OREGON PATIENT SAFETY COMMISSION

Early Discussion and Resolution: Advancing a Culture of Safety in Oregon

July 2014 – June 2020

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

Questions?
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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 innovative EDR program from July 1, 2014 to June 30, 2020: *Early Discussion and Resolution: Public Policy Driving a Culture of Safety in Oregon*. The report satisfies our reporting, evaluation, and recommendation requirements (Oregon Laws 2013, Chapter 5, Section 17(2)).

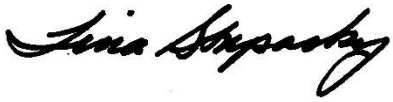
Our evaluation includes data from EDR implementation and supporting evidence from patient safety literature. It is also informed by input collected in 2019 from stakeholders affected by EDR, including community members, healthcare providers and facilities covered by EDR, liability insurers, and the legal and mediation communities.

Through our evaluation, we are convinced of EDR's value to Oregonians. The program encourages a compassionate response to patient harm that promotes transparency and learning, helping to cultivate a culture of safety. Action is needed by the Legislature to remove the sunset provision on EDR, set for December 31, 2023.[i] EDR's continuation would maintain the opportunity for progress and innovation in Oregon's healthcare system and reinforce our state's commitment to patients who have been harmed by medical care, their families, and healthcare providers involved in harm events.

We appreciate the opportunity to submit our evaluation of the EDR program for your consideration.

Respectfully,

John Moorhead, MD
Task Force Co-Chair



Tina Stupasky, JD
Task Force Co-Chair

The Task Force on Resolution of Adverse Healthcare Incidents

Task Force members and their respective seats include:

- Robert Beatty-Walters, trial lawyer
- Robert Dannenhoffer, physician
- Jeff Goldenberg, advocate for patient safety
- Michelle Graham, hospital industry
- Anthony Jackson, public member
- Bob Joondeph, public member
- 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 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] Fear, guilt, anxiety, and grief have all been described by providers as reactions to harm events.[1,6–8] An open conversation is an effective way to help alleviate providers' personal and professional distress; the absence of a conversation may heighten this distress.[9] A failure to talk openly about harm also impedes the ability of healthcare organizations to learn from and address safety issues related to these events for future patients.[10]

"While the estimates of preventable harm vary, we can all agree on this: Behind each number are people and a story. The people begin with the patient and family and extend to loved ones, the health professionals involved in their care, and society at large."

— National Steering Committee for Patient Safety[11(p11)]

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 claims. 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 facilities[ii] when care resulted in serious harm or death—what is now called Early Discussion and Resolution (EDR).[iii] EDR establishes confidentiality protections[iv] for these important conversations to encourage participants to talk candidly about the harm that occurred and seek reconciliation outside of the legal system.

To ensure the ongoing effectiveness of EDR, the Legislature established the Task Force on the Resolution of Adverse Healthcare Incidents ("Task Force") to serve as the evaluative body for the program and recommend changes as necessary. As the Task Force, our evaluation of EDR includes an analysis of data from EDR use (July 2014 – June 2020), a literature review of the evidence base supporting transparency following patient harm, and input from EDR stakeholders across Oregon (2019). Through our evaluation we have identified several guiding culture change principles that are essential to understanding the opportunity EDR creates for progress and innovation in Oregon:

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.
II. **Infrastructure and culture are interdependent.** Our current infrastructure for addressing medical harm through the legal system drives how healthcare providers and facilities respond when a patient is harmed. To make care safer, organizations must cultivate their culture of safety by implementing systems that support transparency and learning following patient harm.

[ii] See Appendix I for a definition of *patient representative*, *healthcare provider*, and *healthcare facility*.
[iii] See Appendix I for a definition or *Early Discussion and Resolution*.
[iv] EDR creates confidentiality protections for written and oral discussion communications. EDR protections do not change other protections afforded by state or federal law. See Appendix I for a definition of *protections*.

The communication and resolution program (CRP) model shows promise for supporting this comprehensive systems-based approach. According to a recent editorial in *BMJ Quality & Safety*, "CRPs appear to improve patient and provider experiences, patient safety, and in many settings lower defense and liability costs in the short term and improve peer review and stimulate quality and safety over time."[12(p2)]

III. **EDR accelerates progress toward a culture of safety.** By encouraging an alternative, more transparent approach for responding to patient harm, EDR is a lever for culture change in Oregon. EDR advances progress toward two important objectives:
    - Minimize the need to escalate patient harm events to the legal system by addressing the needs of patients and families, healthcare providers, and facilities to exchange information and seek resolution for specific harm events.
    - Cultivate the culture of safety necessary to improve our care delivery system and ultimately prevent harm events.

Finally, we dove deeper into the patient and provider experience following medical harm here in Oregon. Three themes emerged that are discussed in this evaluation:

- The substantial effect of medical harm on patients and families can be compounded by the response of healthcare providers and facilities.
- 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.

Through EDR, all Oregonians have an alternate path for responding to patient harm from medical care—a path that allows patients to receive an explanation about what happened and allows healthcare providers and facilities to continue to care for patients and to learn and improve their systems of care to prevent future harm. In the first six years of EDR, 255 Oregonians have requested a conversation through EDR, with 91% of those requests coming from patients or their representative, indicating a need that is not being met by the current system.

Only by reducing harm to patients can we make real progress on the issue of medical liability costs. We strongly recommend that the Legislature remove the sunset provision on EDR[v] to ensure its continued availability to drive culture change in the state for the benefit of all Oregonians. Without action from the Legislature, EDR will cease to exist on December 31, 2023.

The Imperative to Remove the Sunset Provision on EDR

EDR demonstrates Oregon's commitment to patients who have been harmed by medical care, their families, and involved healthcare providers. Removing the EDR sunset will:

- Ensure Oregonians have a way to seek resolution following medical harm before escalation to a traditional legal response.
- Instill confidence that the confidentiality protections EDR affords will remain intact.
- Maintain the infrastructure for shared learning across the healthcare continuum to ensure we can continue to make progress as a state.
- Cement Oregon's role as a national leader in the burgeoning CRP movement.

[v] 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...		Healthcare providers want...
To know their doctor cares about them.	**Empathy**	To know their organization and insurer support them to have an open conversation.
A support person with them so that they don't feel alone during a conversation.	**Support**	To show their concern and offer an apology.
To know what happened and why, and that it won't happen to anyone else.	**Information sharing**	To be open and honest about what happened.
To continue to receive the care and support they need without litigation.	**Reconciliation**	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

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

Six Years of EDR Use in Oregon

July 2014-June 2020

255 **Requests for Conversation submitted**

91% of **Requests for Conversation** were made by **patients** (or their representatives)

Most common event types mentioned in Requests for Conversation

- **42%** Care delay
- **35%** Surgical or other invasive procedure
- **11%** Other
- **9%** Medication event
- **6%** Healthcare-associated infections

Most common locations where those events occurred

- **68%** Hospitals
- **23%** Medical Clinics
- **5%** Ambulatory Surgical Centers
- **2%** Nursing Facilities

43% **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

- **36%** Intend to use a different process and will not incorporate EDR
- **16%** Have already addressed this event through another process
- **6%** Advised against participation by liability insurer
- **5%** Advised against participation by legal counsel
- **2%** Advised against participation by employer

OPSC OREGON PATIENT SAFETY COMMISSION

Introduction

In our complex and constantly evolving healthcare system, harm from medical care can—and does—occur, sometimes resulting in serious injury and even 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.[13–19] Further exacerbating the issue and impeding our collective 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, as 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."[20(p336)]

To make progress, we must improve how we respond to and learn from medical harm, both within individual healthcare organizations and across the healthcare continuum.

