FINAL REPORT
Agency for Healthcare Research and Quality

Title of Project:
Enhancing The Disclosure Of Medical Errors To Patients

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Abstract

Purpose: Disclosure of harmful medical errors to patients increasingly is required, yet there is a significant gap between these expectations for disclosure and current clinical practice. The goal of this Mentored Clinical Scientist Development Award was to conduct empiric and normative studies regarding the disclosure of harmful medical errors to patients.

Scope: Several empiric studies assessed the attitudes and experiences of patients and physicians regarding error disclosure.

Methods: A variety of empiric methodologies were used, including focus groups, surveys, and standardized patient-based simulations. Normative and policy analyses were also conducted.

Results: Patients uniformly desire the disclosure of harmful errors. Physicians in both the United States and Canada support the disclosure of medical errors to patients but are unsure how this general principle should be implemented. As a result, disclosure often fails to meet patients' expectations for these conversations. The 3 years of support provided by this award allowed Dr. Gallagher to produce over 30 publications, including publications in *JAMA*, *The New England Journal of Medicine, Surgery, The Journal of Clinical Oncology, and The Archives of Internal Medicine,* and to obtain grants from AHRQ and the American Board of Internal Medicine Foundation.

Key Words
Communication; Disclosure/legislation and jurisprudence/*standards; Medical Errors/*standards; Truth Disclosure

Narrative

This document represents the final progress report for Dr. Thomas Gallagher's AHRQ Mentored Clinical Scientist Development Award, "Enhancing the Disclosure of Medical Errors to Patients."

The 3 years of support provided by this award allowed Dr. Gallagher to produce over 30 publications, including publications in *JAMA*, *The New England Journal of Medicine, Surgery, The Journal of Clinical Oncology, and The Archives of Internal Medicine*. This support facilitated Dr. Gallagher's promotion to Associate Professor of Medicine, and it helped secure additional funding, including grants from AHRQ, the American Board of Internal Medicine Foundation, and a recent preliminary award from the Robert Wood Johnson Foundation Investigator Award in Health Policy Research Program.

The specific aims of this project were as follows.

1) To describe the attitudes of physicians toward error disclosure and determine whether these attitudes are related to personal characteristics (e.g., demographics, specialty, time in practice) and whether they are consistent with intentions for disclosing medical errors.
2) To describe the attitudes of patients toward error disclosure and determine whether these attitudes are related to personal characteristics (e.g., sociodemographics, past experiences, perceptions of medical care) and how they relate to important outcomes such as trust, satisfaction, and intent to change providers or sue.
3) To assess whether current institutional policies support full disclosure of medical errors.
4) To develop and disseminate a model institutional error disclosure policy and assess the policy's impact on healthcare providers' attitudes toward and experiences with error disclosure.

The support provided by this career development award, supplemented by additional grant funding from the Greenwell Foundation, facilitated several empiric research projects. Highlights from this research are presented below. A complete list of publications is provided at the conclusion of this report.

<u>Patients' and Physicians' Attitudes Toward the Disclosure of Medical Errors</u>

Dr. Gallagher, with additional support from an AHRQ grant to Dr. Victoria Fraser (HS11898-01), led a series of focus groups with patients and physicians regarding their attitudes toward medical errors and their disclosure. Dr. Gallagher and colleagues conducted a total of 13 focus groups, including six groups of adult patients, four groups of academic and community physicians, and three groups of both physicians and patients. A total of 52 patients and 46 physicians participated. The focus groups were audio taped and transcribed using qualitative analysis to determine the attitudes of patients and physicians about medical error disclosure, whether physicians disclosed the information patients desired, patients' and physicians' emotional needs when an error occurs, and whether these needs are met.

The study found that both patients and physicians had unmet needs after medical errors. Patients wanted disclosure of all harmful errors and sought information about what happened, why the error happened, how the error's consequences will be mitigated, and how recurrences will be prevented. Physicians agreed that harmful errors should be disclosed but "choose their words carefully" when telling patients about errors. The paper described in detail different approaches that physicians would take to disclose errors. The study concluded that physicians may not be providing the information or emotional support that patients seek after harmful medical errors. The paper was published in *JAMA* (2003;289:1001-1007), was widely covered in the media, and was awarded the Best Published Research Paper of the Year Award by the Society of General Internal Medicine.

