

Early Discussion and Resolution: Accelerating Adoption of a Culture of Safety in Oregon

July 2014 – June 2019

Submitted pursuant to Oregon Laws 2013, Chapter 5, Sections 17(2) and 18 to House and Senate Interim Committees on Judiciary and Health Care



Questions?

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The Oregon Patient Safety Commission, 2019

The Oregon Patient Safety Commission is a semi-independent state agency that operates multiple programs aimed at reducing the risk of serious adverse events occurring in Oregon's healthcare system and encouraging a culture of patient safety. The Patient Safety Commission's programs include Early Discussion and Resolution and the Patient Safety Reporting Program. To learn more about the Patient Safety Commission, visit oregonpatientsafety.org.

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A Message from the Task Force

The Task Force on Resolution of Adverse Healthcare Incidents (“Task Force”) serves as an evaluative body for Oregon’s Early Discussion and Resolution (EDR) program. The governor-appointed Task Force members include a patient safety advocate, a hospital industry representative, physicians, trial lawyers, and public members. EDR is administered by the Oregon Patient Safety Commission (OPSC).

On behalf of the Task Force, we are pleased to present a report evaluating the implementation and effects of Oregon’s pioneering EDR program from July 1, 2014 to June 30, 2019: *Early Discussion and Resolution: Accelerating Adoption of a Culture of Safety in Oregon*. The report satisfies our reporting, evaluation, and recommendation requirements (Oregon Laws 2013, Chapter 5, Sections 17(2) and 18).ⁱ

Our evaluation includes five years of data from EDR implementation and supporting evidence from patient safety literature. It was also informed by input from the many stakeholders affected by EDR, including community members, healthcare providers, hospitals and other facilities covered by EDR, as well as liability insurers and the legal and mediation communities.

Through our evaluation, we are convinced of the value of EDR for Oregonians to help encourage a compassionate approach for responding to patient harm. This approach promotes transparency and learning, cultivating a culture of safety. And while culture change is slow business, the continued availability of EDR may help to accelerate the culture change necessary to improve the safety of our healthcare system. Removing the sunset provision on EDRⁱⁱ would create the opportunity for progress and innovation in Oregon’s healthcare system and reinforce our state’s commitment to continue to care for patients who have been harmed by medical care.

We are pleased to provide you with our evaluation of the EDR program for your consideration.

Respectfully,



Robert Dannenhoffer, MD
Task Force Co-Chair



Richard Lane, JD
Task Force Co-Chair

Task Force Members and Respective Seats: Robert Beatty-Walters, trial lawyer; Robert Dannenhoffer, physician; Michelle Graham, hospital industry; Anthony Jackson, member at large; Richard Lane, trial lawyer; Saleen Manternach, physician; John Moorhead, physician; Tina Stupasky, trial lawyer; Rep. Ronald H. Noble, House Republican; Rep. Rachel Prusak, House Democrat.

ⁱ Oregon Laws 2013, Chapter 5, Section 18 requires the Task Force to provide an evaluative report to the Legislature on or before October 1, 2018 on whether any improvements to the process are necessary. Although the law took effect on its passage in March of 2013, EDR did not become operative until July 1, 2014 (Oregon Laws 2013, Chapter 5, Section 21(1)). This allowed time for program development and implementation prior to the operative date. To ensure its evaluation covered five years of program implementation, last year the Task Force made a request to the Legislature to submit its evaluation in 2019. This additional year was also used to seek input from stakeholders to inform the evaluation.

ⁱⁱ Oregon Laws 2013, Chapter 5, Section 20 establishes a sunset date of December 31, 2023.

Executive Summary

Despite the best training and intentions of healthcare providers, things can and do go wrong during healthcare. Sometimes these events result in no harm to a patient, while other times they may result in additional or prolonged treatment, disability, or death. A lack of transparency with patients and families about what happened exacerbates the issue and increases the likelihood that patients will take legal action.¹⁻⁴ The silence around patient harm events perpetuates patient and family suffering and may provoke feelings of abandonment and mistrust.⁵ An absence of open conversation also heightens providers' feelings of fear, guilt, anxiety, and grief, as they are left without any way to alleviate their personal and professional distress,⁶ and it impedes our ability to learn from and address safety issues related to these events for future patients.⁷

An open conversation about patient harm events can help everyone move forward, and it promotes learning to help healthcare organizations improve their systems of care, reducing the very events that drive medical malpractice. In 2013, the Oregon Legislature passed an innovative program into law to help address medical liability in the state by promoting open conversation between patients (or their representatives), healthcare providers, and facilitiesⁱⁱⁱ when care resulted in serious harm or death—what is now called Early Discussion and Resolution (EDR).^{iv} EDR establishes confidentiality protections^v for these important conversations to encourage information sharing.

However, implementing a more transparent approach can be challenging. The current framework for responding to patient harm is a series of interdependent structures that function to assign individual blame rather than fix the underlying systems that allow patient harm to occur. We must embrace a new framework that prioritizes transparency, learning, and improvement. This change will require organizations to reevaluate and repurpose existing structures to align with new priorities.

As the Task Force on the Resolution of Adverse Healthcare Incidents (“Task Force”), we evaluate the implementation and effects of EDR on an ongoing basis to determine if any changes to the process are necessary. This evaluation covers five years of EDR in Oregon (July 2014 – June 2019). We analyzed data from EDR use and conducted a literature review to understand the evidence base supporting EDR's transparent approach for responding to patient harm. Additionally, and perhaps most importantly, we heard directly from the stakeholders eligible for EDR in Oregon.

Acknowledging the essential role of culture change in moving toward transparency in healthcare, we have framed our evaluation around the following concepts:

- I. A culture of safety is essential to make progress in patient safety.** Without a culture of safety, well-intentioned patient safety improvement efforts are less effective and unsustainable.

ⁱⁱⁱ See Appendix I for a definition of *patient representative*, *healthcare provider*, *healthcare facility*, and other terms used in this report.

^{iv} See Appendix I for a definition of *Early Discussion and Resolution* and other terms used in this report.

^v The use of EDR creates confidentiality protections that apply to written and oral discussion communications. EDR communications may not be disclosed and are not admissible as evidence in any subsequent adjudicatory proceeding. EDR protections do not change other protections that are afforded by state and/or federal law. For example, Health Insurance Portability and Accountability Act (HIPAA) protections for a patient's medical records and other personal health information remain unchanged with the use of EDR. See Appendix I for a definition of *protections* and other terms used in this report.

II. **Culture change takes time.** Acknowledging this fact, we looked at where the culture of healthcare is today by evaluating our current system for responding to patient harm through the legal system. We identified three interconnected categories that shed light on some of the work we have ahead of us to begin to shift the culture in healthcare and move toward a safer healthcare system:

- Healthcare provider and facility response to medical harm can compound **patient and family** suffering.
- The impact of medical harm events on **healthcare providers** has potentially life—or career—changing consequences.
- **Infrastructure** drives how healthcare providers and facilities respond to medical harm events.

III. **EDR can accelerate progress toward a culture of safety.** Here in Oregon, EDR is a catalyst for change. Through EDR, healthcare providers, facilities, and all Oregonians alike now have a transparent path for responding to patient harm from medical care—a path that allows healthcare providers and facilities to continue to care for patients and to learn and improve their systems of care to prevent future harm.

With open communication following patient harm as EDR’s primary goal, Oregon can learn from leading healthcare organizations across the country that have implemented comprehensive programs with open communication as a core element. Through these programs, called communication and resolution programs (CRPs),^{vi} organizations have seen a decrease in legal defense costs, total liability costs, and time to resolution, as well as a decrease in rate of claims or lawsuits.^{8–13}

Through our evaluation of five years of EDR use in Oregon, we can see that EDR is a lever for culture change. By encouraging an alternative, more transparent approach for responding to patient harm, EDR advances progress toward two important objectives:

- Minimizing the need to escalate patient harm events to the legal system by addressing the needs of healthcare providers, facilities, and patients and families to exchange information and discuss possible resolution of specific harm events.
- Cultivating the culture of safety necessary to make our care delivery system safer and ultimately prevent harm events.

To make Oregon’s healthcare system safer, we must develop and support programs that promote a culture of safety within healthcare organizations, like EDR. Furthering transparency about medical harm, as EDR does, will drive system changes to reduce harm events. Only by reducing harm to patients can we make real progress on the issue of medical liability costs. For long-term culture change to be sustained, EDR should be ongoing.

We strongly recommend that the Legislature remove the sunset provision on EDR^{vii} to ensure its continued availability to drive culture change in the state for the benefit of all Oregonians. The very existence of a sunset provision makes some wary to use the process, uncertain if the confidentiality protections of EDR will remain in place and if incorporating EDR into their process will be worthwhile.

^{vi} See Appendix I for a definition of *communication and resolution program* and other terms used in this report.

^{vii} A sunset date of December 31, 2023 was established for Sections 1 to 10 and 17 to 19 of the 2013 Act.