- **Within individual healthcare organizations:** When organizations have systems in place to proactively and consistently respond to medical harm that also incorporate elements of a culture of safety—such as transparency with patients and families, addressing system causes to identified risks, and a commitment to learn from events for continuous improvement—they are building the skills necessary to address the wide range of safety issues that will inevitably arise. Organizational capacity to respond to patient harm is particularly important with the additional stressors on healthcare organizations related to the COVID-19 pandemic.
- **Across the healthcare continuum:** In the 2020 report *Safer Together: A National Action Plan to Advance Patient Safety*, the National Steering Committee for Patient Safety (NSC) reinforces the critical need for a coordinated effort from all stakeholders across the healthcare continuum. In the report, NSC acknowledges a lack of progress in patient safety despite the many evidence-based practices for harm reduction identified by individual organizations, because they are seldom shared beyond the organization or effectively implemented across multiple organizations. NSC concludes that "It has become clear that reducing preventable harm is a complex endeavor that requires a concerted, persistent, coordinated effort by all stakeholders, and a total systems approach to safety."[11(p11)]

EDR Use in Oregon, July 2014 – June 2020

255

Requests for Conversation Submitted

Figure 1. Requests for Conversation by EDR Year

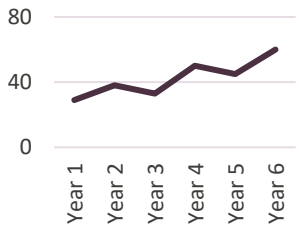
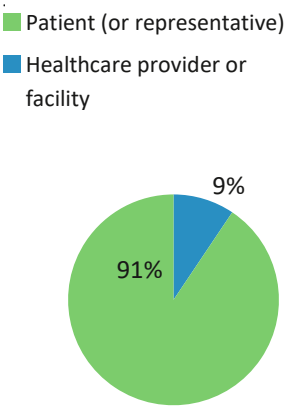


Figure 2. Requests for Conversation by Requester



Oregon Legislators created an innovative program to help accelerate the culture change necessary for improved safety across Oregon's healthcare system—Early Discussion and Resolution (EDR).[vi] The Oregon Patient Safety Commission (OPSC)[vii] was designated to administer EDR and share information and best practices to help Oregon's healthcare system move forward together.

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

In 2013, Oregon Legislators sought to address medical liability in the state by creating EDR, an alternate 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 establishing a safe space for healthcare providers and facilities to talk openly with patients about what happened and work toward restitution. Transparency about medical harm also creates an environment where learning and improvement are possible, positioning EDR to be a lever for culture change in Oregon.

Two other states, Colorado[viii] and Iowa,[ix] 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.

Through EDR, Oregon has also become an important contributor to the national dialogue on advancing patient safety by promoting greater transparency and accountability following unintended patient harm. One example of this is through OPSC's work with the Collaborative for Accountability and Improvement (CAI). CAI is a network of some of the leading innovators and experts in healthcare, law, and patient advocacy working to find a better way to resolve medical harm for patients and providers.

Characteristics of Oregon Patients in EDR Requests for Conversation, July 2014 – June 2020

Figure 3. Patient Gender

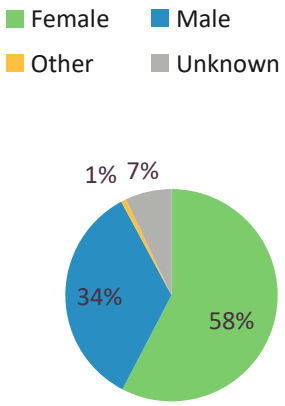
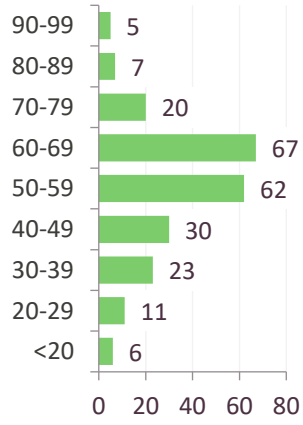


Figure 4. Patient Age Groups



[vi] Oregon Laws 2013, Chapter 5. www.oregonlegislature.gov/bills_laws/lawsstatutes/2013orLaw0005.pdf.
[vii] See Appendix IV for more information on OPSC's role.
[viii] 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.
[ix] Iowa Code §135P (2017): Adverse Health Care Incidents—Communications. https://www.legis.iowa.gov/docs/code/2017/135P.pdf.

EDR: A Lever for Culture Change in Oregon

In July 2014, EDR began accepting Requests for Conversation to help address the core issue that drives medical malpractice claims—patient harm from medical care. EDR promotes talking openly with patients and families when medical care results in serious patient harm or death. 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 claims. Further, it provides a process for patients and families to receive a full explanation about what happened, the lack of which is often cited by plaintiffs as a reason they chose to pursue litigation.[1–4]

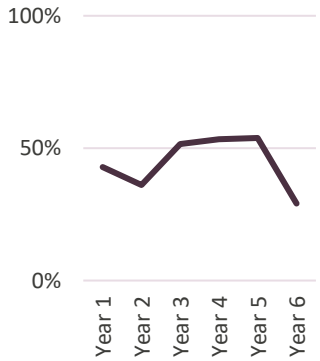
Because EDR is a culture change program at its core, we have used culture change as our lens to evaluate EDR in Oregon, framing our discussion around the following concepts:

I. A culture of safety is essential to make progress in patient safety.
II. Infrastructure and culture are interdependent.
III. EDR can accelerate progress toward a culture of safety.

We have also included key lessons from our in-depth evaluation of EDR, submitted to the Legislature in 2019, updated to reflect additional research.

Our evaluation of the first six years of EDR has demonstrated 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, to 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[x] will remain in place or 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 2020



[x] See Appendix I for a definition of *protections*.

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,* the National Patient Safety Foundation (NPSF) identified leadership support for a culture of safety as the most important of their recommendations for achieving patient safety, noting that progress in patient safety requires an organizational culture that enables and prioritizes safety.[21]

What Culture of Safety Looks Like

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.[23] NPSF describes a strong culture of safety as "one in which health care professionals and leaders are held accountable for unprofessional conduct yet not punished for human mistakes; errors are identified and mitigated before they harm patients; and strong feedback loops enable frontline staff to learn from previous errors and alter care processes to prevent recurrences."[21(p11)]

Without a culture of safety, well-intentioned patient safety improvement efforts are ineffective and unsustainable.[24,25] How we, as a society, respond to medical harm may be impeding progress in patient safety. In a recent article in *BMJ Quality & Safety,* Peter Smulowitz summarized this issue:

> "The reliance on litigation both as a punitive and preventive measure against future mistakes is misguided, and there is simply no way to prevent future errors by holding a single physician responsible for what is often a cascade of human frailties."[26(p346)]

"Improving the culture of safety within health care is an essential component of preventing or reducing errors and improving overall health care quality… Improved culture is not the means to an end but an end itself."

—AHRQ 2019[22]

"...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)]

"There is good reason to believe that both of these aims [(providing an efficient and effective means for providing compensation and effectively preventing medical errors)] would be better accomplished through a system that removed the fear and stigma of personal accusation from medical errors, divorced compensation for injury from the affixing of moral blame, and encouraged reporting and review of errors so that ways to avoid similar errors in the future could be identified."

