FINAL PROGRESS REPORT

1. Title Page

Title of Project: CRP Certification: Promoting Accountability and Learning After Adverse Events

Principal Investigator and Team Members:

Thomas H. Gallagher, MD, Principal Investigator
Karen Brigham, JD, MPH, Project Manager
Paulina Osinska, MPH
Steve Levy, MBA
Monica Salgaonkar, MHA
Jennifer Zech, MSc
Hannah Karson, PMP
Heather Gocke, MS, RNC-OB, CPHRM, C-EFM
Deanna Tarnow, RN, CPHRM

Consultants:
Michelle Mello, PhD, JD
Bruce Cullen, MD
Sarah Armstrong, RN, MSN, JD

Organization: University of Washington

Inclusive Dates of Project: 5/01/2016 – 02/28/2020

Federal Project Officer: Irim Azam

Acknowledgment of Agency Support: This project was supported by grant number R18HS024504 from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

Grant Award Number: 5R18HS024504

2. Structured Abstract

Purpose: We sought to address physicians' concerns about potential regulatory discipline for following Communication and Resolution Program (CRP) principles while fostering shared learning and improvement in the use, effectiveness, and fidelity of CRPs, with the ultimate goal of improved healthcare quality and safety.

Scope: We developed a 3-year demonstration project to assess the potential of the CRP Certification program to incentivize physicians and healthcare institutions to use the CRP approach more regularly and more effectively, to be implemented and evaluated in three states.

Methods: We developed the CRP Certification program, in which a neutral review panel determines whether an adverse event was handled appropriately using CRP principles. Certification reports may be sent to the state board of medicine for consideration in determining whether to pursue disciplinary action. The project was assessed using a multi-modal evaluation plan focused on utility, acceptability, timeliness, and implementation fidelity.

Results: We successfully established the CRP Certification program in Washington and California; 33 cases were reviewed, and 27 cases were certified. The quality of the case submissions improved significantly over time, providing evidence of improvements to organizations' CRPs. The program is ongoing, with plans for national expansion.

Key Words: Communication and Resolution Program, medical error

3. Purpose

Communication and Resolution Programs (CRPs) represent a breakthrough in promoting patient-centered accountability and disseminated learning following adverse events, but physicians and healthcare institutions worry that using a CRP could trigger a punitive response by regulators, such as state boards of medicine. We saw an opportunity to address these concerns while fostering shared learning and improvement in the use, effectiveness, and fidelity of CRPs, with the ultimate goal of improved healthcare quality and safety. We developed the CRP Certification program, in which a neutral review panel determines whether an adverse event was handled appropriately using the key principles of a CRP. For cases that are certified, the organization may submit the certification report to the state board of medicine, which will consider it in determining whether to pursue disciplinary action. The objectives of the study were to:

1. Develop, pilot test, and evaluate the CRP Certification program in Washington state.
2. To expand and evaluate the CRP Certification program in two additional states to assess its suitability for national rollout.
3. To analyze policy and ethical questions associated with taking the CRP Certification program to scale nationally.

4. Scope

Communication and Resolution Programs (CRPs) are transforming the response to adverse events. CRPs address the injured patient's needs through transparency and disclosure along with proactively offering compensation when the adverse event was due to unreasonable care rather than forcing the patient to seek compensation through the tort system. CRPs not only promote patient-centered accountability but also improve quality and safety through analysis of the adverse event and dissemination of lessons learned. CRPs have their origins partly in principles of Just Culture, which recognize that most medical errors are due not to incompetent providers but to a combination of system failure and individual error, creating responsibilities on the part of institutions to hold themselves accountable and to identify and implement improvements.

As implementation of CRPs has progressed, a major barrier emerged, namely physician fear that payments made in a CRP could trigger unwanted involvement of regulators. In Washington, as in many states, payments to a patient over $20,000 must be reported to the board of medicine. The CRP movement is taking place at the same time that many state boards have become much more rigorous, spurred by consumer advocates and the media, who have lambasted state medical boards as too lax and allowing unskilled providers to remain in practice. Some Washington physicians, nervous about strict board oversight, have hesitated to participate in CRPs lest they trigger action against their license. Such payments are also reportable to the National Practitioner Data Bank (NPDB), which physicians consider an onerous "black mark" requiring justification whenever they apply for hospital privileges or liability

insurance. Such reporting is perceived by physicians to be especially problematic when CRP payments are made in cases that do not reflect physician incompetence but rather reflect system failures or situations in which the care did not meet the institution's high standards but could have been defended in court. Physician fear of being held publicly accountable for adverse events that do not reflect a deficit in their competence represents a major impediment to their involvement in CRPs.

