Early disclosure and compensation programs

Introduction

In recent years, early disclosure and compensation (EDC) programs have received increasing attention as an innovative option that health systems might use to address adverse events and the risk management concerns that result from them. Several of the health systems that are implementing such programs have reported positive results. Recent federal funding will facilitate the implementation of new EDC programs and the expansion of ongoing ones in several states. These expanded efforts will help to answer some of the key questions about EDC programs, including: whether they will increase the frequency of liability claims; whether they can succeed in states without traditional liability reforms; whether they can be expanded outside of large integrated health system settings; and whether they will be sustainable when the liability climate worsens in a state.

While the AMA supports traditional reforms, such as the caps on non-economic damages that continue to be effective in California and Texas, the AMA is also supportive of the implementation and testing of innovative reforms to see if they can improve the liability climate for patients and physicians. EDC programs, liability safe harbors for the practice of evidence-based medicine, health courts and administrative compensation programs are a few of the innovative concepts that the AMA would like to see implemented and tested in states on a broader scale. Further, traditional and innovative reforms can complement one another, which may be the optimal route for states to take.

The debate over EDC programs

According to EDC program proponents, disclosing medical errors to patients, besides being the right thing to do, can be an effective risk management tool. The AMA has issued an opinion in its *Principles of Medical Ethics* that addresses communication with patients who experience harm:

> “Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.”

EDC program proponents are optimistic that such programs will lower the number of suits brought against physicians and hospitals, reduce meritless claims, expedite settlements, provide consistency to the compensation paid to injured patients and reduce transactional expenses such as attorney fees. They also hope that open communication with patients will lead to better patient outcomes, and that tying the EDC program to process improvement efforts will help to prevent future adverse outcomes.

There are concerns about EDC programs as well. One of the major concerns is that notifying patients of medical errors will lead to an increase in claims and an increase in subsequent costs. Second, physicians have

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1 AMA E-8.121 Ethical Responsibility to Study and Prevent Error and Harm.
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expressed reservations about establishing an EDC program in a state that does not have traditional liability reforms that could provide a financial backstop if a patient does decide to pursue a claim. Third, there are concerns about establishing an EDC program in a state that does not have an apology inadmissibility statute that could afford the physician protection for portions of the disclosure. Fourth, physicians are concerned about reporting mechanisms such as the National Practitioner Data Bank (NPDB) and state licensing boards, because increased disclosure to patients could lead to more claims against physicians, which in turn could trigger NPDB or state licensing board reporting requirements. Finally, traditional reform advocates have expressed concern that EDC programs will distract from the goal of achieving caps on non-economic damages at the federal and state levels.

These are some of the issues and questions that the EDC programs being established throughout the country can help to answer. This issue brief focuses on the University of Michigan Health System (UMHS) EDC program, implemented in 2001. The UMHS program has become a model for other health systems to replicate. The issue brief also discusses some of the key legislative issues for state medical associations when considering such programs in their state.

University of Michigan Health System EDC program

UMHS procedures

The UMHS program is a comprehensive program that starts before a medical error occurs and focuses on process improvement along with the risk management aspects of an adverse event. According to Boothman, et al, the UMHS program is committed to creating realistic expectations for the patient in the informed consent process and in other communication opportunities with the patient. Creating realistic expectations may prevent some of the surprise or disappointment that the patient and his/her family would otherwise experience when an adverse outcome occurs. The UMHS Department of Risk Management is charged with assisting physicians and other health care providers to identify patient injuries before they become claims. They use an online reporting system to facilitate these efforts. UMHS has been able to foster an institution-wide commitment to this program. This commitment has helped tremendously with its implementation.

As part of the UMHS protocol, after an adverse outcome occurs:

- Patients/families are approached, acknowledged, and engaged in the acute phase;
- Patient care needs are prioritized;
- Patients/families receive answers (to the extent they are known);
- Expectations for follow-up are established, the patient and family understand the situation is being addressed, and the patient and family are doing their parts;
- Patients and families receive acknowledgement of, and an apology for, true mistakes.

They receive a thorough explanation regardless;

The patient’s experience is studied for improvements that later are shared with the patient and family; and

Future clinical care is monitored via metrics established and measured to evaluate efficacy and durability of improvements.

Once the UMHS adverse event protocol is triggered, UMHS follows a claims management model to address the risk management issues related to the adverse event. The UMHS claims management model follows three basic principles:

- Compensate quickly and fairly when unreasonable medical care causes injury;
- Defend medically reasonable care vigorously; and
- Reduce patient injuries (and therefore claims) by learning from patients’ experiences.

