

**A ROADMAP
FOR TRANSFORMING MEDICAL LIABILITY
AND IMPROVING PATIENT SAFETY
IN MASSACHUSETTS**

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**MASSACHUSETTS
MEDICAL SOCIETY**

A Roadmap for Removing Barriers to Disclosure, Apology and Offer in Massachusetts

INTRODUCTION:

The current medical liability system has several fundamental flaws that negatively impact patients, physicians and the health care system as a whole. Today in Massachusetts, litigation is the predominant pathway for harmed patients to seek compensation. Grounded in an adversarial system, this approach directly threatens the therapeutic relationship and a sense of shared purpose between patient and caregiver. It is slow, inefficient and often inequitable: a small minority of harmed patients pursue litigation, and only a fraction of those are compensated.^{i,ii} Litigation costs, language barriers, and other obstacles may also discourage the most vulnerable patients from understanding how they were harmed, and how to seek compensation. The current tort system takes a great emotional toll on patients and doctors alike – one that can persist for years until the case is resolved, or longer. It does not effectively distinguish between individual versus systems-based errors, unnecessarily blaming individual health care providers for multi-factorial errors and restricting critical information flow for systems improvement by generating secrecy and fear following bad outcomes.

For patients, the current system breeds distrust of our healthcare system and impedes efforts to improve patient safety. For physicians, it results in burdensome or unaffordable premiums and a loss of trust in the justice system. It also causes them to view patients as potential litigants, and encourages the practice of defensive medicine.ⁱⁱⁱ For the health care system as a whole, the current liability system thwarts patient safety efforts, drives up the overall cost of health care, and compromises access to care when liability concerns lead physicians to reduce their scope of practice or avoid high risk patients.

Programs that support disclosure, apology, and offer (the “DA&O model”) are attracting wide attention as a potential approach for increasing access to timely and just medical injury compensation, reducing medical liability costs, and more effectively linking adverse events to patient safety improvements. The DA&O approach received national attention in 2006, when then U.S. Senators Barack Obama and Hillary Clinton co-sponsored the National Medical Error and Compensation (MEDiC) Bill.^{iv} Since 2001, successful implementation of the DA&O model at the University of Michigan has led to decreased patient injuries (and claims) as a result of increased reporting, systems improvements following investigation of claims, shorter time to claims resolution, and dramatically decreased costs.^v

Today DA&O programs are predominantly operated by a few self-insured health systems across the country.^{vi} The goals of such programs are to support physicians in disclosing unanticipated care outcomes to patients, create a process for rapid investigation of claims coupled with system improvement to avoid similar incidents from recurring, provide apologies for avoidable injuries, and offer timely and fair compensation in appropriate cases without having to resort to litigation (**Table 1**). Cases in which the standard of care was met are aggressively defended, and all cases are rigorously studied as part of a comprehensive patient safety improvement effort.^{vii} Because any caregiver can activate an investigation, this model removes the onus for initiating a query

from the injured party. In addition to being ethically more palatable, this approach effectively casts a broader net around cases from which the institution can learn and improve, since patients may not be fully aware of cases where preventable harm occurred. It also helps to reinstate clinicians as advocates for their patients, helping to “make them whole” by diminishing the conflict of interest resulting from fear of litigation.

In a joint initiative with the Massachusetts Medical Society (MMS), Beth Israel Deaconess Medical Center (BIDMC) received a planning grant from the Agency for Health Care Research and Quality to tackle medical liability system reform in Massachusetts by examining the potential for DA&O programs in that state. The BIDMC/MMS initiative has four aims: 1) to identify the barriers to implementation of a DA&O model in Massachusetts, 2) to develop strategies for overcoming these barriers, 3) to design a roadmap for DA&O program implementation in this state, and 4) to assess applicability of the roadmap to other states. This document represents that roadmap, based on the results of interviews with key stakeholders in Massachusetts and a verification process with all interviewees.

METHODOLOGY

1. Key stakeholder interviews

a. Interviewees

Interviews were conducted with 27 key stakeholders. Interviewees were selected based on holding leadership positions in organizations central to implementation of the DA&O approach: the Massachusetts legislature, hospital systems (including academic health centers and community hospitals), practicing physicians, liability insurers, health insurers, medical professional associations, patient advocacy organizations, malpractice attorneys, patient safety experts, major physician practice groups, and a major business association (**Table 2**). Overall, 9 out of 27 interviewees were physicians, either practicing or in leadership positions, or both. In addition, interviewees were identified as having sufficient knowledge about existing risk management and claims management models in Massachusetts, the Massachusetts liability environment, disclosure, and/or patient safety to be able to consider, in an informed way, challenges in implementing a DA&O model.

b. Interview content

The interviews were conducted in person by teams of two interviewers with the exception of a single interview conducted by one interviewer, and lasted 45-60 minutes. Interviews were semi-structured and based on an interview guide that drew on the project team’s expertise in qualitative research methods, medical liability reform alternatives, DA&O program implementation, defensive medicine, medical error disclosure, and patient safety. The interviews covered four main areas: 1) the respondent’s institutional setting and relevant experience; 2) perceived barriers to implementation of DA&O programs in Massachusetts healthcare institutions; 3) suggested strategies for overcoming these barriers; 4) overall perception of the potential for the DA&O model to improve the medical liability and patient safety environments in Massachusetts. Each interview was digitally recorded, with the respondent’s permission, and fully transcribed by a professional transcriptionist. Identifying information was redacted, and only the study identifier number was recorded on the transcripts.

