

Title Page

Title of Project: Communication to Prevent and Respond to Medical Injuries: WA State Collaborative

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STRUCTURED ABSTRACT

PURPOSE: Communication is essential to preventing medical injuries and responding when they occur. In addition, the involvement of diverse stakeholders, including patient advocates, liability insurers, attorneys, and regulators, is needed to promote communication and resolution after medical injury.

SCOPE: We created a multicomponent intervention across Washington state for preventing and responding to medical injuries, along with a statewide collaborative (“HealthPact”) to ensure the sustainability of this work.

METHODS: Key components included 1) creating the HealthPact Forum; 2) communication training to prevent and respond to medical injuries; 3) creating a Communication and Resolution Program (CRP) at five healthcare institutions and Physicians Insurance, with an emphasis on cases involving multiple insurers.

RESULTS: Promoting collaboration across these stakeholders, though challenging, was successful. Communication training to prevent medical injuries, as well as disclosure coach training, was widely disseminated: one institution provided this training to over 1,000 healthcare workers. While the CRP was developed and launched, several barriers were identified to resolving cases involving multiple insurers. The work of the project will continue through HealthPact and the new CRP certification process for collaborating with regulators after medical injury. Together, these accomplishments constitute important steps in the gradual process of moving toward patient-centered accountability after medical injury.

KEY WORDS: Patient safety, team communication, error disclosure, medical malpractice, patient-provider relations

I. Overview, introduction to report (Purpose and Scope)

Communication is the missing link to improving patient safety and reducing medical malpractice liability. This supposition has been the guiding principle behind our project, “Communication to Prevent and Respond to Medical Injuries: WA State Collaborative.” The specific aims as originally proposed for this project were:

- 1) To create a multistakeholder collaborative across Washington state to enhance communication to prevent and respond to medical injuries;
- 2) To implement intensive communication training to prevent and respond to medical injuries at 10 partner healthcare institutions;
- 3) To develop and evaluate a collaborative approach to adverse event analysis, disclosure, and compensation between five of these 10 partner institutions and Physicians Insurance; and
- 4) To disseminate the communication training statewide via e-learning modules and assess its impact on patient safety and malpractice liability.

The hallmark of the HealthPact project was in-depth involvement of multiple and diverse stakeholders throughout, including participating healthcare organizations (Providence Everett, Providence Sacred Heart, Providence St. Mary’s, The Everett Clinic, The Polyclinic, The Vancouver Clinic, Swedish Medical Center, Multicare, Peacehealth Southwest), Physicians Insurance (the largest medical professional liability insurer in Washington state), patient advocates, regulators such as the department of health and the Medical Quality Assurance Commission, and plaintiff and defense attorneys. Key accomplishments by specific aim are listed below:

Project Component	Accomplishment
Create multi-stakeholder collaborative	<ul style="list-style-type: none"> • HealthPact Forum launched • 3 well-received HealthPact Forum meetings held • HealthPact transition to FHCQ
Implement communication training to prevent and respond to medical injuries at 10 partner healthcare institutions	<ul style="list-style-type: none"> • Team communication training (including T3 training) designed, implemented • Disclosure and apology coach training designed, implemented
Develop and evaluate collaborative CRP approach between 5 healthcare institutions and Physicians Insurance	<ul style="list-style-type: none"> • CRP designed, launched • Gradual, increasing CRP events • CRP Certification
Disseminate communication training statewide	<ul style="list-style-type: none"> • All training resources available on HealthPact website

In addition to these important accomplishments, another critical project outcome was the establishment by Dr. Gallagher, together with Dr. Tim McDonald, of the Collaborative for Accountability Following Medical Injury. The Collaborative brings together leaders in Communication and Resolution Programs from across the United States and abroad, including Brian Atchinson (PIAA), Rick Boothman, Jeff Driver, Robin Hemphill, Linda Keeney, Steve Kraman, Alan Lembitz, Dennis Olson, Ken Sands, Dave Troxel (The Doctor's Company), Gordon Wallace (CMPA), Bethany Walmsley (Oregon Patient Safety Commission), and Alan Woodward. The Collaborative has three primary goals:

- 1) Strengthen and spread CRPs by providing mentorship and guidance on best practices;
- 2) Create a policy environment that supports, rather than inhibits, CRPs; and
- 3) Cultivate the growing communication of CRP pioneers everywhere.

Drs. Gallagher and McDonald are also key collaborators on the AHRQ-funded "Comprehensive Patient Safety and Medical Liability Communication and Resolution Program Educational Toolkit," further ensuring widespread dissemination of the products from this project.

The core HealthPact project activities fell into the following domains, described in detail below:

- 1) Creation of HealthPact, and holding three HealthPact meetings;
- 2) Development, implementation, and evaluation of communication training both to prevent medical injuries (team communication training) and to respond to medical injuries more effectively (disclosure and apology coach training);
- 3) Defining and exploring strategies for measuring Communication-Sensitive Events (CSEs);
- 4) Creation, dissemination, and evaluation of a Communication and Resolution Program (CRP).

II. HealthPact

"HealthPact" was the name we gave to the multistakeholder collaborative created to provide important input to all aspects of this project and to create a forum for discussion amongst these diverse stakeholders about improving the response to medical injury. HealthPact was governed by a leadership group consisting of two patient advocates, healthcare leaders, and representatives from Washington State Medical Association, Washington State Pharmacy Association, Washington State Hospital Association, Washington State Nurses Association, and the Washington State Association for Justice. This leadership group was based at the Foundation for Health Care Quality and met regularly throughout the 4 years of the project. One critical activity of HealthPact was holding three invitation-only stakeholder meetings. All three were attended by close to 100 individuals and were extremely well received.

The first meeting focused on the general theme of improving communication in healthcare and featured a series of TED-style talks about communication both to prevent and to respond to medical injury. The second meeting began the process of narrowing HealthPact's focus to promoting communication and accountability after medical injury, a theme which carried through to the third meeting as well. A highlight of this third meeting included a 2-hour exercise, designed by our Patient and Family Advisory Committee, to help stakeholders better understand what patients want and expect in the aftermath of medical injury.