The UMHS Department of Risk Management leads the process of distinguishing reasonable care from unreasonable care that has caused a patient injury. UMHS uses experienced nurses to lead the investigation. UMHS also utilizes a secondary committee to review the Department of Risk Management’s finding related to reasonable/unreasonable care. The committee also reviews the findings to determine if peer review, quality efforts or further education are needed in response to the event. If the committee determines that the care was unreasonable and that the unreasonable care contributed to the patient’s adverse outcome, then UMHS will likely try to settle the claim. If the settlement discussions break down or UMHS does not believe that its care necessitates an offer of payment to the patient or the patient’s family, then the patient or his/her family may proceed to the traditional court system for resolution or decide against pursuing a claim.

As stated above, a major concern posed by critics of EDC programs is that disclosure to patients may invite more litigation. Boothman, et al., contend, however, that the traditional legal strategy of “deny and defend” is not cost-effective either.

“(D)eny and defend is an incredibly inefficient and costly (financially, emotionally, and otherwise) response to patient complaints. A recent study showed that overhead costs associated with malpractice litigation are ‘exorbitant’ and demonstrated that ‘for every dollar spent on compensation, 54 cents went to administrative expenses (including those involving lawyers, experts, and courts).’ Of particular interest to this discussion, 37% of the claims examined in the study did not involve errors; claims not involving errors accounted for between 13 and 16% of the system’s total monetary costs, a meaningful percentage.”

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The UMHS claims management model is depicted in the following flow chart

UMHS results

As mentioned above, it is unclear whether EDC models will reduce or increase costs. Cost reductions would come through lower expenses (indemnity and defense) on paid claims. Cost increases, on the other hand, would come through additional expenses on claims that would not otherwise have been brought, but that are a result of the EDC program itself. At this point, it is an open question as to which effect is stronger, and whether the net impact on costs would be a reduction or an increase. The early results from UMHS have been favorable and indicate that EDC programs may be an effective way to lower claim frequency and costs.

In a recent Annals of Internal Medicine article, the authors report on the results from the UMHS program. They compare the UMHS liability claims experience before implementation of the EDC program (1995-2001) to that post-implementation (2001-2007) and note a number of significant changes. About half the claims filed in the first time period resulted in compensation compared to roughly 43 percent in the second. This averages to 53.2 claims paid per year in the first timeframe and 31.7 claims paid after the EDC program was implemented.

UMHS also experienced a decline in the number of filed claims and in the number of claims that resulted in lawsuits. The monthly rate of new claims decreased from 7.03 per 100,000 patient encounters to 4.52 after the implementation of the EDC program. The monthly rate of lawsuits decreased from 2.13 per 100,000 patient encounters to 0.75. The time to claim resolution also shortened from 1.36 years prior to EDC program implementation.


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implementation to .95 years post-EDC program implementation. Finally, the average cost per lawsuit was reduced from $405,921 to $228,308 after EDC program implementation.

EDC simulation results

In contrast to the early results out of the UMHS program, a simulation model of how an EDC program might work suggests the opposite could also be true. Studdert et al. examined the issue in a 2007 Health Affairs paper.\(^5\) Putting together several different data sources, the authors estimated the number of severe medical injuries per year that are both due and not due to negligence, and the shares of the negligent and non-negligent injuries that result in claims. By their estimates, about four percent of non-negligent injuries and 17 percent of negligent injuries lead to claims. They also estimated average compensation costs for the two groups of claims.

Under an EDC program, the above percentages might change. For both the negligent and non-negligent injuries, some parties who would not otherwise have brought a claim may instead decide to do so. At the same time, other parties who would have brought a claim, may choose not to under the EDC program. In order to get a handle on the possible magnitudes of those changes, Studdert et al. presented a panel of experts with the four possible scenarios, and asked them for estimates of how many out of 100 patients would respond in each way.\(^6\) Based on the experts’ estimates, the authors simulated how the total number of filed claims and total compensations costs would change. They estimated that there would be a 95 percent chance that claim volume would increase under an EDC program, and a 94 percent chance that compensation costs would increase.