The Washington Medical Commission (WMC) (formerly the Medical Quality Assurance Commission) agreed to work with us to develop and implement a CRP Certification program pilot. 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 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 and ongoing 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 reviewers will be marked as CRP Certified. While still retaining its full authority, WMC agreed to consider the CRP Certification Report in its investigation of a case and in appropriate cases to close the case with no disciplinary action.

To assess the potential of the CRP Certification program to incentivize physicians and healthcare institutions to use the CRP approach more regularly and more effectively, we proposed a 3-year demonstration project. Starting with a pilot test of the CRP Certification program in Washington state, we planned to expand and evaluate the CRP Certification program in two additional states. We estimated that we would receive 100 case submissions for review by the CRP Certification program in Washington state over 3 years and 50 cases in each of two additional states over 2 years for a total of 200 cases. The data accumulated over the life of the grant would also enable us to analyze the policy and ethical questions associated with taking the CRP Certification program to scale nationally.

5. Methods

Study Design

The CRP Certification program in Washington state was designed through a multi-stakeholder process over an 18-month period before the start of this grant. Key program elements included the CRP Certification Application, the CRP Certification Report, and the CRP Certification Criteria Checklist. A Statement of Understanding between the Foundation for Health Care Quality, the neutral body designated to host the program, and the Washington Medical Commission was signed. The CRP Certification program was approved by the Washington State Department of Health as a Continuous Quality Improvement Program (CQIP), which enables healthcare organizations to share information about an adverse event with the CRP Certification program while maintaining the quality improvement privilege that protects these materials from discovery. We recruited and trained review panel members and developed educational materials and a marketing outreach plan for healthcare institutions and physicians.

Once the program was established in Washington state, we sought to use what we had learned in expanding the program both geographically and interprofessionally. We planned to expand the program into two additional states in order to evaluate its transmissibility to other political contexts, acceptability to a wide variety of stakeholders, and suitability for national rollout. Given the interprofessional nature of healthcare delivery, which includes nurses, pharmacists, other clinicians, and hospital facilities, we also wanted to broaden the program to encompass additional regulatory bodies beyond medical boards.

The CRP Certification program aimed to incentivize physicians, healthcare institutions, and medical malpractice liability insurers to respond to adverse events using the CRP approach, with the broader objectives of meeting the needs of injured patients and their families and fostering improvements in the quality and safety of care. We developed a multi-modal evaluation plan to assess the project, focusing on utility, acceptability, timeliness, and implementation fidelity.

Data sources/Collection

Data Source	Data Elicited
Applications	* Uptake of Certification process * Fidelity to CRP approach * Adherence to CRP key elements * Frequency of Certification * Timeliness of review panel decisions * Contributions to patient safety
Regulator communications	* Proportion of Certified cases closed by Board/Commission as satisfactorily resolved * Timeliness of Board/Commission decisions
Key Informant Interviews	* Stakeholder engagement in the CRP process * Stakeholder perception of the Certification process * Acceptability of Certification to key stakeholders: physicians, patient advocates, healthcare institutions, regulators
Stakeholder Focus Group	* Overall stakeholder perceptions of Certification process and prospects for continuation/expansion

Applications for CRP Certification from organizations and individual physicians constitute an important data source for this project. The elements of the application and review panel's action were synthesized and maintained in an anonymized database. In addition, CRP Certification reports and cover letters sent to submitting individuals and organizations provide a narrative summary of each case, including the review panel's determination, and highlight its strengths and weaknesses.

Thanks to our collaboration with the Washington Medical Commission (WMC), we were notified when certified cases for which the licensee submitted the CRP Certification Report to the WMC were closed as well as the disposition (e.g., no disciplinary action taken). The WMC's Reduction of Medical Error (ROME) Committee came to the Foundation for Health Care Quality and reviewed redacted CRP Certification case files to better understand the materials and provided oral feedback to the PI and project manager.

Key informant interviews were conducted in January and February 2020. Thirty interviewees were identified through purposive sampling and included individuals from organizations that had submitted cases for certification, review panel members, program partners from an expansion state, medical commission members and staff, insurers, and PSO leaders. Semi-structured interviews were conducted by one of three interviewers (TG, KB, and PO). The interviewers followed an interview guide with open-ended questions concerning CRPs in general, expectations and experiences with the CRP Certification program, pros and cons of the program, and suggestions for improving the application and review panel process. The interviews were conducted via Zoom or in person and lasted 30-45 minutes. The interviews

were recorded and transcribed. Interview transcripts were coded by one researcher (KB) based on standard methods of thematic content analysis using Atlas.ti software.