II. U.S. and Canadian Physicians' Attitudes and Experiences Regarding Disclosing Errors to Patients.

Dr. Gallagher followed this focus group paper with a large series of surveys to quantify physicians' attitudes and experiences regarding disclosure. The first of these was a survey of 2,637 physicians in the U.S. and Canada, which achieved a 63 percent response rate. The rationale for comparing U.S. and Canadian physicians' disclosure attitudes is that the two countries have significantly different malpractice environments, and the malpractice environment was previously considered a major determinant of physicians' willingness to disclose errors to patients. The survey found that physicians' error disclosure attitudes and experiences were much more similar than different across countries and specialties, despite differences in the malpractice environments. Ninety-eight percent endorsed disclosing serious errors to patients, and 78 percent supported disclosing minor errors. Seventy-four percent thought that disclosing a serious error would be very difficult. Fifty-eight percent had disclosed a serious error to a patient, 85 percent were satisfied with the disclosure, and 66 percent agreed that disclosing a serious error reduces malpractice risk. The initial paper from this survey compared U.S. and Canadian physicians' attitudes and concluded that they were much more similar than different, despite the different malpractice environments. It was published in *The Archives of Internal Medicine*. (2006;166:1605-1611).

The second paper from this survey compared how physicians would respond to hypothetical error disclosure vignettes. This manuscript described the wide variation that exists regarding what information physicians would disclose to patients about errors. For example, 56 percent of the respondents chose statements that mentioned the adverse event but not the error, but 42 percent would explicitly state that an error occurred. Some physicians would disclose little information: 19 percent would not volunteer any information about the error's cause, and 63 percent would not provide specific information about preventing future errors. Disclosure was affected by the nature of the error and the physician's specialty. Of the respondents, 51 percent who responded to a vignette representing a more-apparent error explicitly mentioned the error compared with 32 percent who received the less-apparent error. Fifty-eight percent of medical specialists explicitly mentioned the error compared with 19 percent of surgical specialists. We concluded that physicians vary widely in how they would disclose errors to patients. Disclosure standards and training are necessary to meet

public expectations and promote professional responsibility following errors. This paper was published in *The Archives of Internal Medicine* (2006;166:1585-1593) and was covered widely in the media, including an editorial in *The New York Times*.

The third paper to be published from this survey addressed the emotional impact of errors on physicians. We documented that stress following medical errors was common, with physicians reporting anxiety about future errors (61 percent), loss of confidence (44 percent), sleeping difficulties (42 percent), reduced job satisfaction (42 percent), and harm to their reputation (13 percent) following errors. Physicians were more likely to report that their job-related stress increased when they had been involved with a serious error, though only one third of physicians involved with near misses reported increased stress. Physicians were more likely to be distressed after serious errors when they were dissatisfied with how error disclosure to patients went, perceived a greater risk of being sued, spent greater than 75 percent time in clinical practice, or were women. Only 10 percent agreed that healthcare organizations adequately supported them in coping with error-related stress. We concluded that many physicians experienced significant emotional distress and job-related stress after serious errors and near misses. We encourage organizational resources be developed for all healthcare professionals so that they can receive the support they need after serious errors. This paper was published in *The Joint Commission Journal on Quality and Patient Safety* (2007;33:5-14) and also received widespread media coverage, including a story in *The Washington Post*.

The fourth major paper from the survey addresses physicians' experiences and suggestions for communicating information about errors that would improve patient safety. This paper is currently in press at *Health Affairs*. Although physicians have been described as "reluctant partners" in reporting errors, we found that most physicians are willing to share their knowledge about harmful errors and near misses with their institutions and wanted to hear about innovations to prevent common errors. However, physicians found current systems to report and disseminate this information inadequate. Physicians relied instead on informal discussions with colleagues to share information about errors and error prevention, which resulted in important information remaining invisible to the institution and the healthcare system. We concluded that efforts to promote error reporting at the state and national level may not reach their full potential unless physicians can be more effectively engaged in error reporting at their institutions.