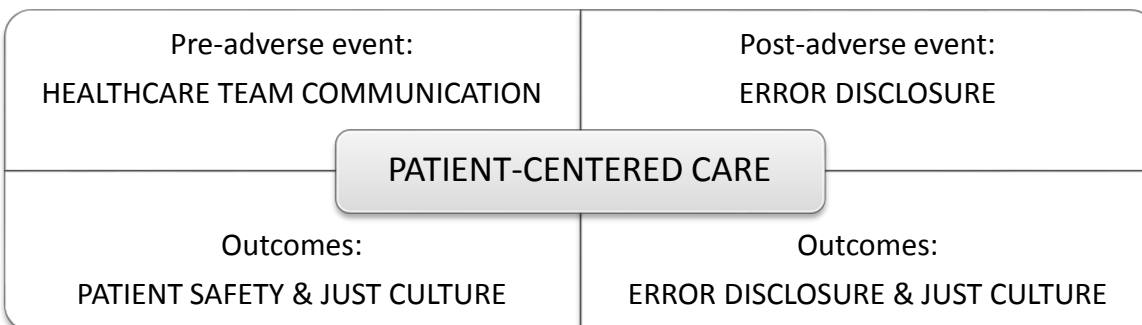
A qualitative evaluation was conducted to document the HealthPact forum leadership group (HPFLG)'s evolution over time. A single evaluator performed nonparticipant observation of the group's work during meetings and conducted one-on-one interviews with group members during March to July 2012 (n=9) and final interviews in 2014 (n=7). During their initial interviews, members of the HPFLG were asked to state their hopes for HealthPact. These tended to be large in scope and focused on HealthPact's role in catalyzing changes in the healthcare system to "break down some of the barriers between providers and patients talking openly and candidly" and bring awareness that, in the healthcare system, the "obligation and accountability is to the patient and their family." All expressed concern that HealthPact and its forums might not be able to move participants from discussion about honesty and transparency in healthcare to action in service of achieving those goals. In part, this concern may have reflected the HPFLG's inability to define its own scope of work and to work effectively and efficiently toward a self-determined set of goals. Maintaining group engagement was challenging. Still, as one group member explained, "this whole project is about spreading change, and I have the sense that a lot of people are taking information from the forums and bringing it back to their organizations. I don't think you can ask very much more than that."

During final interviews, the interviewer read each interviewee the transcribed text of their initial hopes and concerns and asked them to assess and reflect on the HealthPact leadership group's progress and accomplishments. Almost all commented that they had begun their involvement in the group with outsized hopes that were likely unattainable, at least during the span of a grant cycle. As one member said, "our most ambitious goal was that we were going to transform communication in healthcare, which, in looking back at it, is like trying to achieve world peace." That said, there was almost universal agreement that the forums successfully increased the visibility of the issues around communication by bringing together diverse populations of concerned stakeholders, including adversaries (the plaintiff's bar and the defense bar, and to some extent competing hospitals and physicians) to discuss disclosure and resolution. In terms of tangible outcomes, several HPFLG members celebrated the creation of the Patient Family Advisory Council to be housed at the Foundation for Health Care Quality. As one interviewee recounted, conversations in the forums and at the HPFLG meetings demonstrated "that the patient/advocate/family voice is a very necessary part of the conversation and not just as a kind of polite, after-the-fact add-on." Other successes noted were the willingness on the part of hospitals and other entities to support the continuance of HealthPact activities and the continuance of the certification program with MQAC.

III. Communication training design and conceptual model

The quality of communication within a healthcare organization both reflects and shapes an organization's culture. Transparent communication among a healthcare team underlies the delivery of safe patient care. Teams that communicate freely to share vital information and to challenge potential mistakes protect patients from inevitable human errors. Transparent communication is also critical when errors do occur. Honest, open communication is necessary among the healthcare team to allow learning from errors. Transparent communication is also critical between the team and the patient and his/her family for effective disclosure of medical

errors. Shifting to an organizational culture of transparency supports patient-centered outcomes of patient safety and effective error disclosure as well as the provider-centered implementation of “Just Culture” principles. Together, these help create a culture of patient-centered care in a healthcare organization.



Recognizing this link between culture and communication, we reasoned that interventions to improve an institution’s culture of safety would be more likely to succeed by incorporating tools that enhance both of these communication skills. Hence, we developed a multifaceted intervention to improve communication practices around team functioning and disclosure of medical errors. We designed our communication training interventions to incorporate adult learning theory, which recognizes that adults retain information best when the educational material is targeted to their immediate needs, limited in scope, and focused on solving a problem rather than describing underlying theory. As such, sessions were highly interactive, focused on skills building, and referenced local issues identified during a needs assessment conducted by phone prior to each training. In addition, our training was grounded in recent research showing the key importance of interprofessional collaborative practice for high-quality, safe, coordinated patient care. We ensured that our training team and learner groups were interprofessional.

Team Communication Training – Design, Implementation, and Evaluation

The goal of our team communication training was to create a small group of local trainers at each site to provide site-specific and site-controlled team communication training as an enduring resource for each organization. Groups ranged from three to 13 trainers based on the size of the organization. Our successful model emerged to have three steps. First, we asked all prospective local trainers to attend a master TeamSTEPPS training session. This investment in a core trainer team created significant buy-in for the organization and external validation of content expertise for the trainers. Second, we created a 4-hour session for the local training teams to build skills around effective delivery of communication training (T3 training). We scheduled T3 training sessions to include two or three sites to promote creative and synergistic thinking. Participants received a set of training materials, including short PowerPoint presentations, training videos, interactive exercises, and sample training agendas. Key goals of the T3 sessions were to assist teams to a) identify initial set of TeamSTEPPS skills for teaching focus, b) plan team roles for onsite trainings, c) practice debriefing skills, and d) plan for implementation and evaluation of communication skills. The third step was for our experienced training team to offer support and backup and to provide feedback to each site’s training team at their first onsite communication training. We recommended these trainings have approximately 30 interprofessional attendees. Finally, monthly conference calls, open to all sites, were held to identify successful strategies and troubleshoot problems.

We evaluated satisfaction with training sessions via a study-specific, pen-and-paper evaluation instrument. (See evaluation data below.) All team communication and T3 training materials have been published to the HealthPact website to allow open access.

Disclosure Communication Training – Design, Implementation, and Evaluation

The goal of the error disclosure training intervention was to create a cadre of coaches at each site to provide error disclosure guidance to frontline healthcare workers in partnership with risk managers. We sought the close engagement and participation of facility risk managers to create synergy with existing resources for error disclosure coaching. Healthcare organizations identified between 20 and 40 coaches per institution to undergo training, generally formal and informal interprofessional leaders, including physicians, medical directors, nurse managers, risk managers, patient safety officers, and pharmacist

managers. (See Table 1.) Our training team included two physicians with research experience in error disclosure, a nursing faculty member with error disclosure research and ethics consultation experience, a risk manager from a large insurance company, and actors trained to function as standardized patients. Onsite training consisted of a 4-hour interactive session for coaches focused on a combination of disclosure and coaching skills. Content on principles of error disclosure were provided during short periods of didactic material interspersed with interactive exercises and group discussions of video triggers. Didactic material and practice included the “ask-tell-ask” skill, the key to effective coaching. Participants then took turns practicing their disclosure skills in small groups with standardized actors who exhibited angry or sad emotional reactions. Concurrently, participants practiced disclosure coaching skills and providing feedback to their colleagues.

We evaluated satisfaction with training sessions via a study-specific, pen-and-paper evaluation instrument. (See evaluation data below.) All error disclosure communication materials have been published to the HealthPact website to allow open access, including training session agendas, tips for successful coaching, interactive exercises, etc.