A broad range of program stakeholders met annually during the project. The last stakeholder meeting on February 7, 2020, just before the end of the grant, featured a structured focus group discussion to elicit a forward-looking perspective on the future of CRP Certification. The focus group discussion was recorded, transcribed, and analyzed for thematic content.

Intervention: The CRP Certification program

Once a healthcare institution or physician submits an application for CRP Certification, the CRP Certification program manager verifies that the application is complete. In addition to the application, the applicant is encouraged to submit relevant de-identified portions of the medical record and other institutional records to substantiate the statements made in their application including operative reports, diagnostic test results, proof of completion of quality improvement activities, and patient/family and physician satisfaction surveys.

Review panel members meet monthly to review each case and to serve as reliability and quality checks on the CRP Certification process. The discussion is led by a nonvoting Review Panel Chair and focuses on each of the key CRP elements. The Chair reminds the reviewers of the standard for decision making on each element and ensures that each reviewer is given the opportunity to share their perspective. The Chair documents the consensus of reviewers on each element using the CRP Certification Criteria Checklist. Assuming the reviewers believe they have the necessary information to come to a decision, the Chair calls for a vote on certification. Certification is granted based on unanimous agreement by the panel.

Following the review panel meeting, the CRP Certification program manager in coordination with the Chair prepares a CRP Certification Report, which states the disposition of the case (certified, not certified, certified with contingency) and includes all the relevant details of the case. If a case is certified, the involved physician licensee or healthcare organization acting on their behalf may submit the CRP Certification Report to the WMC if it has an open case on the matter due to a financial settlement or patient complaint. The WMC will take the report into consideration in its investigation and determination of any discipline.

In the expansion state of California, the review panel process is quite similar to the Washington program, but the underlying organization and incentive structure is significantly different. BETA Healthcare Group developed their HEART (healing, empathy, accountability, resolution and trust) program for its insured members. BETA HEART is designed to help member healthcare organizations implement their CRPs through an interactive and collaborative process. BETA has defined five domains – culture of safety, rapid event response and analysis, communication and transparency, care for the caregiver, and early resolution; for each domain that an organization demonstrates successful implementation, it receives a 2% renewal premium credit up to 10% annually. Participants in the program are required to submit cases for HEART Validation (based on the Washington CRP Certification program).

Measures

We identified the following measures of the CRP Certification project's success:

- Establishment of the program
- Geographic expansion
- Number of applications received and reviewed
- Diversity of sources of applications
- Proportion of key CRP elements present in submitted cases
- Proportion of applications certified
- Number of quality/safety and CRP lessons identified and shared
- Timeliness of review panel decision following case submission
- Proportion of cases closed as satisfactorily resolved by regulator
- Perceived utility of the CRP Certification program
- Review panel participation over time
- Overall stakeholder perception of CRP Certification and prospect for continuation/expansion
- Interprofessional expansion of the program to additional regulatory bodies
- Development of a plan to sustain the program long term

Limitations

Although we were optimistic about participation in the CRP Certification program, there was some uncertainty regarding the potential uptake of this novel program within Washington and the expansion states. Healthcare organizations and physicians are at varying stages in terms of the maturity of their CRPs, and this could affect their readiness to submit CRP Certification applications. In addition, physicians who practice independently may not have the resources necessary to prepare and submit applications.

We acknowledge the potential for selection bias in cases submitted, but we could not quantitatively assess the frequency with which adverse events potentially eligible for CRP Certification were not submitted for review. In addition, we could not independently verify the information included in applications and supporting materials.

Finally, it is possible that the involved states may not be representative of all state medical boards.

6. Results

Principal Findings

We successfully established the CRP Certification program, which spanned nearly 4 years under the NCE and continues today after the end of the grant that supported its development. Thirty-three cases were reviewed in Washington and California, and the quality of the case submissions has improved dramatically over this period, providing evidence of improvements to organizations' CRPs. Indeed, the community for sharing best practices and lessons learned that was built through this program has proven to be its most attractive aspect for many submitting organizations. Strong ongoing participation by our review panel members also reflects of the broad support the program continues to enjoy.

