OREGON PATIENT SAFETY COMMISSION

Early Discussion and Resolution 2021 Annual Report

The Path Forward

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

OREGON
PATIENT
SAFETY
COMMISSION

The Oregon Patient Safety Commission is a semi-independent state agency that supports healthcare facilities and providers in improving patient safety. We encourage broad information sharing, ongoing education, and open conversations to cultivate a more trusted healthcare system.

Learn more: **oregonpatientsafety.org**

Our Mission

To reduce the risk of serious adverse events occurring in Oregon's healthcare system and encourage a culture of patient safety.

BUILDING A CULTURE OF SAFER CARE—TOGETHER.

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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 our annual report on Oregon's EDR program from July 1, 2020, to June 30, 2021. During this program year, we had a singular goal based on our comprehensive evaluation of the first six years of EDR in Oregon: to recommend that the Legislature act during the 2021 Legislative session to remove the sunset provision on EDR, set for December 31, 2023.[i]

We appreciate the overwhelming support for and passage of SB 110. The EDR sunset will be removed effective January 1, 2022. EDR's continuation reinforces our state's commitment to patients, their families, and healthcare providers. Removing the EDR sunset has:

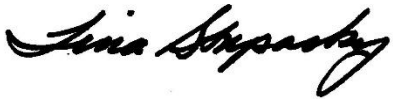
- Ensured Oregonians have a way to seek resolution following medical harm before escalation to a traditional legal response.
- Instilled confidence that the confidentiality protections EDR affords will remain intact.
- Maintained the infrastructure for shared learning across the healthcare continuum to ensure we can continue to make progress as a state.

In this year's report, we look ahead to how EDR can continue to encourage a compassionate response to patient harm that promotes transparency and learning and helps to cultivate a culture of safety in Oregon's healthcare system.

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

- Chandra Basham, trial lawyer
- Robert Beatty-Walters, trial lawyer
- Jeff Goldenberg, advocate for patient safety
- Michelle Graham, hospital industry
- Anthony Jackson, public member
- Bob Joondeph, public member
- Saleen Manternach, physician
- Margaret Mikula, 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

For the past seven years, the Oregon Patient Safety Commission (OPSC) has been operating a groundbreaking culture change program to encourage transparency with patients and families following patient harm—Early Discussion and Resolution (EDR). EDR establishes confidentiality protections[ii] for these important conversations to encourage participants to talk candidly about the harm that occurred and seek reconciliation outside of the legal system. In 2021, the Oregon Legislature removed the sunset provision[iii] for the program, reinforcing our state's commitment to patients, their families, and healthcare providers involved in harm events.

Now that EDR's future is certain, it is an ideal time to plan for what lies ahead. In this report, we take a closer look at how far we've come with transparency following patient harm in Oregon and what we've learned along the way. We will also share some of our goals for the program going forward and next steps as we work to accomplish those goals to ensure EDR continues to advance a culture of safety in Oregon.

Summary of What We've Learned So Far and Next Steps

As the evaluative body for EDR, we (the Task Force on Resolution of Adverse Healthcare Incidents) will support OPSC in their work to identify opportunities to strengthen EDR, ensuring it continues to be an important resource for Oregonians seeking reconciliation for harm events. This will include identifying opportunities to improve our ability to fulfill our program evaluation role and OPSC's ability to share learning.

OPSC will use key lessons from program administration to build on EDR's foundation and make progress toward corresponding program goals. OPSC will:

- **Apply an equity lens to everything they do.** As OPSC moves forward with EDR program planning and improvement work, they will explicitly look at how their decisions can advance health equity and take special care to make sure they do not perpetuate systemic inequities. A focus on equity will be essential for program outreach and awareness initiatives.
- **Continue to learn about and improve EDR in collaboration with interested parties.** Some of the initial assumptions about EDR need to be revisited and revised based on what we've learned. OPSC will tap into expertise across the state to inform their improvement strategies.
- **Evaluate the EDR data collection process.** This evaluation can inform potential improvements to the EDR data collection process and OPSC's ability to share information and best practices.

Key Lessons to Guide EDR Work Going Forward

While we've learned a great deal about EDR, we have identified four lessons to guide our next steps:

- We need better information to understand if the program is equitable.
- We have opportunities to revise founding assumptions.
- We have opportunities to improve data collection processes.
- There is limited awareness of EDR by eligible participants.

[ii] 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*.
[iii] In the 2021 Legislative session, Senate Bill 110 passed removing the sunset provision originally 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 provider 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**	Assistance preparing for a conversation after a harm event and emotional support.
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, show their concern, and apologize.
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

A patient, healthcare provider, or facility can submit a request through OPSC*

Patient or their representative

Healthcare provider or facility

For patient requests, OPSC informs involved provider(s) and/or facility of the request and, if they agree, connects them with the patient

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.

Seven Years of EDR Use in Oregon

July 2014-June 2021

294 **Requests for Conversation submitted**

92% of **Requests for Conversation** were made by **patients** (or their representatives)

Most common event types mentioned in Requests for Conversation

- **43%** Care delay
- **37%** Surgical or other invasive procedure
- **11%** Other event type
- **9%** Medication event
- **6%** Healthcare-associated infections

Most common locations where those events occurred

- **65%** Hospitals
- **25%** Other locations (including doctor's office)
- **5%** Ambulatory Surgical Centers
- **2%** Nursing Facilities

45% **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

- **44%** Intend to use a different process and will not incorporate EDR
- **18%** Have already addressed this event through another process
- **14%** Patient's concerns involve other provider(s)/facility only
- **14%** Other decline reasons
- **10%** Don't believe this meets the definition of an adverse event
- **8%** Advised against participation by legal counsel
- **8%** Advised against participation by liability insurer

OPSC OREGON PATIENT SAFETY COMMISSION

How Far We've Come

Over the past decade, there has been a shift in the expectations of patients and their loved ones. They expect to be more involved in their care, to have access to their health information,[1] and to be fully informed by their providers when their medical care has not gone as planned.[2] During this time, we have also learned that healthcare organizations must have systems in place to consistently and effectively identify and respond to harm events.

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[iv] when care resulted in serious harm or death—what is now called Early Discussion and Resolution (EDR).[v] The Oregon Patient Safety Commission (OPSC)[vi] was designated to administer EDR and share information and best practices to help Oregon's healthcare system move forward together. 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.