The final paper from this survey to date, in press at *Academic Medicine*, reports the attitudes and experiences of trainees regarding disclosing medical errors to patients. The same survey was sent to 490 medical students and 401 residents in medicine and surgery at two academic centers. Although most trainees agreed that serious errors should be disclosed to patients, 87 percent acknowledged at least one factor that might discourage them from doing so. Personal involvement with medical errors was common among senior students (79 percent) and senior residents (98 percent). However, only 34 percent of trainees had received training in error disclosure; 92 percent expressed interest in such training, particularly at the time of disclosure. We concluded that, although many trainees have disclosed errors to patients, only a minority is

prepared to do so. Formal disclosure curricula coupled with supervised practice is necessary to prepare trainees to disclose errors independently to patients by the end of their training.

III. Pediatrics survey.

We adapted the survey sent to adult physicians and distributed it to over 600 pediatric attendings and residents in St. Louis and Seattle. The first paper from the pediatric survey was published in *The Archives of Pediatric and Adolescent Medicine* (2007;161:179-185). We found that most respondents had been involved in errors. Respondents endorsed reporting errors to the hospital, but only 39 percent thought that current reporting systems were adequate. Most pediatricians had used formal error reporting mechanisms, such as an incident report, but many also used informal reporting mechanisms, such as telling a supervisor (47 percent) or a senior physician (38 percent). Respondents endorsed disclosing errors to patients' families, and many had done so. We concluded that pediatricians are willing to report errors to hospitals and disclose errors to patients' families but believe that current reporting systems are inadequate and struggle with error disclosure. A second paper from the pediatric survey reporting the results of pediatric error disclosure scenarios has been accepted (pending minor revisions) to *The Archives of Pediatric and Adolescent Medicine*.

IV. Risk manager survey

The physician survey was also modified for distribution to risk managers. The first paper from the risk manager survey, "Risk Managers' Attitudes and Experiences Regarding Patient Safety and Error Disclosure; A National Survey," was published in *The Journal of Health Care Risk Management* (2006;26:11-16). In that survey, risk managers reported substantial involvement with patient safety. Though 81 percent said that their institution had an error reporting system for physicians to use, only 56 percent agreed that current reporting systems were adequate. Many institutions had an error disclosure policy, but the content of the policy varied widely. Risk managers also reported widely varying involvement in disclosure: 69 percent provide general education, but 24 percent personally disclose errors. We concluded that risk managers have a vital role to play in the developing patient safety movement, especially in the area of transparency in healthcare. A second manuscript comparing the attitudes of risk managers to physician survey participants is under development.

V. How Surgeons Disclose Medical Errors: a Study Using Standardized Patients.

Dr. Gallagher's AHRQ funding, in combination with Dr. Fraser's funding, also supported a study of how surgeons disclose hypothetical errors. The study involved surgeons discussing two error scenarios with standardized patients. Thirty surgeons participated, yielding a total of 69 encounters. The surgeons were rated highest on their ability to explain the medical facts about the error. Surgeons used the word "error" or "mistake" in only 57 percent of disclosure conversations, took responsibility for the error in 65 percent of encounters, and offered a verbal apology in 47 percent. Surgeons acknowledged or validated patients' emotions in 55 percent of scenarios. Eight percent of surgeons discussed how similar errors would be prevented, and 20 percent offered a second opinion or transfer of care to another surgeon. We concluded that, although the

patient safety movement calls for a disclosure of medical errors, significant gaps exist between how surgeons disclose errors and what patient preferences are. Programs should be developed to teach surgeons how to communicate more effectively with patients about errors.

VI. Nurses' Attitudes and Experiences Regarding Disclosure

Dr. Gallagher and colleagues from the University of Washington School of Nursing have completed a series of focus groups with 96 nurses regarding their attitudes and experiences with error disclosure. When errors occurred, nurses felt they should be disclosed but questioned this generality for anxious patients, litigious families, or minor errors. When weighing whether to disclose, nurses worried about patients' or families' negative reactions to disclosure, versus loss of trust if errors were not disclosed. Nurses also worried about the personal and professional consequences of disclosure. After errors occurred, nurses reported poor communication among the team about what patients had or would be told, resulting in nurses responding to patient's and family's questions with deception or avoidance. Nurses wanted to be involved in the error disclosure process, in part to avoid being blamed for errors, yet they reported lacking adequate knowledge and experience to skillfully disclose errors.