The participants in the different components of team communication and error disclosure training are summarized in Table 1, below.

Case Study: Group Health Cooperative

Group Health (GH) is a member-governed, nonprofit healthcare organization serving more than 600,000 members. GH improved team communication to foster a culture of patient safety aligned with GH's organizational values and goals.

GH invested in six interprofessional opinion leaders to become master TeamSTEPPS trainers. Following this training, each attended and actively participated in T3 training in March 2012 to prepare for their initial GH onsite training. All six GH trainers and two R18 study trainers attended the initial training of 24 GH employees. R18 trainers provided just-in-time support and debrief guidance for GH trainers. Over the next year, the team of six GH trainers provided 24 onsite training sessions to over 700 employees in their organization. Attendees were 20% physician, 60% nurse, 15% nonclinical staff, and 5% other clinical staff such as pharmacists. As an organization, GH chose to roll out the team communication training to the labor and delivery, ambulatory surgery, and urgent care areas initially and to focus on four specific TeamSTEPPS skills for implementation: briefs, huddles, debriefs, and CUS. While using the basic materials provided by the R18 team, GH trainers individualized the clinical examples and presentation methods based on feedback.

GH leaders and the training team conducted follow-up “walkarounds” to interview staff on changes in team communication. Repeated measure of a Team Culture survey is planned to assess change.

Table 1. Participants in team communication and error disclosure training

	TEAM COMMUNICATION			ERROR DISCLOSURE
	Master TeamSTEPPS Training for Onsite Trainers	T3 Training for Onsite Trainers	Participants in Initial Onsite Sessions and Rollout to Frontline Clinicians	Coach Training for Onsite Coaches
Number of Participants	71	69	1300+	390

IV. Communication Training Evaluation

Evaluation of TeamSTEPPS communication training and the effectiveness of the error disclosure coach training adopted the World Health Organization's definition to develop "a systematic way of learning from experience and using the lessons learned to improve current activities and promote better planning by careful selection of alternatives for future action." Focus is on the effectiveness, efficacy, adequacy, equity, relevance, and sustainability of training. Our original stated plans included a series of pilot activities followed up with quasi-experimental, online, pre-post assessments. Iterative longitudinal qualitative assessments were envisioned to demonstrate success and address challenges as they arose. Some of our evaluation goals were achieved. A novel online knowledge and skills assessment tool was developed to assess training effectiveness in a pre-post fashion. We adopted John Kotter's eight-stage model of organizational change to assess the "Journey of the Sites," capturing the baseline stage of organizational readiness followed by multiple assessments and evaluations to assess organizational cultural change across time. A questionnaire was developed to measure leader and clinician beliefs regarding cultural change, and parallel semistructured interviews were developed to provide a richer understanding of the challenges and successes of individual organizations. Other existing instruments were planned for use in their full form or were modified to assess attitudes and beliefs toward error disclosure culture. These included the Safety Climate Survey, the Disclosure of Patient Safety Survey, and the Hospital Survey on Patient Safety. However, despite some successes, many of the evaluation tools were not as fully developed, validated, or used within the study as envisioned.

Evaluation efforts conducted included the following:

- Three qualitative interviews were conducted with organizational leaders, and 10 interviews were conducted with participants in the Error Disclosure Coach training. Summary themes are provided in Table 1.
- Training evaluations were administered to a total of 251 trainees, with 159 (63.3%) of trainees completing Error Disclosure Coach training. Summary quantitative results are provided in Table 2.
- Attitude surveys were administered to a total of 251 Error Disclosure Coach trainees and completed by 85 (33.9%). Summary quantitative results are provided in Table 3.
- Eleven of 13 monthly support calls were conducted with trainees from both TeamSTEPPS and Error Disclosure Coach training. Four themes emerged: staff buy-in varied by organization, Error Disclosure Training enhanced Just Culture at some organizations, there was considerable interest in ongoing discussion and sharing cases, and TeamSTEPPS and Error Disclosure are synergistic.

- Other evaluation tools, including an online knowledge/skills video assessment and TeamSTEPPS attitude scales, were not completed by a sufficient number of Error Disclosure Coach trainees to warrant description.

Training Evaluations

Training evaluations consisted of 16 questions in four main categories: content, training, instruction, and increases in efficacy. Training evaluations were administered to a total of 251 trainees and completed by 159 (63.3%) trainees. The participants who provided their discipline were most commonly nurses (27.7%, n=44) and physicians (25.8%, n=41). The remaining respondents included risk managers, pharmacists, and administrators (19.5%, n=31). Mean values for each item and each subscale were consistently high (15/16 item means, and each subscale mean was greater than 4.5). This indicated that the training recipients were positive and responsive to the content, training, and instructors. They also reported high knowledge/self-efficacy to perform learned tasks. The median for all individual items was the high value of 5 for each scale. Although constituting good baseline evidence for the effectiveness of training, the high scores and lack of variability are common to these types of evaluation and don't constitute evidence that the training effects will result in behavioral change or increased effectiveness or efficiency in performance of coaching responsibilities.

Quantitative: Attitude Scales - Error Disclosure Training

Attitude surveys were administered to 251 trainees and completed by 85 (33.9%). These scales included a new instrument that assessed respondent beliefs regarding their organization's stage of integration and acceptance of error disclosure recommendations and standards promoted in the study. This scale, labeled the "Organizational Change Scale," was developed in alignment with John Kotter's eight-stage model for organizational change. Summary aggregate results are provided in Figure 2. These aggregate results illustrate cross-organizational communality and not the state of any one organization. Variability between institutions is demonstrated by larger standard errors. Inspection of the responses from the Organizational Change Scale in combination with comments made in leader and Error Disclosure Coach trainee interviews led us to the following conclusions. First, the organizations have a long way to go to achieve significant change. Response values tend to cluster around neutral values or even toward negative perceptions. Although there is a tendency for respondents to report a sense of urgency that exists to drive change, there is much less confidence—with considerable cross-institution variability—regarding the extent to which stakeholders hold a shared vision and the belief that the vision is communicated and that stakeholders are empowered to act. Because this measure was administered only a single time, we can't say whether the interventions had any impact on organizational culture. The interviews and training evaluations suggested enthusiastic support for conducting the training but also concerns that there did not exist sufficient resources or a shared vision for real change to occur in the near future.