EDR: Public Policy to Address Medical Liability through Open Conversation

Despite the best intentions of healthcare providers, things can and do go wrong during healthcare, resulting in harm to a patient. A lack of transparency with patients and families about what happened exacerbates the issue and increases the likelihood that patients will take legal action.[3–6]

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. EDR establishes confidentiality protections[vii] for these important conversations to encourage participants to talk candidly about the harm that occurred and seek reconciliation outside of the legal system.

In 2016, the Agency for Healthcare Research and Quality (AHRQ) published their toolkit for responding to patient harm and working toward resolution—Communication and Optimal Resolution (CANDOR).[7] The CANDOR Toolkit provides a structured process for implementing a communication and resolution program (CRP). This includes 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. Here in Oregon, Early Discussion and Resolution (EDR) and the legal protections it provides support organizations' efforts to transform how they respond to patient harm through CANDOR implementation (Figure 1).

"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."

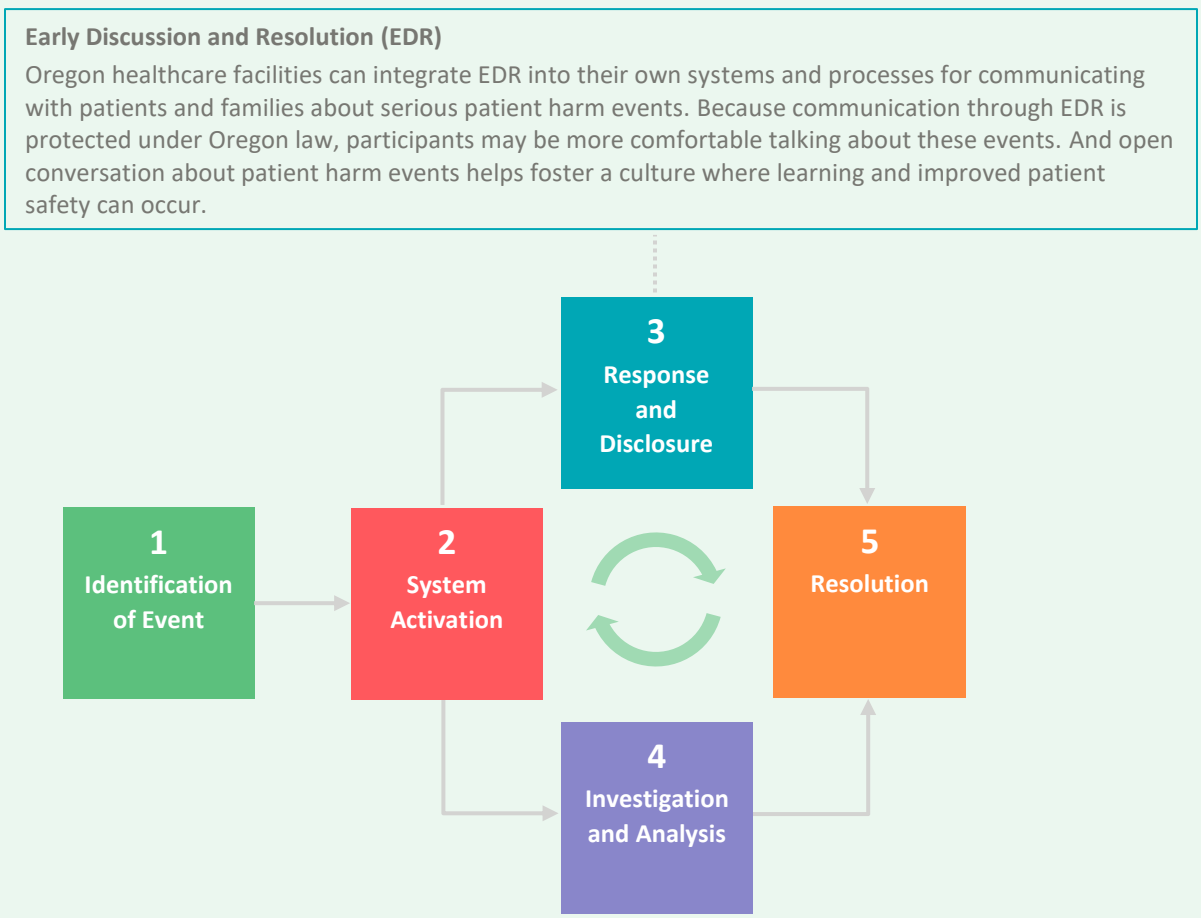
— Thomas Gallagher, Richard Boothman, Leilani Schweitzer, and Evan Benjamin, 2020[8(p2)]

[iv] See Appendix I for a definition of *patient representative*, *healthcare provider*, and *healthcare facility*.
[v] See Appendix I for a definition or *Early Discussion and Resolution*.
[vi] See Appendix II for more information on OPSC's role.
[vii] 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*.

Since EDR was created in Oregon, two other states, Colorado[viii] and Iowa,[ix] have also passed laws to help drive culture change through open communication following patient harm. Many hospitals and health systems across the U.S. have also implemented CRPs.

CANDOR: A Best Practice Toolkit for Responding to Patient Harm

Figure 1. The CANDOR[7] Process: A Model for Responding to Patient Harm and Improving Patient Safety, and Alignment with Oregon's EDR Program



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. In our 2020 evaluative report to the Legislature, we concluded 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 patients and families, healthcare providers, and facilities to exchange information and move toward reconciliation for specific harm events.
- Cultivate the culture of safety necessary to improve our care delivery system and ultimately prevent harm events.

[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.

In the 2021 Legislative session, the Legislature implemented our recommendation to remove the sunset provision on EDR[x] to ensure its continued availability to drive culture change in the state for the benefit of all Oregonians. Senate Bill 110 passed with nearly unanimous support, reinforcing Oregon's commitment to patients who have been harmed by medical care, their families, and involved healthcare providers. Now, we look ahead to ensure EDR can continue to be a lever for culture change in Oregon.

How EDR is a Lever for Culture Change in Oregon

OPSC identified several culture change principles that are essential to understanding the opportunity EDR creates for progress and innovation in Oregon:

- **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.
- **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. Making care safer will require organizations to cultivate their culture of safety by implementing systems that support transparency and learning following patient harm.
- **EDR accelerates progress toward a culture of safety.** By encouraging a more transparent approach for responding to patient harm, EDR is a lever for culture change in Oregon.