We achieved geographic expansion of the CRP Certification program through our collaboration with BETA Healthcare Group, whose innovative BETA HEART program provides hands-on CRP implementation support to member organizations. Members must submit cases to BETA's HEART Validation program (modeled on the CRP Certification program) as a condition of participation in the HEART program, which will ensure an ongoing caseload and, more importantly, feedback and continuous improvement that emerges from the case reviews.

Our success in implementing CRP Certification programs in Washington and California led us to consider the broader possibilities beyond adding a third state to the project. Along with BETA, we initiated discussions with the California Hospital Quality Institute (HQI) and California Hospital Patient Safety Organization (CHPSO) that included the CEOs of both organizations. A broad partnership would allow dissemination of BETA's HEART program across California and even beyond, given CHPSO's 18-state reach. We have also explored partnering with the large national healthcare services company Vizient to expand program nationally via its PSO. PSOs may provide a viable model for nationwide expansion, because they can facilitate sharing confidential case information beyond state borders.

The Washington CRP Certification program was built on a partnership with the Washington Medical Commission, but we were successful in expanding the interprofessional reach of the program. In November 2019, we entered into a Statement of Understanding with the Washington State Board of Osteopathic Physicians and Surgeons similar to the one we have with WMC. The Washington State Pharmacy Quality Assurance Commission has endorsed a partnership, and a draft SOU is currently under review within the Washington Department of Health. In addition, though the CRP Certification program will continue to be based at the Foundation for Health Care Quality, the locus of the general CRP work in Washington is shifting to the Washington State Hospital Association, which provides a strong nexus to the Nursing Commission and Facilities Division.

As the grant period was winding down, we explored various ways that we could ensure the long-term sustainability of the CRP Certification program. In Washington, we worked with State Representative Eileen Cody, who chairs the House Health Care and Wellness Committee, on a

2-year state funding proposal. With her support, the proposal passed the legislature in March 2020 but was vetoed by the governor as the state budgetary impact of the COVID-19 crisis began to emerge. Nonetheless, organizations continue to submit cases and have expressed strong support for maintaining and expanding the CRP Certification program. As a result, we continue to consider potential structural and funding options.

Outcomes

A total of 33 cases were reviewed in Washington and California between May 2016 and May 2020 (Table 1). In Washington, 81% of the cases were certified by the review panel, and four certified cases that were submitted to the Washington Medical Commission were closed without disciplinary action against the involved licensee. Seventy percent of the Washington cases involved severe harm, including nine death cases. Cases in Washington were submitted by nine institutions and one attorney on behalf of an individual physician, with three institutions accounting for two thirds of the cases. Of the five cases that were not certified, one was submitted for advice only. In California, 83% of the cases were certified by the review panel. Two thirds of the cases involved severe harm, including two death cases. The California cases were submitted by six distinct entities.

Table 1. CRP Certification Cases Reviewed in Washington and California, 2016-2020

Location	Cases reviewed to date	Cases Certified	Severe harm cases (temporary severe harm or higher)	Cases closed by WMC with no disciplinary action[1]	Submitting institutions/ clinicians	Average days from submission to final report
Washington	27	22	19	4	10	28
California	6	5	4	N/A	6	74
Total	33	27	23	4	16	36

In 78% of certified cases, risk management was informed of the event within 1 week; for 41%, that notification took place the same day. The initial conversation with the patient and/or family occurred the same day as the event in 44% of cases and within 2 days for two thirds of cases.

Analysis of certified cases revealed strong fidelity to the key CRP elements (Table 2). Moreover, we observed trends over time suggesting that institutions developed more robust caregiver support programs and increased collaboration among the parties involved in responding to adverse events (e.g., risk managers, quality and safety personnel, liability insurers, legal, etc.).

[1] By agreement with the WMC, we are informed of certified cases received by the WMC and their disposition as soon as the cases are closed. To date, every case has been closed with no disciplinary action.

