicians, liability insurers, and attorneys gain confidence about how MQAC responds to CRP certified cases. The stakeholders must understand that MQAC is bound by statute and must be assured through evidence and information provided that institutions have a robust CRP process in place.

A final challenge encountered to date, also involving a need for confidence among stakeholders, has been determining how much information about a CRP Certified case MQAC needs to assess whether additional investigation is warranted. If the process works as intended, there will be enough information in the CRP Certification report submitted to MQAC to enable it to make this determination confidently. We anticipate that as case submissions accumulate, additional fine-tuning of the amount and type of information provided to MQAC will be necessary.

It is conceivable that the public may view CRP certification as an abrogation of MQAC's responsibility. However, there is precedent in Washington State for a nongovernmental agency to improve the outcomes of regulated entities. For example, after the Washington Physician's Health Program (WPHP) demonstrated that it could effectively police, treat, and monitor physicians with substance abuse (and other) disorders, the Washington State legislature granted MQAC the authority to place complaints against a physician enrolled in WPHP "on hold," without investigation, because of confidence that the external body (WPHP) could appropriately handle the situation. MQAC retains its authority at all times to intervene and take action against physicians who fail to participate in the WPHP process. Diagnosis, rehabilitation, and monitoring were found to be far superior to traditional board action in resolving this threat to public safety. Over time, it hoped that the CRP Certification program could evolve into a similar program for cases of medical error involving competent providers.

Normative and Policy Issues Raised

As we embark on the CRP Certification pilot, we anticipate that lessons learned will have broad implications for three important normative and policy issues. First, what is the role of discipline—whether at the institutional or regulatory level—following medical error? In error cases involving severe harm, is evidence of learning alone ever sufficient to satisfy the ethical mandate to hold providers accountable for harmful errors?

Second, under what conditions can a model in which regulators rely in part on investigation by health care institutions where medical errors occur be judged trustworthy and legitimate? Whether the public is persuaded that such an approach, on balance, can be trusted to produce greater safety than the alternative is an open question, as are the factors that will drive the conclusions the public reaches.

Third, we anticipate that MQAC collaboration on CRP will not fully address the worries physicians have about CRP participation because federally mandated reports to the NPDB will remain a barrier. Over time, it will be important to examine how the CRP Certification process could be integrated with the NPDB. One shortcoming of the NPDB is that it requires reporting of claims paid on behalf of a provider in response to a written demand from the patient without distinguishing between cases involving system/human error and those involving the problem the NPDB was designed to solve: provider incompetence. Could the CRP Certification model be used nationally to facilitate more targeted reporting to the NPDB, in turn encouraging physician participating in CRPs?

At their core, these issues revolve around the complexities of implementing Just Culture concepts in the real world. In some respects, the CRP Certification pilot is a narrow experiment in a single state. But the pilot is broad and bold in its ambition. It seeks to include state medical boards with other stakeholders to achieve a common goal: enhancing patient safety. If successful, it could illuminate a path toward realizing the full potential of Just Culture concepts for improving accountability for safe care.

ACKNOWLEDGMENTS

Joint Acknowledgement/Disclosure Statement: This work was supported by grant no. R18HS019531 from the Agency for Healthcare Research and Quality (AHRQ) and the Greenwall Foundation. The content is solely the responsibility of the authors and does not represent the official views of AHRQ, the Greenwall Foundation, or the Medical Quality Assurance Commission. Thanks to Teresa Landreau, J.D., for assisting in the design of the CRP Certification process and William M. Sage, M.D., J.D., for helpful comments on this manuscript. The authors also thank the members of the HealthPact consortium for their support of this work, including the Foundation for Health Care Quality, Physicians Insurance A Mutual Company, the Washington State

Medical Association, the Washington State Hospital Association, the Washington State Association for Justice, and the HealthPact Patient and Family Advisory Council.

Disclosures: None.

Disclaimers: None.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Appendix SA2: CRP Certification Application.

Appendix SA3: CRP Event Review Report.