[x] A sunset date of December 31, 2023, was established for Sections 1 to 10 and 17 to 19 of the 2013 Act.

What We've Learned

In the seven years that the EDR program has been available to Oregonians, patients, families, and healthcare professionals have submitted 294 Requests for Conversation about harm events that occurred in settings across the healthcare continuum, with hospitals as the most frequent setting. Requests have come from patients and providers all over the state because adverse events can, and do, happen anywhere.

EDR Use in Oregon, July 2014-June 2021

294

Requests for Conversation

Figure 2. Requests for Conversation by EDR Year

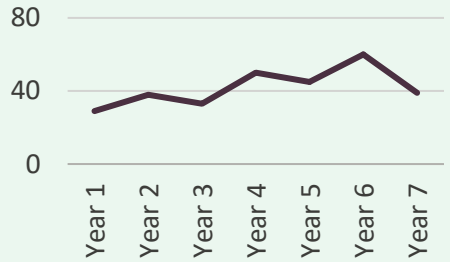


Figure 3. Requests for Conversation by Requester

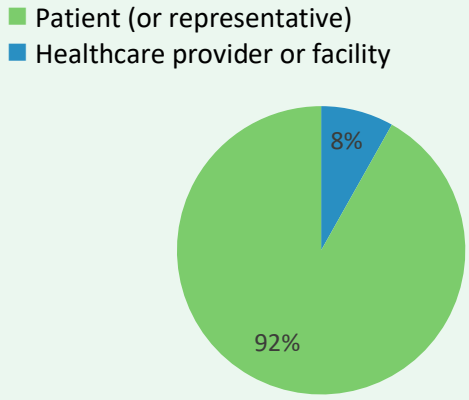


Table 1. Serious Harm Event Location

Location	Percentage
Hospital	65%
Other location (including doctor's office)	25%
Ambulatory surgery center	5%
Hospital satellite facility	2%
Nursing facility	2%
Outpatient renal dialysis center	0.3%
Freestanding birthing center	0.3%

Through our work, we have learned several important lessons that are crucial to our work going forward and must guide our evaluation process.

Lesson 1: We need better information to understand if the program is equitable.

Patient safety is undeniably linked to health inequity—the differences in health outcomes that are systematic, avoidable, and unjust.[9–11] In the past year, professional organizations across the country have issued policy statements recognizing systemic racism as a public health issue that the healthcare system must address explicitly and urgently.[12–14] Local and state governments have followed suit.[15,16] Structural racism and systemic discrimination based on factors such as race, sex, language, and socioeconomic class are reflected in the policies and practices of the U.S. healthcare system.[17]

The EDR program has an opportunity to collect demographic data on the patient harmed by the adverse event at two points in the EDR process: as part of the initial Request for Conversation, if it's made by a patient or patient representative; and at the end of the process as part of a voluntary follow-up survey called a Resolution Report. Stakeholder advisory groups convened in 2013 to advise OPSC on the design of their data collection model recommended this approach to limit how much personally identifiable information a patient would have to provide to request a conversation with their providers. The advisory groups decided that soliciting more information than was necessary to connect the patients and providers for conversation might create an unnecessary barrier to use of EDR. As a result, they kept mandatory fields in the request form to a minimum. An unanticipated result of these choices is that we do not have the same patient demographic data for all requests for conversation (Table 1).

Inconsistent Demographic Data Collection

Table 2. Sources of Patient Demographic Data

Demographic Data Element	Patient Request for Conversation	Provider Request for Conversation	Patient Resolution Report*	Provider Resolution Report*
Patient age	✓			
Patient gender	✓			✓
Patient ethnicity			✓	✓
Patient race			✓	✓
Is a language interpreter needed?	✓			
Patient language			✓	✓
Patient hearing or speech impairment			✓	✓

**Demographic questions are only asked if the respondent says that a conversation took place, which means that only 33% of requests for conversation have even generated an opportunity for someone to provide demographic information.*

See Appendix III. Additional Data for additional EDR data, including demographic data.

In *Advancing Safety and Equity Together*[17], Karthik Sivashanker, M.D., M.P.H., and Tejal K. Gandhi, M.D., M.P.H., recommend a simple first step is to address inequities in healthcare—to apply an equity lens to existing safety data. This data can be stratified by key social determinants of health to help organizations identify and address previously hidden inequities. Sivashanker et al.[18] recommend a multi-tiered approach that starts with looking at access to healthcare (Box 1).

Box 1: A Pragmatic 4-Tiered Measurement Framework for Advancing Equity

From Sivashanker et al. 2020

Although Sivashanker et al. proposed these measurement framework tiers with brick-and-mortar healthcare facilities in mind, they apply equally well to processes like EDR.

Measurement Framework Tiers for Advancing Equity	How the Framework Could be Applied to EDR
Level One: Access "Whether patients can even gain entry to the health care system."	• Ask: Is there equitable entry to the EDR program? • Do: Assess awareness and integrate equity into communication planning
Level Two: Transitions "Whether patients will be offered services equitably as they transit the health care system."	• Ask: Are patients offered conversations equitably • Ask: Does a request for conversation from a patient transition to an actual conversation equitably? • Do: Consistently and systematically collect demographic data and share aggregate data publicly
Level Three: Quality of Care "The quality of care delivered, commonly described through clinical outcomes and associated process measures."	• Ask: What are the outcomes of conversations? • Ask: Do patients get the information they were looking for? • Ask: Do conversations result in resolution? • Do: Collect follow-up data on conversations
Level Four: Socioeconomic and Environmental Impact "The vitality of the socioeconomic and environmental conditions in the neighborhoods and communities served by the institution."	• Ask: Is culture of safety improving in Oregon's healthcare organizations? • Do: Encourage use of "Safer Together" self-assessment for healthcare organizations • Do: Encourage periodic culture of safety surveys

Goal: Prioritize health equity in all EDR program related activities.

To serve all Oregonians, understanding the role equity plays in EDR is critical. Using the framework recommended by Sivashanker et al.[18], OPSC can apply an equity lens to the EDR data collection process to improve the information captured on social determinants of health. Having a better understanding of inequity in EDR will enable OPSC to develop and implement targeted strategies to advance equity in EDR.

At the organizational level, healthcare organizations must also take purposeful action to integrate equity into all their systems of care, including their response to medical harm, by seeking to understand and address inequity in patient safety. Organizations can use IHI's Self-Assessment Tool, included in *Safer*

Together: A National Action Plan to Advance Patient Safety, as a starting place to evaluate their progress on health equity efforts.