Table 2. Percentage of Certified Cases Satisfying CRP Elements (WA n=22; CA n=5)

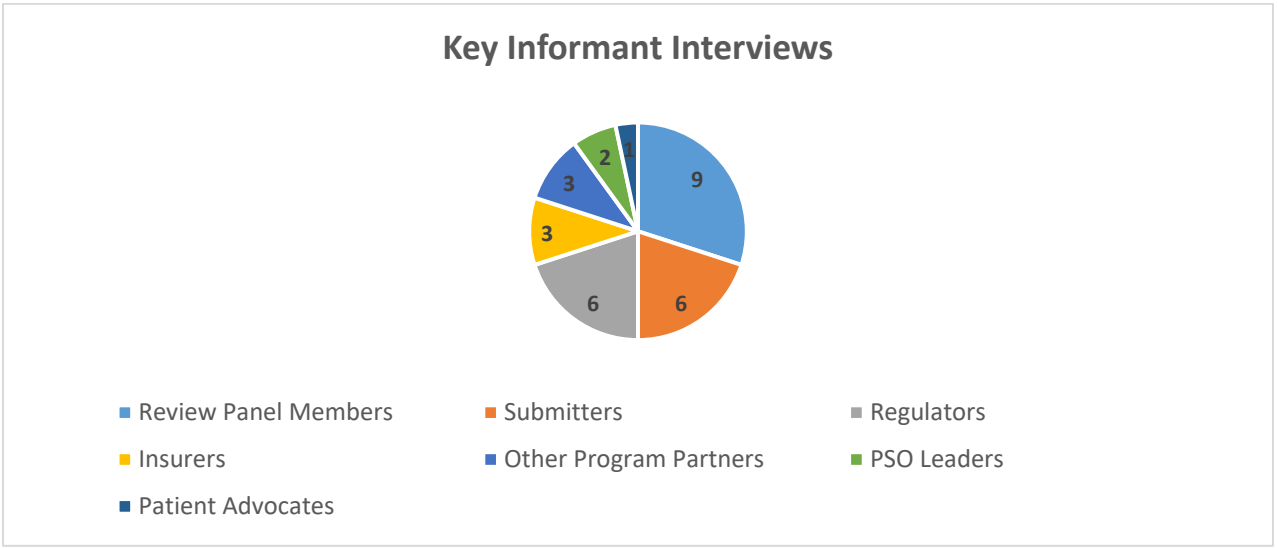
CRP Element	% Washington certified cases	% California certified cases
Timely notification of event to patient/family and risk manager(s)	91	100
Patient immediate needs met	91*	100
Caregiver support offered	86	100
Timely & complete event analysis undertaken	100	80
Licensee and/or System QI gaps identified and measures undertaken to address	100	80
Patient/family offered resolution discussion	91	60
Early financial resolution offered	73	20
Collaboration among CRP partners	77	80

*Not applicable in cases of immediate death

Some applicants submitted cases immediately after a settlement was reached with the patient or family, knowing that the involved licensee would need to report the settlement to the WMC. However, an increasing number of applicants submitted cases for which the CRP process was ongoing in order to solicit advice from the review panel regarding particular aspects of their responses. We explored the motivations for submitting cases as part of our qualitative analysis.

We conducted key informant interviews with 30 of the CRP Certification program's stakeholders in January-February 2020 (Figure 1). Their professional backgrounds included medicine, nursing, risk management, claims, patient safety, legal, and policy. We wanted to better understand their experience with the program, including the stronger and weaker aspects, their suggestions for improvements, and their views regarding the future of CRP Certification.

Figure 1. Participants in Key Informant Interviews (n=30)



Multiple stakeholders emphasized the educational benefit of participating in the CRP Certification process and how it helped organizations improve their own CRPs. As one review panel member expressed it:

> "I think where we've gone is, we're starting to now provide suggestions and feedback to organizations so they can learn and do it better the next time and I think that's a fantastic move that we've made with the panel."

A regulator noted that at the program's inception one of the presumed key motivators for institutions to seek certification would be to help their providers avoid disciplinary action by the WMC. He underscored the evolution of the program to a focus on shared learning:

> "That means there are 22 cases where institutions decided they wanted to seek certification for their own reasons, regardless of the commission's involvement, for learning and improvement, so that is a very positive development that came quicker than I thought it would."

A submitter emphasized that benefit:

> "[E]ach time we submit a CRP I feel like I've learned a little bit more about how to conduct a discussion with the family or what we could have done better or differently, so I would say that's another advantage of taking part in the CRP process, you always look for cases, whether bad or good or a bad outcome."

The learning extends beyond the submitting institution and has statewide implications according to a review panel member who also submits cases:

> "I think our role is to build sustainable CRP programs across Washington state and the organizations that send them in, so we can't blindly certify everything because then we're not going to get where we need to go, but really offer specific, positive and constructive feedback to support all of us in getting to where we want to be."

Despite strong support for the CRP Certification program, submitters acknowledged that the time and effort to prepare an application was a barrier to submitting more cases.

