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Title of Project: Training Doctors to Disclose Unanticipated Outcomes to Patients: Randomized Trial

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I. STRUCTURED ABSTRACT

Purpose

Disclosing unanticipated outcomes to patients is recommended, but institutions and providers struggle with implementation. Many healthcare organizations are training providers in disclosure skills. Yet, it is not known whether training improves patients' ratings of actual disclosure conversations.

Scope

For a randomized trial of clinician disclosure training on patient ratings of the quality of actual disclosures, 419 surgeons and interventional internal medicine physicians in Colorado and Washington were recruited to participate in the project.

Methods

Participating physicians were randomized to an intervention arm (intensive disclosure training including individualized practice with a standardized patient) or control arm (usual care). A study event was an unanticipated outcome that was reported by participating physicians and that was disclosed to the patient. Following study events, physicians and patients evaluated the quality of the disclosure conversation.

Results

In total, 296 qualifying study events were reported. Surveys were returned by 137 patients (46%) and 274 physicians (93%). The mean patient rating of the quality of disclosure was 7 on a 0-10 scale. No impact of the training was evident on the primary outcome (mean patient ratings of the quality of actual disclosures) or on secondary outcomes (patient likelihood of returning to the physician for future care, patient trust in the physicians' knowledge and competence, or trust in the physicians' honesty and integrity). The project succeeded in developing tools to measure patient and provider ratings of the quality of actual disclosures, but more work is needed to understand effective strategies for improving physicians' skills at conducting these difficult discussions.

Key Words: error disclosure, patient safety, patient-provider communication, ethics, medical malpractice, randomized trial

II. PURPOSE

Despite our best efforts, unanticipated outcomes (harms resulting from medical care) are inevitable. Communicating with patients about unanticipated outcomes is difficult, especially when the outcome was due to an error. Though disclosure of unanticipated outcomes is increasingly required, such disclosure currently is uncommon. Failing to communicate effectively with patients following unanticipated outcomes represents a fundamental breach in patient-centered care and may increase malpractice risk.

The movement to disclose unanticipated outcomes to patients is rapidly accelerating. Eight states now mandate disclosure of unanticipated outcomes, and 36 states encourage disclosure by providing legal protections for portions of what is disclosed to patients. Many hospitals are developing explicit disclosure policies. However, few physicians have had training in disclosing unanticipated outcomes to patients and may be ill prepared for these challenging conversations.

One key obstacle to improving disclosure has been uncertainty as to whether improving physicians' disclosure skills can enhance patients' experiences with this difficult period in care. Although many have asserted that enhanced disclosure could increase patient satisfaction and reduce malpractice claims, no trial has evaluated these hypotheses. Therefore, we conducted a randomized trial to determine whether providing physicians with intensive disclosure training affects patient satisfaction with actual disclosures and physicians' malpractice claims. Our project had the following specific aims:

1. To determine whether physician communication training in disclosing unanticipated outcomes to patients affects patient satisfaction with disclosure.
2. To explore whether physician communication training in disclosing unanticipated outcomes to patients affects malpractice claims.
3. To explore whether characteristics of the event (severity of harm, presence of error), the physician, patient, and the environment independently affect the relationship between unanticipated outcome disclosure training and patient satisfaction.

III. SCOPE

To implement this project, we developed partnerships with COPIC, a large Colorado malpractice insurer and University of Washington Medicine (UW), to train their physicians in disclosure and study the training's impact on real-world outcomes, particularly patient satisfaction with disclosure. We recruited over 400 practicing surgeons and interventional internal medicine physicians, randomized them into intervention and control groups, provided intensive disclosure training to the intervention physicians, and measured patient and provider satisfaction with actual disclosure conversations following unanticipated outcomes of care.

IV. METHODS

IV.a. Recruitment

There were two key groups of study participants for this project:

1) Physicians from COPIC and UW Medicine (including Harborview Medical Center and Northwest Hospital)
2) Patients of participating physicians who experienced an unanticipated outcome that met study inclusion criteria

Participating physicians were surgeons (general surgery and all surgical subspecialties) and non-surgeons who frequently performed invasive procedures (ie, pulmonary critical care, emergency, nephrology, cardiology, interventional radiology, etc).

As it became clear that physician recruitment and training would be more labor intensive than originally anticipated, we decided to concentrate our effort primary at COPIC to complete recruitment there and then finalized the recruitment at the University of Washington. This staged recruitment and training approach allowed us to begin data collection at COPIC earlier, with UW data collection beginning thereafter.

Among the COPIC physicians, participants were drawn from the above specialties who practiced in 10 Colorado counties surrounding metropolitan areas to decrease travel time required to reach a videoconferencing facility, which was necessary for the standardized patient training. Recruitment letters and emails were sent by Dr. Lembitz (Vice President of COPIC Risk Management) and Dr. Boyle (COPIC risk manager), asking for participation. In total, 228 COPIC physicians were recruited.