2. Data analysis

The project investigators along with the consulting researcher at the Harvard School of Public Health, developed a coding scheme of interview topics after reading a random sample of transcripts. A definition for each code was developed in a detailed coding manual. The interviewers then extracted, coded, and compiled more than 1400 key statements from the transcripts with systematic review of each transcript for barriers and strategies. Standard methods of thematic content analysis were used to analyze the data and extract themes.^{viii} For key questions, we categorized responses and produced frequency tables. All investigators collaboratively discussed the initial results to reach consensus about how to represent the most common barriers and the proposed strategies in the Roadmap. The group also prioritized and organized the strategies based on frequency with which they were discussed by stakeholders, feasibility, importance, and timeframe required to achieve each strategy. The barriers and strategies were then shared with the project's interviewees for individual feedback. The project team integrated stakeholder feedback comments into the Roadmap prior to presentation at a symposium entitled *Roadmap for Transforming Medical Liability and Improving Patient Safety in Massachusetts* in March 2011. The overall roadmap as well as the barriers and strategies were further refined based on feedback from the approximately 150 symposium participants, which were predominantly physicians.

BARRIERS AND STRATEGIES

Interviews with representatives from stakeholder groups revealed several barriers and potential solutions to implementation of a DA&O model. Here we present the 12 barriers and proposed strategies most frequently cited by interviewees (**Table 3**). Because specific concerns and strategies relating to “Fairness to patients” and “Accountability for the process” were complementary, these are discussed as a single barrier “Fairness and accountability.”

1. Fairness and accountability

“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 maybe they should.”

Massachusetts stakeholders feared the public, plaintiff attorneys, or others may perceive the model as anti-consumer and may be suspicious of the institution's motives. Turning to historic trends in medicine, respondents pointed out that if a profession once so steadfast in hiding mistakes began making offers, patients might counter-intuitively become even *more* suspicious about what the hospital or health care organization was *really* trying to hide. Public perception of institutional under-compensation of patients was the primary substantive concern.

At the same time, providers indicated that while fairness is paramount, legal protection of the peer review process to examine adverse outcomes in detail will be necessary to avoid clinician hesitancy to engage fully in the DA&O process. Current statutes from the Massachusetts general laws state that the “proceedings, reports and records of a medical peer review committee shall be confidential and shall be exempt from the disclosure of public records...but shall not be subject to subpoena or discovery, or introduced into evidence, in any judicial or administrative proceeding, except proceedings held by the boards of registration in medicine, pharmacy, social work, or psychology or by the department of public health.”^{ix} These statutes suggest that

information gleaned from peer review processes within a DA&O program should not place providers at increased risk of liability.

However, the extent of peer review protection for root cause analysis (RCA) processes that are part of a DA&O model and are aimed at quality improvement can get complicated, particularly if a case that triggers an RCA turns into a claim. One key distinction is that an institutional RCA can be viewed as a “look forward” to understand the event in depth in order to learn how the system can avoid similar problems in the future, whereas claims tend to “look backwards” to determine if an individual’s or group of individuals’ actions were reasonable. In many situations, such processes may proceed in parallel as both the institutional RCA (conducted to improve patient safety) and the claims process investigation (conducted to determine whether reasonable care was met) unfold. Peer protections typically refer to the former but not the latter. Some centers link these two investigations by sharing facts of the case only. A second distinction between RCAs that are part of a DA&O model and those applied to quality improvement more broadly construed is that the latter group encompasses a much larger range of events including near misses and no harm events in addition to adverse outcomes. From the perspective of DA&O programs only harmful outcomes would trigger an RCA. Finally, legal considerations may also limit the reach of peer protection. Massachusetts law requires reporting of adverse events to the Department of Public Health^x; this information does not have such protection. Stakeholders emphasized that ensuring appropriate peer protections in the DA&O process will require careful examination and clear definitions for these different but overlapping activities as well as their legal implications. Due to the competing notions of fairness/transparency in peer review, and keeping clinicians involved in these processes safe from liability, any state interested in expanding the DA&O model will need to carefully review its particular peer review and adverse event reporting statutes.

Strategies

Respondents stressed the need to educate the public and media about the approach as a critical step to decrease skepticism. A first priority is to emphasize that the motive for the model is to support patients and provide safer care, not save money. Inherently, after an adverse outcome, patients want to hear what is being done to prevent future similar incidents – a central part of the DA&O model. Emphasizing individual as well as system accountability and that “bad apples” won’t evade sanctions may also ease public concerns. “I think most patients aren’t initially vindictive. I think they just want to make sure that somebody is listening to them and that this won’t happen again. I’m optimistic that there would be wide public acceptance,” one respondent noted.