Lesson 2: There are opportunities to revise initial assumptions and inform strategic decisions about program operations.

When EDR was created by the Oregon Legislature in 2013, it was the first statewide program of its kind. Much of what was known about open communication between patients, their families, and healthcare providers following patient harm was thanks to early leaders at organizations here in the U.S. and in other countries, who implemented communication and resolution programs (CRPs) to support this approach. However, while these first-generation programs shared some elements with Oregon's law, none had all of its features (e.g., established in state law, provides confidentiality protections for communications, allows for patient initiation, extended the statute of limitations on negligence claims, and is voluntary).

Now that we know that EDR will remain a part of Oregon law for the foreseeable future, it is time for OPSC to assess what elements of EDR require updating in light of its seven years of learning from EDR implementation, its conversations with and surveys of stakeholders, and the growing body of research on transparency following patient harm. It is clear that many of the initial assumptions that shaped how OPSC administers the program should be revisited.

Some examples of our initial assumptions and what we have learned since EDR has been operational include:

Initial assumption: There will typically be one conversation between the patient, family, and the healthcare provider and/or facility following a harm event.

What we've learned: There are frequently several conversations, with the initial conversation occurring before a full event investigation and analysis is complete, and follow-up conversations where additional information can be shared, and parties can work toward a shared understanding of what happened and reconciliation. About half of the requests for conversation for which we have this information resulted in multiple conversations (see Figure 19 in Appendix III).

Initial assumption: There will typically be one healthcare organization involved in a harm event.

What we've learned: It's frequently necessary to coordinate with multiple healthcare organizations involved in a harm event. About half of the requests for conversation made by patients have named more than one healthcare organization (see Figure 15 in Appendix III). Different organizations, and their insurers, typically have different processes and philosophies for responding to harm events.

Initial assumption: OPSC will readily be able to notify and receive a participation decision from healthcare providers named in the patient's Request for Conversation.

What we've learned: Notifying providers is often difficult. Many providers are not employed by the facility where the event occurred, and it can be difficult to reach them directly. In addition, obtaining a provider's participation decision and other information needed to assess how the program is working requires further communications. Providers often prefer to delegate these administrative tasks to someone else, just as they would for patient complaints, legal claims, and similar matters. Between July 1, 2019, and June 30, 2021, about

half of the named providers who were not employed by a named facility designated someone else to handle communications with OPSC about the EDR process on their behalf. Those designees included both people inside their organizations (e.g., a practice's risk manager) and outside their organizations (e.g., liability insurance carriers and attorneys).

Initial assumption: EDR will be most important to, and most used by, healthcare providers and facilities.

What we've learned: Patients have initiated 92% of all Requests for Conversation (see Appendix III for breakdowns of specific requester types). EDR gives patients a way to ask for the information, acknowledgement, and/or restitution that they need, which can give them some sense of control over their situation. 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.[19]

Initial assumption: Healthcare providers and facilities will see EDR as a tool to enhance a healthcare organization's internal processes for responding to harm events and will integrate it into their own internal processes, to benefit from EDR's confidentiality protections.

What we've learned: Healthcare providers and facilities see EDR as a separate process. When healthcare providers and facilities choose not to accept a patient's Request for Conversation, OPSC asks why they are declining the request. Half of healthcare facilities and a third of healthcare providers indicated that they were choosing not to participate in EDR because they were instead using an internal process that does not include EDR (see Table 4 in Appendix III for a list of decline reasons). This may indicate a misunderstanding that EDR is a separate process rather than an enhancement to their internal process.

Initial assumption: Analyzing the post-conversation surveys will yield information about best practices in communication following harm that can be shared more broadly.

What we've learned: A review of post-conversation surveys submitted by multiple participants for the same event revealed that, for some requests, the participants submitted conflicting information. The conflicts concerned such things as whether an apology was made. To identify best practices, the evaluation tool must help us to understand these differences.

Goal: Work with interested parties to revisit assumptions based on what we've learned.

With new knowledge and insights about responding to patient harm events and data about how EDR has actually been used in Oregon, we are well positioned to revise some of our initial assumptions. In addition to what we've learned, we are committed to collaborating with interested parties whose expertise and perspectives will help to ensure we are heading in the right direction.

Lesson 3: We have opportunities to improve our data collection processes.

When EDR data collection was initially designed, a key focus was to minimize any perceived barriers to participation by limiting up-front data collection. As such, the Request for Conversation form only asks for data that is essential for program administration, namely the identities of the parties to be connected for a conversation and a brief description of the harm event that the requesting party would like to discuss. Additional data required to fulfill other EDR program mandates (e.g., learning from the conversation process and sharing quality improvement techniques and best practices) is instead sought

through a voluntary follow-up survey called the Resolution Report. Each patient-initiated Request for Conversation can potentially result in multiple Resolution Reports from the patient and each named facility and non-employed provider. Although 72% of requests for conversation have resulted in at least one Resolution Report, fewer than half of participants choose to complete the Resolution Report and others submit it with incomplete information, further contributing to gaps in data (Figure 4).