Oregon's Voluntary Process for Open Conversation after Medical Harm

Early Discussion and Resolution (EDR)

In 2013, the Oregon Legislature created EDR to make progress on medical liability in the state by providing an alternative to the legal system for patient harm from medical care. EDR promotes open conversation between patients (or their representatives), healthcare providers, and facilities when serious patient harm or death results from medical care.

After medical harm, patients and healthcare providers want the same things.

Patients and their representatives want...



To know their doctor cares about them.

A support person with them so that they don't feel alone during a conversation.

To know what happened and why, and that it won't happen to anyone else.

To continue to receive the care and support they need without litigation.



Empathy



Support



Information sharing



Reconciliation

Healthcare providers want...



To know their organization and insurer support them to have an open conversation.

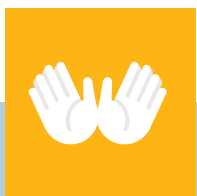
To show their concern and offer an apology.

To be open and honest about what happened.

To maintain their relationship with the patient and avoid litigation.

Open conversations benefit patients, providers, and the healthcare system.

Organizations can use EDR to enhance their process for responding to medical harm to...



Demonstrate a commitment to transparency



Encourage learning from events to improve system of care



Cultivate a culture of safety necessary to make lasting change



Help reduce medical harm events that can lead to litigation

How EDR Works

Patient harm or death from medical care

Requests a conversation

Either the patient or healthcare provider or facility through the Oregon Patient Safety Commission (OPSC)*



Patient or their representative



Healthcare provider or facility



OPSC informs involved provider(s) and/or facility of a patient's request and connects them if they agree to the conversation.



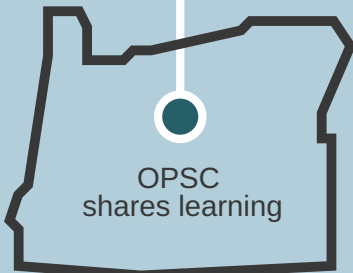
Accept or decline Request for Conversation



Have open, confidential conversation(s)



Report to OPSC about how it went



OPSC shares learning

Five Years of EDR Use in Oregon

July 2014-June 2019

195

Requests for Conversation submitted

89%

of Requests for Conversation were made by patients (or their representatives).



Most common event types mentioned in Requests for Conversation

37% Surgical or other invasive procedure

35% Care delay

11% Other

8% Medication event

7% Healthcare-associated infections



Most common locations where those events occurred

67% Hospitals

23% Medical Clinics

6% Ambulatory Surgical Centers

2% Nursing Facilities

55%

of patient Requests for Conversation were accepted by at least one involved healthcare provider or facility



Main reasons patient Requests for Conversation were not accepted by an involved healthcare provider or facility

- Intended to use or used another process instead
- Did not believe the event was a serious medical harm event
- Advised against participation by liability insurer or legal counsel
- Believed the patient's concerns involved only the other party (provider or facility).



* The Oregon Patient Safety Commission (OPSC) administers Oregon's EDR process.

Introduction

In our complex and constantly evolving healthcare system, adverse events can—and do—occur. Sometimes these events result in no harm to a patient, while other times they may result in additional or prolonged treatment, disability, or death. While there are varying opinions about just how many patients are harmed or die as a result of medical care each year, we know it is far too many.^{14–20} Further exacerbating the issue and impeding our ability to address underlying safety issues is a lack of communication with patients and families about what happened. This perpetuates our current legal framework for responding to medical harm described by Phillips-Bute —"Fear of litigation creates a culture of secrecy and mistrust, and lack of disclosure creates frustrated and angry patients who are more likely to engage in litigation."^{21(p336)}

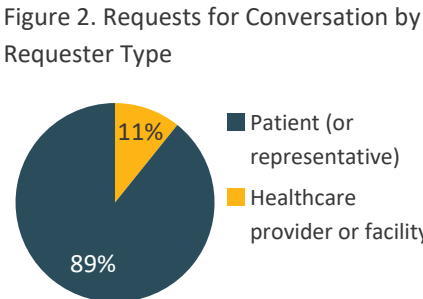
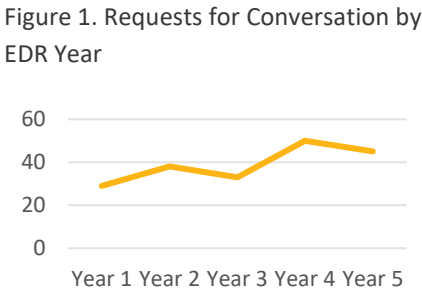
To make progress, we must first take steps to create a culture of safety by improving how we respond to and learn from medical harm, both within individual healthcare organizations and as a state.

- **Within individual healthcare organizations:** When organizations have systems in place to respond to medical harm that incorporate elements of a culture of safety—such as transparency with patients and families, addressing organizational system issues rather than punishing individuals, and a commitment to learn from events for continuous improvement—they are also building the skills necessary to address the wide range of safety issues that will inevitably arise.
- **At the state level:** Many of the challenges to improving patient safety cannot be resolved in isolation by individual organizations; a coordinated and collaborative approach is necessary. To make progress as a state, a central coordinating agency can connect the dots between individual organizations²² and share information and best practices. This enables broader process and system improvements to be put into place statewide.

In 2013, Oregon legislators created an innovative program at the state level to help accelerate the culture change necessary for improved safety across the healthcare system—Early Discussion and Resolution (EDR)—^{viii}and directed the Oregon Patient Safety Commission (OPSC)^{ix} to serve as the central coordinating organization to administer the program, collect information about implementation, and share learning for the benefit of Oregon’s healthcare system.

EDR Use in Oregon, July 2014 – June 2019

195
Requests for Conversation
Submitted



^{viii} Oregon Laws 2013, Chapter 5. www.oregonlegislature.gov/bills_laws/lawsstatutes/2013orLaw0005.pdf. See Appendix III for more detail on the EDR Process.

^{ix} See Appendix IV for more information on OPSC’s role.

Oregon's Pioneering Process to Address Medical Liability through Culture Change

In 2013, Oregon Legislators sought to address medical liability in the state by creating EDR, an alternative approach that encourages transparency with patients and families following patient harm. This was one of the first laws in the country to promote open communication between patients (or their representatives), healthcare providers, and facilities when serious harm or death occurred as a result of care, and it remains the only law that allows patients to initiate the conversation. Conversations through EDR have confidentiality protections^x establishing a safe space for healthcare providers and facilities to talk openly with patients about what happened as they explore the best way to move toward resolution. Transparency about medical harm also creates an environment in which learning for improved patient safety is possible, positioning EDR to be a lever for culture change in Oregon.

Two other states, Colorado^{xi} and Iowa,^{xii} have followed Oregon's lead, passing laws to help drive culture change through open communication following patient harm. Many hospitals and health systems across the U.S. are also implementing processes that support this approach, in advance of legislation in their own states.

Oregon has also become an important contributor to the national dialogue about how to advance patient safety by promoting greater transparency and accountability following unintended patient harm through OPSC's work with the Collaborative for Accountability and Improvement (CAI). CAI is a network of some of the foremost thought leaders and organizations committed to supporting the widespread adoption of communication and resolution programs (CRPs)^{xiii} across the U.S. and internationally.²³ A CRP's primary goal is to prevent patient harm and includes open communication with patients and families as a core element. There is a natural alignment between CRPs and EDR in Oregon.

The Value of the Conversation

EDR promotes open conversation between patients (or their representatives), healthcare providers, and facilities^{xiv} following patient harm. Open conversation can:

- **Prevent an unfortunate situation from escalating.** When a patient (or their representative) does not receive an appropriate response after medical harm, they may file a complaint or lawsuit.^{24–26} Legal processes can be time-consuming, expensive, and painful for everyone involved.^{21,27} Having a conversation and considering fair compensation, when appropriate, may avoid litigation and achieve a more positive result for all parties.

^x See Appendix I for a definition of *protections* and other terms used in this report.

^{xi} Colorado Candor Act: Article 51, Communication and Resolution After an Adverse Health Care Incident (2019). http://leg.colorado.gov/sites/default/files/2019a_201_signed.pdf.

^{xii} Iowa Code §135P (2017): Adverse Health Care Incidents — Communications. <https://www.legis.iowa.gov/docs/code/2017/135P.pdf>.

^{xiii} See Appendix I for a definition of *communication and resolution program* and other terms used in this report.

^{xiv} See Appendix I for a definition of *patient representative, healthcare provider, healthcare facility*, and other terms used in this report.