The work of Studdert et al. is helpful because it shows that EDC programs could lead to an increase in the number of claims and claim costs. It is important to keep this possibility in mind amidst the hopes that EDC programs will offer a better alternative to the current system. However, there are a number of reasons why their estimates may be off, either by a little, or by a great deal. For one, the authors estimate that there is a vast reservoir of unfiled claims, and this is a key factor that drives their results. Similarly, their estimates are directly affected by the responses of their panel who, while they may be experts in the field, may have views different than the average patient. While this paper serves as an important reminder that EDC programs could increase costs, it should not be taken as evidence that they will increase costs.

Examples of other EDC programs

Veterans Administration (VA) Hospital program in Lexington, Kentucky

Most experts point to the EDC program at the Veterans Administration (VA) Hospital Program in Lexington, Kentucky, as the first to gain national attention. Started in 1987, the Lexington VA reviews all deaths and unanticipated outcomes. If the VA discovers a medical error, then the patient or family is contacted, expressions of sympathy are offered and information on filing a claim is presented. This program appears to be sustainable, but there are questions about whether such a program can work outside of the VA system where physicians are not protected by the Federal Tort Claims Act (FTCA). Under the FTCA, the federal government assumes legal responsibility for the disposition of the claim. This removes a significant portion of


\(^6\) The panel of experts included patient safety and legal researchers, hospital-based risk managers and quality assurance directors, senior staff from malpractice liability insurers, plaintiffs’ attorneys, and hospital executives and general counsels. A number of the experts were also practicing physicians and practicing attorneys.
the legal burden that a federally employed physician would otherwise face. It is not clear that physicians without similar protections—the vast majority of practicing physicians—would be willing to participate in EDC programs.

**COPIC Insurance Company 3Rs Program**

The COPIC Insurance Company (COPIC) in Colorado has an EDC program called the 3Rs Program. The 3Rs Program encourages physicians to apologize to injured patients, and it attempts to make the patient whole. The 3Rs stand for:

- Recognize unanticipated events;
- Respond quickly (usually within 72 hours); and
- Resolve the matter promptly.

COPIC’s claim philosophy is to:

- Compensate negligently injured patients;
- Minimize legal costs; and
- Defend physicians whose efforts were appropriate.

COPIC started the 3Rs program in 2000, and it applies to incidents that are estimated to have total costs of less than $30,000.

**University of Illinois College of Medicine at Chicago**

The University of Illinois College of Medicine at Chicago (UIC) established an EDC program in 2006. The UIC program is based on “Seven Pillars.” The pillars are:

- Reporting;
- Investigation;
- Communication and full disclosure;
- Apology and remediation;
- System improvement;
- Data tracking and performance evaluation; and
- Education and training.

The goals of the seven pillars are to reduce harm through transparency and learning and to reduce claims and lawsuits through early, effective, and ongoing communication. Based on its experience thus far, UIC offers

7 Presentation by Timothy B. McDonald, MD, JD at AMA State Legislative Strategy Conference, January 2010.

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some logistical recommendations including waiving patient fees if the care was inappropriate, covering a harmed patient’s immediate out-of-pocket expenses and rapid remediation if warranted. UIC has received a federal grant (discussed below) to see if its program can be implemented in a more broadly-based setting.

**Stanford’s Process for Early Assessment and Resolution of Loss (PEARL)**

Stanford implemented the PEARL program in 2007 by the Stanford University Medical Indemnity & Trust Insurance Co.9 As part of the PEARL program, insurers investigate harmful adverse events reported by physicians, other staff or patients within 90 days of the bad outcome, so long as no legal action has been taken. Investigators try to assess within a week, through consultations with internal physician experts, whether the event could have been prevented. If investigators determine that the adverse event was avoidable, the family is contacted with the results, offered an apology and compensation is discussed. Since establishing the program, annual claim frequency has dropped from 23 to 15 compared with the two years before the program started, resulting in a 38 percent reduction in the overall cost of claims, and a savings of $3.2 million in annual premiums.10

**Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI)**

MACRMI is a Massachusetts alliance of patient advocacy groups, teaching hospitals and their insurers, and statewide provider organizations—including the Massachusetts Medical Society—committed to transparent communication, sincere apologies and fair compensation in cases of avoidable medical harm.11 MACRMI’s term for this approach is Communication, Apology, and Resolution, or CARe.

Components of CARe:

- Communicate with patients and families when unanticipated adverse outcomes occur.
- Investigate and explain what happened.
- Implement systems to avoid recurrences of incidents and improve patient safety.
- Where appropriate, apologize and offer fair financial compensation without the patient having to file a lawsuit.