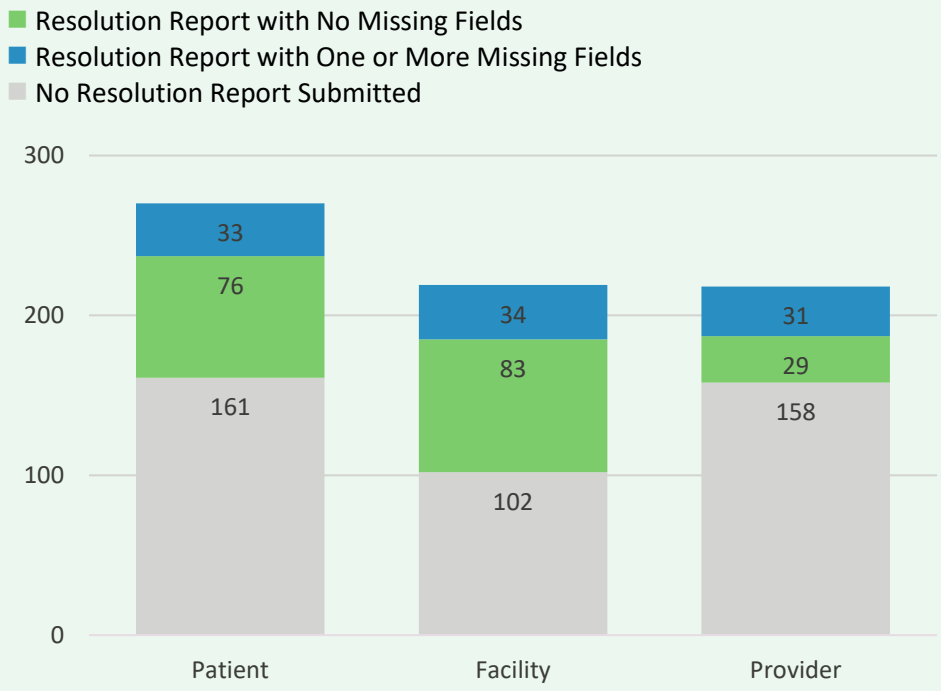
Additionally, the data that is essential for program administration depends on who initiates the EDR process, creating inconsistencies in data collection. For example, in a patient-initiated EDR, OPSC needs contact information for any named facility and provider(s) to notify them of the pending request, as well as information about the patient and the event to inform the facility and provider(s). By contrast, when a facility or provider initiates the process, they are responsible for contacting the patient and other involved providers. OPSC has no program administration needs for specific patient identifying information or information about other involved providers.

Having more consistent and complete data from EDR participants may better facilitate learning about how the process is going and sharing quality improvement techniques and best practices.

Follow-up Data Collection

To increase our understanding of who is using the EDR process and whether the conversations are increasing transparency and helping the involved parties move towards reconciliation, we rely on the data furnished in Resolution Reports. Ideally, everyone involved in the Request for Conversation (patient, provider(s), facility representatives) would submit a complete Resolution Report. This would give us the most nuanced view of the process.

Figure 4. Resolution Report Submission by Participant Type
n=707 potential Resolution Reports



"No Resolution Report submitted" excludes providers or facilities that we could not locate or who did not reply to our initial notification.

Goal: Revisit and revise our priorities and processes for data collection.

After seven years of EDR experience, we have the benefit of hindsight. There are opportunities to redesign EDR's data collection processes to better support our learning goals. For example, patients and providers often report different responses when asked if an apology was offered. Redesigning this question or considering an additional question for clarity, could offer insight into why these differences exist. Evaluating when, how, and what information is collected can help strengthen these processes.

Lesson 4: There is limited awareness of EDR by eligible participants.

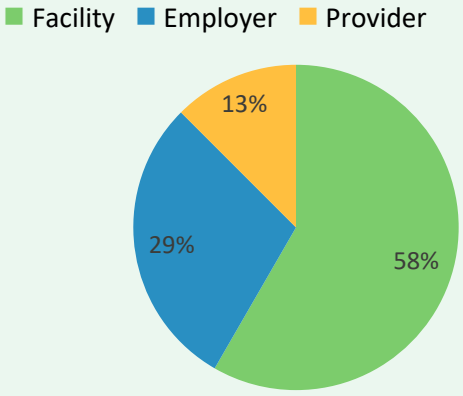
A program intended for situations when care does not go as planned and results in serious injury or death may not be top of mind for either patients or healthcare providers until they need it. The primary focus of patients and providers alike is on having a care experience that goes according to plan.

Because EDR is relatively new and offers a different approach for responding to medical harm, many providers may not be aware of EDR or understand how it might benefit them. Providers may also work within organizations that do not yet have the systems and culture to support open communication with patients and families when serious harm does occur. Without this critical infrastructure and clear support for a transparent approach from senior leadership, awareness of EDR may be limited.

When EDR was first rolled out, our advisory groups believed that the healthcare facilities and providers that were involved in treating more acutely ill patients and/or providing higher risk care would be the primary users of EDR. As such, OPSC's communication and outreach plan primarily focused on building awareness among healthcare professionals such as hospital and ambulatory surgery center risk management staff and physicians. OPSC used primarily lower-touch outreach efforts, such as distribution of English language information materials to Oregon libraries and community centers, to make information about EDR available to the general public on the theory that they could learn about it if they either experienced serious harm as a patient or had a family member who experienced serious harm during medical care. Despite these initial assumptions about who would use EDR, patients have been the primary source of requests to participate in EDR, initiating 92% of the program's requests for conversation. In addition, there are far more provider categories eligible to use EDR than have taken advantage of it.

Healthcare Professional Requests for Conversation

Figure 5. Healthcare Professional-Initiated Requests by Provider Type
n=24



Facility Type (n=14)
- Hospital (100%)

Employer Type (n=3)
- Employer of physicians (67%)
- Employer of Emergency Medical Services Providers (33%)

Provider Type (n=3)
- Physician (100%)

List of Eligible Facility Types and Provider Types

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
- Emergency medical service providers
- Marriage and family therapists
- Massage therapists
- Medical imaging licensees
- Naturopathic physicians
- Nurse practitioners
- Occupational therapists
- Optometrists
- Pharmacists
- Physical therapists
- Physicians
- Physician assistants
- Podiatric physicians
- Podiatric surgeons
- Professional counselors
- Psychologists
- Registered nurses
- Speech-language pathologists

Goal: Develop a strategic communication plan to increase awareness about EDR that prioritizes equitable information dissemination.

OPSC will use what they've learned about how eligible participants find out about, understand, and use EDR, along with communication best practices, to inform the development of a targeted communication plan. Achieving health equity objectives will be a priority in developing the plan.

Next Steps

Summary of Lessons and Goals from EDR Administration

Lesson	Goal
We need better information to understand if the program is equitable.	Prioritize health equity in all EDR program related activities.
We have opportunities to revise founding assumptions.	Work with interested parties to revisit assumptions based on what we've learned.
We have opportunities to improve data collection processes.	Revisit and revise our priorities and process for data collection.
There is limited awareness of EDR by eligible participants.	Develop a strategic communication plan to increase awareness about EDR that prioritizes equitable information dissemination.

Oregon's EDR program was one of the first laws in the country to promote open conversation between patients who have been harmed by their medical care, healthcare providers, and facilities. Now that EDR's future is certain, following the removal of the sunset provision,[xi] it is an ideal time to plan for what lies ahead. OPSC will use the lessons from program administration to inform programmatic changes and accomplish identified goals for EDR going forward.

