

Disclosure, Apology, and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation

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Context: The Disclosure, Apology, and Offer (DA&O) model, a response to patient injuries caused by medical care, is an innovative approach receiving national attention for its early success as an alternative to the existing inherently adversarial, inefficient, and inequitable medical liability system. Examples of DA&O programs, however, are few.

Methods: Through key informant interviews, we investigated the potential for more widespread implementation of this model by provider organizations and liability insurers, defining barriers to implementation and strategies for overcoming them. Our study focused on Massachusetts, but we also explored themes that are broadly generalizable to other states.

Findings: We found strong support for the DA&O model among key stakeholders, who cited its benefits for both the liability system and patient safety. The respondents did not perceive any insurmountable barriers to broad implementation, and they identified strategies that could be pursued relatively quickly. Such solutions would permit a range of organizations to implement the model without legislative hurdles.

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Conclusions: Although more data are needed about the outcomes of DA&O programs, the model holds considerable promise for transforming the current approach to medical liability and patient safety.

Keywords: Medical liability, malpractice, patient safety, disclosure, apology, compensation.

INJURIES TO PATIENTS CAUSED BY MEDICAL CARE CONTINUE TO bedevil both patients and the medical community. The current medical liability system presents critical barriers to improving patient safety, ensuring fair and reasonable resolutions to medical injury disputes, and controlling the cost of health care nationwide (Studdert, Mello, and Brennan 2004). The negative consequences of the medical liability system have been well documented (Kachalia and Mello 2011). Litigation is inherently adversarial, threatening the therapeutic relationship between patient and provider. Only about 2 to 3 percent of patients harmed by negligence pursue litigation, and only about half of these receive compensation (Localio et al. 1991; Studdert et al. 2006). Litigation is a protracted process, taking an average of five years from the time of injury to claim resolution (Studdert et al. 2006). The process also takes a great emotional toll on patients and doctors alike (Cantor et al. 2005; Delbanco and Bell 2007; Waterman, Garbutt, and Hazel 2007; West et al. 2006). Furthermore, the tort system does not effectively distinguish between individual and systemic errors (Reason 2000), and blame is often unnecessarily placed on the health care provider for multifactorial errors far out of his or her control (Hiatt et al. 1989; Mello and Studdert 2008). Concerns about liability inhibit physicians' efforts to improve patient safety and motivate them to practice defensive medicine. As a result, they order medically unnecessary tests or avoid treating high-risk patients. These problems are perpetuated as medical students and trainees learn such practices early in their careers (Brennan, Mello, and Studdert 2006; Kessler and McClellan 1996; Mello et al. 2005; O'Leary et al. 2012; Studdert et al. 2005). The critical flow of information needed to improve these systems is hindered by the secrecy and fear that surround bad outcomes (Boothman et al. 2009; Massachusetts Medical Society 2008).

Professional organizations, patient advocacy groups, and ethicists have long agreed that patients have the right to full disclosure of

unanticipated care outcomes (American Society for Healthcare Risk Management of the American Hospital Association 2003; American Hospital Association Management Advisory Committee 1992; Banja 2001; Institute of Medicine 2001; Wu et al. 1997). Yet patients likely learn about only a third of all medical errors (Blendon, DesRoches, and Brodie 2002; Kaiser Family Foundation 2004), and even when errors are disclosed, the conversation often fails to meet patients' expectations (Gallagher et al. 2003). The lack of open communication and an apology after harmful events erodes trust, hinders patient care, and fuels litigation (Vincent, Young, and Phillips 1994). It also prevents providers and institutions from assuming appropriate accountability and improving patient safety (Sage 2003).

In conjunction with disclosure, health care organization leaders are increasingly recognizing that a pervasive culture of individual blame substantially limits their capacity to improve patient safety and clinical outcomes. Accordingly, organizations are now turning to developing a "just culture" that seeks the root causes of medical errors and promotes a nonpunitive culture (Marx 2001). Rather than eliminating the responsibility of the individual or organization when errors occur, this approach examines both individual and systems-level factors, allows for greater candor, and encourages individuals to participate in systems-level harm prevention and remediation (Clarke, Lerner, and Marella 2007; Connor et al. 2007; Khatri, Brown, and Hicks 2009; Khatri et al. 2007; Marx 2001).

The Disclosure, Apology, and Offer (DA&O) model emphasizes both honest communication with patients and families and a systems approach to errors. It promotes a principled institutional response to unanticipated clinical outcomes in which health care organizations (1) proactively identify adverse events, (2) distinguish between injuries caused by medical negligence and those arising from complications of disease or intrinsically high-risk medical care, (3) offer patients full disclosure and honest explanations, (4) encourage legal representation for patients and families, and (5) offer an apology with rapid and fair compensation when standards of care were not met (table 1). Patient safety interests are better served when errors are captured and handled without protracted litigation, allowing the institution and clinician to concentrate instead on helping the patient and turning lessons learned into safety improvements. Making whole those patients who have been harmed through medical negligence as quickly and fairly as possible after a harmful

TABLE 1
 Characteristics of the Disclosure, Apology, and Offer Model

Objective	Actions Taken by Hospital and Liability Insurer
Increase transparency regarding adverse outcomes and support physicians in disclosing adverse outcomes to patients.	<ul style="list-style-type: none"> ● Disclose adverse outcomes of care to patients and families. ● Investigate via root-cause analysis and explain what happened. ● Provide an apology when appropriate.
Improve patient safety.	<ul style="list-style-type: none"> ● Implement systems to avoid recurrence of incidents, using information from cases of medical injury and near misses to identify safety-enhancing interventions and working with hospital staff to implement them.
Avoid lawsuits, reduce liability costs, and improve access to compensation by meeting the financial needs of injured patients and their families quickly and fairly in the aftermath of an injury.	<ul style="list-style-type: none"> ● Offer financial compensation when care was unreasonable, without the patient having to file a lawsuit. ● Defend cases vigorously when care was reasonable.

error diminishes any conflicts of interest on the part of the physician or the institution to help the patient while avoiding litigation and helps preserve therapeutic relationships between patients and caregivers. The model also enables institutions to focus on protecting future patients from the same experience (Boothman et al. 2009; Kachalia, Kaufman, and Boothman 2010; Kraman and Hamm 1999; Mello and Gallagher 2010).