Stakeholders also emphasized the importance of ensuring patient legal representation in the DA&O process. A standardized and transparent “formula” for compensation can also help gain trust. Involving patients and/or their families in the RCA may be an additional way to strengthen partnership and credibility, though this remains an area of considerable controversy. Several interviewees queried the ideal structure for the RCA. Some felt this should be conducted by the hospital/health care organization, others by insurers with legal expertise, and still others recommended that this effort include an external independent consultant without any financial interest in the outcome. They also debated whether each of these representatives would conduct independent RCAs or work collaboratively in a single investigation. Prompt access to all pertinent medical records also played a key role for the insurers’ perspective on a

comprehensive, timely liability assessment. Overall, striking the right balance between clinicians, insurers, lawyers, peer protection, and external transparency in the root cause analysis and liability assessment will be a key task.

Comprehensive DA&O programs need strong peer review protections as part of RCA efforts that are isolated from claims review/liability assessment processes. Leadership at the Massachusetts Board of Registration in Medicine (BORM) is currently engaged in developing guidelines for the RCA process. Such guidelines will help standardize the process and provide clear definitions about expectations and protections. Developing a mechanism to share key root cause analysis (RCA) findings or a summary of the identified causes should be considered. Respondents felt that a mechanism for sharing “lessons learned” in cases that could readily apply to other hospitals/practice environments would be important for extending the patient safety reach. Finally, some stakeholder suggested adding regulatory processes to further ensure trustworthiness and accountability to external parties, including patients. A few proposed mechanisms for external regulation/dissemination of information included the Department of Health and Human Services (DHHS), the Department of Public Health (DPH), patient safety organizations (PSOs), or Accountable Care Organizations (ACOs).

2. Physician discomfort with disclosure

“...The communication in the past has always been ‘Don't talk about it. Don't say anything. Don't admit to anything.’”

Stakeholders noted that disclosure conversations are difficult, and do not come naturally to most physicians. They felt that most physicians are not adequately trained or supported in disclosure processes, nor do they feel safe apologizing. Pointing to the natural human tendency to avoid the shame of admitting mistakes, stakeholders felt that reluctance to expose one’s errors may be further reinforced by prevailing medical culture. They also raised concerns that incomplete “protection” from the Massachusetts apology law may impede full disclosures.

Strategies

Education featured as the most prominent strategy to overcome physician discomfort with disclosure. As one respondent surmised, “Disclosure is not amateur hour. It requires a certain level of expertise.” Suggestions included developing robust “coaching” models and peer mentoring systems led by physicians previously involved in error and disclosures, involving patients and families in disclosure training, and starting early in medical education. Coupled with training, sharing successful disclosure stories with clinical staff may be an additional strategy to ease clinician fears. Respondents viewed disclosure as a “competency” and advocated formal universal training with clear disclosure protocols and support systems for clinicians. Some respondents suggested including disclosure training as a licensure requirement.

Stakeholders also viewed establishing “just culture” as an important corollary to effective disclosure programs, and recommended turning to the Joint Commission and the Massachusetts Medical Society to develop standards for DA&O and training programs, respectively. Some interviewees advocated for a strong apology law, although others pointed out that the program has been successful at the University of Michigan despite absence of an apology law in that state. They universally agreed that institutional leadership needs to be clear about full support of disclosure and apology. Taken together, these suggestions underscore the importance of

preparing clinicians for challenging bedside conversations and a second key insight: physicians will not disclose if they do not feel safe doing so. Some argue that physicians know how to communicate with patients -- even about sensitive topics -- but refrain from doing so if they fear financial or professional ruin.

3. Concern about increased liability

“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... I think also that there is concern that this information will end up in their credentialing packets.”

Despite acknowledging that concerns about elevated liability stemming from disclosure were unfounded, the majority of stakeholders thought others would view this as a barrier. In particular, respondents flagged the potential concern about risk associated with: 1) alerting patients to the fact of an injury or error, 2) the possibility that admissions could be used against a physician in litigation, 3) the possibility of increased plaintiff attorney interest in cases where error was specifically acknowledged, and 4) the possibility that patients would have heightened expectations about their chances of prevailing in a claim. One respondent remarked that in the absence of a “mandatory pre-litigation review period,” DA&O provides an additional avenue for seeking compensation while doing little to discourage lawsuits, and so could increase the overall cost and frequency of claims.