The 27-item Disclosure Culture scale assessed Error Disclosure Coach trainee beliefs regarding organizational culture around disclosure of minor and serious medical errors. Questions addressed beliefs regarding how error affects patient and colleague trust and the extent to which organizational leadership and clinical staff support disclosure. Respondents had significant experience, with an average of 16.1 years in their specific organization and an average of 13.3 years in their current department. The majority of the respondents comprised nurses (44.7%) and physicians (24.7%). Respondents generally reported agreement to strong agreement that there was support for disclosure of error (serious and minor) to patients, ease of disclosure, and encouragement of colleagues and leadership for clinicians to disclose. A second set of questions asked respondents to report agreement as to whether there was organizational support; adequate training; or concerns of organizational retaliation, malpractice, loss of patient

trust, and professional reputation. All respondents were asked to respond to their agreement for medical staff and separately for nursing staff. For the most part, beliefs regarding medical and nursing staff were similar, with the exception of increased concerns of malpractice litigation for medical staff. In general, respondents agreed to strongly agreed that there was support for both medical and nursing staffs to disclose medical error. Respondents were more neutral—showing both agreement and disagreement—that adequate training was provided for medical and nursing staffs regarding disclosure and whether retaliation constituted a fear. Respondents in general reported more neutral responses to responses of agreement regarding concerns that medical and nursing staffs would lose patient trust or that their professional reputations would be jeopardized by error.

Qualitative Interviews

Interviews with leaders focused on both the challenges and successes of the TeamSTEPPS training and the Error Disclosure Coach training. No interviews were conducted with clinician participants in the TeamSTEPPS training. In our preliminary efforts to interpret the interview data, with plans to link these results with other qualitative efforts conducted as part of the training operations (e.g., monthly call-in meetings), we looked for general emergent themes that captured critical elements across sites. The themes are presented in order from most to least pronounced. The interview data were not sufficiently robust to warrant close inspection of within-site challenges and successes. The themes and their definitions are provided in Table 2. Themes can be summarized as increased need for organizational support, questions regarding what constitutes adequate training, resources available to support sustainability of efforts, continuing uncertainty regarding best-practice management of error, accounting for the perspective and association perceptions of coaches from different disciplines, and innovation in application and support of ongoing error disclosure training.

Table 2: Interview Themes

Theme	Brief Descriptions
Provider Support	Disclosure coaches expressed concern that organizational leadership and a clinician's colleagues will face real and perceived retaliation when reporting error.
What's Enough?	The complexities of coaching a clinician after an error requires an understanding of legal protections, implications for malpractice, emotion handling, ongoing support, and skills for delivery of disclosure. Is a 4-hour training, even when supported by the institution, sufficient to ensure understanding of all critical issues?
Resources	Support for coach training was strong, but concerns arose as to whether there would be sufficient ongoing organizational support to ensure there was time provided for continuing education of coaches, protected time for working with clinicians, and a sufficient number of trained coaches.
Continuing Uncertainty	Medical error is complex, and agreement as to what constitutes a best plan following an error is unclear. There is uncertainty regarding how a disclosure should unfold and what should be disclosed. The "irregularly regular" nature of the incidence of error further complicates this. Actions will often need to constitute consensus beliefs of core personnel and not reflect a consistent, single, definitive process. This may change across time but, currently, considerable uncertainty requiring flexibility and sensitivity to separate beliefs is required.
Perspective Matters	Error disclosure coaches may be pharmacists, physicians, nurses, risk managers, etc. Each perspective brings a different connectedness with different clinician providers and different strengths that can be applied in coaching.

Innovation	Hospitals are complex and sophisticated environments with deeply entrenched cultures. This can constitute hurdles to success but often also provides routes to innovative means and approaches that work well within an individual organizational environment. Monthly “it happens here” meetings and means to anonymously report the occurrence of near misses constitute “mess-up, fess-up” support and encourage without threatening providers.
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Emergent Evaluation Plan and Lessons learned

Elements of the original planned evaluation activities proved impractical or difficult to implement within the timeframe of the study. The most significant limiting factors included 1) time required to complete the University of Washington IRB requirements and meet the IRB requirements of participating organizations within the timeframe of the training activities; 2) reluctance on the part of organizational partners to request their participating clinicians and organizational leadership contribute time to completing standard assessment tools, such as pre-post measures of knowledge, attitudes, and skills perceptions; 3) poor integration of evaluation and training activities resulting from discordant timelines and not having completed sufficient upfront planning to ensure this integration; and 4) few well-validated tools that exist for assessing longitudinal change, requiring considerable time be spent in modifying existing tools or designing new tools.

The philosophy of Developmental Evaluation emerged as a best approach for conducting similar cross-organizational studies in the future. James Patton states that “Developmental Evaluation supports innovation development to guide adaptation to emergent and dynamic realities in complex environments. Innovations can take the form of new projects, programs, products, organizational changes, policy reforms, and system interventions. A complex system is characterized by a large number of interacting and interdependent elements in which there is no central control. Patterns of change emerge from rapid, real-time interactions that generate learning, evolution, and development.”

Following this philosophy of evaluation contributed increased understanding of the processes involved in affecting change and what is necessary to successfully implement and integrate training and evaluation in future efforts. In both the TeamSTEPPS communications training and the Error Disclosure Coach training, we realized the following key findings: First, evaluation efforts, though fundamental to demonstrating success and required by the funding agency and sought after by organizational leadership, require early and continuing connection between organizational leaders and evaluators. This constitutes a core principle of Developmental Evaluation. Qualitatively, we observed a direct relationship between early leadership engagement and the extent that evaluation could unfold successful as planned. Early engagement allows evaluators to be partners in the process, to achieve buy-in for later activities, and to develop methods that are in sync with the existing organizational culture. Second, evaluation activities are most effective and certainly more efficient when they can be established as a part of training. Evaluation that serves the dual role of providing useful and timely feedback to participants serves to reinforce learning and is more positively responded to by participants. This points to the necessity of defining evaluators as key stakeholder in the development of training as well as in all interactions with organizational partners.

V. Communication-Sensitive Events

Introduction

Identification of adverse events (AEs) historically depended on voluntary reporting or labor-intensive manual records review. With the rapid expansion of electronic administrative datasets, (and more recently, electronic medical records), opportunities arose to harness these sources to

more consistently and readily capture AEs. Specifically, the Agency for Healthcare Research and Quality (AHRQ) designed the Patient Safety Indicators (PSIs), a set of evidence-based screening algorithms, based on International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM) administrative data, to identify AEs. In 2010, the Society of Actuaries Health Section sponsored a study, conducted by Milliman, Inc., that examined the economic impact of medical errors (including AEs).

Medical errors and preventable AEs (pAEs) occur for a variety of reasons; determining the cause of each can be revealing. Work completed by The Joint Commission suggests that, among 18 identified causes, lack of adequate communication was listed in the top three for the most recent 3-year timeframe for which data are available (2011, 2012, and 2013). As the HealthPact project provided interdisciplinary communication training to healthcare professionals, it provided an ideal opportunity to study “Communication-Sensitive Adverse Events (CSAEs)” — a term coined by HealthPact investigators.

We first defined a set of CSAEs. To date, we have conducted a baseline analysis that compares the rate of CSAEs in HealthPact participant hospitals with a control group of nonparticipant (non-HealthPact) hospitals and have prepared a manuscript that describes these results. As our pre-post training comparison required both a 1-year timeframe over which HealthPact communication training took place and a 1-year timeframe for follow-up, the complete datasets became available in August 2014, and the analysis is currently underway.