To date, DA&O models have been implemented primarily by a small number of self-insured (captive) hospital systems—the University of Michigan the best-described program—and relatively little data exist about the model’s likely effects in more diverse environments (Kachalia and Mello 2011). The success of DA&O models in achieving the dual goals of promoting patient safety improvements and reducing malpractice costs, however, has garnered support from the Agency for Health Care Quality and Research (AHRQ), the Joint Commission on Accreditation of Health Care Organizations, and other national

organizations (Joint Commission on Accreditation of Health Care Organizations 2005). Nevertheless, relatively few hospital systems and insurers have adopted this model.

The University of Michigan Health System began in late 2001 and early 2002 what has since been called the disclosure, apology and offer (DA&O) model for responding to patient injuries caused while rendering medical care. Initially using the opportunity offered by Michigan's compulsory preliminary notice of intent to sue (required before any Michigan medical malpractice case can be filed) (Michigan Compiled Laws §600.2912b [1994]), unanticipated clinical outcomes are now identified quickly in an increasingly vigilant institutional culture via various means, including voluntary electronic incident reports, patient complaints, caregiver reports, and proactive data pulls of internally derived patient safety indicators. While the process is tailored to each individual case, patients and families are generally contacted by risk management consultants, who ensure that new clinical care needs are met, oversee the hospital's investigation, review patients' and providers' expectations, and ensure full disclosure (Boothman et al. 2009). Patients and families are kept informed, receive full disclosure, and also receive an apology, with an offer of compensation when appropriate (Boothman et al. 2009, Boothman, Imhoff, and Campbell 2012). The program is directly linked to the patient safety and peer review infrastructure that dominates the overriding institutional focus. The Michigan program's claims experience was reported in a before-and-after examination, which documented significant improvements in claims frequency, transactional costs, incidence of litigation, and time-to-resolution (Kachalia, Kaufman, and Boothman 2010). Moreover, these reports found that culturally, the focus had shifted to safety, pushing medical malpractice into the background (Boothman, Imhoff, and Campbell 2012).

In July 2010, the AHRQ awarded approximately \$23 million in grants for approaches to medical injury compensation that also improve patient safety (AHRQ 2010a). Four of the demonstration projects focused on expanding the DA&O program in use at the University of Michigan Health System (AHRQ 2010b), signaling national interest in this model.

As part of a planning grant from this AHRQ program, we examined the prospects for more widespread implementation of the DA&O model. Although some commentators have suggested factors that might account for this model's lack of widespread dissemination, particularly

in settings other than self-insured academic medical centers, this issue has not been empirically investigated previously (Localio 2010; Mello and Gallagher 2010; Mello and Kachalia 2011; Peto et al. 2009). We conducted a key informant interview study of stakeholders concerning their perceptions of the DA&O model, perceived barriers to implementation, and strategies for overcoming them. While our study centered on Massachusetts, we explored themes that are generalizable to other states.

Methods

We conducted semistructured interviews with twenty-seven individuals in leadership positions in organizations or constituencies central to implementing the DA&O approach in Massachusetts. We used a three-stage selection process, in which the study team members first identified major categories of stakeholder groups (e.g., liability insurers and patient advocacy groups), then identified leading organizations in the state in each category, and, last, identified an individual in each organization who either held a top leadership role or had expertise in legal and government affairs. We intended to capture a broad range of perspectives and to interview that person in each organization who knew the most about the potential barriers to adopting a DA&O model.

Three physician-investigators, working in teams of two (with the exception of a single interview conducted by one interviewer), led the interviews, which lasted forty-five to sixty minutes. The interviewers used an interview guide that was pretested on two respondents not included in the analytical sample. The interview guide covered four main areas: (1) the respondent's institutional setting and relevant experience, (2) perceived potential for the DA&O model to improve medical liability and patient safety, (3) perceived barriers to implementing DA&O programs, and (4) suggested strategies for overcoming identified barriers. Each interview was digitally recorded and professionally transcribed. The project was reviewed by the institutional review boards of the Beth Israel Deaconess Medical Center and the Harvard School of Public Health.

We analyzed the transcripts using methods of thematic content analysis (Glaser and Strauss 1967). We developed a coding scheme of interview topics after reading a random sample of transcripts, defining each coding category in a detailed coding manual. One interviewer then

TABLE 2
Interview Respondent Affiliations ($n = 27$)

Stakeholder Group	Number of Respondents
State agencies and legislature	6
Hospital systems:	
Academic medical centers	2
Community hospitals	2
Practicing physicians	3
Liability insurers	2
Health insurers	2
Medical professional associations	2
Patient advocacy organizations	2
Malpractice attorneys	2
Patient safety experts	2
Major physician practice groups	1
Business associations	1

coded each transcript, entering data into Microsoft Excel. Another investigator then compared the interview responses in each category to find emerging themes. For some questions, response frequencies were also tabulated. We then compiled and vetted the preliminary report, first with the interview respondents for individual feedback, and second at a meeting with a larger group of approximately 180 stakeholders, structured to ensure that all viewpoints were solicited.