UW Medicine physicians were recruited in the above specialties at UW Medical Center, Harborview Medical Center, and Northwest Hospital. We pursued recruitment at UW in close collaboration with the relevant clinical departments and their leadership. Dr. Gallagher made a number of presentations to Divisions and Departments during the recruitment phase. Though this approach was time consuming, relationship building with institutional leadership led to a successful recruitment process and data collection phase. Department chairs also sent emails to physicians in their departments informing physicians about the study. Overall, 191 UW physicians were recruited.

Patients of study physicians at both COPIC and UW who experienced an unanticipated outcome that met study inclusion criteria were asked to participate in the study by completing and mailing in a post-event survey.

IV.b. Disclosure Training

Study physicians randomized to the intervention group received a total of 3+ hours of disclosure training. This training consisted of a 2-hour background training and a 1-hour individualized, standardized patient training session before data collection and access to a just-in-time refresher webcast training throughout the duration of data collection.

IV.b.1. Background Training

The initial background training was intended to ensure that all physicians in the intervention group had mastered basic disclosure skills. This training was originally planned as a webcast but was changed to 2-hour in-person group

sessions to increase advanced learners' engagement and education. Dr. Gallagher taught these background sessions in-person at COPIC and at UW (Background Training materials listed in *Products*). A number of UW physicians' schedules did not permit them to attend larger group training sessions, so Dr. Gallagher held one-on-one background training sessions with a subset of UW physicians. At UW, Dr. Gallagher ran background training sessions from October 2011 to March 2013. He led seven large group background training sessions and 16 individual or small-group (three or fewer study physicians) background training sessions. The trainings consisted of didactic material, question-and-answer time, and small-group role play practice time.

IV.b.2. Standardized Patient Training

After study physicians in the intervention group participated in a background training session, they were scheduled for a 1-hour personalized training session with a standardized patient. We created four standardized cases for these trainings: two for medicine physicians and two for surgery physicians (Standardized Patient Cases listed in *Products*). We had a roster of approximately six standardized patients whom we trained in all four of the cases. Each study physician, therefore, learned two cases (either medicine or surgery depending on their specialty) and practiced disclosing each case to a standardized patient. Regardless of medicine or surgery, in the first case, the standardized patient played a sad patient; in the second case, the standardized patient played an angry patient. This allowed each study physician in the intervention group to practice disclosing an unanticipated outcome in medical care to a sad person and an angry person. After each disclosure conversation, a facilitator led a discussion of things that went well and things that the physician would like to improve upon using the "ask-tell-ask" model. This facilitation and discussion was based on the Key Disclosure Skills list, developed by research staff (Key Disclosure Skills Document listed in *Products*).

After the standardized patient training session, study physicians were emailed an individualized copy of what they did well and what they identified as improvement opportunities (Standardized Patient Session Feedback Template listed in *Products*). COPIC physicians completed these 1-hour standardized patient trainings through high-speed video conference, and UW physicians completed these trainings in person with the standardized patients. We ran these trainings from March 2011 through April 2013. Because we successfully completed these standardized patient training sessions via videoconference, we have shown that this method is generalizable, allowing physicians in rural and underserved areas to benefit from this highly portable experience in the future.

IV.b.3. Just-in-Time Disclosure Videos

With technical assistance from Pacific Standard Television, we created error disclosure videos that study physicians in the intervention arm had access to for "just-in-time" learning as a refresher course throughout the data collection period (Just-in-Time Error Disclosure Videos, listed in *Products*). We created a

customized video for COPIC physicians and one for UW physicians. The videos are approximately 18 minutes long and are composed of both didactic material and case examples. Though these online refresher courses were not a standardized part of the training, all intervention physicians at COPIC and UW had access to them for use at their discretion.

IV.c. Partner Engagement and Project Management

Throughout the study, we held monthly calls between UW researchers and project staff at COPIC to ensure the project was running smoothly and to discuss any needed procedural adjustments in real time. We also engaged with UW risk management multiple times a month to discuss the flow of the project. As the post event data was collected, we began holding regular calls with Dr. Studdert and Dr. Cook to discuss data management and analysis.

IV.d. Data Collection

IV.d.1. Event Inclusion and Exclusion Criteria

In order for an event to be included in this study, it must have been an unanticipated outcome AND involve harm to the patient that was more than minor AND be disclosed by a study physician to a patient and/or family. There were a number of situations that would exclude an event from the study: the patient had retained an attorney, the patient had filed a complaint to the state body that promotes the delivery of quality healthcare by enforcing physician licensure qualifications and consistent standards of practice, the patient made a written demand for payment, the patient died, the patient was a minor, a disclosure conversation did not occur, minor or no harm to the patient occurred, or the study physician declined to include the event in the study.

IV.d.2. Baseline Questionnaire

Study physicians in both the intervention and control groups completed a previously validated baseline questionnaire (Baseline Questionnaire listed in *Products*) regarding their knowledge and attitudes about error disclosure. It also collected basic demographic data. Study physicians in the intervention group completed this questionnaire before receiving any additional training. Most study physicians completed this questionnaire online; for study physicians who found the online format a barrier, they completed it on paper and research staff entered their data into a database.