— May & Aulisio 2001[27(p144)]

II. Infrastructure and Culture are Interdependent

Despite the increasing expectation that patients or their families will be fully informed when medical harm occurs, current practice often falls short of this expectation.[10,28] The infrastructure that exists for responding to these events through the legal system is not designed to encourage transparency with patients and families. Instead, these systems often focus on assigning individual blame or addressing specific harms for what are frequently system errors, and, as designed, do not foster a culture of safety.[20,29–31]

To develop the necessary culture of safety, organizations must have systems in place to consistently and effectively respond to patient harm, and prioritize patient safety, transparency, and learning. This requires healthcare leadership to overhaul existing systems for responding to medical harm. Oregon can learn from leading healthcare organizations across the country that have implemented comprehensive programs for responding to patient harm called communication and resolution programs (CRPs). In a recent *BMJ Quality & Safety* editorial, national CRP experts wrote "CRPs appear to improve patient and provider experiences, patient safety, and in many settings lower defense and liability costs in the short term and improve peer review and stimulate quality and safety over time."[12(p2)]

In 2016, the Agency for Healthcare Research and Quality (AHRQ) published their CRP toolkit for responding to patient harm and work toward resolution— Communication and Optimal Resolution (CANDOR).[33] The CANDOR Toolkit provides a structured process for ongoing communication with and care for the affected patient and family, support for involved healthcare providers , a focus on system-based learning to prevent recurrence, and compensation for patient and families where appropriate. CANDOR provides organizations with a roadmap to build and sustain a culture of safety. And here in Oregon, OPSC's programs align with organizations' efforts to implement CANDOR by supporting two core elements of the model (Figure 5).

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

—W. Edwards Deming

"[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"

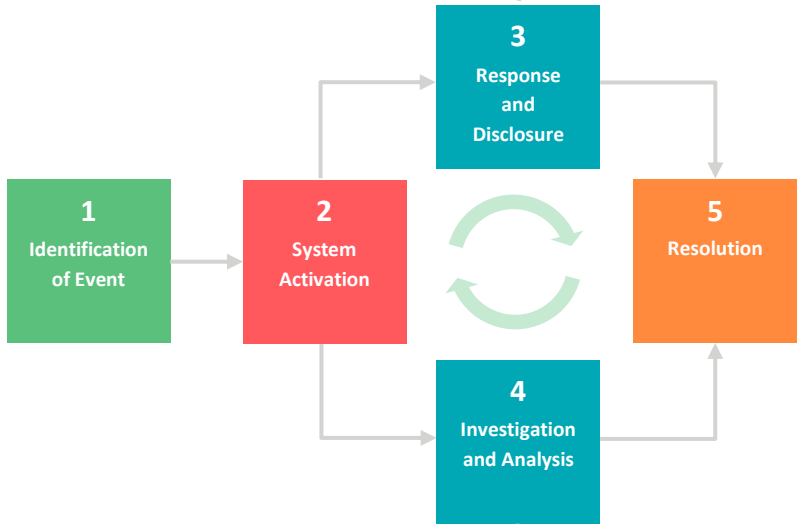
—Lambert et al. 2016[32(p2512)]

"When patients are harmed, CRPs honour patients' trust and caregivers' selfless dedication with honesty, transparency, best efforts at reconciliation for all and relentless determination to improve."

—Gallagher et al. 2020[12(p3)]

Figure 5. The CANDOR[33] Process: A Model for Building and Sustaining a Culture of Safety, and Alignment with OPSC's Programs

Early Discussion and Resolution (EDR): Oregon healthcare facilities can integrate EDR into their own systems and processes for communicating with patients and families about serious patient harm events.



Patient Safety Reporting Program (PSRP): Oregon healthcare facilities contribute information from their adverse event investigation and analysis to a database for continuous learning, without fear of blame or punishment. The Oregon Patient Safety Commission shares this aggregated information statewide to help organizations minimize risk and design safer systems of care.

"Fundamentally CANDOR and other comprehensive CRP approaches seek to "normalize compassionate honesty" as a cultural transformation goal in the organizations where they are implemented. CANDOR, as with all CRPs, represents a paradigm shift from a traditional, defensive posture to a more timely, open, and honest response to patient harm."

—McDonald et al. 2018[34(p74)]

Fundamentally changing the infrastructure for responding to patient harm to move toward a transparent, patient-centered approach requires commitment and support from the highest levels of leadership, both within organizations and at the policy level.

- **Organizational leadership:** Leadership in healthcare organizations must prioritize building systems that allow for a quick response to patient harm and other risks. These systems must cultivate a culture of safety by focusing on learning, ongoing problem solving to strengthen systems of care, and supporting the people working within those systems. Evidence-based tools like CANDOR can serve as a roadmap for organizations committed to implementing a CRP approach to drive a culture of safety and improve care delivery.
  State-level leadership: Legislative leaders in Oregon have prioritized this issue by developing and supporting EDR to help pave the way for change. Continued support for EDR and other

"While leadership and governance structures vary across health care organizations (e.g., not all organizations are governed by a board of directors), all leaders have an obligation to substantially advance patient and workforce safety by committing to safety and the elimination of harm."

—National Steering Committee for Patient Safety 2020[11(p17)]

policies and programs that drive culture change is necessary to continue to make progress and sustain it.

COVID-19 has Highlighted the Need for Robust Systems that Cultivate a Culture of Safety

Attending to patient and provider safety has never felt more urgent than during the COVID-19 pandemic. An organization with a culture of safety and systems in place to quickly respond to and address safety issues that arise during the normal course of providing care will be better equipped to navigate the additional stressors brought on by the pandemic.

Pre-existing safety issues can be exacerbated by things like fatigue, burnout, illness, and poor psychological safety, inhibiting the ability of healthcare providers to safely deliver care and contributing to adverse events.[36] Whether the safety issue is related to the safe administration of medication, having adequate personal protective equipment for staff, or even having adequate staffing levels, an organization with a culture of safety will be better equipped to navigate these situations.

Building organizational capacity to address safety issues on an ongoing basis is more important than ever as organizations face this pandemic, and a culture of safety is foundational to these efforts. Leadership must continue to prioritize and resource systems that promote culture development to keep their patients and providers safe.

"COVID-19 offers a unique opportunity to reflect on two common catchphrases pertinent to a systemic understanding of our world: *nothing happens in isolation*, and *context is everything*."

—Sturmberg & Martin 2020[35(p5)]

"The uncertainties triggered by COVID-19 have not only shown the fragility of health and national systems but also highlighted the intrinsic and tacit dynamics underpinning them."

—Sturmberg & Martin 2020[35(p1)]

III. EDR Accelerates Progress toward a Culture of Safety

Although culture change takes time, EDR continues to serve as a catalyst for change in Oregon. Healthcare providers, facilities, and Oregonians alike have a more transparent path for responding to patient harm from medical care. Oregon's approach allows healthcare providers and facilities to continue to care for patients, support involved providers, and build their capacity to proactively respond to and address safety issues that arise.

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

—Mello et al. 2016[37(p2566)]

State lawmakers can continue to demonstrate that Oregon is a national role model by prioritizing and driving 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."[37(p2567)]

"Other cultural manifestations are created or shaped externally, perhaps by the macro policy environment (for example, service configurations or reward systems), but over time these can influence shared ways of thinking and even deeper assumptions (about who or what is valued, for example)."