Methods

HealthPact investigators created master lists of CSAEs from a start list of national clinical quality metrics, augmented by HealthPact expert clinicians. The first data source in which we searched to identify CSAEs was the Comprehensive Hospital Abstract Reporting System (CHARS), an administrative database of all inpatient discharges statewide, maintained by the Washington State Department of Health. The data are publicly available; therefore, use did not require approval from an Institutional Review Board (IRB). The second data source was Washington State’s Surgical Care and Outcomes Assessment Program (SCOAP), a statewide clinical registry pertaining to a subset of inpatient surgical procedures collected for quality improvement (QI) purposes and administered by the Foundation for Health Care Quality. The registry is composed of patients who have undergone general (bariatric, nonelective appendectomy, colon), vascular, or spine surgeries. SCOAP data were obtained through data use agreements. These study procedures received approval from the University of Washington IRB. For the baseline analysis, each dataset consisted of data from 2009 through 2011.

To analyze CHARS data, two previously published data analysis approaches were employed: 1) AHRQ PSI algorithms (version 4.4, March 2012), and 2) the Milliman actuarial approach. Both approaches rely on ICD-9-CM diagnosis codes to flag potential CSAEs in an administrative dataset. The AHRQ algorithms incorporate screening criteria for each PSI to exclude conditions present on admission and usually specify a PSI-specific denominator. In contrast, the Milliman actuarial approach does not exclude conditions present on admission but instead uses “error estimate multipliers” to approximate the frequency with which each listed injury type occurs as the result of a medical error. The Milliman approach does not specify a method to calculate the rate of each error, so the metrics were mapped to similar AHRQ PSIs, and adjusted frequencies were divided by the corresponding AHRQ PSI denominator to calculate a rate. For the CHARS dataset, descriptive statistics were used to characterize hospital and patient attributes. Because CSAE rates were generally very low by both the PSI and Milliman methods, rate ratios were used to compare baseline CSAE rates between HealthPact and non-HealthPact hospitals. The two methods of CSAE identification (PSIs and Milliman) were compared.

Multivariate logistic regression was used to investigate associations between hospital and patient characteristics and the incidence of each type of CSAE.

The CSAEs available in the SCOAP registry parallel but do not directly map to either the AHRQ PSI or the Milliman metrics, so they were estimated separately. Furthermore, we added to the list of CSAEs the QI metrics available in the SCOAP registry. A relevant denominator was applied to each type of CSAE and each type of QI metric. The SCOAP analysis mirrored the CHARS analysis with the same four HealthPact hospitals and 52 non-HealthPact hospitals.

Results - CHARS Analysis: We employed all 19 AHRQ PSI metrics and 31 Milliman metrics in the CHARS analysis. Mapping the AHRQ PSIs to Milliman metrics resulted in eight paired matches, two triplet matches, and four quadruple matches, for a total of 14 matched groups. In addition, five AHRQ and 13 Milliman CSAE metrics were described singly. When compared with non-HealthPact hospitals (n=93), HealthPact hospitals (n=4) were larger in bed size, all urban, and all not for profit (versus district). A smaller proportion of HealthPact hospitals had an intensive care unit (ICU). From 2009 to 2011, the number of unique patients in the CHARS dataset was 1,896,509; 211,593 (11.2%) of these patients experienced at least one CSAE. Overall, the counts and rates of each CSAE were very low, in many instances less than 0.001% of those at risk for each separate CSAE, depending on the specific denominator used. For several CSAEs, the counts were higher using the Milliman method. The majority of the rate ratios were less than 1, favoring HealthPact hospitals. The adjusted analysis revealed that the odds of a CSAE occurring in a HealthPact hospital were 8% less than in a non-HealthPact hospital (odds ratio: 0.92; 95% confidence interval (CI): 0.92, 0.95). In both the unadjusted and adjusted analyses, those who experienced a CSAE were 15 years older; were admitted emergently, were discharged to another facility or deceased; were insured by Medicare; and had a primary diagnosis of infections and parasitic diseases, diseases of the respiratory system, or injury and poisonings (versus having complications of pregnancy or childbirth). The odds of a patient experiencing a CSAE were less than 1 for patients cared for in a hospital with a bed size less than 200, cared for in a rural location, who had 'other' insurance, or who were uninsured.

Results - SCOAP Analysis: Patterns of hospital characteristics in the SCOAP dataset were similar to those in the CHARS dataset. Data from the same four HealthPact hospitals contributed to the SCOAP analysis; 52 non-HealthPact hospitals contributed data. The number of hospitals that participate in SCOAP varies annually. The number of unique patients in the SCOAP dataset was 52,041; 5,004 (9.7%) of these patients experienced at least one CSAE. When comparing across datasets, patients in the SCOAP dataset were approximately 3 years older than those in the CHARS dataset, whereas the distributions of other comparable patient characteristics were similar across the two datasets. Overall, the counts and rates of CSAEs were low, in many instances less than 1%. As in the CHARS analysis, most of the ratios were less than 1, favoring HealthPact hospitals. Rates and rate ratios for the SCOAP analysis were approximately two to four orders of magnitude greater than in the CHARS analysis due to differences in the way denominators are calculated for each data source. The same directions in odds ratios are reflected in the CHARS and SCOAP logistic regression analyses, with two exceptions—rurality and the uninsured—although the latter is significantly different from an odds ratio of one in neither the CHARS nor the SCOAP analysis. When comparing trends over time, no meaningful patterns emerge.

The results for SCOAP quality metrics ranged from a high of prophylactic antibiotics being administered within 60 minutes of incision (98% in 2009) to a low of prophylaxis administered for deep vein thrombosis (DVT) within 24 hours of incision (53% in 2009).

Most ratios centered around one, suggesting similar adherence to QI metrics between HealthPact and non-HealthPact hospitals. No strong trends in improvement emerged over time.

Discussion

We have assembled a clinically relevant set of CSAEs that may be abstracted from an ICD-9-CM administrative database, such as Washington State's CHARS, or a registry, such as SCOAP. Furthermore, we have compared two established abstraction methods: AHRQ PSI algorithms and the Milliman actuarial approach. As previously noted, the Milliman method did not define either exclusion criteria or a denominator for each CSAE, so we believe the Milliman method identifies CSAEs with lower specificity than the AHRQ PSI method. This is a likely explanation as to why, for most CSAEs, the calculated CSAE rates are considerably higher when using the Milliman method compared with the AHRQ PSI method.

In both datasets, the rates of each CSAE were generally very low for both HealthPact and non-HealthPact hospitals. This could be due to clinician under-reporting or lack of adequate and accurate documentation in the medical record. Alternatively, the low CSAE rate may accurately reflect the numbers of CSAEs occurring in clinical care. For most CSAEs, the rate ratios favored HealthPact hospitals, although there is no clear trend over time. These findings cannot be explained by the HealthPact communication training intervention, as these analyses predate that training. These results may be due to chance or to patient or institutional characteristics.