IV.d.3. Data Collection Time Period

Because physician recruitment was staggered, with recruitment at COPIC finishing first, data collection began at COPIC first. Data collection at COPIC ran from September 2011 to December 2013 (27 months), and data collection at UW ran from August 2012 to December 2013 (16 months).

IV.d.4. Study Marketing at UW

After intervention physicians completed the baseline questionnaire, background training and standardized patient training, they were eligible to report study

events. Control physicians were eligible to report study events after completing the baseline questionnaire. During the data collection period, physicians were asked to report unanticipated outcomes that may have qualified as study events to COPIC or UW risk management, respectively. At COPIC, unanticipated outcomes are routinely reported, as physicians must report events in order to receive liability coverage. Therefore, reporting rates at COPIC were relatively high. At UW, reporting of unanticipated outcomes is much less standardized and varies greatly between individual physicians. Because of this, we launched a marketing campaign for UW physicians about the study. We engaged Pyramid Communications, a strategic marketing and communications firm, to provide expertise in marketing to UW physicians. With Pyramid Communications' assistance, we developed study flyers that were posted in UW departments, talking points for Dr. Gallagher to cover during calls with each participating division/department head, laminated wallet cards, laminated badge cards, laminated just-in-time pocket cards, and a series of strategic emails sent monthly to UW study physicians (Study Reminder Flyer, Division/Department Study Remind Talking Points, Reminder Wallet Card, Reminder Badge Card, Key Disclosure Skills Pocket Card, Reminder Email Text listed in *Products*). Research staff routinely attended departmental meetings to remind study physicians to report eligible events.

Throughout the project, we also worked with HSD to adjust the mailed packets sent to study physicians and patients to increase response rate. This included waiving the need for HIPAA authorization, adding $20 in compensation for every returned patient survey, adding a follow-up mailing and follow-up phone calls to patients and physicians, working with UWMC Patient and Family Education Services to make the contents of the mailings more patient friendly, creating an information sheet to accompany the mailings, adding a thank you letter to patients, and waiving the need for documentation of patient consent.

IV.d.5. Identifying Events From Morbidity and Mortality Conferences
Because there was more variability in unanticipated event reporting habits between physicians at UW than at COPIC, we were concerned that some qualifying study events at UW were not being reported into the study. Therefore, we began working with the general surgery department to collect unanticipated events that were reported at their Morbidity and Mortality (M&M) conferences, many of which met inclusion criteria for this study. We hired a part-time student employee to spend time on this process from the UW risk management side. General surgery sent M&M sheets to UW risk management biweekly. The student employee then identified events that involved an enrolled study physician and had a disclosure conversation with a patient or patient's family member. He then contacted those study physicians and asked if the event met all study inclusion criteria and if they would like to enroll the event in the study. If so, he enrolled the event, passed it on to an appropriate risk manager, and data collection proceeded as usual from that point. We did not expand this collection process through M&M conferences to other specialties during this study due to

time available for risk management to work on this study, but it was helpful in identifying study events, and the model could be used for unanticipated event identification in other settings.

We also began collecting events from general surgery's Morbidity and Mortality conferences, then asking eligible study physicians if they would like to enroll them in the study to catch eligible events that may not have been reported by an individual physician. We hired an additional part-time student employee for UW risk management to assist with outreach and data collection for UW physicians.

IV.d.6. Post Event Survey
After an event was reported to COPIC or UW and the event met eligibility criteria, the physician and the patient were mailed a letter explaining the study and a post-event survey asking them to rate the quality of the disclosure conversation. Patient surveys also included a short demographics portion (Post Event Physician Survey and Post Event Patient Survey listed in *Products*). Completed surveys were mailed to the research staff at UW. If physicians or patients did not mail back the survey after 10 business days, a second mailing packet was sent. If there was still no response within 10 business days after the second mailing packet, a risk manager at COPIC or UW called the physician or patient to ask them if they would like to participate. Before the IRB modification was made to waive need for documentation of consent, a completed patient survey also required a signed consent form in order to be eligible.

IV.d.7. Event Record
After an eligible event was reported to COPIC or UW, risk management compiled information about the event that formed an event record. This data included information about severity and preventability for the event, as determined by COPIC and UW risk management.

IV.e. Maintaining Confidentiality

We have followed a data management plan that maximizes confidentiality of research data. Dr. Cook, our project statistician, is located at Group Health Center for Health Studies and oversaw the data linkages and assembly. COPIC and UW maintained linkages between patient and physician identifiers and name, as well as identifiers to reported events. Each physician and patient post-event survey was mailed back to UW research staff with identifiers, not names. UW researchers knew the names of physicians participating in the study and questionnaire and survey results.