Strategies

General consensus among stakeholders was that providing data is the key to allaying fears about increased liability: “Nothing will relieve the anxiety more than seeing that it works.” Recommendations included sharing the Michigan data, generating new pilot data in Massachusetts and rapidly disseminating results to help dispel misconceptions. Respondents underscored the importance of a “top down” approach – suggesting that first convincing hospital/health care organization leadership will enable them to then support and encourage their physicians. “[I think] the two big drivers are going to be data [and] leadership. As the CEOs, CMOs and department chairmen get aboard the rest of the people will come...The main strategy for somebody who wants to move this [is] to recruit the leadership and convince them and then they will help convince the rest of the troops.” Some stakeholders again favored a stronger apology law. Others speculated about movement toward enterprise liability or a no-fault system akin to worker’s compensation or – on a state level – to the National Vaccine Injury Compensation Fund.

4. Physician name-based reporting:

“I think the model of ‘This is a systems issue and not assignable to a particular physician’ is probably the only way to go.”

Respondents viewed name-based physician reporting as a barrier – predominantly referring to National Practitioner Data Bank (NPDB) reporting, but occasionally also specifically discussing reporting to the state Board of Registration in Medicine (BORM) or the Department of Public Health (DPH). Many found it objectionable that physicians suffer reputational harm even when errors are due, even in part, to systems failures. “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 [their fault]." Others pointed out physicians' potential resistance to settlement because of their desire to avoid a "black mark" on their record.

Strategies

Education and process change took top rank as strategies for this barrier. Several respondents pointed out that clinicians often have an exaggerated perception of how often NPDB and BORM data are actually used. Clarifying reporting requirements, as well as realistic implications of reporting, is a first step. Physicians should also be assured that cases in which the standard of care was met will not be settled. Finally adopting process change, regulation, or legislation that allows institution-based reporting for adverse outcomes deemed to be system failures and reserving individual physician reporting for acts of negligence or recklessness is essential to address physician concerns, according to stakeholders ("It's not constructive to be reporting people for things that were not within their individual control"). Clarification and potential modification of reporting requirements by the BORM is needed.

5. Charitable immunity law

"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."

Although the topic of charitable immunity was frequently mentioned, many stakeholders did not feel this was an insurmountable obstacle. Stakeholders did note that charitable immunity has two potential detrimental effects on DA&O programs. First, they speculated that hospitals/health care organizations might be relatively uninterested in DA&O programs because they carry limited financial liability. Second, they worried that because physicians are the "deep pockets" in the current system when hospitals/health care organizations have limited financial liability, they may be reluctant to participate in disclosure. Many stakeholders viewed this issue through the prism of patient safety, suggesting that if organizations don't have enough "skin in the game" they will not be adequately invested in making hospitals and health care systems safer. A related topic was the issue of "joint and several liability," raised by stakeholders in the context of further reinforcing the flawed approach of applying individual blame to adverse events that are often based on systems level errors.

Strategies

Pointing to the longstanding tradition of Charitable Immunity in Massachusetts, most stakeholders viewed steps to reform its potential untoward effects on DA&O cautiously. While repealing the law or raising the cap on hospital/health care organization liability were mentioned frequently, stakeholders agreed that the most realistic and effective approach would be to encourage hospitals and health care systems to recognize and assume system liability through a voluntary waiver-by-settlement approach. Many saw this as a natural extension of enterprise liability and Accountable Care Organizations. Essentially all stakeholders agreed that voluntary ownership by institutions of systems-based errors reflects a more appropriate level of liability for these types of adverse outcomes.

6. Difficulty coordinating insurers:

“You don't have to worry about allocating costs if you have a closed model and you have a captive insurer. Nobody has to worry about who's paying for what.”

Many respondents believed that challenges in coordinating different insurers presented a significant barrier. They were concerned about fairness to a hospital/health care organization participating in DA&O if co-defendants in the same case were not all part of a DA&O model at their respective hospitals/health care organizations or with their respective insurers – conditions that could lead to “gaming” the system. They worried that such lack of coordination could also draw out the process, running counter to one of the central DA&O program goals: expediency. As one insurer representative stated, “[W]e 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.” Despite these concerns, respondents felt that inter-insurer coordination concerns could be addressed in Massachusetts due to the limited number of insurance carriers. Nonetheless, participants agreed that moving toward a DA&O approach as a state would require the agreement and cooperation of all the insurers: “It's going to have to be all the major insurers getting together and deciding “This is the policy in the state.”

Strategies

Respondents underscored the importance of a collaborative approach focusing on education to bring insurers together around shared set of values that support patients. Convening a forum for insurers to cooperatively resolve codefendant issues is a priority. Other suggestions included involving the Commissioner of Insurance, the Office of Patient Protection, or formal regulation/legislation. Most stakeholders felt this could be handled collegially.

7. Opposition by liability insurers

“I have heard no complaints of any significance about [the current] system being challenged. If there is a working economic model on the current insurance structure [liability insurers] could be a surprising opponent or impediment to changing the system”

Several stakeholders observed that the current system is familiar and relatively predictable for the liability insurers, and the impact of a change to a more proactive DA&O model cannot be predicted and thus may be opposed by this constituency. One noted that unless the financial impact of such a change could be quantified, one would continue to see resistance from the liability insurers.