—Mannion and Davies 2018[38(p2)]

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

- **EDR creates confidentiality protections[xi] 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 EDR's first six years, 91% of 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.[39]
- **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

[xi] See Appendix I for a definition of *protections*.

employment relationships. Patients often don't know where to 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 reconciliation. This enables broader processes and system improvements to be put into place statewide, to the benefit of all Oregonians.

In the complex and rapidly changing healthcare delivery system, patient safety work is ongoing. With the introduction of new processes, systems, and technologies in healthcare, new and often unanticipated risks are also introduced. To effectively manage the wide range of safety issues that will arise, healthcare organizations must both anticipate these risks and continually adjust their systems.

"Because some patients will be reluctant to report breakdowns to care team members, it may be advisable for clinicians to explicitly acknowledge this and offer an alternative contact."

—Fisher et al. 2020[40(p268)]

"Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations."

—National Patient Safety Foundation 2012[21(p14)]

Additional Efforts to Drive Culture Change in Oregon

In addition to administering EDR, OPSC shares information and best-practice strategies for responding to patient harm and cultivating a culture of patient safety. Examples of how OPSC has supported Oregon's healthcare community, as well as the public, to help drive culture change include:

- **Cultivated early adoption of a transparent approach.** OPSC convened the Oregon Collaborative on Communication and Resolution Programs (OCCRP), to help organizations build capacity to respond to medical harm with transparency and strengthen their culture of safety.
- **Made best-practice information and education broadly available.** 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 through educational offerings. (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.

The Current State: Where We Are on Our Culture Change Journey

We sought to understand where the culture of healthcare is today, recognizing that there is variation among healthcare organizations. We've categorized key lessons for EDR into three interconnected themes 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:

- The substantial effect of medical harm on patients and families can be compounded by the response of healthcare providers and facilities.
- 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.

It is also important to note that pinpointing the impact of EDR on medical liability claims or patient safety is difficult at the state level, even more so than within individual healthcare organizations. 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:

- There is no mechanism to capture the total number of qualifying harm events occurring[13,19,21,43,44] or the number of statewide claims related to these events.[45]
- Organizations that have chosen to use EDR may be simultaneously working on other initiatives, making it difficult to isolate the role of EDR.

Additionally, we will never be able to quantify the future harms prevented by the patient safety improvements that are a key component of an organization's response to patient harm.[46] This is often the nature of patient safety work. We must remain focused on the value of this work—to prevent patient harm.

"What is clear is that healthcare now needs to assume collective responsibility. It needs to tackle its safety problems as a sector through coordinated, interdependent and integrated action and collective, consensual solutions."

—Dixon-Woods & Pronovost 2016[41(p488)]

"Patients and families experience harm from the harmful event itself, but they can also experience secondary harms from how the event was handled."

—Ottosen et al. 2018[42(p1)]

Evaluation Data Sources

Key lessons from EDR implementation in Oregon have been drawn from a comprehensive analysis process that includes:

- **EDR program data:** Collected by OPSC from July 1, 2014 to June 30, 2020.
- **Stakeholder input:** A qualitative analysis (see Appendix II) of input from the many stakeholders affected by EDR across Oregon, including healthcare consumers, healthcare providers, and facilities, as well as liability insurers and the legal (trial and defense lawyers) and mediation communities.
- **Literature review:** A summary of patient safety research to understand the foundational evidence base for transparency following patient harm.

Key Lessons

The substantial effect of medical harm on patients and families can be compounded by the response of healthcare providers and facilities.

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 factors 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.[47,48] 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.[49,50]

"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

"…[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

"…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

"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

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, they feared that they may 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 especially in smaller and rural communities where options for care may be limited. These sentiments were echoed in our survey data as well. One respondent wrote, "Some patients feel that they would be labeled 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.[51] 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."[52(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.[1,3,31] Over the course of the first six 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

"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

"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

"I think [mediator participation is] equally as threatening [as] when a patient comes in with their lawyer."

—Healthcare Professional 29

"If you're in a mediation, you're in lawsuit land."

—Healthcare Professional 14

contains both support for the idea of attorney participation on behalf of the patient[3,29,34,53,54] and recognition that attorney participation is not without its drawbacks.[29,53] We found the same range of opinions in our stakeholder survey responses and stakeholder interviews.

- Attorneys and/or mediators need the right experience and training to effectively support patients.[3,53–55] 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.
- Attorney and/or mediator participation also puts an additional logistical and financial burden on patients.[27] 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.[31] 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.[53,54]
- 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.[53] 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. Healthcare providers and/or facilities are likely to have legal representation, risk management, and clinical experts at the table for these conversations. Patients may be seeking the support of an attorney or mediator to help level the imbalance of power during the conversation.

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.

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

—Healthcare Professional 21

"I would think the patient involved is almost always going to feel like they don't hold the power in that situation."

—Mediator 3

"Because of the rarity of suits, most physicians have little familiarity with them. The consequences of being sued are perceived as potentially disastrous to one's medical reputation, psychological well-being, and financial stability. Finally, physicians tend to view lawsuits as random events, unpredictable and uncontrollable, because they are not viewed as related to the quality of care provided.29 These factors may lead to a fear of suits that seems out of proportion to the actual risk of being sued."

—Carrier et al. 2010[56(p1591)]

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.[6,57] 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.[1,47,48] Thirty-four states, 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).[58] 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.[6,8,31,59] Providers also fear reputational damage from regulatory action or a report to the National Practitioner Data Bank (NPDB) following a payment made on their behalf.[29,57,59,60] 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.[61] Interestingly, of the 198 patient Requests for Conversation OPSC received during the evaluation period, only 6% could be associated with a later court filing.[xii]

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 is said or written about you appears in conjunction with media-related fears. Loss of professional reputation among their peers was identified exclusively by healthcare providers as a fear.

There are barriers for providers to participate in open conversation. Research suggests that healthcare providers are often uncomfortable

"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

[xii] Requests for Conversation were compared against the Oregon eCourt Case Information (OECI) system (https://publicaccess.courts.oregon.gov).

openly discussing a medical harm event with a patient.[62,63] This discomfort may stem from a lack of training in disclosure, and/or a cultural reluctance to admit involvement in negative patient outcomes.[29,53] Despite a culture that may reinforce an expectation of perfection,[64] healthcare providers are human, and they do 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 emotions 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, 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 use EDR to initiate conversations with patients following medical harm. Only 9% of the requests for conversation submitted in the first six years of implementation were submitted by healthcare providers, employers of providers, or facilities. Moreover, more than half of the requests for conversation submitted by patients in the first six years (56%) were declined by all named facilities and healthcare providers.

"The challenge of effectively disclosing and resolving adverse medical outcomes will continue to be most formidable for health care systems with independent medical staffs with separate liability carriers."

— O'Connell 2019[65(p217)]

"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

EDR Enhances Processes for Responding to Patient Harm

EDR is a tool that is intended to enhance a healthcare organization's internal processes for responding to patient harm. When healthcare providers and facilities choose not to accept a patient's Request for Conversation, OPSC asks why they are declining the request. Over one-third of these responses indicated that providers and facilities were using an internal process and choosing not to include EDR. This may indicate a misunderstanding that EDR is a separate process rather than an enhancement to their internal process.

Over the six years of the program, healthcare providers and facilities have given 255 decline reasons (multiple reasons can be given). Some requests result in one party accepting and another declining. These are the most frequently given:

- 36% Intend to use a different process and will not incorporate EDR
- 16% Have already addressed this event through another process
- 6% Advised against participation by liability insurer
- 5% Advised against participation by legal counsel
- 2% Advised against participation by employer

"If they can believe in the process and they can believe that it can work, then they will get there. And they will participate."