A number of patient characteristics were associated with increased odds of experiencing a CSAE. These characteristics make logical sense, as patients with these characteristics may be experiencing a higher severity of illness, implying a greater complexity of care and perhaps posing a greater risk for any AE. Our results are consistent with previously published associations between AHRQ PSIs and mortality, length of stay, and cost. Although the finding that small and rural hospitals are associated with a lower rate of CSAEs was an unexpected finding, we propose that these hospitals may refer complex patients to larger, more urban settings for advanced specialty care. Adherence to SCOAP quality metrics did not differ significantly between HealthPact versus non-HealthPact hospitals.

To our knowledge, this is the first published description of a CSAE. As many medical errors that lead to AEs are attributable, at least in part, to communication, defining the concept of a CSAE provides a useful construct for analyses of the impact of communication interventions on AEs. Use of the specific databases used in this analysis is also unique. The level of granularity provided in both datasets enables a more complete picture of hospital care in Washington.

The HealthPact intervention took place throughout 2012. At present, we are analyzing the data that compare the pre-intervention timeframe (2009-2011) to the post-intervention timeframe (2013). The preliminary results of this analysis suggest that the intervention may have had a positive (downward) effect on the occurrence of CSAEs. This manuscript is forthcoming.

Conclusion

The important role of interprofessional communication in mitigating errors is increasingly being recognized. In this context, we found baseline CSAE rates to be low. We believe this may be a reporting issue and that CSAEs occur relatively frequently. We posit that this new CSAE metric may be useful for tracking the impact of communication training. Our subsequent analysis, comparing the pre-versus-post intervention rates, will inform this position.

VI. Claims/Compensation

A key aim of the HealthPact project was *to develop and evaluate a collaborative approach to adverse event analysis, disclosure, and compensation between five partner healthcare institutions and Physicians Insurance*. (Physicians Insurance is the dominant liability insurance carrier for physicians in Washington state, representing more than half the state's physicians.) This collaborative approach, known as the Communication and Resolution Program (CRP), is modeled on the University of Michigan Health System (UMHS) and a handful of other academic medical centers. The crux of the program is that healthcare providers who injure a patient should report the incident promptly, disclose it to the patient or family, initiate and carry out a timely investigation of why the injury occurred, feed back investigation findings to the patient/family, and proactively seek an appropriate resolution, which may include financial compensation. Our objective was to assess whether that single-institution model could be successfully extended outside the context of a self-insured academic medical center.

Specifically, we sought to implement and evaluate a CRP in the context of an "open system." CRP models have predominantly been implemented within self-insured hospital systems that employ a large proportion of the physicians who practice there, or "closed systems." In contrast, in open systems, the facility and physicians carry separate insurance, and most physicians are not employed by the hospital. The companies that insure the physicians are distant from the point of care, may be for-profit corporations, and may cover physicians who are dispersed over a wide geographic area.

Why does this distinction matter? One reason is that, when both a hospital and a physician in an open system are named in a malpractice suit, their respective insurers may end up in an adversarial posture. Each faces off not only against the plaintiff but also potentially against its co-defendants in the battle to determine liability. Another reason is that, when hospitals do not employ or insure physicians, they have a lesser degree of control over how they behave. It may be more difficult to get physicians to engage in routine reporting and disclosure of adverse events and to cooperate in early settlement processes. This project aimed to determine whether a collaborative CRP program, operated jointly by a physician insurer and hospital insurers, could overcome these barriers to success.

Distinctive Features of the HealthPact CRP

The CRP shares several features with CRPs implemented by UMHS and other institutions. It is a voluntary process from which all parties can opt out at any time. Patients are welcome to involve an attorney or other advocate. All events receive a disclosure, provision of support services to the involved family and caregivers, and some level of investigation, and all should result in billing being held pending the investigation and feedback being given to the family regarding the investigation findings. Only care that was unreasonable, however, should prompt an offer of compensation.

There were some distinctive aspects of this CRP, however. First, although some institutions have, in practice, put only serious-harm cases through their resolution process, we decided to make all incidents of unanticipated harm that were more than mere inconvenience to the patient eligible for the CRP. Second, the CRP required the partner organization that was first notified of the incident to report the incident promptly to other involved organizations participating in the CRP (and to reach out to nonparticipating organizations to invite them to join in reaching a collaborative resolution). For example, an obstetrical injury at a partner hospital involving an obstetrician insured by Physicians Insurance should result in the hospital risk manager calling Physicians Insurance immediately to report the incident and collaboratively decide on next steps. Third, resolution is to be decided jointly between the involved partner organizations. They should meet to review investigation findings, evaluate the patient's needs, make a decision

about whether compensation or other remedies are indicated, determine what to say to the family in subsequent disclosure conversations, and identify any systems improvements needed to prevent the incident from recurring.

Stakeholder Engagement and CRP Design Process

The CRP was designed through an extensive process that included multistakeholder input from malpractice insurers, defense attorneys, healthcare organizations, patient advocates, plaintiff attorneys, regulators (medical, nursing, pharmacy, and osteopathy boards and the Department of Health), and others in 2011 to 2012. We invested in this process so that we could create a CRP that is viewed as patient centered and fair. The first year of the project focused on obtaining input from these groups on the key elements of the CRP. Thereafter, annual meetings were held to bring them together and push forward with solutions to identified problems.

We also created a CRP Working Group composed of the above stakeholders to identify solutions to ongoing challenges around CRP implementation through the end of the project in 2014. One focus of its work was patient education—how to ensure that patients were informed about the CRP and their legal rights. A second was developing models of patient representation. The group recognized a need for at least some patients to have an attorney represent them in the CRP process and worked to identify pathways for connecting patients to high-quality legal representation at reasonable cost. A third was provider outreach. The group helped create a brochure to explain the program and its benefits and encourage participation.

We also involved key stakeholders in responding to a barrier to physician buy-in to CRP participation that the project identified. Fear of punitive action by the state board of medicine, (the Washington State Medical Quality Assurance Committee, or MQAC) was chilling physicians' willingness to report adverse events and participate in the CRP. To address this problem, project leaders worked collaboratively with MQAC to create an alternative pathway to ensure physician competence and quality of care in facilities that operate CRPs, known as "CRP Certification." CRP Certification is a voluntary process whereby institutions/insurers can choose to have CRP cases reviewed by an independent committee to determine if all key elements of the CRP were met (e.g., early reporting, disclosure, analysis and learning, resolution). For CRP cases that are certified (all criteria are met), the expectation is that the Board will not conduct an additional investigation. In a watershed development, MQAC unanimously agreed to a pilot test of the CRP Certification process. Conversations are ongoing with other state regulators, including the Department of Health and the Boards of Nursing, Pharmacy, and Osteopathy, about joining the CRP Certification program.