Results

The interview respondents represented a broad range of stakeholder groups in Massachusetts (table 2). Of the twenty-eight stakeholder groups in the original sampling frame, twenty-seven were interviewed (96%). Two individuals from the original invitation list did not respond; one was replaced with a stakeholder of similar background, and the other did not have a specific replacement. The remaining invitees agreed to be interviewed or provided a delegate. Overall, nine of the twenty-seven (30%) respondents were physicians. Both major malpractice insurers in the state were included, as were several smaller self-insured hospital systems.

TABLE 3
Appealing Aspects of the DA&O Model

Element Cited	% (n)
Ethical and professional considerations	89 (24/27)
Reduces legal risk and costs	74 (20/27)
Improves safety culture in hospital	56 (15/27)
Improves dispute resolution process	37 (10/27)
Serves patients' needs better	37 (10/27)
Pragmatic considerations (e.g., feasible, politically salable, would make hospital look good)	11 (3/27)

Appeal of the DA&O Model

Asked what aspects, if any, of the DA&O model they found appealing, the respondents most frequently cited ethical and professional considerations (table 3), including open and compassionate responses to medical injuries. As a hospital representative pointed out, "The appealing part would be that it's the right thing to do, that it removes all those legal curtains, the discomfort and the barriers that make it hard to have a conversation with someone and just say, 'We're sorry we hurt you. We want to make it right for you.'" The potential for reduced legal costs was another prospect that the respondents found appealing. Others emphasized that the model was central to improving safety culture. A state official remarked, "It encourages learning. It encourages preventing the next problem so you're not just covering something up. You're saying, 'Let's really look at what happened. Let's get it out in the open and let's have a good conversation.' Then the next time, it's less likely to happen." Summing up these impressions, one respondent called the model "a huge win for patients, [who] suffer as much as anybody in the courts, maybe more. It'll be a huge win for providers emotionally. It will be a huge win from a financial perspective because the right people will be getting compensated in a more timely manner and there will be far less waste in the process." Finally, pragmatic considerations were mentioned as additional benefits, for example, that the DA&O model would be feasible and even popular in an environment in which political gridlock has precluded the legislative adoption of tort reforms.

Alternative Approaches

The majority of respondents felt that for improving the medical liability and patient safety environments in Massachusetts, no alternative held greater promise than the DA&O model. Those respondents who offered alternatives primarily discussed complementary strategies like a mandatory prelitigation review period or, for cases not resolved by the DA&O model, expert witness standards, caps on noneconomic damages, or the use of health courts.

Barriers to Implementing the DA&O Model and Strategies for Overcoming Them

Our interviews revealed several barriers to the widespread implementation of the DA&O model (table 4) and also strategies for surmounting them. Here we summarize the most commonly cited barriers and solutions. Later, in our discussion, we evaluate the relative significance of the barriers in light of the feasibility of the suggested solutions. With the exception of charitable immunity, all the barriers cited here are issues that transcend the Massachusetts context.

Charitable Immunity. At the time of this study, Massachusetts law limited to \$20,000 the tort liability of any charitable corporation, trust, or association (which includes nonprofit hospitals and health care institutions) (Mass. Gen. Laws Ann. ch. 231, § 85K [2012]). This law covers nearly all hospitals in Massachusetts. Our respondents mentioned this law more often than any other barrier to implementing the DA&O model, noting that hospitals' limited financial responsibility for medical injuries may undercut their interest in liability reform and incentives for investment in patient safety. The stakeholders also worried that because physicians are the "deep pockets" in the current system, they may be reluctant to participate in disclosure.

The stakeholders agreed that fundamental changes to the charitable immunity law, which applies to all Massachusetts nonprofit organizations, were unlikely but also unnecessary in order to advance the DA&O model. A more practical approach, they suggested, is to encourage nonprofit institutions to compensate medical injuries at a fair value, regardless of any legal insulation from large awards at trial. Since the charitable immunity law does not affect settlements, hospitals could (and often do) choose to offer compensation above the cap, out of a sense of fairness,

TABLE 4
Barriers to Implementing DA&O Model

Barrier Cited	% (n)	Illustrative Quotations
Charitable immunity	81 (22/27)	"You don't necessarily need to take charitable immunity away to make a program like this fly. What you need to do is convince the institutions to waive their charitable immunity and take systems-level responsibility." —A hospital representative
Physicians' discomfort with disclosure	78 (21/27)	"Disclosure is not amateur hour. It requires a certain level of expertise." —A physician
Attorneys' interest in maintaining the status quo	74 (20/27)	"They believe they are doing God's work in protecting patients, and they get paid handsomely for that. This is going to affect their pocketbook, and it's going to affect their livelihood." —A health insurer representative
Coordination across insurers	74 (20/27)	"We might not have enough time to get everybody together, to get everybody to assess what's going on and then make a determination. In the meantime, the patient is still sitting there." —A health insurer representative
Physicians' name-based reporting	70 (19/27)	"The systems issues are bigger than the doctor issues in most cases, so it's hard to say, 'Doctor, you're the one who's going to get the ding,' when we know it wasn't [his/her fault]." —A physician representative of a community/teaching hospital
Concern about increased liability	59 (16/27)	"I think that there are concerns on the part of the physician that even with a well-vetted model like this, that it may still expose them to greater malpractice liability. I think there are many who feel that if they just don't come forward, maybe the patient won't notice or won't do anything or take any further actions." —A health insurer representative
Forces of inertia	48 (13/27)	"Well, it's change! It's big change. All the traditional impediments to any change would certainly be in force here." —A hospital representative