IV.f. Human Subjects Division IRB Modifications

Human subjects protections issues were extremely important for this project, given the sensitive nature of disclosing outcomes in medical care that did not go as planned. This is true for physicians, who are having delicate conversations with patients and are stepping up to report these events and conversations to risk management, and it is especially true for patients, who were asked to talk about how those conversations with their providers went. It was of utmost importance to uphold full human subjects

compliance for this study. We also made a number of changes throughout the course of the project to increase study event identification and ease of participation. Because of these factors, we submitted and obtained many human subjects division IRB modifications.

Initial IRB approval in 9/1/2009
Modification Approved 3/30/2010

- Increased total training time for intervention group to 3.5 hours (2hours in person, 30-min refresher) to increase likely effectiveness: changed from webcast to in person
- Revised recruitment letters for UW and COPIC physicians for increased training time readability and flow
- Added information sheet for COPIC physicians

Modification Approved 6/3/2010

- Modified consent materials to reflect that a Federal Certificate of Confidentiality was not necessary for AHRQ studies
- Removed the need for HIPAA authorization, because patient information was from Risk Management

Modification Approved 4/9/2012

- Gained approval for the patient and physician post-event survey
- Gained approval for the Event Record form
- Edited the Patient Information Letter and Patient Information Follow-Up Letter to simplify language: worked with the UWMC Patient and Family Education Services to lower the literacy level and make the documents patient and family friendly
- Gained approval for the Physician Information Letter and the Physician Information Follow-Up Letter
- Gained approval for Patient Thank-You Letter
- Added patient compensation, so that any patient who returned a survey received $20 in compensation: to increase patient response rates
- Revised the patient consent form to lower the literacy level and make the layout and information in the document more patient and family friendly: worked with the UWMC Patient and Family Education Services
- Added Northwest Hospital as a site (in addition to UWMC and COPIC) so that UW-employed physicians who worked at Northwest Hospital could be added to the research subject recruitment pool

Modification Approved 7/10/2012

- Added phone calls to patients as part of recruitment process; gained approval for a Patient Recruitment Phone Script so that risk managers at COPIC and UW could call patients who did not return a survey or opt-out document after 10 days of the second mailing

Modification Approved 2/26/2013

- Gained approval for collecting study events from Department of Surgery Morbidity and Mortality (M&M) faculty meetings: surgery sent M&M event lists to HSRM, who then screened the events to identify eligible study events and then asked the disclosing study physician if he/she would like to enroll the event: to

increase the number of eligible study events collected

- Gained approval to waive the requirement of receiving documented consent from patient participants: removed the Patient Consent Form from recruitment packet, edited Patient Initial Recruitment Letter and Patient Follow-Up Recruitment Letter: to increase patient response rate
- Gained approval for a Patient Information Statement

V RESULTS

Va. Participation

In total, 419 physicians were recruited for this study between both COPIC and UW, breaking down to 228 recruited COPIC physicians and 191 recruited UW physicians. We experienced physician dropout at both COPIC and UW throughout the study; at the end of data collection, there were 183 participating COPIC physicians and 140 participating UW physicians, making a total of 323 participating physicians.

Table 1 presents the demographic characteristics of participating physicians who completed the baseline questionnaire, those who reported an unanticipated outcome into the study, and those for whom a completed post-event survey was received from a patient. The randomization procedures were successful in ensuring roughly equal distribution of physicians across the intervention and control groups by gender, site (COPIC vs. UW), specialty, years in practice, and percent time in clinical practice.

Vb. Baseline Questionnaire

Physicians completed the baseline questionnaire before they received training (intervention physicians) and before reporting events (all study physicians).

Vc. Reported Events

Overall, 541 unanticipated outcomes were reported into the study throughout the data collection period, 452 events were reported at COPIC, and 90 events were reported at UW. Of this total number of reported unanticipated outcomes, eligible study events comprised a subgroup. Throughout the duration of the data collection period, COPIC had 228 qualifying events reported and 223 non-qualifying reported events. UW had 68 qualifying events reported and 22 non-qualifying events. In total, 296 qualifying study events were reported. The discrepancy between the number of reported events between COPIC and UW largely was due to the fact that COPIC's data collection period ran 27 months, whereas data collection at UW ran 16 months.

Table 2 presents the event characteristics both of all qualifying study events as well as those events in which patients returned a completed survey. The study events were assessed by the risk managers who completed the event record to have added 5 days or fewer to the patients' hospital stay and to have been in the severity category of "minor (temporary)" or "major (temporary)." Almost none of the study events were associated with permanent harm or death. Almost three quarters of the study events were associated with surgical procedures and were judged by the risk managers to have little evidence that the unanticipated outcome was preventable.

Vd. Post Event Survey

For each reported eligible event (296 qualifying reported events total), a post-event survey was sent to both the participating physician and the patient involved in the unanticipated outcome. We received a total of 274 returned and completed physician surveys (response rate 93%): 215 from COPIC study physicians and 59 from UW study physicians.