- **Maintain the patient-provider relationship.** The relationship between the patient and the healthcare provider is the keystone of care,^{28,29} and both can feel great unease when it is compromised. An open conversation about what happened and direct steps toward reconciliation can restore trust and heal a strained or fractured relationship.²⁴
- **Bring greater peace of mind to everyone involved.** Healthcare providers can experience fear, guilt, anxiety, and grief if they have been involved in the serious injury or death of a patient,^{1,6,25} even if they are not at fault.³⁰ Patients may be in pain, shock, and grief.^{24,25,31} They want information about what happened, why it happened, what impact it may have on their health, and what is being done to improve care for future patients.^{5,24,25} An open conversation and an acknowledgment of the patient’s experience can help the patient heal. It can also be beneficial for the healthcare provider by alleviating feelings of personal and professional distress.⁶
- **Help address medical malpractice and associated costs.** Some organizations have implemented programs with open communication as a core element, called CRPs. These organizations proactively tell patients and families what happened, offer them compensation when appropriate, and take action to prevent similar events. By implementing this comprehensive approach, these organizations have experienced various improvements in litigation rates and associated costs, including decreased legal defense costs, total liability costs, rate of claims or lawsuits, and/or time to resolution.⁸⁻¹³ Another study showed that organizations saw no negative financial impact after implementing a CRP approach.³²
- **Encourage learning from events to improve patient safety.** Acknowledging patient harm events and talking openly with patients and families about what happened is the first step toward learning and making safety improvements.^{7,21} Patients and families may also offer new information that can inform an organization’s event analysis and be integrated into an improvement plan to prevent recurrence.^{33,34}

Characteristics of Oregon Patients in EDR Requests for Conversation, July 2014 – June 2019

Figure 3. Patient Gender

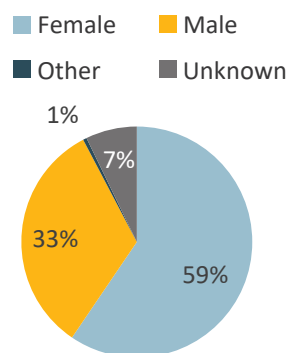
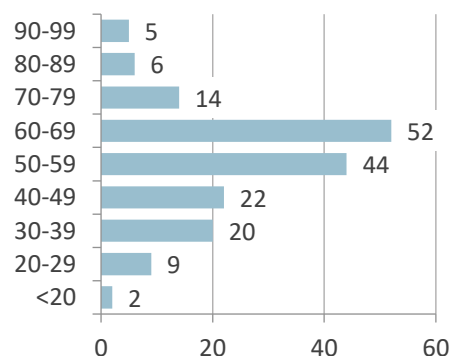


Figure 4. Patient Age Groups



Implementation and Effects of EDR

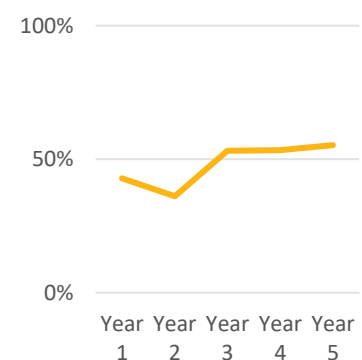
In July 2014, EDR began accepting Requests for Conversation to help address the core issue that drives medical malpractice—patient harm from medical care. EDR promotes talking openly with patients and families when serious patient harm or death results from medical care. In addition to providing an alternate path for addressing patient harm events, this transparent approach allows healthcare organizations to learn and improve their systems of care, reducing the events that drive medical malpractice. Further, it provides a process for patients and families to receive a full explanation about what happened, the lack of which may be a motivator to pursue litigation.¹⁻⁴

However, for healthcare organizations to successfully implement a more transparent approach to patient harm, they must first cultivate a culture of safety. With this in mind, we have used a vision for culture change as our lens to evaluate five years of EDR implementation in Oregon (July 2014 – June 2019), and we have framed our evaluation around the following concepts:

- I. A culture of safety is essential to make progress in patient safety.
- II. Culture change takes time.
- III. EDR can accelerate progress toward a culture of safety.

Our main take away is that **EDR is a lever for culture change in Oregon**. EDR is helping to improve the safety of our healthcare system, which can in turn reduce medical harm events that may lead to litigation. Recognizing that culture change takes time, removing the sunset provision on EDR would ensure that it remains available to drive culture change in the state, benefiting all Oregonians. The very existence of a sunset provision makes some wary to use the process, uncertain if the confidentiality protections of EDR^{xv} will remain in place, and whether incorporating EDR into their process will be a worthwhile investment.

Figure 5. Percent of Patient Requests with at Least One Acceptance, by EDR Year, July 2014 – June 2019



^{xv} The use of EDR creates confidentiality protections that apply to written and oral discussion communications. EDR communications may not be disclosed and are not admissible as evidence in any subsequent adjudicatory proceeding. EDR protections do not change other protections that are afforded by state and/or federal law. For example, Health Insurance Portability and Accountability Act (HIPPA) protections for a patient’s medical records and other personal health information remain unchanged with the use of EDR. See Appendix I for a definition of *protections* and other terms used in this report.

Evaluating EDR's Effectiveness in Oregon

This evaluation looks beyond data from EDR and includes:

- **EDR implementation data:** Data collected by OPSC from July 1, 2014 to June 30, 2019.
- **Stakeholder input:** A qualitative analysis (see Appendix II) of input from the many stakeholders affected by EDR, including healthcare consumers, healthcare providers, and facilities, as well as liability insurers and the legal (trial and defense lawyers) and mediation communities. We gathered input from stakeholders across Oregon, in three ways:
 1. **Survey:** 320 respondents provided us with high-level insight into stakeholder views.
 2. **Group interviews:** Nine interviews held in geographically diverse locations across the state (i.e., South Coast, Columbia Gorge, Central Oregon, and Portland Metro Area) gave us a deeper understanding of stakeholder views.
 3. **Key informant interviews:** These 10 interviews were a unique opportunity to hear directly from individual stakeholders and better understand their perspectives.
- **Literature review:** An evaluation of patient safety research to understand the foundational evidence base for transparency following patient harm.

OPSC, as the administrative entity for EDR,^{xvi} is committed to continuous learning and improvement about the EDR process for Oregonians. As the first program of its kind, OPSC monitors all aspects of EDR implementation and reports to the Task Force and the OPSC Board of Directors. Sometimes OPSC identifies needed improvements, such as online system enhancements, and addresses them operationally, within the scope of their role as program administrator.

“This is an important law that helps patients, providers, and helps develop a culture of safety and learning.

—Survey Respondent

“Humans make mistakes and families can understand that if they are treated with courtesy, honesty and compassion...in the long run it is much better to discuss the negative aspect of the care to the fullest extent with those responsible for the patient and the patient.”

—Survey Respondent

“Provider-Patient-Family conversations are so important at all stages of care, and whether or not a mistake or adverse event has taken place. They can be an appropriately humbling experience for clinicians. And in my experience, so long as intentions were good, and mistakes weren't glossed over, patients and families almost universally appreciate honesty and candor in these circumstances... it's just the right way to treat my patients and their families.”

—Survey Respondent

^{xvi} See Appendix IV for more information on OPSC's role.

I. A Culture of Safety Is Essential to Make Progress in Patient Safety

In its report *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years After To Err is Human*³⁵, the National Patient Safety Foundation identified leadership support for a culture of safety as the most important of their recommendations for achieving patient safety. Without a culture of safety, well-intentioned patient safety improvement efforts are ineffective and unsustainable.

A recent study published in the *Journal of Patient Safety* found that a facility's organizational culture impacts the efficacy of Just Culture training—a specific methodology intended to end the “shame and blame” response to adverse events.³⁶ The relationship between a culture of safety and effective patient safety programs was also noted by Armstrong et al., who found that the use of a quality measurement tool expressly designed to avoid blame in an organization lacking a culture of safety was, in practice, experienced as a “blame allocation device.”^{37(p163)} Without a culture of safety, the tool undermined patient safety work, despite its intent and careful design.

Our current infrastructure for responding to medical harm through the legal system focuses on individuals, and more specifically on assigning blame. Dr. Lucian Leape, a professor at Harvard School of Public Health and patient safety expert, has argued that we need to dispel two myths that perpetuate blame:

1. **The perfection myth:** “If people try hard enough, they will not make any error.”^{38(p140)}
2. **The punishment myth:** “If we punish those who do make errors, they will make fewer of them.”^{38(p140)}

In his 1997 testimony to the U.S. Congress, Leape stated that, “[T]he single greatest impediment to error prevention is that we punish people for making errors.”³⁹ Improving the safety of our healthcare system requires a shift in focus from punishing individuals to fixing systems by addressing the core reasons why mistakes occur. This systems approach is essential to building a culture of safety.

“...we need to better understand the aspects of the culture of medicine that contribute to the feeling of fear for reputation and shame, otherwise we will be unable to make advances in the field as individuals, institutions, and as a profession.”

—Helo & Moulton 2017^{1(p779)}

“Thank you for EDR! As a medical provider who sometimes makes errors (we all do) I am relieved that EDR is available to me and to my patients. Thanks so much!”