> "The only true con that I can see is that it just adds to the workload; it's a fairly considerable investment of time to put together a good application."

Part of the challenge is integrating the application process into existing workflows:

> "It just includes information that's not in our typical business record. I mean the information is there but it's not kept in that structure so we have to recreate a – it has to be manually cut-and-pasted or rewritten to meet that structure."

Nonetheless, submitters did not identify suggestions for streamlining the application process:

> "I mean I think you've got all the key elements that you need to have, so I don't think we could take anything away. It's easy to upload. I don't really have any suggestions other than we just have to do it."

None of the submitters included feedback from the patient and/or family as part of their applications. A patient advocate who is a review panel member explained the challenge this presents and proposed a potential way forward:

> "I think one of the big areas and again, I mentioned it before, is trying to find a way of how this is working with patients and families; it's very difficult. Once we've gone through a case or an organization has submitted a CRP and they've gone through that process with a patient and family it's very awkward and I'm not sure that it's appropriate for them to come back at the end of that and talk to the patient and family and say, well how did that go; it just doesn't feel right and it certainly I think would leave a bad taste in the mouths of patients and families, particularly with a severe event. But if there was a way that we could have an outside group or something come in and try to get feedback from the patient and family I think that's one of the big pieces we're missing. What is that perspective from the patients and families, and how can we improve the CRP process to help them?"

Another review panel member and submitter agreed that using a third party to gather this feedback would be the best approach and would facilitate sharing best practices with organizations participating in the CRP Certification program.

> "You know 'we're participating with a group helping us to learn from patients' experiences in CRP programs, can you tell me generally what was helpful to you as a patient or family member, or what wasn't helpful to you; did you think you were treated fairly?' We would learn, I think, more that way and then be able to give feedback to the individual groups. So for instance, if patients and family members say, generally speaking having a family meeting is really helpful, and at that meeting here is who we want to see and we're looking at that application and the patient and family meetings with a risk manager and a quality manager, but no physicians involved in the care were there. That might be helpful to the group to say you know next time it's really important if you want to get engender trust that you make sure you involve medical providers involved in the care, or something more of that nature."

Broader public awareness of CRP as a resource was also identified as an important goal in this regard.

> "I would also like to see a little bit more visibility outside with the public, so the public understands what CRP is and that patients and families would have an expectation and know what it is and have an expectation that if a medical error

> happened that there would be something in place that organizations would follow to ensure that everything possible is being done to help the patient and family get over that medical error, and that organizations are going to be able to implement processes to make sure it doesn't happen again. I'm not sure that that's a year or two away, but that would be my ultimate goal."

In terms of the review panel meeting process, two issues were recurrent: complaints that the discussions sometimes drifted too far into the clinical details, leaving insufficient time to address the CRP elements, and concern regarding the lack of participation by the physicians involved in events in the review panel meetings.

> "[T]he one thing that's I think at times a problem is we get buried too much in the discussion of individual clinical practices without knowing what's gone on and without anybody there to provide any information, to ask questions and people start discussing their own clinical background and experience and it often, I think, becomes irrelevant to the discussion and that sort of drags on sometimes."

Some review panel members believe this tendency to delve into the clinical "weeds" stems from the fact that the involved physicians often are not present to respond to questions at the review panel meetings. One panel characterized physicians' participation as a responsibility:

> "[C]linicians have not been involved in any of this discussion and one of my observations is that the discussion has involved a variety of administrators, risk managers and people who sit in on behalf of the clinicians, the physicians or whomever, and they come up with policies and procedures and it's almost as if the clinicians abdicated their responsibility to be involved in this type of thing to the degree that I think they should be, and I think the solutions that are advanced having to do with processes of education and communication that get written down on paper and are expected to be followed by people learning them are a poor substitute for direct communication with the people involved, not only in terms of the educational part of it and maybe changing behavior that way, but also just in terms of the conduct involved in the cases."

However, several representatives of submitting institutions cited lack of time due to clinical duties as well as psychological barriers to physicians' participation in the review panel meetings. This issue was also discussed at our February 7, 2020, Stakeholder Meeting, at which we conducted a focus group discussion.

> "If you're going to have a meeting with physicians it's a good idea to have it after six o'clock to nine in the evening and before seven o'clock in the morning or on the weekends. If you try to get physicians outside of that time they're working and they consider activities other than patient care a distraction."