Continued

TABLE 4—Continued

Barrier Cited	% (n)	Illustrative Quotations
Fairness to patients	44 (12/27)	"I think that some patient advocates might see it as a way to convince people indirectly or maybe even more directly not to sue when may be they should." —A public official
May not work in other settings	41 (11/27)	"We don't employ our physicians. We have to convince them to come to the table in a disclosure conversation if we were to go to a financial compensation model." —A hospital representative
Insufficient evidence	30 (8/27)	"I think what would be very, very useful is the availability of other empirical data from other locations across the country to confirm the observations in Michigan." —A hospital representative
Supporting legislation needed	30 (8/27)	"In states where it's been successful, the courts are overturning a lot of the legislative changes, so it's really an uphill battle." —A malpractice insurance representative
Accountability for the process	19 (5/27)	"I could imagine there could be groups out there that feel like, 'Oh, yeah, well, it's going to be run by the hospital. This is like the fox in the chicken coop! The hospitals and the doctors, the people who screwed up to begin with, are going to execute this very nice, just system! . . . [They] may want to regulate the process in some way.'" —A physicians' group representative

compassion, and/or regret over avoidable injuries. Many respondents saw this as consonant with the shift toward accountable care organizations (ACOs), which focus on organizational accountability above individual responsibility for care outcomes. Essentially all the stakeholders agreed that a voluntary assumption of responsibility for systems-based errors reflected a more appropriate level of institutional accountability.

In August 2012 a provision increasing the charitable immunity cap to \$100,000 for medical liability was signed into law (ch. 224 of the Acts of 2012). Since the cap is still very low, the stakeholders' concerns are still relevant, and the suggested voluntary accountability on the part of institutions also remains salient.

Physicians' Discomfort with Disclosure. The stakeholders noted that most physicians are not adequately trained or supported in disclosure processes, since such open communication about error is a radical departure from prior practices (often based on legal advice) and prevailing medical culture. They also raised concerns that incomplete legal protection for statements of apology in Massachusetts might impede full disclosures, a concern that also applies to other states (Mastroianni et al. 2010).

Suggested strategies include robust "coaching" models, peer-mentoring systems led by physicians experienced in error disclosure, and involving patients and families in disclosure training. Respondents advocated clear disclosure protocols, support systems for clinicians, strong institutional leadership, and the establishment of a "just culture" (Marx 2001). The respondents viewed disclosure as a critical skill for physicians and advocated formal universal training (perhaps led by the Joint Commission) starting early in medical education, and perhaps even as a licensure requirement. Some advocated stronger legal protections for statements of apology in order to prevent their use as inculpatory evidence in malpractice suits, but others pointed out that the DA&O program at the University of Michigan has succeeded despite the absence of an apology law in that state until very recently.

Attorneys' Interest in Maintaining the Status Quo. The stakeholders anticipated resistance to the DA&O model from both plaintiff and defense attorneys. Some felt that it was predominantly a financial issue, reflecting an assumption that attorneys' compensation would decrease under a model that promoted early settlement. Others referred to plaintiff attorneys' belief that the tort system protects patients' interests by ensuring that patients are always represented by attorneys and can have their cases decided by a neutral adjudicator. Defense attorneys may share the

view that the status quo best serves their clients' interests, since it likely results in settlement in fewer cases and does not involve the routine disclosure of adverse outcomes. Yet the respondents felt that the level of resistance in the legal community may not be as vociferous as might be assumed and would be inadequate to block the model if health care organizations and insurers chose to move ahead, since legislation was not a prerequisite for the DA&O model.

The stakeholders suggested emphasizing that the DA&O model endorses legal representation for patients, is more cost-effective for plaintiff attorneys, and usually results in a higher proportion of harmed patients receiving compensation efficiently. The model does not abridge any of patients' existing rights, as they can opt out and pursue litigation at any time before accepting a settlement offer. In addition, the respondents felt the DA&O model was more likely to meet patients' needs by helping "make the patient whole" without the "lottery" of the litigation process. Pointing out that the current litigation model is extremely protracted, some respondents thought that attorneys might see merit in a model with a more efficient resolution.

Coordination across Insurers. Many respondents noted that DA&O models have been used primarily in self-insured hospital systems and that implementation would be more challenging if the facility and the physicians were insured by different companies. One concern was about "gaming" in multiple-defendant cases: if one insurer was committed to openness and accepting responsibility but another was not, liability might not be fairly apportioned. The respondents worried that such lack of coordination could also draw out the process, defeating one of the DA&O model's goals, expediency. Also a key concern for insurers was prompt access to all pertinent medical records so as to facilitate a comprehensive, timely liability assessment.

The respondents felt that interinsurer coordination concerns could be addressed collegially through a collaborative approach focused on supporting patients. Others suggested involving the state commissioner of insurance, and/or the Office of Patient Protection, either informally or through a regulatory intervention.

Physicians' Name-Based Reporting. Usually referring to the National Practitioner Data Bank (NPDB), but also to the state Board of Registration in Medicine (BORM) or the Department of Public Health (DPH), many respondents felt it unfair that physicians' reputations could suffer because of requirements to report malpractice claim settlements in the

name of individual physicians, even when the errors were caused by a failure of the system. Others pointed out that in order to avoid a “black mark” on their record, physicians may resist settlement efforts. However, as several respondents suggested, clinicians may not have a complete understanding of how often NPDB and BORM data are actually used and to what end. They believed that decisions to withdraw a physician’s credential to practice at a hospital or to initiate disciplinary proceedings based on malpractice claims reports were more rare than physicians think. The stakeholders suggested clarifying actual implications of reporting, and assuring physicians that cases meeting the standard of care would not be compensated. Furthermore, the respondents noted that it would be important to emphasize to physicians that unlike the current system, proactive settlement would allow institutions to investigate the event and assign responsibility to the institution for systems-based errors, which generally encompass the large majority of adverse events. Even in those cases in which settlements were made on the behalf of a physician, they were likely to be at a lower value than through the court system and were also likely to be settled early and in a more predictable fashion than cases that proceeded to a lawsuit.