—Survey Respondent

Culture of Safety: How We Do Things Here is in Pursuit of Safety

Culture of safety is an organization's shared perceptions, beliefs, values, and attitudes that combine to create a commitment to safety and an effort to minimize harm.⁴⁰ The Joint Commission identifies the following key features of a culture of safety:

- “Staff and leaders that value transparency, accountability, and mutual respect.
- “Safety is everyone's first priority.
- “Behaviors that undermine a culture of safety are not acceptable, and thus should be reported to organizational leadership by staff, patients, and families for the purpose of fostering risk reduction.
- “Collective mindfulness is present, wherein staff realize that systems always have the potential to fail and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed.
- “Staff who do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events.
- “By reporting and learning from patient safety events, staff create a learning organization.”^{41(p6)}

“I believe the most effective and efficient way to reduce the risk of serious adverse events from occurring in Oregon's healthcare system, or any healthcare system, is to encourage a culture of patient safety... [by] encouraging the education and training of providers and healthcare staff and leaders to put patient well-being before profits and personal ego; creating an environment in which it's safe for providers to admit their mistakes with the knowledge they will make improvements with the help of the clinic/facility involved; and being committed to the improvement of healthcare policies and procedures across the state.”

—Survey Respondent

II. Culture Change Takes Time

The Institute of Medicine published its seminal work, *To Err is Human*,⁴² nearly 20 years ago, shining a light on the issue of patient safety, estimating that 98,000 people in the U.S. die each year as a result of medical care. Since then, some estimates have suggested that the number of patients that die may be four times as many.¹⁶ And while there is an increasing expectation that patients or their families will be fully informed when these events occur, current practice often falls short of this expectation.^{7,43}

Progress in transparency within individual organizations requires support from the highest levels of leadership, both within their organizations and at the state level. In a recent U.S. survey, less than 40% of quality and safety leaders rated their board's understanding of disclosure and apology as "high," and fewer indicated that their board had a comprehensive understanding of safety concepts related to transparency with the public about error and harm.⁴⁴ In Oregon, Legislative leadership have prioritized this issue by developing and supporting EDR at the state level. Continued support for EDR and other programs that support culture change will be necessary for making and sustaining progress in the long term.

Changing Systems is Fundamental to Changing Culture

In 2007, the Lucian Leape Institute defined five concepts it felt were fundamental for culture change in healthcare, and without which system-level improvements would not be successful: **medical education reform, care integration, joy and meaning in work, patient and family engagement, and transparency.**⁴⁵ While progress in these areas has been made,⁴⁶ culture change takes time.⁴⁷

Where We Are

The current infrastructure for responding to patient harm is a series of interdependent structures and processes built around a legal framework. This existing infrastructure often focuses on individual blame for what are frequently system errors, and it does not foster a culture of safety.^{21,27,48,49} Improving the safety of our healthcare system will require a cultural shift from blaming individuals to fixing systems by addressing the core reasons why mistakes occur.

To inform our evaluation, we sought to understand where the culture of healthcare is today, recognizing that there will be some variation

"...culture change occurs, as one participant put it, 'at glacial speed.'"

—Mello et al. 2016^{47(p2566)}

"Every system is perfectly designed to get the results it gets."

—W. Edwards Deming

among facilities. We identified three interconnected categories that shed light on some of the work we have ahead of us to continue to shift the culture and move toward a safer healthcare system:

- Healthcare provider and facility response to medical harm can compound patient and family suffering.
- The impact of medical harm events on healthcare providers has potentially life—or career—changing consequences.
- Infrastructure drives how healthcare providers and facilities respond to medical harm events.

Healthcare provider and facility response to medical harm can compound patient and family suffering.

There is an asymmetry in information, education, and experience between patients and healthcare providers and facilities. This puts patients at a disadvantage following medical harm. There was broad agreement from EDR stakeholders in Oregon that an inherent power differential exists between the patient and provider, and that it can act as a barrier to patients and family members speaking up or feeling like full participants in a conversation after a medical harm event. Nearly two-thirds of stakeholder survey respondents (63%) believed that there are barriers or risks for patients (or their representatives) to having a conversation. The most commonly cited were patients’ lack of information or understanding and the patient-provider power differential.

Research shows that patients may find conversations difficult—most have never been in a similar situation before and may have limited medical knowledge.^{24,50} In conversations, they are often at the table with experienced healthcare providers and facility representatives who know how the process should work, have medical knowledge and vocabulary, and have many resources at their disposal. Patients harmed by their care who attempted to speak with their healthcare provider were often unsatisfied with the conversation and left feeling that their concerns had not been addressed.^{51,52}

Patients fear speaking up about an event may damage their reputation. In stakeholder interviews, community members and healthcare professionals told us that patients worry that damage to their relationship with their provider could impact their future care. Specifically, that they could be seen as combative or as a troublemaker and would no longer be able to get care in their community if they spoke up. Several stakeholders mentioned that this was a concern in smaller and rural communities where options for care may be limited. These sentiments were echoed in the stakeholder survey data as well. One respondent wrote, “Some patients feel that they would be

“And I can tell you that if you're not practiced in discussions, or negotiations, or fact finding, then sitting across the table from the provider, there's usually two to three of them, can be quite daunting...”

—Oregon Patient 1

“...if I summon the courage to talk to my provider and the provider doesn't receive it well and he's the only provider in town who can manage my care, have I, by speaking for myself, damaged my future possibilities for staying healthy?”

—Oregon Community Member 17

“...[patients] don't know the right questions to ask. They don't know the right people to go to. They don't speak the language. And they're terrified. And...there's a huge emotional attachment to the experience.”

—Oregon Healthcare Professional 3

labelled as ‘difficult’ and they might be abandoned by their providers.” Research suggests that patients need a lot of support and positive reinforcement from healthcare providers and staff in order to feel safe speaking up.⁵³ In fact, Doherty and Stavropoulou found that assuming an active role in speaking up may actually feel dangerous to patients: “...consequently patients may be actively protecting their personal safety by assuming a relatively passive role.”^{54(p261)}

Patients need support for conversations with healthcare providers and facilities. Studies of patient experience of conversation after harm have found that patients want—and can benefit from—having a support person with them during the conversation.^{1,3,49} Over the course of the first five years of EDR, patients have expressed a need to have a support person at the conversation with them. Survey respondents expressed this as well; a majority (83%) of respondents thought that patients (or their representatives) may need help to participate as an equal in a conversation with their provider(s) about a harm event. Both survey respondents and stakeholder interview participants identified particular skills with which patients needed help. Some suggested specific types of support people that might have those skills. For example, one of the most frequently identified things patients need help with is understanding. This may be understanding medical terminology or understanding why something happened and what it means. Other frequently identified areas of support included the need for help asking questions, articulating concerns, clearly stating what they want out of the conversation, and facilitating the conversation so it goes smoothly, as well as the need for emotional or moral support. Although there were differences in perception about what stakeholders understood a patient advocate to mean, patient advocate, attorney, and friend or family member were most frequently identified to provide patient support.

Attorney and mediator participation may reinforce a legal framework for conversations. The EDR law allows a patient to bring anyone, including a lawyer, to an EDR conversation for support. The literature contains both support for the idea of attorney participation on behalf of the patient^{3,27,55,56} and recognition that attorney participation is not without its drawbacks.⁵⁵ We found the same range of opinions in the stakeholder survey responses and stakeholder interviews.

- Attorneys and/or mediators need the right experience and training to effectively support patients.³ There are currently no evidence-based recommendations for what the right attorney or mediator experience and training looks like; however, a sound understanding of the goals of EDR is critical.

“Having a support person there can, number one, make [patients] feel comfortable, like it's okay for them to say those things.”

—Healthcare Professional 17

“The presence of lawyers changes the nature of the discussion. I've long believed—and maybe I'm wrong about this—that the presence of lawyers has a chilling effect on the conversations.”

—Defense Attorney 15

“We don't engage our attorneys in these conversations because it just feels adversarial from the get-go.”

—Healthcare Professional 29

- Attorney and/or mediator participation also puts an additional logistical and financial burden on patients. In the current system, there's no central location where patients can easily find qualified attorneys who understand the goals of EDR, and many patients simply cannot find a lawyer to represent them.⁴⁹ The cost of hiring an attorney or mediator may add to the financial hardship that a medical harm event can create or deepen.
- Attorney participation can change the dynamic of the conversation, sometimes making it feel more adversarial.⁵⁵
- Healthcare providers and facilities reported that they may be less willing to participate in a conversation with a patient if the patient brings an attorney.⁵⁵ Healthcare providers and facilities may perceive that a patient who brings an attorney to a conversation is indicating an intent to sue. In the stakeholder interviews, some healthcare professionals reported having similar perceptions about mediator participation in the conversation. While a patient may be seeking the support of an attorney or mediator to help level the imbalance of power during the conversation, they may be unintentionally signaling an intent to litigate to the healthcare provider or facility.

Support for patients should be independent of the facility where the event occurred. During the stakeholder interviews, “friends and family” were identified as being able to support the patient and the patient’s interests during conversations. Some interviewees stated that they believe the patient support person must be independent of the facility. Some stated that, from their own experience, they know that a facility employee cannot truly serve the patient and be a representative of the facility. Others hypothesized that this might be an area of mistrust for the patient.