We received a total of 137 returned and completed post-event surveys from patients who were eligible for including in the study (response rate 46%). Of those 137 returned patient post-event surveys, 106 were from COPIC patients, and 31 were from UW patients. Participating in the study was entirely optional, and we received 29 opt-out decisions from patients, 27 from COPIC patients, and two from UW patients. We were particularly interested in eligible study events for which we received the post-event survey from both the study physician and the patient for the same study event. We received 103 of these physician/patient completed survey pairs from COPIC and 26 from UW, making the total number of physician survey-plus-patient survey returns for the same study event 129.

Ve. Event Record

Risk managers at COPIC and UW, respectively, completed an event record for each reported qualifying study event. Thus, we have completed event records for 300 study events: 230 from COPIC study events and 70 from UW.

Vf. Analysis of primary and secondary outcomes

Table 4 presents a comparison of the primary study outcome, patient satisfaction with the overall quality of disclosure as assessed on a scale of 0 (extremely low quality) to 10 (extremely high quality). The mean unadjusted patient satisfaction with disclosure rating was 7.37 in the control group and was 7.68 in the intervention, a difference that was not statistically significant. The figure below presents the histograms for patient satisfaction with disclosure in the intervention and control groups and graphically highlights the similarities between these groups.

Multivariate modeling to adjust for potential covariates, including MD sex, site (COPIC vs. UW), hospital days attributed to the unanticipated outcome, degree of disability, patient sex, patient age, and patient education, produced mean patient satisfaction with disclosure in the control group of 7.43 compared with 7.63 in the intervention group, a difference that was not statistically significant. Dichotomizing patient satisfaction with disclosure at the scale's midpoint (5 or lower vs. 6 or greater) to identify those who rated the disclosure as "excellent" did not detect a statistically significant difference between the intervention and control groups.

Table 5 presents an analysis of a group of secondary outcomes, including patient likelihood of returning to the physician for future care, trust in the physicians' knowledge and competence, and trust in the physicians' honesty and integrity. No significant differences between the intervention and the control groups were detected in either the unadjusted or adjusted models.

Table 1. Demographic characteristics by randomization and outcome ascertainment at the MD level.

	All Who Completed Baseline Questionaire		Amongst those that experienced at least one medical error		Amongst patients that returned a completed post event survey	
Variable	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
TOTAL, n (row %)	190 (51.6)	178 (48.4)	60 (48.4)	64 (51.6)	38 (50.7)	37 (49.3)
Female, n (%)	120 (63.5)	123 (69.5)	34 (56.7)	39 (60.9)	21 (55.3)	22 (59.5)
COPIC, n (%)	106 (55.8)	88 (49.4)	50 (83.3)	39 (60.9)	33 (86.8)	24 (64.9)
Surgery Speciality, n (%)	130 (68.4)	113 (63.5)	52 (86.7)	49 (76.6)	32 (84.2)	28 (75.7)
Years in Speciality, n (%)						
Less than 1 year	2 (1.1)	5 (2.8)	0 (0.0)	3 (4.8)	0 (0.0)	2 (5.6)
1 to 2 years	5 (2.6)	9 (5.1)	0 (0.0)	4 (6.3)	0 (0.0)	3 (8.3)
3 to 4 years	20 (10.6)	12 (6.8)	3 (5.0)	2 (3.2)	3 (7.9)	0 (0.0)
5 to 10 years	43 (22.8)	44 (25.0)	17 (28.3)	14 (22.2)	9 (23.7)	8 (22.2)
11 to 20 years	63 (33.3)	60 (34.1)	18 (30.0)	24 (38.1)	14 (36.8)	17 (47.2)
21 years or more	56 (29.6)	46 (26.1)	22 (36.7)	16 (25.4)	12 (31.6)	6 (16.7)
Percentage of time in clinical practice, n (%)						
0%	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1-25%	9 (4.7)	9 (5.1)	0 (0.0)	3 (4.7)	0 (0.0)	1 (2.7)
26-50%	16 (8.4)	12 (6.8)	3 (5.0)	3 (4.7)	2 (5.3)	2 (5.4)
51-75%	37 (19.5)	26 (14.7)	1 (1.7)	7 (10.9)	0 (0.0)	4 (10.8)
100%	128 (67.4)	130 (73.4)	56 (93.3)	51 (79.7)	36 (94.7)	30 (81.1)

Table 2. Event characteristics by randomization and amongst those who completed outcome ascertainment