Recognizing, however, that the fear of name-based reporting under current reporting requirements might be a major roadblock to gaining physicians’ acceptance of and participation in DA&O programs, the respondents widely endorsed a modification of NPDB and BORM reporting requirements to allow institution-based reporting for adverse outcomes attributable to system failures.

Concern about Increased Liability. While the majority of stakeholders believed that DA&O programs decreased liability risk, they feared that many clinicians or insurers might not agree. The respondents thought that physicians would be concerned about alerting patients to an injury or error, making statements that might be used in litigation, piquing plaintiff attorneys’ interest in cases in which error was specifically acknowledged, and raising patients’ expectations about their chances of recovering money in a claim.

The general consensus among stakeholders was that information was key to allaying fears. Recommendations included education about the effects of existing DA&O programs on the volume and cost of malpractice claims, and generating and disseminating new data by trying out the model in additional settings like Massachusetts to help dispel misconceptions. Strengthening the state’s apology law was also proposed

as a useful strategy. At the time of the study, and until only recently, Massachusetts's apology law protected only those statements of regret "expressing sympathy or a general sense of benevolence" relating to accidental injuries, but not statements of explanation or responsibility (Mass. Gen. Laws Ann. ch. 233, § 23D [2012]).

Forces of Inertia. The respondents recognized significant operational and cultural shifts implicit in the DA&O model. Pointing out that the legal, insurance, and medical communities all have some degree of commitment to the current system, they cautioned that acceptance of the change may be slow.

The stakeholders suggested strategies both to make the case that such a change was worth making and to reduce organizations' transition costs. They advocated a statewide resource ("centralized tool kit") to assist patients, clinicians, and organizational leadership with educational materials; data on the DA&O model, policies, procedures, and algorithms; and expert references or contacts to assist with implementation, to share tools, and to minimize duplication. They highlighted the importance of building an institutional infrastructure for DA&O models and utilizing opinion leaders and patient advocates to convey the difference that the model could make for patients. They also suggested that a broad-based coalition comprising the state hospital association, medical society, BORM, DPH, health insurers, and patient advocacy organizations could use their collective influence to overcome inertia.

Fairness to Patients. Many stakeholders feared that the public, plaintiff attorneys, or others might perceive the DA&O model as "anticonsumer" and become suspicious of the motives of institutions that adopted it. Their primary concern was that the public would view the DA&O model as an attempt to persuade patients to settle cases of serious injury quickly, for small amounts of money, and without the benefit of counsel.

The respondents stressed the need to educate the public and media about the DA&O approach, in order to decrease skepticism. The first priority, they said, was to emphasize that the model's primary goal was to support patients and provide safer care, and that reducing costs was a secondary benefit. Underscoring individual as well as system accountability and stressing that "bad apples" would not escape disciplinary sanctions might also ease the public's concerns. Ensuring that patients had access to attorneys in the DA&O process and developing a standardized and transparent "formula" for compensation might help win the public's trust. Involving patients and/or their families in the investigation was

also proposed as a way to strengthen partnership and credibility. The interviewees also recommended both demonstrating the gains for patient safety derived from the model and ensuring a mechanism for sharing “lessons learned” in cases that could readily apply to other health care organizations.

At the same time, the respondents stressed that legal protection of the peer-review process would be needed to help clinicians safely engage in the DA&O process and that comprehensive event root-cause analyses should be isolated from claims management and liability assessment. Some stakeholders also suggested that external regulation might be needed to ensure accountability. For example, the state DPH, patient safety organizations, or ACOs could set standards for the DA&O process, monitor institutions’ DA&O activities, and disseminate information about outcomes.

May Not Work in Other Settings. Some stakeholders noted that compared with large academic centers, small hospitals may face greater resource constraints, such as risk-management staff and the institution’s ability to gamble on an approach that might increase liability costs. In addition, they felt that hospitals whose physicians were only loosely affiliated with the facility, rather than directly employed by it, might have fewer levers with which to influence those physicians to change their reporting and disclosure practices. The stakeholders were also concerned that small institutions (and physicians’ practice groups) may face substantial barriers in organizing robust and timely investigation processes. Since private practitioners often volunteer their time at local hospitals for peer review, additional time demands could prove unrealistic. Similarly, using the DA&O model in an ambulatory setting or in community health centers may require special resources and approaches tailored to those settings. Finally, some suggested that the culture in rural areas might be less amenable to full transparency than would that of the urban/suburban areas where DA&O programs currently operate.

To overcome this barrier, the respondents favored a centralized resource center, standardized policies for inpatient and ambulatory settings, and universal training and education for physicians and clinical leaders, as well as an oversight mechanism to ensure adherence to these guidelines. They also recommended financial support for physicians taking on additional quality improvement responsibilities, particularly if their contributions were voluntary.

Discussion

DA&O programs have the potential to improve both medical liability and patient safety (Boothman et al. 2009; Kachalia, Kaufman, and Boothman 2010; McDonald et al. 2010). The approach continues to attract attention, including the interest and financial support of the federal government. Yet despite broad dissemination of positive results from exemplary DA&O programs (Boothman et al. 2009; Kachalia, Kaufman, and Boothman 2010; Mello and Gallagher 2010), the model has not been broadly adopted by health care institutions or even self-insured hospitals. This study examined why.

We confirmed some of the potential barriers identified in previous commentary (Kachalia and Mello 2011; Localio 2010; Mello and Gallagher 2010; Peto et al. 2009), uncovered new ones, and measured the frequency with which diverse stakeholders perceive them as problems. The study also highlighted potential solutions that stakeholders view as feasible and important to pursue. Our findings can help physician-leaders, educators, patient advocates, and policymakers identify and prioritize next steps to prepare environments other than closed (captive) systems for a DA&O model.