The impact of medical harm events on healthcare providers has potentially life—or career—changing consequences.

Healthcare providers may fear punishment, malpractice lawsuits, or damage to their professional reputation and identity if they are involved in a patient harm event, even if they are not at fault.

Physicians regularly worry about making a medical error that will harm a patient. They reported their worst fears about errors included lawsuits, loss of patient trust, the patient telling friends about their bad experience, loss of colleagues' respect, and diminished self-confidence.^{25,30} In disclosure conversations, the fear of a potential lawsuit may play a role in physicians’ hesitancy to admit to medical error or offer sympathy to affected patients, even though patients report that they want honesty with disclosure.¹ Thirty-four states,

“As soon as the word 'lawyer' came up, risk management kicked in...The hospital was willing to meet and now they're not willing to meet, because all of the sudden it becomes a potential legal risk.”

—Community Member 18

“If you're in a mediation, you're in lawsuit land.”

—Healthcare Professional 14

“[Physicians] have their malpractice insurer who is saying, ‘don't talk to anybody.’ You have the hospital trying to sort out what's their role in the situation, separate from the physician. You have the research that shows that if a physician talks to a patient, that it's much less likely to result in a lawsuit. But everybody is saying to the physician, “you can't.” So even those physicians who are compassionate, who do feel badly, don't feel supported to talk to the patient.

—Oregon Community Member 17

“I think we live in fear. We're scared we're going to get sued.”

—Healthcare Professional 21

including Oregon, and the District of Columbia have enacted partial apology laws that aim to encourage expressions of sympathy (excluding admissions of liability) by making them inadmissible in a subsequent malpractice trial. Five other states have full apology laws (including admissions of liability).⁵⁷ Fear of litigation is associated with fear of loss of reputation because of the impact providers believe litigation could have on their insurance premiums, hospital privileges, license and public persona.^{25,49,58,59} Providers may philosophically agree with the idea that we should be open with and learn from adverse events, but the fear of reputational damage or discipline can act as a counterweight to change.⁶⁰

In stakeholder interviews, loss of public reputation was identified as a provider fear by a broad spectrum of respondents (e.g., community members, healthcare professionals, which includes healthcare providers, insurers). One aspect of this is the role of media (including social media) in risk to public reputation. A theme of lack or loss of control over what's said or written about you appears in conjunction with media-related fears. Loss of professional reputation among your peers was identified exclusively by healthcare providers as a fear.

There are barriers for providers to participate in open conversation.

Research also suggests that healthcare providers are often uncomfortable openly discussing a medical harm event with a patient.^{31,61} This discomfort may stem from a lack of training in disclosure, and/or a cultural reluctance to admit involvement in negative patient outcomes.^{27,55} Helo and Moulton describe this cultural reluctance as a paradox that

"... stems from a physician's sense of duty—borne from the Hippocratic Oath's 'first, do no harm,' which unintentionally places an unbearable burden on the shoulders of physicians by leading them to believe that errors are altogether forbidden"^{1(p774)}

Despite a culture that may reinforce this *perfection myth*,³⁸ healthcare providers are human, and they will make mistakes.

A majority (87%) of respondents to the stakeholder input survey believed that there were barriers or risks for healthcare providers to have a conversation after an adverse event. Respondents who identified themselves as working in a medical or health-related field were more likely to believe this to be true (90% versus 76%). During OPSC's stakeholder input interviews, Oregon healthcare professionals described how the intensity of the emotion they feel after being involved in a patient harm event can make it difficult to engage in open communication. Those emotions can include guilt or culpability,

"Every doctor wants the best care for their patient and if something goes wrong, they feel like they're failures. And so, it's kind of their self-questioning of their ability to do their job."

—Oregon Insurer 1

"[We need] a system where whenever something happens that immediately that support is there. You know, 'we're going to help you through this.' ... we forget the people... we try to depersonalize it so we can look at system issues and yet it's the people that are really affected. And how do we support that team and help them have that conversation and move on from that [harm event] with learning and not with self-flagellation?"

—Oregon Healthcare Professional 26

"You're coming down hard on yourself for everything...then you throw in something bad...and, oh, my God... given just the culture of physicians in general and then you throw this on top of it. It's really hard for some people because you beat yourself up about everything no matter what."

—Oregon Healthcare Professional 24

shame or embarrassment, and feeling like a failure. Ultimately, involvement in a patient harm event is an existential threat to a provider, making them question their professional competence, or if they'll be able to continue their career.

Through EDR implementation data, we find that few healthcare providers or facilities initiate conversations with patients following medical harm. Only 11% of the requests for conversation submitted in the first five years of implementation were submitted by healthcare providers, employers of providers, or facilities. What's more, half of the requests for conversation submitted by patients in the first five years (51%) were declined by all named facilities and healthcare providers.

EDR is Not a Separate Process

Healthcare providers and facilities are asked to tell OPSC why they are declining a patient's request for a conversation about a harm event. They can choose multiple options. Some requests result in one party accepting and another declining. The 180 decline reasons given by healthcare providers and facilities over the first five years of the program included:

- 35% "I intend to use a different process and will not incorporate EDR"
- 19% "I have already addressed this event through another process"
- 7% "Advised against participation by liability insurer"
- 4% "Advised against participation by legal counsel"
- 2% "Advised against participation by employer"

Infrastructure Drives How Healthcare Providers and Facilities Respond to Medical Harm Events.

The involvement of multiple participants with a variety of employment and indemnification relationships adds complexity. A single unintended harm event may involve a variety of employment and indemnification relationships. This may be confusing for patients or their families, who are typically unaware of these complexities, and it may result in a disjointed, duplicative, or delayed response experienced by patients or their families following a medical harm event.⁴⁷

Healthcare providers, and physicians in particular, might not be employed by the facility where an event they are involved in occurs. Without an employment relationship, the event investigation and resolution are likely siloed and duplicative, and there may be

"You have the hospital trying to sort out what's their role in the situation, separate from the physician."

—Community Member 17

"I've worked in a lot of settings with a lot of different dynamics and setups on how this is handled. In some facilities, despite best effort, the facility's values and mission may differ from the provider, especially when they're an independent provider, not employed by the facility."

—Healthcare Professional 3

incentives to “...shift the blame for medical errors to one another rather than collaborate on a joint resolution.”^{47(p2551)} Additionally, the insurers for the healthcare provider and the facility may have differing structures and philosophies about proactively negotiating settlements.^{12,47}

Of the patient Requests for Conversation^{xvii} through EDR that named a facility and at least one healthcare provider, 63% of the named healthcare providers were independent contractors (91/144) at the facility where the event occurred. This employment relationship, which is typically unknown to the patient, may result in the facility and the healthcare provider each choosing to manage a patient’s Request for Conversation through EDR independent of the other. From the patient’s perspective, even if a facility does not employ a healthcare provider, both the facility and provider share in the responsibility for their care. The necessary coordination when multiple participants are involved may cause a delayed response, and a delay can create uncertainty and induce anxiety for patients.¹

Healthcare providers need support, too. Patient harm events are traumatic not only for the patient and family, but also for the healthcare provider.⁶ Healthcare providers whose own emotional needs have not been met may be less able to support patients and families in the wake of unintended harm. Organizations need systems in place to support healthcare providers following patient harm events.⁶² While many healthcare organizations have employee assistance programs or selectively refer healthcare providers to mental health professionals, few are equipped to proactively offer peer support to all affected healthcare providers immediately following an event.⁶³ Leaders in the CRPs movement, such as Tim McDonald, MD, JD, have observed that an affected provider is not always in a condition to initiate and manage communications about the serious harm event with their patient.⁶⁴

Healthcare providers need ongoing training on how to have effective conversations. Many healthcare providers now receive training in how to disclose an adverse event.⁷ However, there should be a system for consistent, patient-centered training that is available both on-demand and on a routine basis.^{3,4,61} Promising research suggests that providers with previous exposure to disclosure training had more positive responses on disclosure culture scales.⁷

Healthcare providers and facilities need infrastructure to respond to patients and families after medical harm. Not responding to a patient harm event in a timely and effective manner can lead to absence of

“I recognize that many providers are highly traumatized by adverse events.”

—Healthcare Professional 30

“Are we doing the best possible thing for the patient, when we don't prep [the provider]?”

—Healthcare Professional 20

“I think that is occurring. Just that the medical school, students are being taught about apologizing and having these kinds of conversations, and I think starting to, at least, be aware that there's a skill set needed to do this.”

—Healthcare Professional 21

^{xvii} See Appendix I for definitions of terms used in this report.

healing, loss of trust, and impeded learning for improved care.^{1,24} A lack of a timely response may also make patients more likely to file a lawsuit.⁶² Infrastructure to support a prompt and compassionate response is necessary. Some organizations have implemented elements of a CRP to support a consistent, systematic response to patient harm; however, adoption is not widespread.^{47,65} CRPs provide guidelines to help healthcare providers communicate with patients and their families about the event in a way that rebuilds trust and promotes ongoing communication.