Although each organization had a formal policy encouraging disclosure of errors to patients, many nurse participants were unaware of the existence or contents of these policies. Participants felt, however, that organizational policies would be useful if they could mandate broader participation by team members in the disclosure process. The pivotal role of nurse managers was highlighted by all focus groups. Nurse managers often were described by participants as maintaining the local, informal culture. Those who had a systems approach versus a "name, blame, and shame" approach were viewed as encouraging a culture of transparency that culminated with disclosure of errors to the patient.

Manuscripts reporting the results of these nursing focus groups are in the final stages of preparation for submission.

VII. Other Disclosure Publications.

In addition to his empiric work in error disclosure, Dr. Gallagher's career development award supported several review articles and policy analyses on disclosure. Dr. Gallagher and Dr. Wendy Levinson published an overview of the topic of disclosure and an action plan to guide the medical profession in enhancing disclosure (*Arch Intern Med* 2005; 165:1819-1824). Dr. Gallagher also published a review of empiric studies on disclosure in *The Journal of Clinical Outcomes Management* (2005; 12:253-259). Dr. Gallagher explored the specialty-specific dimensions of disclosure in the oncology setting in the publication "Confronting Medical Errors in Oncology and Disclosing Them to Cancer Patients" in *The Journal of Clinical Oncology* (2007;12:1463-1467). Drs. Gallagher and Levinson reviewed the status of disclosure efforts in Canada with the publication "Disclosing Medical Errors to Patients: A Status Report in 2007" in *The Canadian Medical Association Journal* (2007; 1773:265-267). Finally, Dr. Gallagher

published a high profile review of disclosure in *The New England Journal of Medicine* (2007; 356:2713-9).

VIII. Other Peer-Reviewed Publications

In addition to the empiric studies described above, Dr. Gallagher's K award supported his participation in several other research projects, including:

- A focus group study of physicians' and nurses' perspectives on error reporting in hospitals (see reference #2 below).
- A study of patients' concerns about medical errors in emergency rooms (see reference #3 below).
- A survey of 2,078 recently hospitalized patients regarding their attitudes about and participation in error prevention (see reference #7 below).
- A survey of 1,656 recently hospitalized patients regarding their concerns about medical errors during their hospitalization (see reference #12 below).

IX. Policy Development

In addition to his research activities and other disclosure publications, Dr. Gallagher collaborated with the National Quality Forum to develop a Safe Practice on disclosure. This new Safe Practice, one of the 30 NQF Safe Practices, was formally launched in 2007. This disclosure policy provides a road map for organizations to enhance their disclosure policies and practices. The NQF Safe Practices are also noteworthy because they are used by the Leapfrog group in their public reporting and pay-for-performance activities. Dr. Gallagher wrote an article describing this new Safe Practice, entitled "Disclosing Unanticipated Outcomes to Patients: The Art in Practice," which appeared in *The Journal of Patient Safety* (2007; 3:158-165).

X. Career Development Activities. Dr. Gallagher's career development proposal was truncated from the proposed 5 years of support to 3 years. This shortening required him to focus the majority of his attention on his research and grant writing activities, reducing his formal course work. However, he continued to actively consult with his primary mentor, Dr. Stephen Finn, and to work closely with his co-mentors, Dr. Wendy Levinson, Eric Larson, Bernard Lo, and David Bates. This group of mentors was instrumental in helping Dr. Gallagher launch a successful research career and be promoted to Associate Professor.

XII. Future activities

This award allowed Dr. Gallagher to successfully compete for an AHRQ grant entitled, "Using Team Simulation to Enhance Error Disclosure to Patients and Safety Culture." This project involves a randomized trial to assess if a team-based simulation intervention will improve healthcare workers' skills, knowledge, and attitudes in team communication and in error disclosure. The simulation involves a team responding to two cases of harmful errors by 1) discussing the event, responsibility, and blame; why the error happened; and how recurrences will be prevented, 2) planning whether and how to to disclose the event to the patient, and 3) disclosing the error to a standardized patient. A disclosure coach (risk management personnel) will help the teams discuss the error, plan the disclosure, and provide feedback. To enhance the clinical realism, a

"standardized team member" (trained actor) will ensure that teams confront key challenges and articulate their reasoning for their actions. Each team will be composed of a physician, a nurse, a disclosure coach, and a standardized team member playing the role of nurse or pharmacy manager.