—Healthcare Professional 29

Existing 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. It may also result in a disjointed, duplicative, or delayed response experienced by patients or their families following a harm event.[37]

"They looked at me and said, we don't have any liability because they're not our employee, which I found to be amazing. But I had no idea."

—Patient 1

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 incentives to "…shift the blame for medical errors to one another rather than collaborate on a joint resolution."[37(p2551)] Additionally, the insurers for the healthcare provider and the facility may have differing structures and philosophies about proactively negotiating settlements.[37,66]

"How disjointed is our system if somebody was treated at [Hospital A], but then they go to [Hospital B] and get their diagnosis. The people at [Hospital A] have no idea if they were off base to begin with."

—Healthcare Professional 16

Of the patient Requests for Conversation[xiii] through EDR that named a facility and at least one healthcare provider, 55% of the named healthcare providers were independent contractors (103/188) 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]

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

—Healthcare Professional 30

Few healthcare organizations have systems in place to offer the type of support healthcare providers need if they are involved in a harm event. Patient harm events are traumatic not only for the patient and family, but also for the healthcare provider.[9] 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.[67] 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.[68] 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.[69]

"The goal isn't to shame individual clinicians but to build resilient systems around them that support optimal behaviors."

—Sivashanker and Gandhi 2020[70(p310)]

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

—Healthcare Professional 20

Healthcare providers need ongoing training on how to have effective conversations. Many healthcare providers now receive training in how to disclose an adverse event.[10] However, there should be a system for consistent, patient-centered training that is available both on-demand and on a routine basis.[3,4,63] Promising research suggests that providers with previous exposure to disclosure training had more positive responses on disclosure culture scales.[10]

"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

Healthcare providers and facilities need systems in place 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 healing, loss of trust, and impeded learning for improved care.[1,48] A lack of a timely response may also make patients more likely to file a lawsuit.[67] Infrastructure to support a prompt and compassionate response is necessary. Some organizations have

"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."

—Mello et al. 2016[37(p2567)]

[xiii] See Appendix I for definitions of terms used in this report.

implemented elements of a CRP to support a consistent, systematic response to patient harm; however, adoption is not widespread.[37,55] 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. However, O'Connell 2019 cautions that even with best practices or toolkits, full disclosure and fair resolution of harm events will not be "more likely without a counterweight of solid ethical commitment and a reliable structure for ensuring adherence."[65(p217)]

"Other innovators began to design, launch, and publish their own versions of CRPs, none of which to date have reported a negative financial impact."

—McDonald et al. 2018[34(p73)]

CRPs Show Promise for Addressing Medical Liability

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.[71]

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)

"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

Despite promising findings from early CRPs, concern remains that increased transparency about harm events will increase liability,[72] which is also echoed by stakeholders 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."[72(p1836)]

"Because one of the concerns that providers have about this process is that it basically lays out a road map for litigation."

—Healthcare Professional 14

We have work to do to live up to our ideals and meet the expectations of Oregonians. 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

"The momentum for change is now too great for any stakeholder group to brush aside demands for transparency."

—Gallagher et al. 2007[63(p2717)]

vast majority of respondents (91%) did, however, believe that conversations about those events can contribute to or lead to improved safety for future patients. 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.

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**, absence of a conversation 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 root[47] 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 an effective way to alleviate their personal and professional distress.[9] Moral distress is also a root cause of provider burnout.[73]
- **For the healthcare system**, silence squanders an opportunity to improve systems of care by addressing the underlying safety issues.[10,74,75] It degrades the institutional culture and climate. Ultimately, it reduces public trust in healthcare.

Inequity in healthcare is systematically linked to patient safety. We cannot have a conversation about patient harm without acknowledging the relationship between patient safety and health inequity—the differences in health outcomes that are systematic, avoidable, and unjust.[76–78] Factors such as race, sex, language, and socioeconomic class contribute to pervasive health inequities in the U.S. healthcare system.[70] One study[77] identified race differences for serious harm events by both type of event and hospital setting for events reported in a voluntary reporting system. There is, however, limited information about why these differences exist. Organizations must take purposeful action to integrate equity into all their systems of care, including their response to medical harm, by seeking to understand and address the root causes of inequity in patient safety.

"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

"[T]here is no such thing as high-quality, safe care that is inequitable. Observations like this one frequently provoke a defend-and-deny reaction because of our tendency to personalize critiques of systems. But inequity in health care is a systems-based problem that requires a systems-based approach."

—Sivashanker and Gandhi 2020[70(p310)]

"Inequities result in a concentration of harm in specific population groups, based on characteristics such as race, ethnicity, sexual orientation, gender, age, disability, and income and must be considered when designing safety efforts to ensure that inequities are being addressed."

— National Steering Committee for Patient Safety 2020[11(p16)]

Conclusion and Recommendation

Through our evaluation of six years of EDR implementation in Oregon (July 2014 – June 2020), 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:

- Minimize 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 seek resolution for specific harm events.
- Cultivate the culture of safety necessary to improve our care delivery system 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 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.[xiv] EDR's continuation reinforces our state's commitment to patients who have been harmed by medical care, their families, and healthcare providers involved in harm events and maintain the opportunity for progress and innovation in Oregon's healthcare system.

"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

"Provider-Patient-Family conversations are so important at all stages of care. 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

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

—Survey Respondent

"The real tragedy — and the real opportunity — is that [systemic problems] are solvable problems. We know what to do about criminal justice. We know what to do about hunger. We know how to give people homes. We know how to use science as a basis for policy. We know how to address a whole host of systemic issues. We have the answers. We are just not yet using what we know. Isn't it time that we do so?"

—Berwick 2020[79]

[xiv] 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 Collaborative for Accountability and Improvement
- 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

References

1. Helo S, Moulton C-AE. Complications: acknowledging, managing, and coping with human error. *Transl Androl Urol*. 2017;6(4):773-782. doi:10.21037/tau.2017.06.28

2. Mazor KM, Simon SR, Gurwitz JH. Communicating with Patients About Medical Errors: A Review of the Literature. *Arch Intern Med*. 2004;164(15):1690-1697. doi:10.1001/archinte.164.15.1690

3. Moore J, Bismark M, Mello MM. Patients' Experiences with Communication-and-Resolution Programs After Medical Injury. *JAMA Intern Med*. 2017;177(11):1595-1603. doi:10.1001/jamainternmed.2017.4002

4. Nazione S, Pace K. An Experimental Study of Medical Error Explanations: Do Apology, Empathy, Corrective Action, and Compensation Alter Intentions and Attitudes? *Journal of Health Communication*. 2015;20(12):1422-1432. doi:10.1080/10810730.2015.1018646

5. Hemmelgarn C. Commentary: Silence. In: *Advances in Patient Safety and Medical Liability*. Agency for Healthcare Research and Quality; 2017:5-7. Accessed October 30, 2019. https://www.ncbi.nlm.nih.gov/books/NBK508084/pdf/Bookshelf_NBK508084.pdf#page=12

6. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors. *JAMA*. 2003;289(8):1001-1007. doi:10.1001/jama.289.8.1001

7. Shepherd L, LaDonna KA, Cristancho SM, Chahine S. How Medical Error Shapes Physicians' Perceptions of Learning: An Exploratory Study. *Academic Medicine*. 2019;94(8):1157-1163. doi:10.1097/ACM.0000000000002752