How OPSC Will Make Progress Toward Identified Goals

OPSC will identify opportunities to help ensure EDR continues to serve Oregonians, as well as opportunities to improve our ability to fulfill our program evaluation role and OPSC's ability to operate the program and share learning.

Prioritize Health Equity

To serve all Oregonians, OPSC will apply an equity lens to everything they do. As OPSC moves forward with EDR program improvement work, they will explicitly look at how their decisions can advance health equity and take special care to make sure they do not perpetuate systemic inequities. Additionally, a data process evaluation, discussed shortly, will help inform our understanding of the equity of the EDR program.

OPSC will also use what they learn to develop a strategic communication plan, aimed at increasing awareness about EDR among eligible participants. A focus on equity must be central to this effort.

Continue to Learn and Improve EDR In Collaboration with Interested Parties

Some of the initial assumptions about EDR, while well-intentioned, have not played out as expected. Data from program administration, research related to transparency following patient harm, and input from EDR stakeholders across Oregon have given us new knowledge and insights about EDR. Now, OPSC can revise those initial assumptions and move forward with improvement work with a new

[xi] In the 2021 Legislative session, Senate Bill 110 passed removing the sunset provision originally established for Sections 1 to 10 and 17 to 19 of the 2013 Act.

understanding of how EDR is used. And just as OPSC did in the initial roll out of EDR, they will collaborate with Oregonians, including industry interested parties and community members, to inform strategies for improving EDR and for responding to patient harm events.

Evaluate the EDR Data Collection Process

As a first step, OPSC will engage a program evaluation consultant to evaluate the EDR data collection process to identify opportunities to improve when, how, and what information is collected during the EDR process. OPSC will use this evaluation to inform changes to the EDR data collection process and other improvements to program operations.

OPSC will use the improved dataset to identify opportunities to make EDR more equitable. They anticipate that the data will be particularly useful in the development of the EDR strategic commutations plan that emphasizes equitable information dissemination.

Additionally, information from our data process evaluation will help shape longer-term EDR program planning. As the Task Force, we anticipate that the process evaluation may also shed light on opportunities to strengthen the legislative foundation for EDR.

Conclusion

In partnership with OPSC, we are committed to being responsive to new knowledge and insights. At this time, OPSC is ready to build on EDR's strong programmatic foundation by incorporating key lessons learned during seven years of program administration, input from diverse stakeholders, research findings, and insights from an outside evaluator. OPSC will examine each aspect of the program and all potential changes using an equity lens, with a commitment to ensure that EDR serves all Oregonians equitably. Specific improvement goals for EDR include:

- Prioritize health equity in all EDR program related activities.
- Work with interested parties to revisit assumptions based on what we've learned.
- Revisit and revise our priorities and process for data collection.
- Develop a strategic communication plan to increase awareness about EDR that prioritizes equitable information dissemination.

We look forward to supporting OPSC in their continuous quality improvement efforts for EDR. Our intention is that, as a result of these efforts, EDR will be positioned to support transparency following patient harm and encourage a culture of patient safety across Oregon's healthcare system.

Acknowledgements

We are grateful for the dedicated stakeholders and community leaders who contributed to the implementation of EDR and helped to ensure its continued availability for Oregonians. The hard work of so many highlights the growing desire for a better approach to resolving patient harm events.

These include, but are not limited to:

- The Oregon State Legislature
- The Oregon Patient Safety Commission Board of Directors
- 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

References

1. Moscovitch B. Americans Want Federal Government to Make Sharing Electronic Health Data Easier. The Pew Charitable Trusts. Published September 16, 2020. Accessed June 15, 2021. https://pew.org/3hqjFEV

2. Kaldjian LC. Communication about medical errors. *Patient Educ Couns*. 2020;Online ahead of print:5 pages. doi:10.1016/j.pec.2020.11.035

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

4. 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

5. 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

6. 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

7. 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

8. Gallagher TH, Boothman RC, Schweitzer L, Benjamin EM. Making communication and resolution programmes mission critical in healthcare organisations. *BMJ Qual Saf*. 2020;29(11):875-878. doi:10.1136/bmjqs-2020-010855

9. 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

10. Thomas AD, Pandit C, Krevat SA. Race Differences in Reported Harmful Patient Safety Events in Healthcare System High Reliability Organizations. *J Patient Saf*. 2020;16(4):e235-e239. doi:10.1097/PTS.0000000000000563

11. 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)

12. American Academy of Family Physicians (AAFP), Cullen J. AAFP Letter to Domestic Policy Council Director Opposing Systemic Racism. Published online June 10, 2020. Accessed June 15, 2021. https://medialib.aafp.org/dam/AAFP/documents/advocacy/prevention/strategy/LT-DPC-OpposingSystemicRacism-061020.pdf

13. American Medical Association (AMA). New AMA policies recognize race as a social, not biological, construct. American Medical Association. Published November 16, 2020. Accessed June 15, 2021. https://www.ama-assn.org/press-center/press-releases/new-ama-policies-recognize-race-social-not-biological-construct

14. American Public Health Association (APHA), Benjamin G. Racism is an ongoing public health crisis that needs our attention now. American Public Health Association (APHA). Published May 29, 2020. Accessed June 15, 2021. https://www.apha.org/news-and-media/news-releases/apha-news-releases/2020/racism-is-a-public-health-crisis

15. Multnomah County. Multnomah County declares racism a public health crisis. Multnomah County. Published April 9, 2021. Accessed June 15, 2021. https://www.multco.us/multnomah-county/news/multnomah-county-declares-racism-public-health-crisis

16. Representative Andrea Salinas, Representative Teresa Alonso León, Representative Courtney Neron. *HB 2337: Relating to Equity; Declaring an Emergency.*; 2021. Accessed June 15, 2021. https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/HB2337

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

18. Sivashanker K, Duong T, Resnick A, Eappen S. Health Care Equity: From Fragmentation to Transformation. *NEJM Catalyst*. Published online September 1, 2020. Accessed April 15, 2021. https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0414

19. 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

20. 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

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.[20]
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

Term	Definition
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 • Emergency medical service providers • Marriage and family therapists • Massage therapists • Medical imaging licensees • Naturopathic physicians • Nurse practitioners • Occupational therapists • Optometrists • Pharmacists • Physical therapists • Physicians • 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.