We have work to do. Only 31% of respondents to the stakeholder input survey believed that most healthcare providers tell their patients if an adverse event occurred during their medical care, with 45% believing that this does not occur (24% did not know). The vast majority of respondents (91%) did, however, believe that conversations about those events can contribute to or lead to improved safety for future patients.

Silence Perpetuates Harm

Silence after medical harm has negative consequences for patients and families affected by harm events, for the healthcare providers involved, and for the healthcare system as a whole.

- **For patients and families**, silence may compound the injury and may provoke feelings of abandonment and mistrust.⁵ In the absence of a clear explanation about what happened, suspicions of wrongdoing may take root⁵⁰ and patients may see a lawsuit as their only way of getting information.¹⁻⁴
- **For healthcare providers**, silence may heighten and prolong their feelings of fear, guilt, anxiety, and grief, as they are left without any way to alleviate their personal and professional distress.⁶
- **For the healthcare system**, it squanders an opportunity to improve systems of care by addressing the underlying safety issues.^{7,33,34} It degrades the institutional culture and climate. Ultimately, it reduces public trust in healthcare.

“There's a lot of fear in the system, and in individuals, that results in needed conversations not happening.”

—Oregon Community Member 17

“And if we don't discuss it, then they go to an attorney to try and get answers. They just have no other resource.”

—Healthcare Professional 21

Where We Want to Be

Ninety-nine percent of respondents to the stakeholder input survey agreed that a conversation should take place between a healthcare provider and patient (or patient representative) following serious patient harm or death. Ninety-seven percent agreed that a conversation should take place in cases of less serious harm. Respondents also agreed that these conversations benefit both patients and healthcare providers.

Moving toward a transparent, patient-centered approach for responding to medical harm will require a reevaluation and repurposing of existing infrastructure.

Here in Oregon, we can learn from organizations across the U.S. that successfully implemented programs to support open communication, like CRPs. The CRP model addresses the need for systemic change through a comprehensive system overhaul. A healthcare organization with a CRP will respond consistently and compassionately to each harm event by communicating transparently with patients and families, investigating what happened and offering an explanation, apologizing when warranted, taking responsibility, proactively offering compensation, and taking steps to improve systems of care.

Open Communication Linked to Progress in Medical Malpractice

The University of Michigan Health System (UMHS) was a leader in developing a CRP model aimed at addressing the reasons people turn to lawyers by incorporating communication, full disclosure, and learning from events to improve care. The program saw a decrease in the average monthly rate of new claims, average monthly rate of lawsuits, median time to claim resolution, patient compensation, and non-compensation-related legal costs.⁶⁸

Pre-implementation (1995-2000)

- 7.03 claims per 100,000 encounters
- 2.13 lawsuits per 100,000 encounters (avg. monthly rate)
- 1.36 years to resolution (median)

Post-implementation (2001-2007)

- 4.52 claims per 100,000 encounters
- 0.75 lawsuits per 100,000 encounters (avg. monthly rate)
- 0.95 years to resolution (median)

Other healthcare organizations have followed UMHS in implementing CRPs (see box). However, concern that this approach will increase

“[CRPs] have demonstrated that effective communication with patients and families in the immediate aftermath of patient harm, regardless of the cause of that harm, can lead to organizational learning, improved surrogate measures of patient safety, and reduction in medical liability”

—Lambert et al. 2016^{13(p2512)}

liability remains,³² and is echoed here in Oregon. Countering this concern, an evaluation of CRP implementation in four Massachusetts hospitals showed that none of the hospitals experienced worsening liability trends after CRP implementation, which, the authors suggest demonstrates “...that transparency, apology, and proactive compensation can be pursued without adverse financial consequences.”^{32(p1836)}

Measuring the Effectiveness of EDR at the State Level

Ideally, we would be able to demonstrate the effectiveness of EDR at the state level by quantifying annually how many instances of unintended patient harm resulting in serious injury or death were resolved using EDR for open conversation. However, no state, including Oregon, has a mechanism to accurately capture the total number of qualifying harm events occurring^{14,20,35,42,69} or the number of statewide claims related to these events.⁷⁰ What we can say is that of the events that resulted in an EDR request, only 5% could be associated with a later court filing. Additionally, we will never be able to quantify the number of patients who were not harmed because of patient safety improvements made in response to a conversation that was initiated through EDR. This is the nature of patient safety work; however, an acknowledgment of these limitations should always be accompanied by a reminder of the value of this work—to prevent patient harm.⁷¹

"The names of the patients whose lives we save can never be known. Our contribution will be what did not happen to them. And, though they are unknown, we will know that mothers and fathers are at graduations and weddings they would have missed, and that grandchildren will know grandparents they might never have known, and holidays will be taken, and work completed, and books read, and symphonies heard, and gardens tended that, without our work, would never have been."

—Donald M. Berwick, MD, MPP, President Emeritus, Institute for Healthcare Improvement^{71(p44)}

III. EDR Can Accelerate Progress toward a Culture of Safety

Although culture change takes time, programs like EDR here in Oregon can serve as catalysts for change. Healthcare providers, facilities, and Oregonians alike now have a new, more transparent path for responding to patient harm from medical care—a path that allows healthcare providers and facilities to continue to care for patients and to learn and improve their systems of care to prevent future harm.

Leadership from lawmakers at the state level can continue to prioritize and drive public policy that encourages a culture of safety. According to recent research from Mello et al., “The experience of pioneering institutions shows that when done right, the [CRP] model is powerful – and no other medical liability reform approach holds as much promise for improving safety.”^{47(p2567)}

EDR accelerates progress towards a culture of safety in several ways:

- **EDR creates confidentiality protections^{xviii} for all aspects of information sharing following patient harm to help create the psychological safety necessary for healthcare providers to talk openly with patients (or their representatives).** This creates the opportunity for patients to receive the information, acknowledgement, and support they need, and it paves the way for learning and patient safety improvement.
- **EDR creates a path for patients (or their representatives) to ask for a conversation.** In the first five years of EDR in Oregon, 89% of all requests for a conversation have come from patients. This sends a clear message that patients want transparency after medical harm. EDR gives patients some sense of control over their situation, by empowering them to ask for the information and acknowledgement that they need. Many organizations have a complaint or grievance process in place; however, using one of these processes to make a formal complaint may be stigmatizing for patients and a source of additional distress.⁷²
- **When patients (or their representatives) request a conversation through EDR, OPSC connects them to involved healthcare providers and/or facilities.** Given the complex nature of how healthcare is provided, a single patient harm event can involve multiple healthcare providers with multiple employment relationships. Patients often don’t know where to

“...I think that that the EDR process and all these learnings, all these things the state of Oregon is doing...[this] good work is really, it is changing the culture.”

—Oregon Healthcare Professional 29

“I have worked with providers to have these discussions, and while never easy, they have tremendously improved each situation I've been part of.”

—Survey Respondent

^{xviii} See Appendix I for a definition of *protections* and other terms used in this report.

start. As a neutral third party, OPSC helps notify those involved and, as a first point of contact, can share information about EDR with those healthcare providers and facilities.

- **EDR is a mechanism for broader learning and system improvement so that we can make progress as a state.** Through EDR implementation, OPSC can connect the dots between individual organizations and share information and best practices, including effective strategies for communicating with patients and families after patient harm events, and exploring the potential for resolution. This enables broader process and system improvements to be put into place statewide, benefiting all Oregonians.

Additional Efforts to Drive Culture Change in Oregon

In addition to administering EDR, OPSC helps healthcare providers and facilities learn about effective strategies for communicating with patients and families after patient harm events and encourage a culture of patient safety. In service to this role, OPSC has implemented strategies to support Oregon healthcare organizations and drive culture change. Examples of these strategies include:

- **Cultivate early adoption of a transparent approach.** OPSC convened the Oregon Collaborative on Communication and Resolution Programs (OCCRP), to help participating organizations build their capacity to respond to medical harm with transparency and strengthen their culture of safety. Five participating organizations used OCCRP to develop peer support programs for their providers involved in a medical harm event.
- **Make best-practice information and education available to Oregon healthcare organizations.** OPSC has brought some of the foremost patient safety advocates, innovators, and practitioners in the nation to Oregon to serve as OCCRP faculty, and to educate interested members of the healthcare community and the public at its annual patient safety event. (See a list of educational offerings in Appendix V.) OPSC also regularly shares best-practice information for responding to patient harm events across the state.

“This is an important law that helps patients, providers, and helps develop a culture of safety and learning.”

—Survey Respondent

“For providers and patients to engage in the conversations that could be healing and helpful to their ongoing relationship and to the organization's demonstration of [their] commitment to a culture of patient safety.”

—Healthcare Professional 29

Conclusion and Recommendations

Through our evaluation of five years of EDR implementation in Oregon (July 2014 – June 2019), we can see that EDR is a lever for culture change in Oregon. By encouraging an alternative, more transparent approach for responding to patient harm, EDR advances progress toward two important objectives:

- Minimizing the need to escalate patient harm events to the legal system by addressing the needs of healthcare providers, facilities, and patients and families to exchange information and discuss possible resolution of specific harm events.
- Cultivating the culture of safety necessary to make our care delivery system safer and ultimately prevent harm events.