The barriers we found fell into four broad categories: (1) *cultural barriers* such as physicians' discomfort with disclosure and apology and anxiety about potentially greater liability exposure, attorneys' tendency to cling to the adversarial legal system, and general resistance to change; (2) *legal barriers* like charitable immunity and physicians' fears of name-based reporting of malpractice settlements; (3) *logistical obstacles* like the complexities of interinsurer coordination and practical challenges in small hospitals and noncaptive practice settings; and (4) *political barriers*, such as the challenges of securing strong apology laws and other enabling legislation and of assuring the public that the DA&O approach is fair to patients and adequately holds health care providers accountable.

Examining the frequency with which various barriers were cited by diverse stakeholders is important to understanding the overall environment for a broad rollout of the DA&O approach. To understand the most important barriers to DA&O adoption, however, we must consider both this frequency and the difficulty of overcoming the barrier. Some of the most frequently mentioned barriers can be surmounted relatively easily. For example, interinsurer coordination is eminently achievable given that many states have only a small number of insurers serving the

market and that their interests are aligned in terms of avoiding litigation and improving patient safety. Attorneys' opposition was a commonly cited barrier, but defense attorneys act at the direction of their clients, and plaintiffs' attorneys are likely to quickly grasp the benefits of early settlement processes, as they have in the existing DA&O programs. Conversely, some of the less tractable barriers were mentioned relatively infrequently by our respondents. Most notably, the role of institutional leadership was not commonly cited but is likely to prove critical, as successful DA&O programs have, to a large extent, grown out of the dedicated efforts of an institutional champion, and true culture change requires commitment from the top. Charitable immunity still stands out as a barrier that is both widely recognized and difficult to remove, even with the recently raised cap. But it is a problem unique to Massachusetts, and stakeholders agreed that while it may dampen interest in the DA&O model, no law change is required to move forward with the model.

While none of the obstacles was viewed as insurmountable, the general consensus of our respondents was that overcoming these obstacles would require coordinated, focused action and a larger evidence base to convince wary stakeholders. The challenge of catalyzing this concerted action across diverse stakeholders without incontrovertible evidence that the model would be successful in new settings may explain why there has not been greater use of the model, despite the intense interest of both health systems and insurers in the University of Michigan's success story.

The stakeholders' overall attitude was enthusiastic and cautiously optimistic. While the DA&O model was nearly universally recognized as a promising way forward, some respondents also were skeptical whether other stakeholders would be willing to break the status quo and support a new approach. In particular, some respondents worried that plaintiff and defense attorneys as well as professional liability insurers may be reluctant to proceed with the DA&O program, since they felt that these parties may benefit financially from the current system. Since we completed these interviews, however, the Massachusetts Medical Society, the Massachusetts Bar Association, and the Massachusetts Academy of Trial Attorneys developed consensus language to establish (1) a mandatory six-month prelitigation notification period, including sharing of all pertinent medical records (Mass. Gen. Laws Ann. ch. 231§ 60L [2012]) and (2) stronger apology protections, including statements of explanation, responsibility, or regret (Mass. Gen. Laws Ann. ch. 233§ 79L [2012]). These items were signed into law as part of a

comprehensive payment reform bill in August 2012 (ch. 224 of the Acts of 2012). In addition, several hospitals and their professional liability insurers in Massachusetts are participating in a multi-institution pilot for implementing the DA&O model (Massachusetts Medical Society 2012).

Next Steps: What Organizations and the States Can Do

Most of the strategies that the stakeholders proposed are actionable items that health care systems and state organizations can pursue on their own. The first step is to develop a broad-based educational campaign regarding the DA&O approach, along with disclosure training programs and DA&O policies and procedures. Development of a statewide, web-based repository of tool kits, guidelines, best practices, outcomes data, and other resources could be of significant benefit to organizations, especially small and underresourced hospitals, in building the case for the DA&O model and rolling out programs. Professional associations and other stakeholder organizations, hospitals that have successfully launched DA&O programs, the leaders and sites of the ongoing AHRQ demonstration projects, and state regulators all could be valuable contributors.

Health care organizations also need robust event analysis and loop-closure processes applicable to a variety of clinical settings. Statewide guidelines for the event root-cause analysis, for example, currently under development by the Massachusetts BORM, could help standardize the process. Similarly, discussions between the Massachusetts Medical Society and the Massachusetts BORM are under way to make recommended modifications to name-based reporting requirements and develop consensus language to pave the way to reforms that prevent systems-related errors disclosed as part of a DA&O program from being attributed to an individual physician. The enabling liability reform provisions recently passed in Massachusetts or similar supportive legislation in other states, while not necessary to institute DA&O, might encourage organizations to adopt the model. Specifically, a strong apology law that protected statements of explanation, responsibility, or regret, as well as a mandatory six-month prelitigation review period, may facilitate acceptance of the DA&O model by health care providers and insurers. Considerable work is already being done as part of the AHRQ demonstration projects to tackle issues like interinsurer coordination, support of small hospitals

and community practices, and the inclusion of patients and families in the event analysis (AHRQ 2010a, 2010b; Kachalia and Mello 2011). Lessons learned from these efforts can also help guide organizational leaders. Finally, progress may rely on creating a forum to convene stakeholders and establish a coalition of like-minded leaders committed to the DA&O model.