Evaluation Design

We designed a multicomponent evaluation to assess the success of the CRP. First, we evaluated **CRP implementation**. To assess the extent to which the CRP actually changed policies, structures, and processes within the implementing sites, we conducted interviews with organization leaders and frontline risk and claims managers at the beginning and end of the project. In 45-minute, semistructured telephone interviews, we elicited information on the organization's process for responding to unanticipated care outcomes; how respondents perceived the CRP to differ from its pre-existing practices; how completely respondents felt their organization was able to implement the CRP; and what factors facilitated and obstructed implementation. Data from these interview transcripts are being juxtaposed with information obtained through meetings and contacts with the partner sites and analysis of case-level data on incidents that were handled through the CRP to gauge how successfully sites were able to implement the CRP.

Second, we sought to measure the **effect of the CRP on malpractice costs and other liability outcomes**. Specifically, we sought to measure the effect of the CRP on the volume, costs, and disposition of claims and incidents at each hospital; to compare experiences across hospitals; and to identify factors associated with incidents being resolved without litigation, being resolved without payment, and being resolved with high patient and physician satisfaction ratings. To collect data for this evaluation component, we trained risk or claims managers at each site in use of a custom-built data entry form on the REDCap platform. These individuals were asked to prospectively enter information about each case as it progressed through the CRP. The data fields included a description of the incident, patient, investigation methods, and findings and involved providers and organizations; communications with the patient and among CRP partners; decisions made about resolution; barriers encountered in executing the CRP process; and the outcomes of the case in terms of indemnity payments and whether it progressed to a formal claim or lawsuit. Our evaluation plan called for comparing key outcomes in this prospectively collected data to historical controls for the same organization.

Third, we sought to assess **client satisfaction with the CRP**. We designed two survey questionnaires to measure satisfaction among physicians and patients/family members who had a case go through the CRP. Questions measure satisfaction with both the communication and the resolution elements of the program and focus on both process and outcome.

CRP Implementation Process

The CRP was launched at five facilities and Physicians Insurance. Three were hospitals affiliated with a single hospital system. Two were multispecialty physician clinics. Sites were distributed throughout Washington state.

We viewed implementation as an ongoing process that would continue over the life of the project. The CRP was officially “launched” for the purposes of demarcating a starting point for data collection when the sites had completed the preliminary assessments necessary to gauge what changes were needed to their usual processes in order to align with the CRP key elements. Some sites started in a greater state of alignment than others.

A number of implementation supports were provided:

- **Implementation toolkit:** We developed descriptions of the key elements of the program and the criteria for what constitutes a qualifying CRP event (a “Study Event”). At the beginning of the project, each site received these materials as part of an implementation workbook that stepped them through each key element and asked them to reflect on their existing policies and processes and what might need to change. (Elements of this workbook have since been used by partners in Utah and Oregon and in the Implementation Toolkit project being led by HRET). Risk managers also received a detailed manual describing how to enter data about Study Events into the study database.
- **Trainings:** We conducted a half-day disclosure coach training session at each site. Project staff visited each site to make presentations describing the CRP and its benefits to clinicians and administrative staff. Risk and claims managers received training in how to collect data for the evaluation via a webinar.
- **Individualized site readiness assessment:** Based on the workbook materials and interviews with several leaders and frontline risk managers at each site, project investigators conducted an assessment of each site’s readiness to implement the CRP. This identified areas where their structures, policies, and processes required adjustment in order to align with CRP key elements. We communicated these findings to the sites and encouraged them to make these changes.

- **One-on-one implementation coaching:** In addition to the early feedback about how to align their processes to match the CRP key elements, each site received ongoing support. In the first year of the project, the support focused on ensuring that risk managers were comfortable with the data collection. Then, in December 2012, an Implementation Consultant was added to the project team (Sarah Armstrong, RN, JD) to stay in closer touch with risk managers, troubleshoot problems, and encourage fidelity to the key elements and data collection plan. Through regular phone calls and site visits, Ms. Armstrong assessed barriers to full implementation and reported back to the project team about recommendations and progress made.

Key Findings

F1. Implementing the CRP

Our partner sites demonstrated great interest and excitement in the enterprise of rolling out the CRP yet experienced barriers to implementation. The sites experienced small victories in resolving particular cases and streamlining some working relationships but, overall, were not able to successfully implement a collaborative CRP. Most sites reported that they were applying the CRP process to their own cases (i.e., those that did not involve another insurer), even if they were not pursuing the collaborative process. However, they provided few data that would permit us to verify this claim.

Several challenging and deeply entrenched barriers to ensuring to full and consistent CRP implementation were identified through our interviews and observations of the sites:

- **Reluctance to be in the vanguard.** When it came time to begin applying the CRP to events, each site hung back, waiting for another to go first. Risk and claims managers preferred to learn from initial experimentation by others. Some also seemed to be waiting for an ideal case to come along to cut their teeth on; they did not want to begin with a high-stakes case or with a case too minor to merit the effort. The result was a significant delay in routing *any* case to the CRP.
- **Practical constraints arising from the liability insurer's distance from the point of care.** A simple problem greatly inhibited the ability of Physicians Insurance to carry out the CRP: claims managers could not get timely access to the patient's medical records. They first had to secure the patient's written authorization, which could take months. A second problem emerging from PI's distance from the point of care was its reliance on hospital partners to learn about incidents. Its insured physicians often did not promptly notify it when incidents occurred, and hospital risk managers did not reach out as they were supposed to (believing, in many cases, that the insured physician had contacted the insurer or that they should not interpose themselves in the physician's relationship with his/her insurer).
- **Delays in incident reporting.** Sites generally reported improvement in timely incident reporting by their clinical staff over the life of the project, but many still mentioned this as a barrier to executing the CRP as envisioned at the end of the study. Physicians received training and information about the need for timely incident reports but were reportedly chilled by their fear of the consequences that might ensue (e.g., from MQAC). At three sites, clinical staff also reportedly disliked the cumbersome reporting system.
- **Lack of a clear implementation plan with assigned roles and responsibilities.** Although sites completed the implementation workbook, identifying a to-do list for implementing the CRP, it was rare for them to follow up by creating implementation teams and concrete plans for bridging gaps between their existing practice and the CRP key elements. Consequently, at some sites, little or nothing changed.
- **Overcoming distrust and missteps.** Despite the enthusiasm for the CRP at the outset of the project and reports during baseline interviews that the partners had good pre-existing

relationships with one another, some of the partners had difficulty working collaboratively because of distrust in one another. In at least two cases, hard feelings arose over how one of the organizations handled an incident. Involved personnel and their managers had difficulty getting past these incidents, and the negative experiences undermined support for the CRP. In the case of two partners, the need for improved communication was acknowledged and addressed in a highly constructive manner, including a large meeting of stakeholders that produced a protocol for handling points of friction in the collaborative CRP process. However, another perceived misstep in a subsequent case derailed the progress the organizations had made in smoothing their relationship.