Term	Definition
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 *(Referred to as "patient harm" or "medical harm" in this report)*	Unanticipated consequence of patient care that is usually preventable and 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. 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 III. Additional Data

Characteristics of Oregon Patients in EDR Requests for Conversation

Figure 6. Patient Ethnicity
n=96

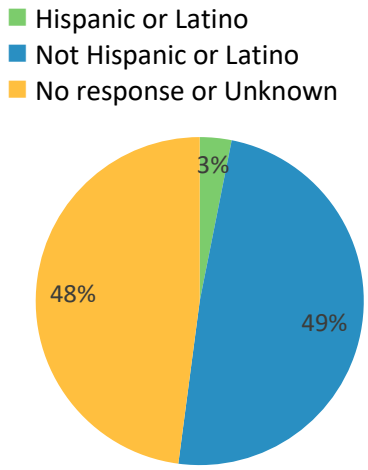


Table 3. Patient Race
n=80

Race	Number	Percent
American Indian or Alaskan Native	1	1%
Asian	3	4%
Black or African American	1	1%
White	43	54%
Other	1	1%
No response or Unknown	32	40%

Note: Respondents may select more than one race so percentages may not total 100%.

Figure 7. Patient Age
n=270

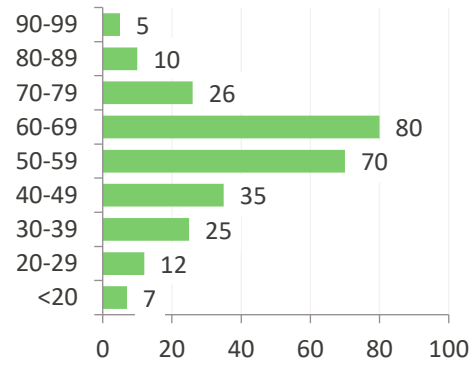


Figure 8. Patient Gender
n=294

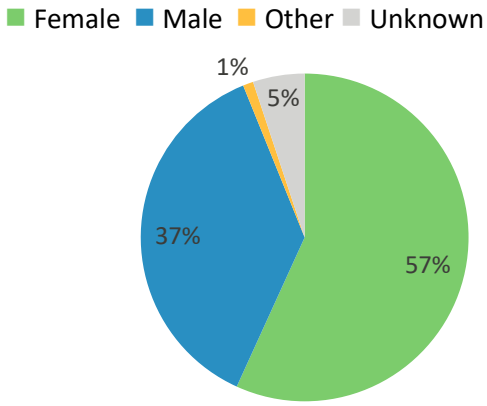


Figure 9. Patient language
n=96

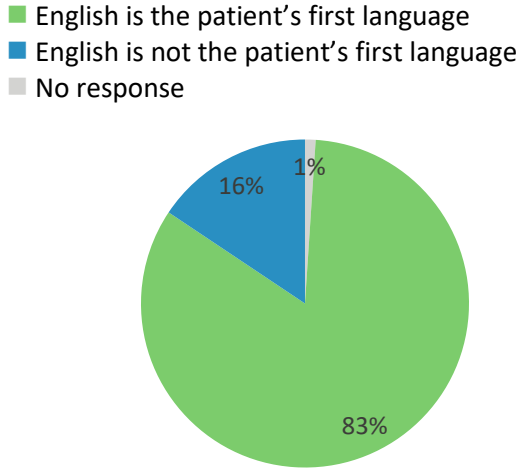
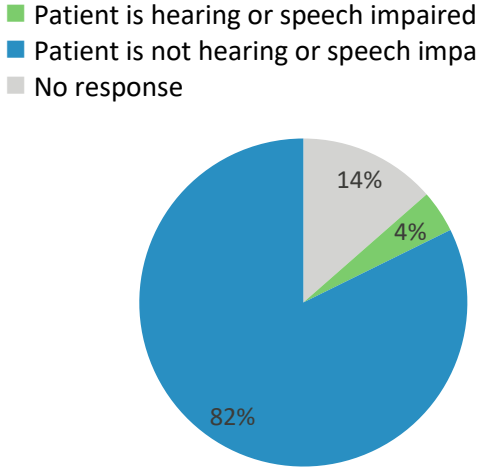