Our study was limited by the relatively small size of our sample of respondents. While we included stakeholders from a broad array of backgrounds, capturing a wide range of viewpoints, it is possible that the respondents—although typically leaders of their respective organizations—did not adequately represent the full spectrum of views of their stakeholder group. Some of the respondents also might have been more familiar with the DA&O approach than their members. Furthermore, since the interviewees were asked to think about barriers in largely hypothetical terms (i.e., without experiencing the DA&O process firsthand), the respondents could have misperceived, or missed, various barriers.

Another limitation relates to the unique circumstance of Massachusetts's charitable immunity law. Massachusetts may be a more challenging environment for implementing the DA&O approach than other states. Although the other barriers identified by our respondents are generalizable outside Massachusetts, the respondents' views of the feasibility of the DA&O model may reflect their view from the shadow of the charitable immunity law. Given the general enthusiasm for the program despite this limitation in Massachusetts, its actual feasibility in or beyond Massachusetts may be even higher.

Conclusions

Notwithstanding the challenges to wide-scale implementation, there was a striking degree of consensus among the stakeholders that the DA&O model holds great potential to improve medical liability and patient safety. It was viewed as more promising than any other liability reform option, both on its merits and because it would not be stymied by political gridlock in state legislatures, as other tort reforms frequently have been. The potential role for DA&O programs in the broader context of federal health reform efforts is intriguing. The model offers an avenue for bringing diverse stakeholders together because—unlike

traditional liability reforms such as damages caps—it offers a plausible “value proposition” to patients. DA&O programs may prove not only to constrain liability costs but also to improve access to compensation, strengthen linkages between the liability system and patient safety, increase health care organizations’ accountability and patient advocacy, and promote transparency in regard to medical error.

References

- AHRQ (Agency for Healthcare Research and Quality). 2010a. *Medical Liability Reform and Patient Safety: Demonstration and Planning Grants*. Rockville, MD. Available at <http://www.ahrq.gov/qual/liability> (accessed January 6, 2011).
- AHRQ (Agency for Healthcare Research and Quality). 2010b. *Medical Liability Reform and Patient Safety: Demonstration Grants*. Rockville, MD. Available at <http://www.ahrq.gov/qual/liability/demogrants.htm> (accessed January 6, 2011).
- American Hospital Association, Management Advisory Committee. 1992. *Ethical Conduct for Health Care Institutions*. Chicago.
- American Society for Healthcare Risk Management of the American Hospital Association. 2003. *Disclosure of Unanticipated Events: The Next Step in Better Communication with Patients*. Chicago: American Hospital Association.
- Banja, J. 2001. Moral Courage in Medicine—Disclosing Medical Error. *Bioethics Forum* 17(2):7–11.
- Blendon, R.J., C.M. DesRoches, and M. Brodie. 2002. Views of Practicing Physicians and the Public on Medical Errors. *New England Journal of Medicine* 347(24):1933–40.
- Boothman, R.C., A.C. Blackwell, D.A. Campbell Jr., E. Commiskey, and S. Anderson. 2009. A Better Approach to Medical Malpractice Claims? The University of Michigan Experience. *Journal of Health & Life Sciences Law* 2(2):125–59.
- Boothman, R.C., S.H. Imhoff, and D.A. Campbell. 2012. Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk through Disclosure: Lessons Learned and Future Directions. *Frontiers of Health Services Management* 28(3):13–28.
- Brennan, T.A., M.M. Mello, and D.M. Studdert. 2006. Liability, Patient Safety, and Defensive Medicine: What Does the Future Hold? In *Medical Malpractice and the U.S. Health Care System: New Century, Different Issues*, ed. W.M. Sage and R. Kersh, 93–114. Cambridge: Cambridge University Press.

- Cantor, M.D., P. Barach, A. Derse, C.W. Maklan, G.S. Wlody, and E. Fox. 2005. Disclosing Adverse Events to Patients. *Journal on Quality and Patient Safety* 31(1):5–12.
- Clarke, J.R., J.C. Lerner, and W. Marella. 2007. The Role for Leaders of Health Care Organizations in Patient Safety. *American Journal of Medical Quality* 22:311–18.
- Connor, M., D. Duncombe, E. Barclay, S. Bartel, C. Borden, E. Gross, C. Miller, and P. Reid Ponte. 2007. Creating a Fair and Just Culture: One Institution's Path toward Organizational Change. *Joint Commission Journal on Quality and Patient Safety* 33(10):617–24.
- Delbanco, T., and S.K. Bell. 2007. Guilty, Afraid, and Alone—Struggling with Medical Error. *New England Journal of Medicine* 357(17):1682–83.
- Gallagher, T.H., A.D. Waterman, A.G. Ebers, V.J. Fraser, and W. Levinson. 2003. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors. *JAMA* 289(8):1001–7.
- Glaser, B., and A. Strauss. 1967. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Chicago: Aldine.
- Hiatt, H.H., B.A. Barnes, T.A. Brennan, N.M. Laird, A.G. Lawthers, L.L. Leape, A.R. Localio, J.P. Newhouse, L.M. Peterson, K.E. Thorpe, P.C. Weiler, and W.G. Johnson. 1989. A Study of Medical Injury and Medical Malpractice. *New England Journal of Medicine* 321:480–84.
- Institute of Medicine, Committee on Quality of Health Care in America. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press.
- Joint Commission on Accreditation of Health Care Organizations. 2005. *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*. Washington, DC.
- Kachalia, A., S.R. Kaufman, and R. Boothman. 2010. Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program. *Annals of Internal Medicine* 153:213–21.
- Kachalia, A., and M.M. Mello. 2011. New Directions in Medical Liability Reform. *New England Journal of Medicine* 364(16):1564–72.
- Kaiser Family Foundation, Agency for Healthcare Research and Quality, and Harvard School of Public Health. 2004. National Survey on Consumers' Experiences with Patient Safety and Quality Information. Available at <http://www.kff.org/kaiserpolls/pomr111704pkg.cfm> (accessed August 15, 2012).
- Kessler, D., and M. McClellan. 1996. Do Doctors Practice Defensive Medicine? *Quarterly Journal of Economics* 111:353–90.
- Khatry, N., G.D. Brown, and L. Hicks. 2009. From a Blame Culture to a Just Culture in Health Care. *Health Care Management Review* 34(4):312–22.