Variable	Total Events		Events amongst patients that returned survey	
	Control	Intervention	Control	Intervention
EVENT CHARACTERISTICS				
Hospital Days				
None	58 (43.6)	40 (24.8)	25 (41.0)	21 (27.3)
1-5 days	60 (45.1)	96 (59.6)	29 (47.5)	46 (59.7)
6-10 days	10 (7.5)	17 (10.6)	5 (8.2)	7 (9.1)
11-20 days	2 (1.5)	5 (3.1)	2 (3.3)	2 (2.6)
More than 20 days	3 (2.3)	3 (1.9)	0 (0.0)	1 (1.3)
Degree of Disability				
Emotional Only; No physical injury (Fright)	1 (0.8)	5 (3.1)	1 (1.6)	1 (1.3)
Insignificant (temporary); Injury not requiring treament	7 (5.3)	4 (2.5)	3 (4.9)	3 (3.9)
Minor (temporary); Minor injury requiring additional treatment	54 (40.6)	47 (29.2)	27 (44.3)	28 (36.4)
Major (temporary); Injury requiring ongoing treatment	68 (51.1)	103 (64.0)	30 (49.2)	44 (57.1)
Minor (permanent): Permanent injury without compromise to ADL's	2 (1.5)	2 (1.2)	0 (0.0)	1 (1.3)
Signficant (permanent): Permanent injury with compromise to ADL's	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major (permanent): Severe injury	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Grave (permanent): Most serious injury	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Outcome Associated with:				
Diagnosis	1 (0.9)	4 (3.3)	0 (0.0)	0 (0.0)
Surgical Procedure/Operation	101 (78.3)	107 (72.3)	45 (76.3)	54 (74.0)
Medical Procedure	28 (25.2)	36 (30.0)	16 (30.8)	17 (29.3)
Anesthesia	1 (0.9)	1 (0.8)	0 (0.0)	1 (1.7)
Drug	2 (1.9)	7 (5.6)	1 (2.0)	3 (5.0)
Other	1 (0.9)	3 (2.5)	0 (0.0)	1 (1.7)
Confidence that unanticipated outcome preventable				
Little or no evidence that unanticipated outcome was preventable	98 (74.2)	118 (73.3)	46 (76.7)	62 (80.5)
Slight to modest evidence that unanticipated outcome was preventable	3 (2.3)	6 (3.7)	2 (3.3)	3 (3.9)
No likely that unanticipated outcome was preventable	10 (7.6)	12 (7.5)	5 (8.3)	5 (6.5)
More likely than not that unanticipated outcome was preventable	5 (3.8)	9 (5.6)	1 (1.7)	1 (1.3)
Moderate/strong evidence that unanticipated outcome was preventable	1 (0.8)	3 (1.9)	0 (0.0)	1 (1.3)
Virtually certain evidence that unanticipated outcome was preventable	15 (11.4)	13 (8.1)	6 (10.0)	5 (6.5)

Table 4. Primary Outcome: Patient Satisfaction with Disclosure

Analysis	Control		Intervention		Mean Difference between Groups		P-Value
Patient Satisfaction							
Unadjusted Mean (95% CI)	7.37	(6.60, 8.14)	7.68	(7.09, 8.26)	0.30	(-0.66, 1.27)	0.54
Adjusted Mean (95% CI)	7.43	(6.65, 8.20)	7.63	(7.08, 8.18)	0.21	(-0.78, 1.19)	0.68
Excellent Patient Satisfaction							
Unadjusted Proportion (95% CI)	0.73	(0.61, 0.84)	0.77	(0.69, 0.85)	0.04	(-0.10, 0.18)	0.60
Adjusted Relative Risk* (95% CI)	1 (Ref)		1.06	(0.88, 1.29)	NA		0.53

GEE with independent error structure and robust standard errors

*Adjusted Variables include MD Sex, Site (Copic versus UW), Hospital Days (None,1-5, 6 or more), Degree of Disability (Continuous), Patient Sex, Patient Age (<45,45-64,65 or older), Education (<College Grad vs College Grad or greater)

Table 4. Primary Outcome: Patient Satisfaction with Disclosure

Analysis	Control		Intervention		Difference between groups		P-Value
	mean	**(95 % CI)**	**mean**	**(95 % CI)**	**diff**	**(95 % CI)**	
Unadjusted	7.29	(6.53, 8.06)	7.69	(6.97, 8.40)	0.40	(-0.65, 1.44)	0.46
Adjusted							

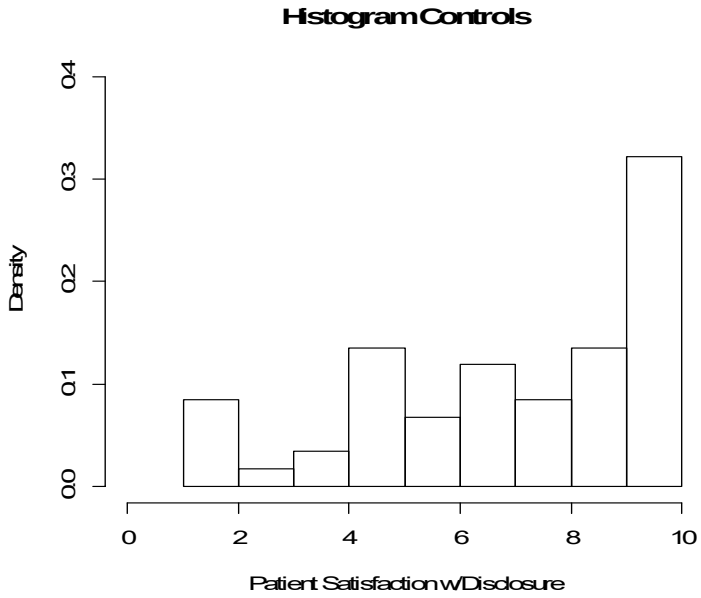
Linear mixed model with random intercept
(potential issues due to skewed data)