Figure 10. Patient Hearing or Speech Impairment
n=96



Who Requests Conversations through EDR

Figure 11. Requests for Conversation by Requester
n=294

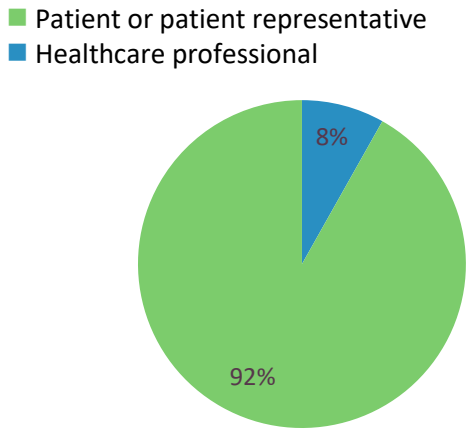


Figure 12. Healthcare Professional Requester Type
n=24

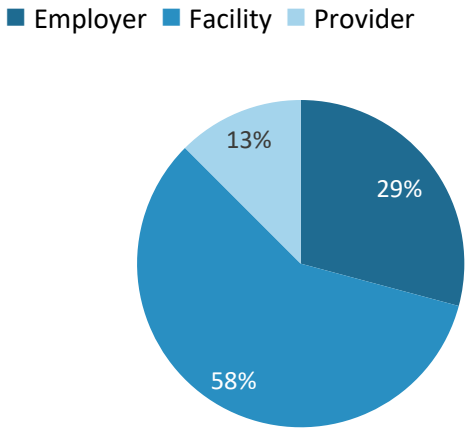


Figure 13. Patient or Patient Representative Requester Type
n=276

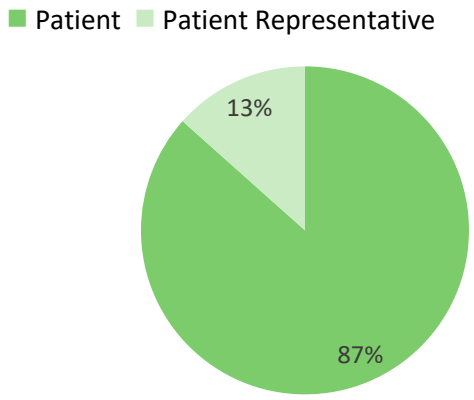


Figure 14. Patient Representative Requester Type
n=37

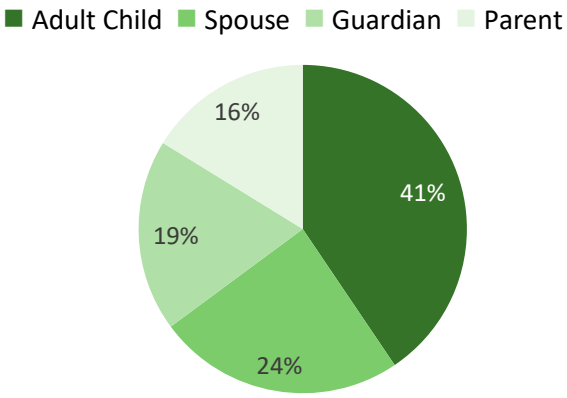
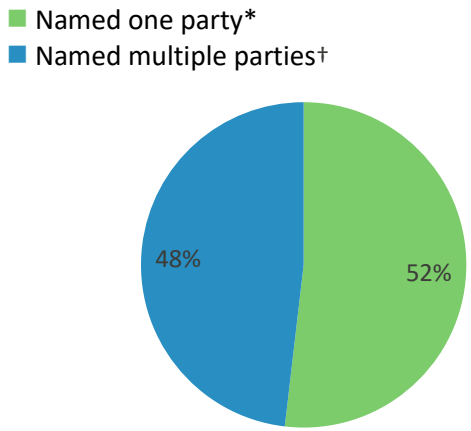


Figure 15. Proportion of Requests for Conversation Naming One or Multiple Parties
n=270



*A request naming one party may have named a facility alone, a facility and one or more employed providers, or a single provider at a doctor's office or "other" location.

†A request naming multiple parties may have named multiple non-employed providers or a facility and one or more non-employed providers.

EDR Participation

Figure 16. Will anyone participate in EDR, July 2014-June 2021
n=291

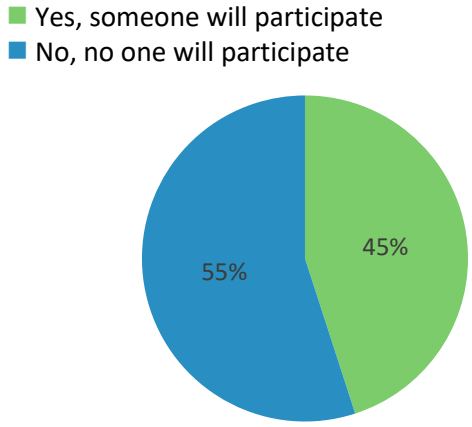


Figure 17. Percent of Requests for Conversation with at Least One Acceptance, by EDR Year
n=291

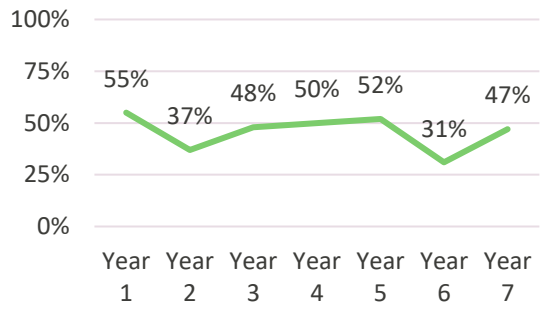


Table 4. Reasons Facilities and Providers Declined to Participate in EDR
n=252 facilities and providers that declined EDR

Decline Reason	Percent of Named Facilities and Providers That Used This Decline Reason
Intend to use a different process to address this event and will not incorporate EDR	44%
Have already addressed this event through another process	18%
Other	14%
Patient's concerns involve other provider(s), facility only	14%
Don't believe this meets the definition of an adverse event	10%
Advised against participation by legal counsel	8%
Advised against participation by liability insurer	8%
Patient abandoned/discontinued process	2%
Unclear patient representative authority	1%

Note: facilities and providers may select more than one decline reason, so percentages will not total 100%

Figure 18. Did a conversation occur?
n=210 Requests for Conversation associated with one or more Resolution Reports

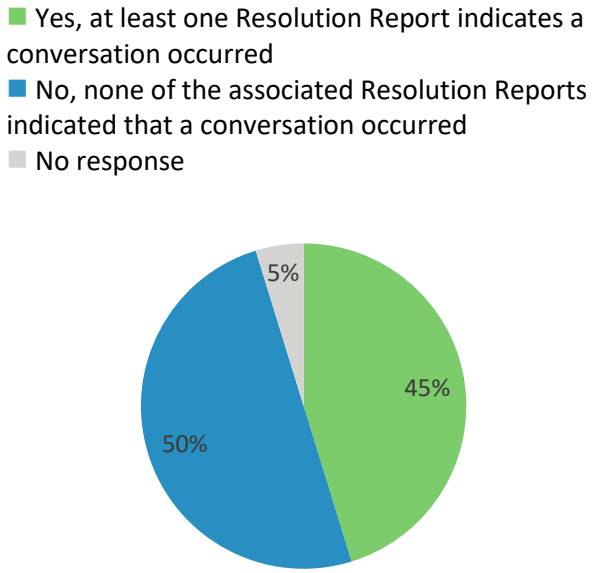
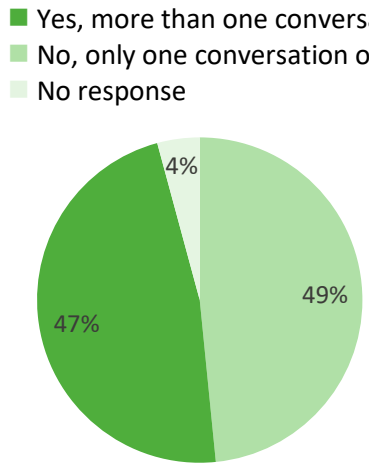


Figure 19. Was there more than one conversation?
n=95 Requests for Conversation associated with one or more Resolution Reports wherein at least one Resolution Report indicated a conversation occurred



Event Types

Table 5. Event Types Mentioned in Requests for Conversation

n=294

Event Type	Percent
Care delay	43%
Surgical	37%
Other	11%
Medication event	9%
HAI	6%
Product or device event	5%
Patient protection	1%
Environmental event	1%
Fall	1%
Blood	0.3%
Obstetrical event	0.3%
Radiologic	0.3%

Appendix IV. 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