The project is using an innovative web-based assessment that will test the efficacy of the intervention in improving participants' communication skills, knowledge, and attitudes. This study has generated an additional project, to be funded by the American Board of Internal Medicine Foundation, that will allow additional development of this web-based assessment instrument.

List of Publications and Products

A. Peer-reviewed manuscripts

1. Gallagher TH, Waterman A, Ebers A, Fraser V, Levinson W. Patients' and physicians' attitudes towards the disclosure of medical errors. *JAMA*, 2003;289:1001-1007.
2. Jeffe DB, Dunagan WC, Garbutt J, Burroughs TE, Gallagher TH, Hill PR, Harris CB, Bommarito K, Fraser, VJ. Physicians' and Nurses' Perspectives on Error Reporting in Hospitals. *Joint Commission Journal on Quality and Safety*, 2004;30:471-479.
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4. Gallagher TH, Lucas M. Should we disclose harmful medical errors to patients? If so, how? *J Clin Outcomes Manage*, 2005;12:253-259.
5. Gallagher TH, Levinson W. Disclosing harmful medical errors to patients: A call for professional action. *Archives of Internal Medicine,* 2005;165:1819-1824.
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9. Gallagher TH, Garbutt JM, Waterman AD, Flum DR, Larsen EB, Waterman BM, Dunagan WC, Fraser VJ, Levinson W. Choosing your words carefully; how physicians would disclose harmful errors to patients. *Arch Intern Med.* 2006;166:1585-1593.
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12. Burroughs TE, Gallagher TH, Waterman AD et al. Patients' concerns about medical errors during hospitalization. *Joint Commission Journal on Quality and Safety*, 2007;33:5-14
13. Surbonne AS, Rowe M, Gallagher TH. Confronting medical errors in oncology and disclosing them to cancer patients. *Journal of Clinical Oncology.* 2007;12:1463-1467.
14. Gallagher TH, Studdert DM, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med* 2007;356:2713-9.
15. Waterman AD, Garbutt JM, Kapp JM, Hazel E, Dunagan WC, Levinson W, Fraser V, Gallagher TH. How Medical Errors Affect Physicians' Occupational Stress. *Joint Commission Journal on Quality and Safety* 2007;33:467-476.
16. Levinson W, Gallagher TH. Disclosing medical errors to patients: A status report in 2007. *CMAJ* 2007;177(3)265-267.
17. Gallagher TH, Denham C, Leape L, Amori G, Levinson W. Disclosing unanticipated outcomes to patients: The art and practice. *J Patient Safety* 2007;3:158-165.
18. Garbutt JM, Waterman AD, Krygiel Kapp JM, Hazel E, Dunagan WC, Levinson W, Fraser V, Gallagher TH. Lost Opportunities: Physicians' experiences and suggestions for communicating information about errors to improve patient safety. In press, *Health Affairs*.
19. White AA, Gallagher TH, Garbutt J et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. In press, *Academic Medicine.*

B. Book Chapters

20. Patients' and physicians' attitudes regarding the disclosure of harmful medical errors. American Society of Clinical Oncology 2005 Educational Book.
21. Sara Kim, PhD, Doug Brock, PhD, Tom Gallagher, MD, Peggy Odegard, PharmD, CDE, BCPS, Carolyn Prouty, DVM, Lynne Robins, PhD, Sarah E Shannon, PhD, RN. Developing On-Line Cases for Teaching Critical Thinking Skills: A Session in Survey of Educational Technology. In Teaching Critical Thinking and Clinical Judgment in the Health Sciences, Noreen Facione and Peter Facione (Eds.) Califonia Academic Press. In press.
22. Gallagher TH, Prouty CD. A general internist's perspective. In Professionalism in medicine: The case-based guide for medical students. Spandorfer, Pohl, Rattner, and Nasca (Eds). Cambridge University Press, New York, New York. In press, 2008.
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C. Other Publications

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