- Khatri, N., J. Halbesleben, G.F. Petroski, and W. Meyer. 2007. Relationship between Management Philosophy and Clinical Outcomes. *Health Care Management Review* 2(32):128–39.
- Kraman, S.S., and G. Hamm. 1999. Risk Management: Extreme Honesty May Be the Best Policy. *Annals of Internal Medicine* 131: 963–67.
- Localio, A.R. 2010. Patient Compensation without Litigation: A Promising Development. *Annals of Internal Medicine* 153:266–67.
- Localio, A.R., A.G. Lawthers, T.A. Brennan, N.M. Laird, L.E. Herbert, L.M. Peterson, J.P. Newhouse, P.C. Weiler, and H.H. Hiatt. 1991. Relation between Malpractice Claims and Adverse Events Due to Negligence. Results of the Harvard Medical Practice Study III. *New England Journal of Medicine* 325:245–51.
- Marx, D. 2001. *Patient Safety and the “Just Culture”: A Primer for Health Care Executives*. New York: Columbia University Press.
- Massachusetts Medical Society. 2008. *Investigation of Defensive Medicine in Massachusetts*. Waltham, MA. Available at www.massmed.org/defensivemedicine (accessed August 15, 2012).
- Massachusetts Medical Society. 2012. Physicians, Hospitals, Health Groups Announce Initiative to Improve the Medical Liability Environment in Massachusetts, April 18. Available at <http://www.massmed.org/AM/Template.cfm?Section=Home6&CONTENTID=71013&TEMPLATE=/CM/ContentDisplay.cfm> (accessed June 23, 2012).
- Mastroianni, A., M.M. Mello, S. Sommer, M. Hardy, and T.H. Gallagher. 2010. The Flaws in State “Apology” and “Disclosure” Laws Dilute Their Intended Impact on Malpractice Suits. *Health Affairs* (Millwood) 29(9):1611–19.
- McDonald, T.B., L.A. Helmchen, K.M. Smith, N. Centomani, A. Gunderson, D. Mayer, and W.H. Chamberlin. 2010. Responding to Patient Safety Incidents: The “Seven Pillars.” *Quality & Safety in Health Care* 19(6):e11 (epub. March 1, 2010).
- Mello, M.M., and T.H. Gallagher. 2010. Malpractice Reform—Opportunities for Leadership by Health Care Institutions and Liability Insurers. *New England Journal of Medicine* 362(15):1353–56.
- Mello, M.M., and A. Kachalia. 2011. New Directions in Medical Liability Reform. *New England Journal of Medicine* 364(16):1564–72.
- Mello, M.M., and D.M. Studdert. 2008. Deconstructing Negligence: The Role of Individual and System Factors in Causing Medical Injuries. *Georgetown Law Journal* 96:599–623.
- Mello, M.M., D.M. Studdert, C.M. DesRoches, J. Peugh, K. Zapert, T.A. Brennan, and W.M. Sage. 2005. Effects of the Malpractice Crisis on Specialist Supply and Access to Care. *Annals of Surgery* 242:621–28.

- O'Leary, K.J., J. Choi, K. Watson, and M.V. Williams. 2012. Medical Students' and Residents' Clinical and Educational Experiences with Defensive Medicine. *Academic Medicine* 87(2):142–48.
- Peto, R.R., L.M. Tenerowicz, E.M. Benjamin, D.S. Morsi, and P.K. Burger. 2009. One System's Journey in Creating a Disclosure and Apology Program. *Joint Commission Journal on Quality and Patient Safety* 35(10):487–96.
- Reason, J. 2000. Human Error: Models and Management. *BMJ* 320(7237):768–70.
- Sage, W.M. 2003. Medical Liability and Patient Safety. *Health Affairs* (Millwood) 22(4):26–36.
- Studdert, D.M., M.M. Mello, and T.A. Brennan. 2004. Medical Malpractice. *New England Journal of Medicine* 350(3):283–92.
- Studdert, D.M., M.M. Mello, A.A. Gawande, T.K. Ghandi, A. Kachalia, C. Yoon, A.L. Puopolo, and T.A. Brennan. 2006. Claims, Errors, and Compensation Payments in Medical Malpractice Litigation. *New England Journal of Medicine* 354:2024–33.
- Studdert, D.M., M.M. Mello, W.M. Sage, C.M. DesRoches, J. Peugh, K. Zapert, and T.A. Brennan. 2005. Defensive Medicine among High-Risk Specialist Physicians in a Volatile Malpractice Environment. *JAMA* 293(21):2609–17.
- Vincent, C., M. Young, and A. Phillips. 1994. Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action. *The Lancet* 343(8913):1609–13.
- Waterman, A.D., J. Garbutt, and E. Hazel. 2007. The Emotional Impact of Medical Errors on Practicing Physicians in the United States and Canada. *Joint Commission Journal on Quality and Patient Safety* 33(8):467–76.
- West, C.P., M.M. Huschka, P.J. Novotny, J.A. Sloan, J.C. Kolars, T.M. Habermann, and T.D. Shanafelt. 2006. Association of Perceived Medical Errors with Resident Distress and Empathy: A Prospective Longitudinal Study. *JAMA* 296:1071–78.
- Wu, A.W., T.A. Cavanaugh, S.J. McPhee, B. Lo, and G.P. Micco. 1997. To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine* 12(12):770–75.

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