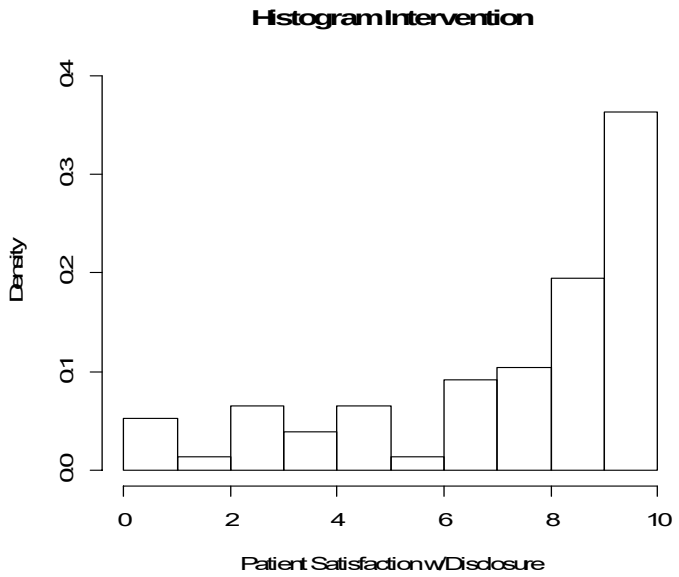
Table 5. Secondary Outcomes

Analysis	Control		Intervention		Mean Difference between Groups		P-Value
Patient Likelihood of Future Care							
Unadjusted Mean (95% CI)	1.97	(1.61, 2.33)	1.85	(1.62, 2.09)	-0.11	(-0.54, 0.32)	0.60
Adjusted Mean (95% CI)	1.98	(1.64, 2.33)	1.83	(1.59, 2.07)	-0.59	(-0.59, 2.82)	0.49
Likely Patient Future Care							
Unadjusted Proportion (95% CI)	0.73	(0.62, 0.85)	0.76	(0.69, 0.83)	0.03	(-0.11, 0.16)	0.70
Adjusted Relative Risk* (95% CI)	1 (Ref)		1.05	(0.87, 1.27)	NA		0.61
Patient Trust MD's Knowledge							
Unadjusted Mean (95% CI)	1.77	(1.49, 2.04)	1.75	(1.43, 2.06)	-0.02	(-0.44, 0.40)	0.93
Adjusted Mean (95% CI)	1.7	(1.38, 2.02)	1.8	(1.48, 2.13)	0.10	(-0.38, 0.58)	0.68
Agree Patient Trust MD's Knowledge							
Unadjusted Proportion (95% CI)	0.95	(0.89, 1.00)	0.88	(0.81, 0.95)	-0.07	(-0.16, 0.02)	0.14
Adjusted Relative Risk* (95% CI)	1 (Ref)		0.89	(0.79, 1.00)	NA		0.05
Patient Trust MD's Honesty/Integrity							
Unadjusted Mean (95% CI)	2.07	(1.71, 2.43)	2.2	(1.85, 2.55)	0.13	(-0.37, 0.63)	0.62
Adjusted Mean (95% CI)	2.08	(1.72, 2.43)	2.21	(1.88, 2.55)	0.13	(-0.38, 0.65)	0.61
Agree Patient Trust MD's Honesty/Integrity							
Unadjusted Proportion (95% CI)	0.86	(0.77, 0.96)	0.82	(0.74, 0.89)	-0.05	(-0.17, 0.07)	0.45
Adjusted Relative Risk* (95% CI)	1 (Ref)		0.95	(0.83, 1.08)	NA		0.43

GEE with independent error structure and robust standard errors

*Adjusted Variables include MD Sex, Site (Copic versus UW), Hospital Days (None,1-5, 6 or more), Degree of Disability (Continuous), Patient Sex, Patient Age (<45,45-64,65 or older), Education (<College Grad vs College Grad or greater)


Histogram Controls
Density
0.0
0.1
0.2
0.3
0.4
0
2
4
6
8
10
Patient Satisfaction w/Disclosure


Histogram Intervention
Density
0.0
0.1
0.2
0.3
0.4
0
2
4
6
8
10
Patient Satisfaction w/Disclosure

Vg. Discussion

Efforts to improve the disclosure of unanticipated outcomes to patients have been ongoing for much of the past 10 years. Many of these programs include providing physicians with training in how best to conduct these difficult discussions with patients. Yet, despite these efforts, progress to improve the actual conduct of these discussions has been slow. Our study, the first randomized trial conducted of the impact of disclosure training on patients' evaluation of the quality of actual disclosures, did not detect any measurable effect of the training on patient ratings. Nonetheless, the study represents an important milestone in the field and points toward critical areas for next steps.