Strategies

A variety of strategies were suggested to increase the level of comfort among liability insurers with the DA&O model. Some focused on gathering more data to better quantify the financial bottom line of a new model, including potential involvement of actuaries from the liability insurer community. Others focused on sending a clear message of direct early involvement of the liability insurers at the onset of the process, such as ensuring timely access to relevant medical records for the liability assessment. Still others focused on more aggressively educating liability insurers, and their governing boards, on the existing evidence in support of this model and that its benefits far exceed monetary considerations, or even leveraging contracts in support

of D&O models. One interviewee pointed out that as additional data are collected, once one insurer participated, others would likely join as well.

8. Concern that model may not be replicable in certain settings

“I think the set of facilitators and barriers will likely vary significantly across ... different settings [such as] size of the organization and the character and even the culture.”

Respondents were split on this issue, but those who did see “different settings” as a barrier highlighted the following hospital/health care organization characteristics as increasing the degree of difficulty: small size (financial and risk management staff resources), rural location (culture), and health care systems where the physicians are not employed by the hospital/health care organization (lack of control).

Stakeholders were particularly concerned that small hospitals/health care organizations or individual health care providers may face substantial barriers in organizing robust and timely RCA processes, and that the model in general may not work as well in settings where the physicians’ relationship with the hospital or health care enterprise is not as clear. As one hospital representative stated, “We don’t employ our physicians. We have to convince them to come to the table in a disclosure conversation or if we were to go to a financial compensation model.” Since private practitioners often volunteer their time to local hospitals/health care organizations during peer review processes, additional peer review or comprehensive RCA processes could place unrealistic demands on these providers. Practitioners not affiliated with hospitals/health care organizations may require additional support in order to participate in disclosure, carry out a timely RCA, and engage in the DA&O process. Similarly, others raised concerns that DA&O in the ambulatory setting and/or community health centers may require specific resources and approaches tailored to that setting, since operational guidelines for disclosure, timely RCA, and even reporting systems may not be as well-developed as in the in-patient sector.

Strategies

Several respondents proposed ways to provide resources to institutions facing greater implementation challenges, such as creating a centralized resource center, standardized policies, provision of training and education for physicians and clinical leaders, and possibly a statewide risk-pooling or reinsurance scheme, particularly for smaller hospitals/health care organizations. Funding considerations are implicit, since physicians taking on additional quality improvement responsibilities will require compensation, particularly if their current contributions are voluntary. One interviewee suggested a standardized approach to define the scope and expectations of physician responsibilities when things go wrong in both in-patient and ambulatory settings, as well as an oversight mechanism to ensure adherence to these guidelines.

9. Attorneys’ interest in maintaining the status quo

“There is a strong constituency within the legal profession that does believe very strongly in the preservation of the jury trial system for civil dispute resolution and that physicians,

although they have high training simply are among the citizenry that are subjected to that same system.”

Numerous stakeholders believed that there would be resistance to the DA&O model from both plaintiff and defense attorneys. However, opinions on the reasons for this resistance varied. Some felt that this was predominantly a financial issue, under the assumption that attorney compensation would decrease under a new model. A few observers mentioned that the level of resistance within the legal community may not be as vociferous as one would assume, and inadequate to effectively block the model if hospitals/health care organizations and insurers chose to move ahead.

Strategies

The majority of suggested strategies for this barrier focused on education. Specifically, stakeholders suggested educating attorneys that the model endorses legal representation for patients, that it is more cost effective for plaintiff attorneys, and that it likely results in a higher proportion of harmed patients receiving compensation more quickly. At the same time, the model does not abridge any of patients’ existing rights, as they can opt out and pursue litigation if they choose. One respondent suggested that Massachusetts attorneys may benefit from hearing the experience from Michigan attorneys that have participated in the University of Michigan program. Another raised the fact that the information sharing derived from the DA&O process can help plaintiff attorneys assess the merits of a case. Finally, interviewees pointed out that although tort in principle was developed as public protection from unmet health care industry responsibilities, in practice, it creates an impediment to patient safety. While lawsuits can “educate the system” in some cases, more global meaningful changes in patient safety are unfortunately often dwarfed by the secrecy resulting from the threat of litigation (or the litigation process itself).

Education efforts should emphasize that the DA&O model is a much more effective vehicle to improve patient safety, given its focus on transparency, reporting, and loop closure on event investigation. Meeting patients’ needs, individually and collectively, is the central focus – both by helping to “make the patient whole” without the “lottery” of the litigation process and by a stated responsibility to patients to avoid error recurrences as part of the disclosure process. Pointing out that the current litigation model is extremely protracted, with substantial backlog and exorbitant costs, some interviewees thought attorneys might see merit in a model with more efficient resolution and decreased workload.

10. Difficulty of getting supporting legislation passed

“In states where it has been successful the courts are overturning a lot of the legislative changes so it’s really an uphill battle.”