To make Oregon’s healthcare system safer, we must develop and support programs that promote a culture of safety within healthcare organizations, like EDR. Furthering transparency about medical harm, as EDR does, will drive system changes to reduce harm events. Only by reducing harm to patients can we make real progress on the issue of medical liability costs. For long-term culture change to be sustained, EDR should be ongoing.

We strongly recommend that the Legislature remove the sunset provision established in Oregon Laws 2013, Chapter 5, Section 20.^{xix} This will ensure EDR remains available to continue to drive culture change in the state, to the benefit of all Oregonians.

“I believe that we all have a long way to go to improve patient safety and transparency. EDR is a good place to start.”

—Survey Respondent

“[This approach is] just the right way to treat my patients and their families.”

—Survey Respondent

“This is crucially important work. I hope Oregon will be a model for other states.”

—Survey Respondent

^{xix} Oregon Laws 2013, Chapter 5, Section 20 establishes a sunset date of December 31, 2023.

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- The Oregon Patient Safety Commission staff
- The advisory committee to and participants in the Oregon Collaborative on Communication and Resolution Programs
- Members of the healthcare community
- All those who contributed to the stakeholder input process
- The many individuals who have come forward to share their ideas and tell their stories
- The people of Oregon, and those patients and family members who have sought EDR following medical harm
- The Oregon State Legislature

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Appendix I. Important Terms for this Report

Term	Definition
Communication and Resolution Program (CRP)	A comprehensive, systematic program for reporting and responding to medical harm events. Some of the key elements of CRPs are continuous communication with patients and families throughout the process, event analysis, system improvements, emotional support for caregivers, and compensation when appropriate. ⁵
Early Discussion and Resolution (EDR)	<p>Early Discussion and Resolution (EDR) provides a constructive way forward after medical harm (i.e., serious physical injury or death) and promotes learning for improved patient safety (Oregon Laws 2013, Chapter 5). Either a patient (or their representative), a healthcare provider, or facility can initiate EDR by requesting a conversation through the Oregon Patient Safety Commission (OPSC). When these conversations are initiated using EDR, they have confidentiality protections, encouraging healthcare providers and facilities to talk openly with patients about what happened as they explore the best way to reach resolution.</p> <p>When OPSC receives a Request for Conversation, it plays a dual role in EDR administration:</p> <ul style="list-style-type: none"> • Connector: OPSC connects patients (or their representatives) to involved healthcare providers when patients request a conversation through EDR. • Educator: Using research and information collected through EDR administration, OPSC helps healthcare professionals learn about effective strategies for communicating with patients and families after medical harm events. OPSC also disseminates best practices for resolving these events.
Healthcare facility*	<p>A licensed healthcare facility as listed in Oregon Laws 2013, Chapter 5. Healthcare facilities are:</p> <ul style="list-style-type: none"> • Ambulatory surgery centers • Freestanding birthing centers • Hospitals (including any licensed satellite facility) • Nursing facilities • Outpatient renal dialysis centers
Healthcare provider*	<p>A licensed healthcare provider as listed in Oregon Laws 2013, Chapter 5. Healthcare providers are:</p> <ul style="list-style-type: none"> • Audiologists • Chiropractors • Dental hygienists • Dentists • Denturists • Direct entry midwives • Emergency medical • Occupational therapists • Optometrists • Pharmacists • Physical therapists • Physicians • Physician assistants

Term	Definition
	<ul style="list-style-type: none"> service providers • Marriage and family therapists • Massage therapists • Medical imaging licensees • Naturopathic physicians • Nurse practitioners • Podiatric physicians • Podiatric surgeons • Professional counselors • Psychologists • Registered nurses • Speech-language pathologists
Patient’s representative*	<p>A patient may have a representative for the purposes of Early Discussion and Resolution if a patient is under the age of 18, has died, or has been confirmed to be incapable of making decisions by their doctor. This following list names, in order, the people who can serve as a patient’s representative. Only the first person in this list, who is both willing and able, may represent the patient:</p> <ul style="list-style-type: none"> • Guardian (who is authorized for healthcare decisions) • Spouse • Parent • Child (who represents a majority of the patient’s adult children) • Sibling (who represents a majority of the patient’s adult siblings) • Adult friend • A person, other than a healthcare provider who files or is named in a notice, who is appointed by a hospital
Protections	<p>Initiating EDR by submitting a Request for Conversation through OPSC establishes confidentiality protections. These confidentiality protections apply to discussion communications for EDR (Oregon Laws 2013, Chapter 5, Section 4). All written and oral communication is confidential, may not be disclosed, and is not discoverable or admissible as evidence in any subsequent adjudicatory proceeding. However, if a statement is material to the case and contradicts a statement made in a subsequent adjudicatory proceeding, the court may allow it to be admitted.</p> <p>EDR protections do not change other protections that are afforded by state and/or federal law. For example, Health Insurance Portability and Accountability Act (HIPPA) protections for a patient’s medical records and other personal health information remain unchanged with the use of EDR.</p>
Request for Conversation	<p>A Request for Conversation is a brief form that includes information about a specific physical injury or death event from medical care. A request can be submitted by a patient, a patient’s representative (in certain circumstances), a healthcare facility representative, or a healthcare provider. Submitting a Request for Conversation starts the Early Discussion and Resolution process. The request lets the other party know that the requestor would like to talk to them about what happened.</p>
Serious adverse event	<p>Unanticipated consequence of patient care that is usually preventable and results in the death of or serious physical injury to a patient. Serious</p>

Term	Definition
<i>(Referred to as “patient harm” or “medical harm” in this report)</i>	physical injury is an injury that: <ul style="list-style-type: none"> • Is life threatening; or • Results in significant damage to the body; or • Requires medical care to prevent or correct significant damage to the body. Early Discussion and Resolution is for serious adverse events.

*Term defined in Oregon Administrative Rules 325-035-0001 through 325-035-0045.

Appendix II. Qualitative Data Collection and Analysis Methodology

The Oregon Patient Safety Commission (OPSC) collected input from EDR stakeholders through group and key informant interview and a survey. The following is a summary of OPSC's qualitative data collection and analysis methodology.

Interviews

- **What:** OPSC held 10 key informant interviews and nine group interviews. Interviewees were selected via a convenience sample of stakeholders from around Oregon (Portland Metro, Central Oregon, South Coast), including patients, providers, risk and quality managers, insurers, mediators, and lawyers.
- **Why:** OPSC collected baseline data to inform the Task Force's five-year evaluation.

Survey

- **What:** Electronic survey gathering opinions on conversations after harm open from April through Mid-September.
- **Who:** The survey was open to any and all Oregonians, promoted via social media campaigns, internal mailing lists, healthcare partner mailing lists, and links on OPSC's website.