8. Delbanco T, Bell SK. Guilty, Afraid, and Alone — Struggling with Medical Error. *New England Journal of Medicine*. 2007;357(17):1682-1683. doi:10.1056/NEJMp078104

9. Elwy AR, Itani KMF, Bokhour BG, et al. Surgeons' Disclosures of Clinical Adverse Events. *JAMA Surg*. 2016;151(11):1015-1021. doi:10.1001/jamasurg.2016.1787

10. Etchegaray JM, Gallagher TH, Bell SK, Dunlap B, Thomas EJ. Error disclosure: a new domain for safety culture assessment. *BMJ Qual Saf*. 2012;21(7):594-599. doi:10.1136/bmjqs-2011-000530

11. National Steering Committee for Patient Safety. *Safer Together: A National Action Plan to Advance Patient Safety*. Institute for Healthcare Improvement (IHI); 2020:41 pages. Accessed September 22, 2020. www.ihi.org/SafetyActionPlan

12. Gallagher TH, Boothman RC, Schweitzer L, Benjamin EM. Making communication and resolution programmes mission critical in healthcare organisations. *BMJ Qual Saf*. Published online May 5, 2020. doi:10.1136/bmjqs-2020-010855

13. Classen DC, Resar R, Griffin F, et al. "Global trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)*. 2011;30(4):581-589. doi:10.1377/hlthaff.2011.0190

14. deVries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. 2008;17(3):216-223. doi:10.1136/qshc.2007.023622

15. James JT. A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. *Journal of Patient Safety*. 2013;9(3):122. doi:10.1097/PTS.0b013e3182948a69

16. Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal Trends in Rates of Patient Harm Resulting from Medical Care. *New England Journal of Medicine*. 2010;363(22):2124-2134. doi:10.1056/NEJMsa1004404

17. Levinson DR. *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*. Department of Health and Human Services Office of Inspector General; 2014. Accessed December 9, 2019. https://oig.hhs.gov/oei/reports/oei-06-14-00530.asp

18. Levinson DR. *Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries Report*. Department of Health and Human Services Office of Inspector General; 2018. Accessed January 14, 2019. https://oig.hhs.gov/oei/reports/oei-06-14-00530.asp

19. Woods DM, Thomas EJ, Holl JL, Weiss KB, Brennan TA. Ambulatory care adverse events and preventable adverse events leading to a hospital admission. *Quality and Safety in Health Care*. 2007;16(2):127-131. doi:10.1136/qshc.2006.021147

20. Phillips-Bute B. Transparency and Disclosure of Medical Errors: It's the Right Thing to Do, So Why the Reluctance. *Campbell L Rev*. 2013;35(3):333-354.

21. National Patient Safety Foundation. *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human*. National Patient Safety Foundation; 2015.

22. Agency for Healthcare Research and Quality. Patient Safety Primer: Culture of Safety. AHRQ Patient Safety Network. Published September 2019. Accessed December 1, 2020. http://psnet.ahrq.gov/primer/culture-safety

23. Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM. Promoting a Culture of Safety as a Patient Safety Strategy: A Systematic Review. *Ann Intern Med*. 2013;158(5_Part_2):369. doi:10.7326/0003-4819-158-5-201303051-00002

24. David DS. The Association Between Organizational Culture and the Ability to Benefit From "Just Culture" Training. *Journal of Patient Safety*. 2019;15(1):e3-e7. doi:10.1097/PTS.0000000000000561

25. Armstrong N, Brewster L, Tarrant C, et al. Taking the heat or taking the temperature? A qualitative study of a large-scale exercise in seeking to measure for improvement, not blame. *Social Science & Medicine*. 2018;198:157-164. doi:10.1016/j.socscimed.2017.12.033

26. Smulowitz P. The illusion of perfection. *BMJ Qual Saf*. 2020;29(4):345-347. doi:10.1136/bmjqs-2019-010501

27. May T, Aulisio MP. Medical malpractice, mistake prevention, and compensation. *Kennedy Inst Ethics J*. 2001;11(2):135-146. doi:10.1353/ken.2001.0014

28. Wu AW, McCay L, Levinson W, et al. Disclosing Adverse Events to Patients: International Norms and Trends. *Journal of Patient Safety*. 2017;13(1):43-49. doi:10.1097/PTS.0000000000000107

29. Bell SK, Smulowitz PB, Woodward AC, et al. Disclosure, Apology, and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation: Disclosure, Apology, and Offer Programs. *The Milbank Quarterly*. 2012;90(4):682-705. doi:10.1111/j.1468-0009.2012.00679.x

30. Clinton HR, Obama B. Making Patient Safety the Centerpiece of Medical Liability Reform. *New England Journal of Medicine*. 2006;354(21):2205-2208. doi:10.1056/NEJMp068100

31. Sage WM, Gallagher TH, Armstrong S, et al. How Policy Makers Can Smooth the Way for Communication-And-Resolution Programs. *Health Affairs*. 2014;33(1):11-19. doi:10.1377/hlthaff.2013.0930

32. Lambert BL, Centomani NM, Smith KM, et al. The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes. *Health Services Research*. 2016;51(S3):2491-2515. doi:10.1111/1475-6773.12548

33. Agency for Healthcare Research and Quality. Communication and Optimal Resolution (CANDOR) Toolkit. Agency for Healthcare Research and Quality. Published May 17, 2016. Accessed September 17, 2018. https://www.ahrq.gov/patient-safety/capacity/candor/modules.html

34. McDonald TB, Van Niel M, Gocke H, Tarnow D, Hatlie M, Gallagher TH. Implementing communication and resolution programs: Lessons learned from the first 200 hospitals. *Journal of Patient Safety and Risk Management*. 2018;23(2):73-78. doi:10.1177/2516043518763451

35. Sturmberg JP, Martin CM. COVID-19 – how a pandemic reveals that everything is connected to everything else. *Journal of Evaluation in Clinical Practice*. 2020;In press:7 pages. doi:10.1111/jep.13419

36. Agency for Healthcare Research and Quality. Patient Safety Primer: COVID-19: Team and Human Factors to Improve Safety. AHRQ Patient Safety Network. Published May 2020. Accessed June 4, 2020. http://psnet.ahrq.gov/primer/covid-19-team-and-human-factors-improve-safety

37. Mello MM, Armstrong SJ, Greenberg Y, McCotter PI, Gallagher TH. Challenges of Implementing a Communication-and-Resolution Program Where Multiple Organizations Must Cooperate. *Health Services Research*. 2016;51(S3):2550-2568. doi:10.1111/1475-6773.12580

38. Mannion R, Davies H. Understanding organisational culture for healthcare quality improvement. *BMJ*. 2018;363:k4907. doi:10.1136/bmj.k4907

39. McCreaddie M, Benwell B, Gritti A. Traumatic journeys; understanding the rhetoric of patients' complaints. *BMC Health Services Research*. 2018;18(1):551. doi:10.1186/s12913-018-3339-8

40. Fisher KA, Smith KM, Gallagher TH, Huang JC, Mazor KM. We Want to Know—A Mixed Methods Evaluation of a Comprehensive Program Designed to Detect and Address Patient-Reported Breakdowns in Care. *JCJQPS*. 2020;46(5):261-269. doi:10.1016/j.jcjq.2020.01.008

41. Dixon-Woods M, Pronovost PJ. Patient safety and the problem of many hands. *BMJ Qual Saf*. 2016;25(7):485-488. doi:10.1136/bmjqs-2016-005232