Stakeholders agreed that legislative changes would be helpful to DA&O implementation, but might be difficult to institute. The specific areas for legislative reform included a stronger “apology law” that protects full apology from being evidence of liability and a “pre-litigation review period” that stipulates a defined timeframe between the reporting of an adverse event and initiation of a lawsuit and the sharing of pertinent medical records. Respondents acknowledged

that beyond the logistical complexity of legislative change in even the best of circumstances, each of these proposed approaches would be likely to have an opposing constituency.

Strategies

To enhance the chances of passing enabling legislation, interviewees noted the importance of educating legislators as well as the media about DA&O models, and to involve physician groups in educational efforts. Comments emphasized the importance of identifying key supporters among the legislators as well as other key stakeholders such as state court judges who are dissatisfied with the status quo. One interviewee suggested working through the Cost and Quality Council to bundle DA&O legislation with payment reform. Several respondents emphasized positioning any legislative initiative as a patient safety measure, as opposed to liability reform.

While many interviewees cited legislative reform as a barrier, several of these same individuals also mentioned that much could be done to advance DA&O models without waiting for legislative changes. For example, moving forward with education and voluntary demonstration projects could contribute results that help make the case for pursuing new legislation.

11. Forces of Inertia

“Well, it's change! It's big change. All the traditional impediments to any change would certainly be in force here.”

Approximately half of the respondents acknowledged that the move to DA&O is a significant shift, both operationally and culturally, and thus will have to overcome significant inertia and fear of change. Because the legal, insurance, and medical communities all have some commitment to the current system, acceptance of change may be slow.

Strategies

Stakeholders focused on the need for further analysis of and education about the new model, and then collaboration to create momentum around implementation. Data on the shortcomings of the current system should be provided, as well as additional analysis to support that a DA&O model would work in the Massachusetts environment. Interviewees also suggested creating resources, such as a toolkit of information, to support leaders in explaining the benefits of a new system. They underscored the importance of capitalizing on opinion leaders and patient representatives to emphasize the difference that the model can make for patients. Interviewees also observed that there were multiple stakeholders that could use their influence to collaboratively overcome forces of inertia, including the Massachusetts Hospital Association, the Massachusetts Medical Society, the BORM, the state DPH, Health Insurers, and governing bodies of provider and patient advocacy organizations. One respondent suggesting going as far as creating health insurance contracts that help align incentives for a disclosure/apology/offer approach.

12. Insufficient evidence that the DA&O approach works

“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 of Michigan.”

While no interviewee challenged the findings demonstrated at the University of Michigan, eight individuals expressed concerns that the success of that system could be due to unique elements in

that state and healthcare system, and that the evidence base was insufficient to generalize to Massachusetts. Some individuals pointed out that emerging data at other centers like the University of Illinois might help allay such concerns. Still others acknowledged that ultimately, hospital/health care organization and insurer leaders in Massachusetts may have to “suspend disbelief” and take a risk.

Strategies:

Interviewees suggested that the perceived lack of evidence could be mitigated by further data from institutions that have implemented DA&O models, analysis of the impact, and dissemination of findings. Pilot programs in organizations with different characteristics can help build the evidence base. Findings from systematic review of existing DA&O models can inform an understanding of model elements that are most important for success, as well as elements that are most easily generalized to different settings. Interviewees felt that once success elements are identified, they should be disseminated as broadly and quickly as possible.

ALTERNATIVES AND APPEALING FACTORS

“I think it’ll be a huge win for patients, a huge win. I think they 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. That’s a lot of benefits.”

The majority of interviewees felt that no alternative held greater promise for improving the medical liability and patient safety environments in Massachusetts than the DA&O model. With the exception of health courts (discussed by less than a quarter of interviewees) those that advocated for alternatives primarily discussed complementary strategies like a mandatory pre-litigation review period, expert witness standards for those cases that are not resolved by the DA&O model, and caps on noneconomic damages (Table 4).

Stakeholders noted several appealing aspects of the DA&O model, most frequently citing ethical and professional considerations (Table 5). A hospital representative said, “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.’” Others emphasized that the model is 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.”

DISCUSSION AND RECOMMENDATIONS

This project gathered information about the D&O model from 27 individuals, representing a spectrum of stakeholder groups including the Massachusetts legislature, hospital systems (including academic health centers and community hospitals), practicing physicians, liability insurers, health insurers, medical professional associations, patient advocacy organizations,

malpractice attorneys, patient safety experts, major physician practice groups, and a major business association. Several key findings emerged. First, and perhaps most striking, was the degree to which the stakeholders in aggregate felt that the DA&O model holds great potential for Massachusetts – more than any other alternative. Second, ethical considerations trumped cost-saving implications as most appealing aspects of adopting the model. In fact, the most commonly cited factor supporting the model across constituencies is that it was ethically the “right thing to do.” Third, respondents consistently viewed the DA&O model – above all else -- as a patient safety priority. Emphasizing that the current system has major safety gaps, interviewees noted that full disclosure, apology, and appropriate compensation for events where the standard of care is not met provides a potent methodology to fill such patient safety gaps since there is an intrinsic commitment to transparency and system improvement. Opening communication pathways, re-establishing a shared purpose (and diminished hostility) between patient and provider, and encouraging reporting are key steps to improving patient care. Interviewees routinely underscored the importance of approaching the model (and its publicity) from a patient safety platform (rather than malpractice reform). Fourth, a majority of identified barriers and solutions have more universal implications – potentially applicable to other states considering a DA&O model. Finally, while some of the proposed strategies are likely to require significant time and resources to implement, (such as altering legislation or regulatory standards), the majority are “actionable items” that could be pursued relatively quickly and easily. Below is a set of recommendations to serve as a roadmap for reform, divided into those that can be implemented in the near term, and those that will take longer to achieve:

Immediate Strategies Allowing for Rapid Progress

1. Education and Training

The importance of education was cited by the majority of stakeholders, and it is clear that a well-executed effort to inform key constituencies on the design of DA&O models and its demonstrated benefits is a cornerstone of any roadmap for reform. Targets for an educational program include:

- **The public (including patients and the media):** To emphasize and demonstrate the numerous benefits of the approach, in particular the improvement to patient safety, and the faster and more equitable resolution to adverse events. News articles can highlight the stories of patients who do not want to sue and favor this rational and fair approach. It must be readily apparent to the public that the primary goal of the DA&O model is to benefit patients and improve patient safety.
- **Physicians:** To highlight the patient safety benefits of the model and benefits to physicians, including the creation of a transparent and supportive environment that enables rebuilding trust and healing, and the significant potential to decrease malpractice risk. To increase comfort with challenging disclosure conversations and develop mechanisms that keep physicians “accountable but safe.”
- **Hospital/health care organization leadership:** To increase awareness that the model enhances patient safety, has not been demonstrated to increase liability risk, and provides a mechanism for health care organizations to take responsibility for the actions of their health care system as a whole.
- **Attorneys:** To emphasize that the proposed model strongly endorses legal counsel, allows broader access to equitable compensation for patients, and improves safety in

health care institutions. Underscore that patients maintain the ability to pursue litigation.

- Insurers: To actively engage insurers in early and integrated participation when things go wrong. To model anticipated effects on the “bottom line,” as a way of addressing potential financial concerns.

Recommendation: Create a centralized educational resource center for education and training of the various constituencies outlined above. This resource could be created and maintained in collaboration with existing institutions or organizations committed to patient safety, such as the Betsy Lehman Center or the Massachusetts Coalition for Prevention of Medical Errors. Population-specific resources (for institutional leaders, clinicians, and patients, for example) can promote educational efforts. A statewide resource center can also draw on larger health care enterprise tools to assist smaller hospitals and health care enterprises with implementation of the model.

2. Leadership

Support for DA&O model will be accelerated by identifying key figures in leadership positions, giving them the information and tools needed to advocate for DA&O, and the opportunities to express their support. This includes leaders in patient advocacy, the physician community, the legal profession, insurers, and legislators.

Recommendation: Identify champions among leadership in each stakeholder group and engage them in promoting the model and its benefits by developing a clear communication plan to reach each group, and a set of resources to do so (centralized educational resources). Physician groups can lobby for the model based on the fact that it is the right thing to do for patients. Opinion leaders and patient representatives should emphasize the difference the model can make for patients. Hospital/health care organization leaders can support their staff, and demonstrate reliable accountability and willingness to actively engage with physicians and patients after harmful events. The Massachusetts Hospital Association can advocate for the model by holding up early adopters as good examples for other hospitals/health care organizations. Determining potential supporters (and possible opponents) in the House and Senate leadership as well as the Governor’s office will help get enable legislation passed. Champions from the plaintiff and defense bar can help market the model to their colleagues.

3. DA&O model guidelines

Perceptions that a DA&O system could put patients at a disadvantage, or decrease accountability within the health care system, can be addressed by offering specific implementation guidelines. These guidelines should address operational issues such as ways to encourage patients to have appropriate counsel, timely access to pertinent medical records for all involved parties, proper performance of and mechanisms to share key findings in the root cause analyses, the need for appropriate apology, a fair and standardized method for determining compensation, appropriate involvement of the patient and family, and institutional acceptance of liability when errors stem from a system-based root cause. A separate set of disclosure guidelines should also be developed and implemented as part of the education strategy above.

Recommendation: Develop implementation guidelines that offer practical strategies for addressing operational issues and help to ensure fairness and accountability.

4. Collaborative Working groups

Collaboration among stakeholders, including patients/families, physicians, health care enterprises, insurers, attorneys, and legislators is important to the success of this model. Developing a strong, broad-based coalition to advocate for the implementation of the model state-wide will be a key next step. In addition, conversation within and between stakeholder groups will enable critical activation.

Recommendation: Convene a focused group or groups of individuals who can work collaboratively to identify key issues in the DA&O model that require attention so that it is well-suited for Massachusetts. These can include:

- A broad based coalition with representation of all constituencies that is committed to advancing the model;
- Barrier-specific task forces that can hone in on tangible steps for implementation of key strategies for that given barrier;
- Insurers' forum to work through the insurer-specific issues, such as timely access to medical records, insurer perspectives on the root cause analysis process and liability investigation, and how to handle co-defendants with different insurance carriers;
- Attorney forum to discuss the needs and visions of this constituency within a DA&O framework.