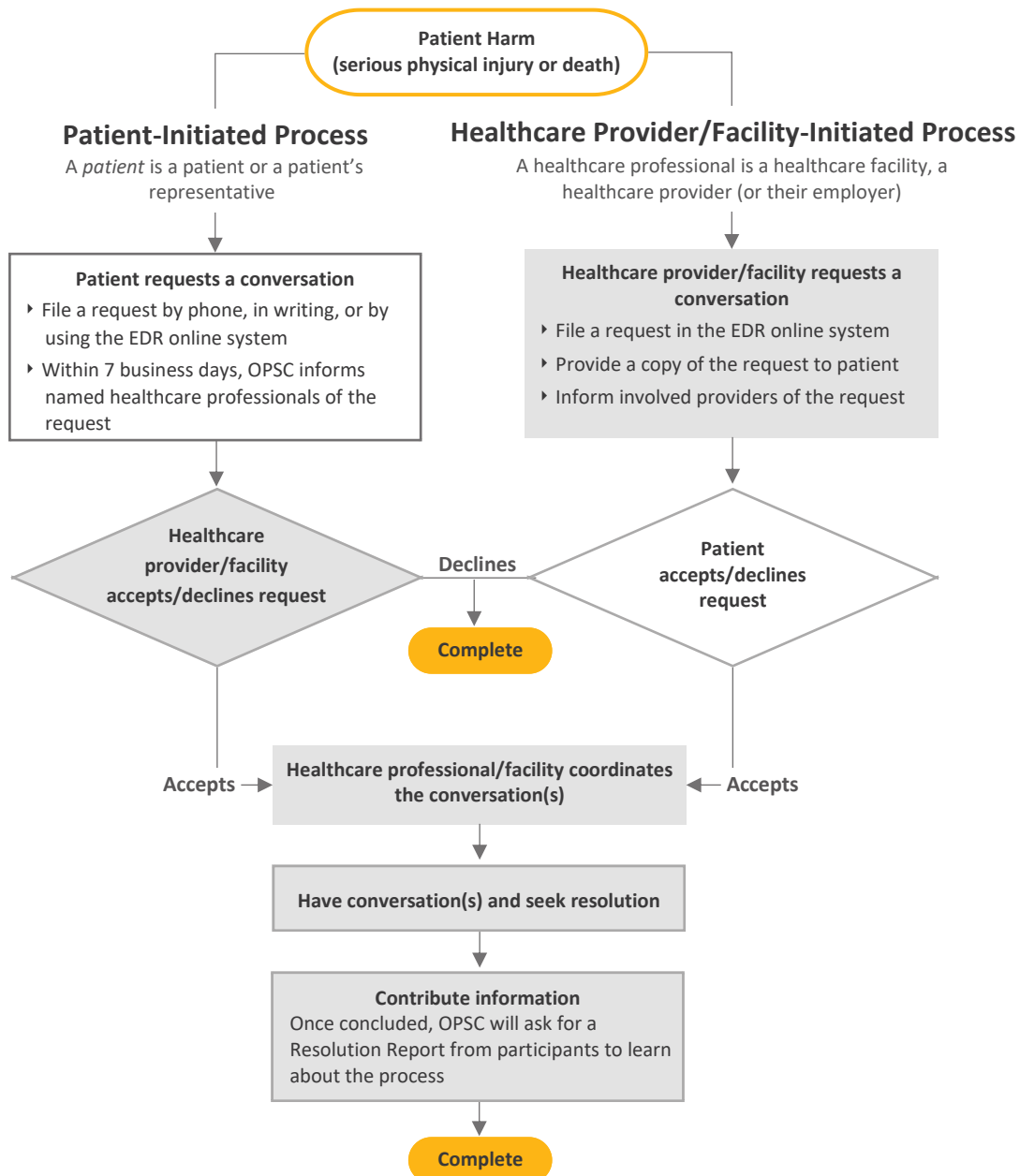
Content Analysis

- **What:** OPSC staff independently reviewed and coded interview data, reconciling any coding differences. Coded interview data was combined with survey data for analysis. The themes identified in analysis were used as supporting evidence for the Task Force's five-year evaluation.
- **Why:** There is a limited body of work of opinions related to having a conversation after a patient harm and none of it includes a state-wide program open to patients as well as providers, like EDR.

Appendix III. The Early Discussion and Resolution Process

When a patient is harmed by medical care (i.e., serious physical injury or death), either a patient (or a patient’s representative), a healthcare provider, or a facility can initiate Early Discussion and Resolution (EDR) by completing a Request for Conversation, through the Oregon Patient Safety Commission (OPSC), to talk to the other party about what happened and move toward resolution. If both parties agree to participate, they will come together for an open conversation coordinated by the healthcare provider or facility.

- Patient (or patient’s representative)
- Healthcare provider and/or facility
- Patient and healthcare provider and/or facility



Appendix IV. OPSC's Role in EDR

The Oregon Patient Safety Commission (OPSC) is responsible for the implementation of Early Discussion and Resolution (EDR).

When serious harm from medical care occurs (i.e., serious physical injury or death), either a patient (or their representative), a healthcare provider, or facility can initiate EDR by requesting a conversation through OPSC. OPSC plays a dual role in EDR administration:

- **Connector:** OPSC connects patients (or their representatives) to involved healthcare providers when patients request a conversation through EDR.
- **Educator:** Using research and information collected through EDR administration, OPSC helps healthcare professionals learn about effective strategies for communicating with patients and families after medical harm events. OPSC also disseminates best practices for resolving these events.

OPSC serves in a neutral capacity, offering information that can help both patients and healthcare professionals use the process effectively. OPSC does not provide advice to or advocate for either patients or healthcare professionals. Once a request is made and the involved parties agree to have a conversation, the healthcare professional coordinates the conversation(s). OPSC is not present for the conversations.

After the conversation(s) have concluded, OPSC asks participants to share information about their experience in a voluntary questionnaire. OPSC shares trends and other deidentified and aggregated information for statewide learning.

In addition to its role implementing EDR, OPSC also provides staff support for the Task Force on Resolution of Adverse Healthcare Incidents and maintains a qualified mediator list as an optional resource for EDR participants. Each mediator on the list meets standards for education and experience developed by members of the Oregon Mediation Association and the Alternative Dispute Resolution section of the Oregon Bar Association. EDR participants are free to choose mediators who are not on this list.

Appendix V. Educational Offerings to Support Culture Development

The Oregon Patient Safety Commission (OPSC) helps healthcare providers and facilities learn about effective strategies for communicating with patients and families after patient harm events and encourage a culture of patient safety. OPSC has brought some of the foremost patient safety advocates, innovators, and practitioners in the nation to Oregon to educate interested members of the healthcare community and the public. OPSC also regularly shares best-practice information for responding to patient harm events across the state.

Topic	Faculty
2014-2015	
Introduction to Early Discussion and Resolution (EDR) <i>20 offerings for a broad range of EDR stakeholder audiences</i>	OPSC Staff
Peer Support Program Development Day	Rick van Pelt; Susan Scott, PhD, RN, CPPS; Bill Lang; Carl Washington; Jeane Robinson, MD; Warren Jendall, MD; Ron Hofeldt, MD
Embracing the Patient in Patient Safety	Dan Ford
2016-2017	
Effective Response to Adverse Events: Compassion, Learning, and Resolution	OPSC Staff
Fundamentals of Communications and Resolution Programs	Timothy McDonald, MD, JD; Heather Wong, JD, MBA
Promoting Just Culture in High Consequence Organizations*	John Westphal
Care for the Caregiver*	Susan Scott, PhD, RN, CPPS
Communicating Towards Resolution*	Rick Boothman, JD
Adverse Event Reporting and a Culture of Safety*	Nikki Centomani, RN, BSN, ARM, MJ
Adverse Event Investigations and Analysis*	Julie Duncan, BN, MN, CPHQ; Marcia Rhodes
How Liability Insurance Affects the Implementation of Communications and Resolution Programs*	Julie Duncan, BN, MN, CPHQ; Marcia Rhodes
The Patient Perspective on Communication and Resolution*	Carol Gunn, MD, CIH
Professional Liability and Resolution: Collaborative Relationships with Internal and External Stakeholders*	Claire Hagan, MHL; Lorie Larsen-Denning, RN, MBA, CPCU, RPLU, DFASHRM
Mediation in the Context of EDR and Communication and Resolution Programs*	Sam Imperati, JD
Communication with Patients and Families in the Wake of Patient Harm*	Bruce Lambert, PhD
Cultivating your Learning Organization; Hardwiring your CRP to Sustain Progress Through Change*	Heather Wong, JD, MBA

Topic	Faculty
Communication: Is it What You Hear, What You Say, or What You See?	Carole Hemmelgarn
Rhetoric to Reality: Communication Following Adverse Events	Thomas Gallagher, MD
Patients and Providers Healing in Tandem	Carole Hemmelgarn; Thomas Gallagher, MD
Advancing Patient-Centered Care	Tiffany Christiansen; Diane Waldo
Avoid Band-Aid Solutions: Strengthening Adverse Event Investigations	OPSC Staff
<i>Multiple offerings</i>	
Building Strong Root Cause Analysis Action Plans Using Human Factors	OPSC Staff
<i>Multiple offerings</i>	
Mock Root Cause Analysis demonstration and training	OPSC Staff
After an Adverse Event: Open Communication Promotes Healing and Safer Patient Care	OPSC Staff
Speak Up for Patient Safety: Before, During, and After an Adverse Event	OPSC Staff
<i>Multiple offerings</i>	
2018-2019	
Responding to Unexpected Harm in Residential Settings	OPSC Staff
<i>Two offerings</i>	
Responding to Unexpected Harm in the Dental Setting	OPSC Staff
Essential Tools and Practices for Every Healthcare Setting	Timothy McDonald, MD, JD; Martin Hatlie, JD
Walking the Talk: Healing, Learning, and Safer Healthcare Through Open Communication	Jo Shapiro, MD
Foundations of Peer Support*	Jo Shapiro, MD
Peer Supporter Training*	Jo Shapiro, MD
Beyond Peer Support: Community Efforts that Complement Your Peer Support Program*	Jo Shapiro, MD; Donald E. Girard, MD; Marty Wilde, JD, MHL, MHA; Amanda Borges; Krista Wood; Lee Faver, PhD, ABPP
The Impact of Clinician Burnout and Trauma on Patient Safety*	Jo Shapiro, MD
Professionalism and a Culture of Patient Safety*	Jo Shapiro, MD
Using Experience to Refine Your Peer Support Program*	Jo Shapiro, MD
Having the Initial Conversation with a Patient and Family in the Wake of Patient Harm*	Jo Shapiro, MD
Responding to Patient Harm Events: An Update on Oregon's EDR Process	OPSC Staff
<i>Five offerings</i>	
Responding to Patient Harm Events the Oregon Way	OPSC Staff

* Offered as a part of the Oregon Patient Safety Commission's Oregon Collaborative on Communication and Resolution Programs (OCCRP).