42. Ottosen MJ, Sedlock EW, Aigbe AO, Bell SK, Gallagher TH, Thomas EJ. Long-Term Impacts Faced by Patients and Families After Harmful Healthcare Events. *J Patient Saf*. 2018;In press. doi:10.1097/PTS.0000000000000451

43. Institute of Medicine (US) Committee on Quality of Health Care in America. *To Err Is Human: Building a Safer Health System*. (Kohn LT, Corrigan JM, Donaldson MS, eds.). National Academies Press; 2000. Accessed October 4, 2018. http://www.ncbi.nlm.nih.gov/books/NBK225182/

44. Shojania KG, Dixon-Woods M. Estimating deaths due to medical error: the ongoing controversy and why it matters. *BMJ Qual Saf*. 2017;26(5):423-428. doi:10.1136/bmjqs-2016-006144

45. Mello MM, Studdert DM. Building a National Surveillance System for Malpractice Claims. *Health Services Research*. 2016;51(S3):2642-2648. doi:10.1111/1475-6773.12623

46. Berwick DM. *Promising Care: How We Can Rescue Health Care by Improving It*. John Wiley & Sons; 2013.

47. Boothman RC, Blackwell AC, Campbell, Jr. DA, Commiskey E, Anderson S. A Better Approach to Medical Malpractice Claims? The University of Michigan Experience. *Journal of Health & Life Sciences Law*. 2009;2(2):125-159.

48. Duclos CW, Eichler M, Taylor L, et al. Patient perspectives of patient–provider communication after adverse events. *International Journal for Quality in Health Care*. 2005;17(6):479-486. doi:10.1093/intqhc/mzi065

49. Iedema R, Allen S, Britton K, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study. *BMJ*. 2011;343(jul25 1):d4423-d4423. doi:10.1136/bmj.d4423

50. Mazor KM, Greene SM, Roblin D, et al. More than words: Patients' views on apology and disclosure when things go wrong in cancer care. *Patient Education and Counseling*. 2013;90(3):341-346. doi:10.1016/j.pec.2011.07.010

51. Bell SK, Roche SD, Mueller A, et al. Speaking up about care concerns in the ICU: patient and family experiences, attitudes and perceived barriers. *BMJ Qual Saf*. 2018;27(11):928-936. doi:10.1136/bmjqs-2017-007525

52. Doherty C, Stavropoulou C. Patients' willingness and ability to participate actively in the reduction of clinical errors: A systematic literature review. *Social Science & Medicine*. 2012;75(2):257-263. doi:10.1016/j.socscimed.2012.02.056

53. Mello MM, Boothman RC, McDonald TB, et al. Communication-and-resolution programs: the challenges and lessons learned from six early adopters. *Health Aff (Millwood)*. 2014;33(1):20-29. doi:10.1377/hlthaff.2013.0828

54. Van Niel MB, DeVoe T, Shah R, Sands KEF. *Patient Representation in Communication and Resolution Programs*. University of Florida J. Hillis Miller Self-Insurance Program; 2016:10 pages.

55. Gallagher TH, Mello MM, Sage WM, Bell SK, McDonald TB, Thomas EJ. Can Communication-And-Resolution Programs Achieve Their Potential? Five Key Questions. *Health Affairs*. 2018;37(11):1845-1852. doi:10.1377/hlthaff.2018.0727

56. Carrier ER, Reschovsky JD, Mello MM, Mayrell RC, Katz D. Physicians' Fears of Malpractice Lawsuits are not Assuaged by Tort Reforms. *Health Affairs*. 2010;29(9):1585-1592. doi:10.1377/hlthaff.2010.0135

57. Oliver D. David Oliver: Fear in medical practice. *BMJ*. 2019;367:l6030. doi:10.1136/bmj.l6030

58. McMichael BJ, Van Horn RL, Viscusi WK. "Sorry" Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk. *Stanford Law Review*. 2019;71(2):341-409.

59. Hobgood C, Tamayo-Sarver JH, Elms A, Weiner B. Parental Preferences for Error Disclosure, Reporting, and Legal Action After Medical Error in the Care of Their Children. *Pediatrics*. 2005;116(6):1276-1286. doi:10.1542/peds.2005-0946

60. LeCraw FR, Stearns SC, McCoy MJ. How U.S. Teams advanced communication and resolution program adoption at local, state and national levels. *Journal of Patient Safety and Risk Management*. 2020;In Press:7 pages. doi:10.1177/2516043520973818

61. Kaldjian LC, Forman-Hoffman VL, Jones EW, Wu BJ, Levi BH, Rosenthal GE. Do faculty and resident physicians discuss their medical errors? *Journal of Medical Ethics*. 2008;34(10):717-722. doi:10.1136/jme.2007.023713

62. Bismark MM. The power of apology. *N Z Med J*. 2009;122(1304):96-106.

63. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med*. 2007;356(26):2713-2719. doi:10.1056/NEJMra070568

64. Dunbar J, Reddy P, May S. *Deadly Healthcare*. Australian Academic Press; 2011.

65. O'Connell D. Disclosure After Adverse Medical Outcomes: A Multidimensional Challenge. *Journal of Clinical Outcomes Management*. 2019;26(5):213-218.

66. Smith KM, Smith LL, Gentry JC (Jack), Mayer DB. Lessons learned from implementing a principled approach to resolution following patient harm. *Journal of Patient Safety and Risk Management*. 2019;24(2):83-89. doi:10.1177/2516043518813814

67. Vanhaecht K, Seys D, Schouten L, et al. Duration of second victim symptoms in the aftermath of a patient safety incident and association with the level of patient harm: a cross-sectional study in the Netherlands. *BMJ Open*. 2019;9(7):e029923. doi:10.1136/bmjopen-2019-029923

68. White AA, Brock D, McCotter PI, et al. Risk Managers' Descriptions of Programs to Support Second Victims after Adverse Events. *J Healthc Risk Manag*. 2015;34(4):30-40. doi:10.1002/jhrm.21169

69. McDonald TB. Essential Tools and Practices for Every Healthcare Setting. Presented at the: 7th Annual Oregon Patient Safety Forum, Oregon Patient Safety Commission; March 2018; Portland, OR. Accessed September 13, 2018. https://oregonpatientsafety.org/docs/resources/2018_Patient_Safety_Forum_Main_Slide_Deck.pdf

70. Sivashanker K, Gandhi TK. Advancing Safety and Equity Together. *N Engl J Med*. 2020;382(4):301-303. doi:10.1056/NEJMp1911700

71. Kachalia A, Kaufman SR, Boothman R, et al. Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program. *Annals of Internal Medicine*. 2010;153(4):213-221. doi:10.7326/0003-4819-153-4-201008170-00002

72. Kachalia A, Sands K, Niel MV, et al. Effects of a Communication-and-Resolution Program on Hospitals' Malpractice Claims and Costs. *Health Affairs*. 2018;37(11):1836-1844. doi:10.1377/hlthaff.2018.0720

73. Dzeng E, Curtis JR. Understanding ethical climate, moral distress, and burnout: a novel tool and a conceptual framework. *BMJ Qual Saf*. 2018;27(10):766-770. doi:10.1136/bmjqs-2018-007905

74. Etchegaray JM, Ottosen MJ, Burress L, et al. Structuring Patient and Family Involvement in Medical Error Event Disclosure and Analysis. *Health Affairs*. 2014;33(1):46-52. doi:10.1377/hlthaff.2013.0831

75. Ottosen MJ, Sedlock EW, Aigbe A, et al. Developing the Improving Post-Event Analysis and Communication Together (Impact) Tool to Involve Patients and Families in Post-Event Analysis. *Journal of Nursing & Interprofessional Leadership in Quality & Safety*. 2016;1(1):1-17.