Longer Term Strategies

1. Enabling Legislation

While the consensus opinion is that a D&O model can be advanced even in the absence of a change in legislation, enabling legislation still should be pursued to further encourage acceptance of this model.

Recommendation: Develop a formal strategy to advance legislative changes to address, independently:

- Protection of apology;
- Mandatory pre-litigation review (i.e. "cooling off") period;
- Timely access to pertinent medical records for all involved parties;
- Changes to the National Practitioner Data Bank and state Board of Registration of Medicine reporting requirements;
- Additional tort reforms independent of DA&O, such as: improving expert witness qualifications and improving the ability of the Massachusetts tribunal system to select out unmeritorious cases and minimize "gamesmanship" in the litigation process; establishing health courts; eliminating joint and several liability; permitting periodic payments and consideration of collateral sources. Tighter regulations on the current system could encourage adoption of the DA&O model.

2. Data Collection and Dissemination

Concern remains that the full impact of a DA&O model is incompletely understood, especially as it is imported to settings with different characteristics from those that have published their experiences to date. Collection and dissemination of additional data will be an important step for addressing concerns that disclosure may initiate litigation or increase liability, and for demonstrating the potential cost savings associated with the model.

Recommendation: Identify settings in Massachusetts that are already pursuing DA&O, and formally analyze the impact. Pursue pilot implementation of DA&O programs, targeted specifically in settings that are understudied to date, such as smaller hospitals/practice environments. Although full data collection and dissemination is a longer-term goal, immediate dissemination of available data (from other states as well as any existing pilots in Massachusetts), and identification of new pilot sites should be addressed within the “Immediate Strategy” timeline.

CONCLUSION

The central message from the interviews was clear: support for the DA&O approach was overall very strong among the respondents, and no single alternative model appeared to hold more promise for improving patient safety and promoting fairness and trust. Implementing such a model was consistently perceived as simply the “right thing to do” ethically, with cost savings as an additional benefit. Many of the proposed strategies can be pursued relatively quickly and easily, enabling a fundamental transformation from the current flawed approach to patient safety and medical liability, and putting Massachusetts and other states firmly on the road to creating a fair, efficient, reliable, just and accountable health care system that more effectively supports patient safety.

Table 1: Characteristics of the Disclosure, Apology and Offer Model

Objective	Actions
To increase transparency to patients and to the institution about adverse outcomes and to support physicians in disclosing adverse outcomes to patients.	<ul style="list-style-type: none"> • Disclose to patients and families when adverse outcomes of care occur. • Investigate via root-cause analysis and explain what happened. • Provide an apology where appropriate.
To improve patient safety.	<ul style="list-style-type: none"> • Implement systems to avoid recurrence of incidents, using information from cases of medical injury to learn about opportunities for safety-enhancing interventions and working with hospital staff to implement the interventions.
To avoid lawsuits, reduce liability costs, and improve equitability of compensation by meeting the financial needs of injured patients and their families quickly in the aftermath of an injury.	<ul style="list-style-type: none"> • Offer financial compensation where appropriate without the patient having to file a lawsuit. • Defend cases vigorously when not associated with an error.

Table 2: Interview Respondent Affiliations

Stakeholder Group	Number of Respondents
State agencies and legislature	6
Hospital systems:	4
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

Table 3: Barriers to DA&O Model Implementation

Barrier	# of Respondents
Charitable immunity law	22
Physician discomfort with disclosure and apology	21
Attorneys' interest in maintaining the status quo	20
Coordination across insurers	20
NPDB or state reporting requirements	19
Concern about increased liability risk	16
Forces of inertia	13
Fairness to patients	12
May not work in other settings	11
Insufficient evidence	8
Supporting legislation	8
Accountability for the process	5

Table 4: Alternatives to the DA&O model

Suggested alternatives or adjuncts to DA&O	# of Respondents
No alternative is superior	14
Health courts / other fast adjudication system	6
Caps on damages	3
Mandatory pre-litigation review period	2
Patient compensation fund	1
Alternative Dispute Resolution agreements	1
Expert witness regulations	1
Enterprise liability	1
Mandatory prejudgment interest	1

Table 5: Aspects of the DA&O model that Massachusetts stakeholders found appealing

Theme	# of Respondents
Ethical and professionalism considerations	24
Reduces legal costs/risk	20
Improves safety culture within hospital	15
Improves dispute resolution process	10
Serves patients' needs better	10
Pragmatic considerations (feasible; politically saleable; would make hospital look good)	3

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^{viii} Glaser B, Strauss A. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Aldine Publishing Company, Chicago. 1967.

^{ix} Massachusetts General Laws. Chapter 211. Section 204.

^x Massachusetts General Laws. Chapter 111. Section 51H.