Given the time constraints, one submitter explained how she involves the physician in the certification process:

> "[O]ur practice has been to have them involve them in reviewing the documents which they typically do with us like when we're responding to a patient grievance or that type of thing; we involve them and we talk to them about it and we ask them to ensure the accuracy of what we're submitting on their behalf, but I don't think there is any great desire on the part of physicians to have one more venue where they have to bare their souls to people they don't know."

Another key criticism of the current program was the lack of sharing lessons learned through the CRP Certification process more widely:

> "I think one of the real strengths is the benefit of being able to share lessons learned across organizations and I think that's an area that still has an opportunity for optimization."

The PSO model was highlighted as an ideal vehicle to achieve this goal.

> "I think a patient safety organization that's national should fit really underneath that umbrella. I think PSOs are purposed for learning development and dissemination, and I think that that's primarily where it should sit."

Indeed, participants in both the key informant interviews and the focus group expressed support for expanding the program nationally.

> "Washington is one of a few states leading this work nationally, and I think it has the potential to take hold as more of a national movement and that we have the ability to be on the forefront of that, and then as far as CRP certification goes, I don't know of other states doing a similar certification process and granted it really is – whereas CRP has a process and a response to event could be rolled out systematically nationally…[F]ederal protection like a PSO could be valuable and could bring more organizations into the process."

<u>Ethics and Policy Analysis</u>

The design and implementation of the CRP Certification program has since its inception included important ethical and health policy considerations. The goal of the CRP Certification program, to encourage the effective use of CRPs thereby meeting the needs of patients, families, and healthcare providers after harm events, is not controversial. However, especially during the stakeholder engagement that occurred during the program's design and early roll-out phase, concerns were raised about whether the CRP Certification program could inadvertently lead to regulators such as boards of medicine to be less aware of physicians who were struggling to practice safely. This concern would have been especially pertinent had the design of the CRP Certification program included any degree of delegation of the board of

medicine's authority to investigate quality of care complaints to the CRP Certification Review Panel.

Several factors combined to essentially illuminate this concern. First, the Washington Medical Commission decided that it would continue to conduct parallel investigations into complaints they had received even if that complaint was going through the CRP Certification review process. This ensured that the CRP Certification Review Panel's decision, in those cases in which institutions chose to submit recertification report to the commission, would serve simply as a supplement to normal commission processes rather than a replacement. In addition, the application was designed to require an attestation by submitters that they had no concerns about the competence of any providers involved in the case. Over time, as the Certification program continues to grow, we anticipate that this issue of the relationship between the Certification review process and regulator action could re-emerge, and we will be prepared to respond accordingly.

One health policy issue that we also anticipated could be a concern at the outset turned out not to be as the certification program was implemented, namely how the Certification review process would interface with mandatory reporting requirements, such as to the state medical commission and to the National Practitioner Data Bank. All mandatory reporting requirements remained in effect and have been strictly observed throughout.

Two additional ethical issues remain under active discussion by the stakeholders in the CRP Certification process. One critical issue has been balancing the confidentiality of the CRP Certification application and reports with the need for public transparency about patient harm events. This is an especially challenging issue, because healthcare organizations prize the quality improvement protections that shield some information about adverse events from public disclosure, and the medical commission is properly understood as a source of transparency about how adverse events have been addressed in healthcare. Ultimately, the balance that was struck included maintaining the state-authorized quality improvement protections that would prevent CRP Certification applications and report from public disclosure and having the medical commission draft a letter describing the CRP Certification process that could be included in any file of a case date they chose to close without disciplining the provider, if that decision in part may have been based on a CRP Certification report.

The other ongoing challenge remains how to effectively integrate the voices of patients and families into the Certification review process. Although there has been a robust patient advocate presence on the review panel, it has remained difficult to include the perspective of the injured patient and their family during the review process. If left unaddressed, this could give the impression that the CRP Certification process is skewed in favor of healthcare providers and institutions. A patient and family survey tool is provided with the CRP Certification application that organizations could use to collect and submit feedback from patients about their experiences with the CRP process, but, to date, none of the applicants chose to submit this information. We are actively exploring other alternatives, such as partnering with patient

and family advocates to interview injured patients and families or perhaps seeking input from the attorney representing the patient and family, should one be present. Ultimately, the success of the CRP Certification program will hinge on demonstrating not only that the review process is trustworthy but also that all key stakeholders, including the injured patient and family, are fully integrated into the process.