76. Okoroh JS, Uribe EF, Weingart S. Racial and Ethnic Disparities in Patient Safety. *J Patient Saf*. 2017;13(3):153-161. doi:10.1097/PTS.0000000000000133

77. Thomas AD, Pandit C, Krevat SA. Race Differences in Reported Harmful Patient Safety Events in Healthcare System High Reliability Organizations. *J Patient Saf*. Published online December 21, 2018. doi:10.1097/PTS.0000000000000563

78. Wyatt R, Laderman M, Botwinick L, Mate K, Whittington J. *Achieving Health Equity: A Guide for Health Care Organizations*. Institute for Healthcare Improvement (IHI); 2016:46 pages. (Available at ihi.org)

79. Berwick DM. Division, Cooperation, and the Opportunities Presented by COVID-19. IHI Improvement Blog. Published November 25, 2020. Accessed December 1, 2020. http://www.ihi.org/communities/blogs/division-cooperation-and-the-opportunities-presented-by-covid-19

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)	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. When OPSC receives a Request for Conversation, it 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.
Healthcare facility*	A licensed healthcare facility as listed in Oregon Laws 2013, Chapter 5. Healthcare facilities are: • Ambulatory surgery centers • Freestanding birthing centers • Hospitals (including any licensed satellite facility) • Nursing facilities • Outpatient renal dialysis centers
Healthcare provider*	A licensed healthcare provider as listed in Oregon Laws 2013, Chapter 5. Healthcare providers are: • Audiologists • Chiropractors • Dental hygienists • Dentists • Denturists • Direct entry midwives • Occupational therapists • Optometrists • Pharmacists • Physical therapists • Physicians

Term	Definition
	• Emergency medical service providers • Marriage and family therapists • Massage therapists • Medical imaging licensees • Naturopathic physicians • Nurse practitioners • Physician assistants • Podiatric physicians • Podiatric surgeons • Professional counselors • Psychologists • Registered nurses • Speech-language pathologists
Patient's representative*	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: • 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	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. 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.
Request for Conversation	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.
Serious adverse event	Unanticipated consequence of patient care that is usually preventable and

Term	Definition
(Referred to as "patient harm" or "medical harm" in this report)	results in the death of or serious physical injury to a patient. Serious physical injury is an injury that: • 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.

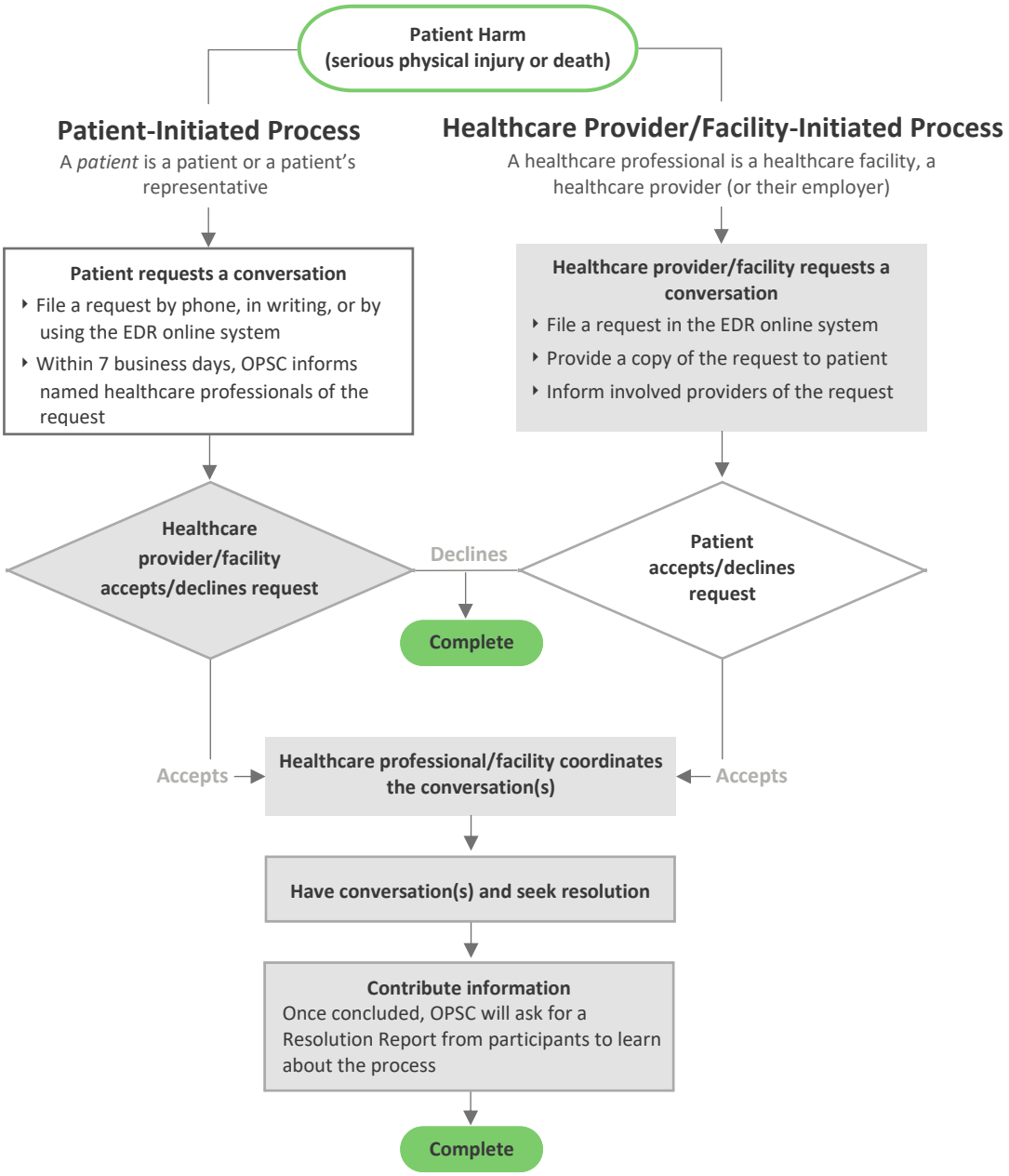
Content Analysis

- **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

Since Early Discussion and Resolution launched in 2014, 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) *20 offerings for a broad range of EDR stakeholder audiences*	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

Topic	Faculty
Cultivating your Learning Organization; Hardwiring your CRP to Sustain Progress Through Change*	Heather Wong, JD, MBA
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 *Multiple offerings*	OPSC Staff
Building Strong Root Cause Analysis Action Plans Using Human Factors *Multiple offerings*	OPSC Staff
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 *Multiple offerings*	OPSC Staff
2018-2019	
Responding to Unexpected Harm in Residential Settings *Two offerings*	OPSC Staff
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

Topic	Faculty
Responding to Patient Harm Events: An Update on Oregon's EDR Process *Five offerings*	OPSC Staff
Responding to Patient Harm Events the Oregon Way	OPSC Staff
2020	
Medical Harm: Moving Beyond Deny and Defend	Eric B. Lindauer, JD; Shannon Alexander, MBA, RN, CPHRM; Thomas H. Gallagher, MD, MACP; Leilani Schweitzer

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