Objectives of CARe:

- Improve communication and transparency about adverse outcomes.
- Support patients and families to help achieve a fair, timely and healing resolution to medical harm.

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8 McDonald TB. Alternative Approaches in Responding to Medical Errors. Trial. 2013.

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Support clinicians in disclosing unexpected outcomes to patients.

Improve patient safety by learning from errors and near misses and preventing future harm.

Provide an alternative to lawsuits and their unnecessary costs by meeting the financial needs of injured patients and their families quickly in the aftermath of an injury, without resorting to litigation.

CARe is about timely communication of important information and supporting families through an adverse outcome. The hospital or healthcare worker will meet with the injured patient and/or family member(s) and explain what happened and why; apologize; and discuss what will be done to prevent it from happening again.

The communication process begins immediately following an adverse event, with staff conveying what is known at the time about what happened, how it will affect the patient’s care, and how the hospital will support the patient and family. It continues after an investigation by the hospital or healthcare facility into the injury, when a determination is made by the patient safety team regarding whether or not it was caused by medical management.

In the Resolution stage of the CARe process, hospital representatives explain their findings about what led to the adverse outcome, and whether a medical mistake was involved. If the hospital or health care provider did make a mistake which resulted in the injury, the patient and/or family will meet with representatives of the hospital and its insurance company and family may be offered financial compensation if appropriate. The patient is encouraged to bring an attorney to any meetings, particularly those in which there is a discussion of financial compensation, but an attorney is not required.

If the care leading up to the injury was found to have been reasonable, the patient and/or family are given a thorough explanation and a chance to ask questions to help them understand what occurred. The health care facility also explains that it will stand behind the providers and defend the care in any legal proceedings that the patient or family chooses to bring. It also explains that all cases are rigorously studied as part of a comprehensive patient safety improvement effort.

Massachusetts’ early disclosure program is in its early stages, as enabling legislation was adopted in 2012. The 2012 Payment Reform legislation included a comprehensive adoption of the so-called Michigan model of “disclosure, apology and offer” to resolve patients’ claims of medical malpractice. This includes the establishment of a 182-day “cooling off” period to permit the disclosure, apology and offer process. The legislation also provided strong apology protections, sharing of pertinent medical records, and expectations of full disclosure.

**States and health systems receive grants to test EDC programs**

The Agency for Health Care Research and Quality (AHRQ) funded several grant requests in 2010 that will investigate, implement and evaluate EDC programs. The following is a list of the grant recipients and AHRQ’s description of the projects:

**Timothy McDonald, M.D., J.D., University of Illinois at Chicago, IL – $2,998,083**

The project is designed to fill the evidence gap regarding the impact on patient safety and litigation rates of programs that feature improved communication with patients, transparency, disclosure of adverse events, early offers of compensation, and learning from mistakes. It will evaluate the impact on medical liability reform and patient safety outcomes of extending an existing EDC program from an academic hospital setting to diverse hospitals in the greater Chicago area.
Eric Thomas, M.D., M.P.H., University of Texas Health Science Center, Houston, TX - $1,796,575

The project will review the use of an EDC model, which informs injured patients and families promptly and makes efforts to provide prompt compensation. It will identify best practices for using disclosure to improve patient safety, and disseminate best practices to serve patients' needs and improve safety for subsequent patients. The project will investigate disclosure and compensation in the UT system over a three-year period, identify best practices for using disclosure to improve patient safety, and disseminate best practices with a focus on incorporating patient and family input into efforts to understand why errors occur.

Thomas Gallagher, M.D., University of Washington, Seattle, WA - $2,972,209

The project creates a statewide initiative involving communication training for health care workers and a collaboration between hospitals and a malpractice insurer to improve adverse event analysis, disclosure, and compensation. The goal is to enhance the culture of health care communication in order to improve patient safety and decrease medical malpractice liability.

Judy Kluger, J.D., New York State Unified Court System, New York, NY - $2,999,787

This project aims to protect obstetrical and/or surgery patients from injuries caused by providers' mistakes and reduce the cost of medical malpractice through the use of an expanded and enhanced Judge-Directed Negotiation Program currently used in New York's courts, coupled with a new hospital early disclosure and settlement model. To date, more than 200 cases have gone through the judge-directed negotiation program, and the project has already been expanded the Erie County, New York, jurisdiction, which includes the Buffalo area. Key stakeholders are also involved in the program through a consortium of five major teaching hospitals in New York City, the New York State Department of Health, and New York City medical liability insurers.