- **Risk managers' and claims managers' heavy workloads.** As has been reported by other demonstration projects, some frontline staff charged with carrying out the CRP reported that their excessive workloads posed a barrier to doing the tasks of the CRP—and all of them reported workload as a barrier to documenting their work in the project's data collection system. Our sites varied dramatically in the size and resources of the office responsible for administering the CRP. Few sites devoted additional resources to these offices to accommodate the additional work involved in the CRP, and only one was adequately resourced at the outset to accommodate the workload.
- **Persistent focus on serious-harm events.** Related to the workload problem, risk managers found themselves unable to process every case that met the Study Event definition through the CRP program. They continued to triage unexpected, serious-harm events for attention. The reasons they devoted less attention to minor-harm events and “known complications” are likely both practical (their capacity constraint) and cultural. At most institutions, it is a significant culture change to widen the risk-management lens to consider what steps should be taken in response to events that are not seriously harmful but are surprising and distressing to patients. Project staff were unable to lead sites to this new perspective, notwithstanding repeated messaging that such events are important to report and study because they cause patient distress, may lead to malpractice claims, and may be preventable, thereby representing opportunities for patient safety improvement.
- **Major disruptions and distractions.** Each site coped with major institutional changes (e.g., budget cuts, mergers, adoption of new electronic records systems) during the study period. Risk and claims managers were called upon to play a major role in implementing these changes and reported a significant diversion of their time away from the CRP.
- **Uneven support for the CRP among key personnel in the organization.** At the outset of the project, top leaders at all of the partner sites expressed strong support for the CRP philosophy and the project. However, staff turnover—including some high-level leaders—during the project period led to enervated leadership support at some sites. At one site, a new leader was openly skeptical of the approach, chilling risk managers' participation in the project. At another, top leaders remained supportive, but a gulf emerged in the frontline staff. Some worked energetically to apply the CRP to their cases, while others largely disregarded it and the project. Despite their support for the project, the executives did not recognize and rectify this disparity.

Our overall conclusion is that operating CRPs in which two or more insurers must collaborate to resolve cases is highly challenging and likely requires several preconditions not present for our sites, including a commitment from physicians to collaborate with facilities to resolve incidents, mechanisms for quickly transmitting information to remote insurers, tolerance for missteps in early attempts at collaboration, and clear protocols for joint investigations and resolutions.

Our experience also accords with a key finding of other demonstration projects, including the New York project: CRPs are unlikely to succeed when the primary force pushing their

implementation, operation, and evaluation forward comes from outside the organization. As outsiders, the project team could not ensure that organizations changed practices that needed to change in order to align with the CRP key elements. Our attempts to encourage movement along these lines sometimes encountered resistance from hospital and insurer personnel, who had other priorities.

F2. Evaluating the CRP

We were able to carry out the evaluation of CRP implementation. However, we encountered significant difficulties carrying out the other components of the evaluation. As discussed above, site personnel were selective about what cases they chose to put through the CRP. Another problem was risk/claims managers' inability to adhere to their initial commitment to enter data about CRP cases into the study database. Despite intensive and sustained effort by the project team to ensure that these individuals understood how to enter data, why it was needed, and what knowledge the information would generate—and received regular reminders about the need to record the work they were doing on CRP cases—risk/claims managers rarely documented their work in the study database.

Over the project period, we heard several explanations for this. Some risk managers became frustrated with REDCap early in the project after the University of Washington's IT department required that users switch to new login information. Project staff then walked risk managers through the process in real time. Some risk/claims managers reported that the REDCap form was difficult to use—though metadata indicated that most people had spent only a few minutes in REDCap. In response, we distributed a paper version of the form, which risk managers liked.

Some felt that the data form was too long. In response, we developed a short form, but we experienced only a modest bump in data entry thereafter. A likely explanation is that reporting even the basic elements needed to assess compliance with the CRP takes time and effort—not to enter the data so much as to obtain the information. For example, documenting a disclosure communication might involve calling one or more of the individuals present for the conversation to learn what was said as well as reviewing the medical record.

In summary, the same problems that inhibited implementation of the CRP inhibited data collection: some sites' leaders did not strongly signal that the project was a priority, and persons responsible for operating and recording the work of the CRP had excessive workloads. The cognitive burden of learning a new database system and the wide scope of the data collection compounded these problems. Discussions with other demonstration project leaders have revealed these to be challenges that other CRP demonstration projects have also encountered.

Although we saw an uptick in data entry in the last several months of the project period, at the end of the period, we ended up with only 30 CRP cases documented in REDCap across all sites. Because this number was so low, we concluded that administering the patient and provider satisfaction surveys that we developed would not yield useful data. The site that contributed the most events also got cold feet about sending out a patient survey, feeling that it could threaten the trust it had built with patients and families.

We are left in a perplexing situation. In the end-of-project interviews, site personnel reported that they were generally following the CRP process, at least for serious-harm events. Yet, when the project team requested information on the number of cases (beyond those reported in REDCap) that had been handled through the CRP, many risk/claims managers could not provide a number, and others gave a small number—and one that we have no means of validating by examining what actually occurred in those cases. Under these circumstances, our

judgment is that it would not be reasonable to attempt to draw inferences about the effect of the CRP by examining organization-level outcomes, such as total malpractice costs and volume of claims, before and after CRP implementation. Any observed changes could not firmly be attributed to the CRP, and a lack of change would tell us little about how the CRP works when fully implemented.

This experience has generated useful lessons for the HRET Toolkit project and other CRP efforts going forward. One is that it is critical to measure implementation of CRPs. In this and other demonstration projects, incomplete implementation and inconsistent application of the CRP have confounded efforts to gauge the full potential of the project to reduce costs and volume of claims. Organizations that fail to confirm that the CRP was carried out as planned risk drawing false conclusions about its potential effectiveness in improving liability outcomes.

A second lesson is that, because risk and claims managers must enter the data about CRP cases, the demands of data collection must be adjusted to the available resources. Ideally, organizations should increase the FTE of their risk/claims departments—by as much as 1 FTE in large organizations—to allow time to adequately record the work of the CRP. If this is not possible, data collection needs to be more circumscribed than was the case in this demonstration project. It is also advantageous to build data collection into the organization's existing risk management database software, to reduce the demands on personnel who are already thinly stretched. We are applying these lessons in the HRET Toolkit project: we have developed a shorter data form and worked with the field test sites to build it in to the database screens that risk managers are accustomed to seeing when they open a new event file.

VII. Products and Publication

Products

All the curricula and evaluation material for the team communication training and disclosure coach trainings are available online at www.healthpact.org. In addition, all the material related to the development of the Communication and Resolution Program are also available at this website. These materials have also been fully integrated into the CRP Toolkit being developed as part of the AHRQ-funded project with HRET.

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