Discussion

This project has helped us better understand how CRPs exist within their broader context with all the other stakeholders involved. Clearly, organizations are at different stages in the development of their CRPs, and there is still some resistance from certain quarters as traditional models are challenged. Yet, at the same time, we are seeing innovative and unexpected alliances that are supporting organizations and medical staff as they implement and improve their CRPs. As an example, BETA Healthcare Group is actively collaborating with their insurance marketplace competitors in California to develop protocols to cooperate in responding to adverse events in multi-insurer environments.

Likewise, the CRP Certification program has revealed a strong sense of solidarity among otherwise competing healthcare entities as they support each other in developing and strengthening their CRPs. We were heartened to see the degree of trust and goodwill among submitters, who were not afraid to "air their dirty laundry" in this setting. Indeed, though the CRP Certification process was designed to allow submitting organizations the opportunity to maintain their anonymity when calling into the Review Panel meeting to respond to questions, every submitter readily identified themselves and their institution. In addition, submitters did not shrink from bringing very difficult cases: one third of the cases submitted in Washington and California involved the death of a patient.

At the inception of this project, we assumed that the "carrot" of a certification report that could be submitted to the medical commission would be a key incentive for participation in CRP Certification. However, the shared learning integral to this process has emerged as an even greater motivation and perceived benefit for participants. The value of this shared learning has been reflected in the improved quality of the case submissions over time.

Despite this shift in emphasis, our relationships with regulators remain indispensable. In August 2019, we invited the WMC's Reduction of Medical Error (ROME) Committee to come to the Foundation for Health Care Quality to review redacted case files to help the commissioners better understand the review process and the materials panel members consider. Part of the impetus for this review was the fact that, at that point, only three CRP Certification reports had been submitted to the WMC. Although WMC continues to conduct parallel investigations of cases for which certification reports have been submitted, it nonetheless has signaled that they are viewed positively. This has been borne out as the WMC has reported that, to date, four submitted cases have been closed with no disciplinary action. In addition, we have made inroads in expanding the interprofessional reach of the CRP Certification program to include osteopathic physicians and pharmacists and hope to add the nursing and facilities regulators as the Washington State Hospital Association (WSHA) takes the lead on CRP activities in the state.

As the CRP Certification review process has evolved over the past 4 years, we have been fortunate to have a diverse group of review panel members who have been committed to supporting and building the program. Along with our broader group of stakeholders, they have provided input and guidance that has helped us we address challenges related to different aspects of the program. We are currently refining the review process to ensure that the meetings remained focused on the CRP response and do not devolve into second guessing clinical decisions that have already been through peer review. Rotating the meeting chairs to include nonclinical panel members, such as patient advocates, has helped in this regard. On a broader level, BETA is currently developing a more efficient review panel approach based on the NIH grant review process. The COVID-19 pandemic has also driven innovation: our May review panel meeting was successfully held via PHI-protected Zoom.

The breadth of our stakeholder group is enabling us to address key challenges that have been identified:

- To obtain patient feedback about the CRP process in an appropriate and empathetic way, we are working with the patient advocacy group Washington Advocates for Patient Safety to design a pilot project in which patient advocates will interview patients and families who have been through a CRP.
- To ensure broader dissemination of clinical and CRP lessons learned through submitted cases, we are leveraging the reach of WSHA, which has become the focal point of CRP activities in the state and has excellent communication outreach resources, including a PSO.
- To ease the burden of the application process which has dampened the number of submissions, we are working with risk management and event software companies to integrate CRP data collection into their products so that generating CRP Certification applications can become a seamless part of the workflow.

Conclusions

We accomplished our overarching goal of supporting greater adherence to CRP model with the development of a program that supports continuous improvement through shared learning. We continue to engage our broad range of stakeholders as we strive to refine and expand the program and ensure its long-term success.

Significance

The development, rollout, and expansion of the CRP Certification program constitutes an important proof of concept and provides a wealth of learning to guide the continued growth of the program.

Implications

The CRP Certification program is a model for providing CRP feedback and mutual support and for partnering with a broad spectrum of stakeholders that can be scaled nationally.

7. List of Publications and Products

Gallagher TH, Farrell ML, Karson H, Armstrong SJ, Maldon JT, Mello MM, Cullen BF. Collaboration with Regulators to Support Quality and Accountability Following Medical Errors: The Communication and Resolution Program Certification Pilot. Health Serv Res 2016; 51(Suppl 3):2569. doi: 10.1111/1475-6773.12557.

CRP Certification Application

CRP Certification Report

CRP Certification Checklist