Early observations note that judge-led conferences have not encountered any major obstacles, and, notably, far more judges signed up for training than initially expected. Attorneys have been receptive to a more hands-on approach to discovery and are very open to early settlement negotiations. Defense attorneys have demonstrated improved communication with hospitals and carriers regarding early case conferences.

Dianne Garcia, J.D., Multicare Health System, Tacoma, WA - $299,985

The project will develop a plan for implementing an integrated medical liability and patient safety program based on identifying avoidable patient safety problems, and providing an acknowledgement, apology, and standardized compensation to patients who have been harmed or their families.

Elizabeth Guenther, M.D., M.P.H., University of Utah, Salt Lake City, UT - $300,000

This project will implement and evaluate a system-wide evidence-based, ethical, and legally sound policy on disclosing safety issues and other unanticipated outcomes of care. The goal is to develop a standardized protocol that will be used for disclosure of these events to patients and their families.

Kenneth Sands, M.D., M.P.H., Beth Israel Deaconess Medical Center, Boston, MA - $300,000

The main goal of the project is to develop a roadmap for implementation of a "disclosure-and-offer" patient safety initiative in Massachusetts, which may be applicable to other states. The ultimate goal is to create a new medical liability system that improves patient and provider trust, reduces fear, and improves patient safety.

Key questions and considerations

As discussed above, there are some key issues and concerns that entities considering implementing an EDC program should analyze before establishing such a program.

Entity size and resources

UMHS was aided in creating its program by the fact that it is a large integrated system that is self-insured. As a result, many of the key decision-makers shared common ethical and risk management goals in creating the program. For other large institutions, the key question is whether they can generate an institution-wide commitment to creating a successful EDC program. For smaller physician practices, the key question is whether they can create a successful EDC program without all of the resources that a large integrated system is able to dedicate to a program including, a risk management department, an online incident reporting database, trained communicators, etc.

Current liability protections

Also helping UMHS with the establishment of its EDC program is the existence of several traditional liability reforms enacted by the state legislature. First, Michigan’s cap on noneconomic damages provides a financial backstop for unsettled claims that migrate to the civil courts.13 Second, Michigan has a mandatory six-month pre-suit notice period. This gives UMHS officials a chance to review the incident and have discussions with the patient before a lawsuit is filed.14 Notably, one misconception about Michigan’s liability statutes is that the state has an apology inadmissibility statute. This is actually not the case, and it calls into question whether an apology inadmissibility statute is necessary for the successful operation of an EDC program.

Another question for interested entities to consider is whether their state’s peer review statute will offer protections for any of the materials prepared during the disclosure process. Interested entities should also review the confidentiality of settlement discussions in their respective state, because this may shield some discussions with the patient from having them introduced in court if the claim proceeds to litigation. Finally, entities considering an EDC program may want to consider blanket confidentiality for disclosure discussions. Such a law would appear to go against the intent of the UMHS EDC program which emphasizes transparency and disclosure, but depending on a state’s liability climate, this may be a necessary step to ensure the success of the program.

Liability insurer and reporting concerns

If physicians plan to participate in an EDC program, they have to be sure that their liability insurer, or possibly their employer, does not place restrictions on such participation. If there are restrictions, then they

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13 MCLS § 600.1483 (2010)
14 MCLS § 600.2912b (2010)
should be eliminated. Maintaining communication with the patient and continuity of care should trump insurer concerns on this point. Another major issue for physicians to consider is that UMHS is able to accept liability for its employed physicians. Therefore, concerns by physicians about NPDB and state licensing board reporting requirements are mitigated. There may be a need, however, to amend the NPDB requirements and/or state laws in order to create an exception for EDC programs for physicians who are not employed by a health system. Some of the AHRQ EDC program grantees are investigating this issue as well, so there may be some innovative ideas on the horizon.

Conclusion

The current liability system continues to hinder the physician-patient relationship. Fixing the system is a top priority for the AMA. While traditional reforms continue to have a positive impact in many states, it is important to seek innovative reforms that could complement traditional reforms, or perhaps stand on their own. This could help states with caps improve their liability systems further, and it could help to improve the liability climate in states unable to implement traditional reforms for either political or judicial reasons. EDC programs are among the most promising of the innovative reforms being discussed and established, and the AMA will continue to monitor their progress as the programs move forward.