Prior to this study, measures to rate patient and provider assessment of the quality of actual disclosures were not in use at any healthcare institutions in the US or abroad. Some of this hesitance to reach out to patients following unanticipated outcomes and survey them about the quality of the disclosure conversation reflected persistent fear that doing so might trigger litigation. Our study developed and deployed such measures of both patient and provider assessment of the quality of actual disclosures in 296 unanticipated outcomes in two different care delivery settings. Patient satisfaction surveys were received back from nearly 50% of the patients and over 90% of the physicians, and no adverse events were associated with the survey process itself. It is axiomatic that it is not possible to improve a clinical process that one cannot measure. Institutions and malpractice insurers now have access to a validated tool that they can use to begin assessing and improving the quality of actual disclosure conversations.

We were not able to detect an impact of the training on patient assessment of the quality of actual disclosures. Several factors may have been responsible for this finding. In this and many other projects, physician fear of the consequences of adverse event reporting and lack of confidence in Just Cultures continues to be widespread. Most of the unanticipated outcomes reported by physicians to this project were ones deemed by risk manger reviewers not to have been preventable. It is possible that the disclosure training skills would have had a more significant effect on patient ratings of the quality of disclosure discussions for those unanticipated outcomes due to errors. In addition, since the study began, greater attention has been paid to the importance of coupling disclosure conversations with early and proactive offers of financial compensation in situations when the care was not appropriate, in the form of "communication and resolution programs." However, our project focused solely on the disclosure conversation itself, which may have limited its impact on patient ratings of the disclosure experience. Last, many new disclosure policies and recommendations recognize the critical role that just-in-time disclosure coaching has on physicians' abilities to conduct these discussions well. Although the disclosure intervention provided intensive baseline training, including the opportunity for physicians to practice and receive feedback individually from standardized patients, these trained physicians may have had trouble using these skills when the need to have this discussion actually arose with the patient. Additional analysis of the study data is ongoing to determine what impact the training may have had on secondary outcomes.

This project is already having an important impact on the field. To date, it has led to 14 peer-reviewed publications, many of which were in high-impact journals, including *JAMA, Health Affairs, New England Journal of Medicine, Chest, Academic Medicine, and BMJ Quality and Safety*, with more publications expected over the next year. The project also led to the development and validation of a vast array of tools and resources to support and assess the disclosure process. Many of the tools are being incorporated into the AHRQ Communication and Resolution Process (CRP) Toolkit that Dr. Gallagher and colleagues are helping develop in collaboration with HRET, the Health Research and Education Trust.

VI.a. LIST OF PRODUCTS

The project team created a number of products through the life of this grant. All the products listed here are described in the text above. The majority of these products will be included in the AHRQ Communication and Resolution Toolkit that we are helping develop.

- Baseline Questionnaire
- Background Training Materials (PowerPoint training slides, background articles, case vignettes)
- Standardized Patient Cases (4 cases: Medicine 1, Medicine 2, Surgery 1, Surgery 2)
- Standardized Patient Session Feedback Template
- Key Disclosure Skills Document
- Study Reminder Flyer
- Division/Department Study Remind Talking Points
- Key Disclosure Skills Pocket Card
- Reminder Wallet Card
- Reminder Badge Card
- Reminder Email Text
- Event Record
- Post-Event Physician Survey
- Post-Event Patient Survey
- Just-in-Time Error Disclosure Videos

VI.b. LIST OF PUBLICATIONS

1. **Gallagher TH**. Clinical Crossroads: A 62 year-old woman with skin cancer who experienced wrong site surgery. *JAMA*. 2009;302(6):669-677.
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4. Dudzinski DM, Hebert PC, Foglia MB, **Gallagher TH**. The disclosure dilemma: Large scale adverse events. *NEJM* 2010;363(10)978-986.
5. Mastroianni A, Mello MM, Shannon S, Hardy M, **Gallagher TH**. The flaws in state 'apology' and 'disclosure' laws dilute their impact on malpractice suits. *Health Affairs* 2010;9:1611-1619.
6. Truog R. Browning D, Johnson J, **Gallagher TH**. Talking with patients and families about medical error: A guide for education and practice. 2010. Baltimore, The Johns Hopkins University Press.
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8. Bell SK, Delbanco T, Anderson-Shaw L, McDonald TB, **Gallagher TH**. Accountability for medical error: Moving beyond blame to advocacy. *CHEST* 2011;140:519-526.
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10. Brown SD, Truog RD, Lehman CD, Bowning DM, **Gallagher TH**. Stepping our further from the shadows: Disclosure of harmful radiologic errors. *Radiology* 2012:262;381-386.
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13. **Gallagher TH**, Levinson W. Physicians with multiple patient complaints: Ending our silence. *BMJ Quality and Safety.* Jul 2013;22(7)521-524.
14. Prouty CD, Foglia MB, **Gallagher TH.** Patient experiences of a large scale adverse event. In press, *Journal of Clinical Ethics*.