

Lessons from Four Years of Early Discussion and Resolution Implementation

July 2014 – June 2018

Submitted pursuant to Oregon Laws 2013, Chapter 5, section 18 to House and Senate
Interim Committees on Judiciary



Question?

Contact Beth Kaye, Director Early Discussion and Resolution

beth.kaye@oregonpatientsafety.org

503-227-2632

The Oregon Patient Safety Commission, 2018

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, the Patient Safety Reporting Program, and various quality improvement initiatives. To learn more about the Patient Safety Commission, visit oregonpatientsafety.org.

Table of Contents

A Message from the Task Force.....	iii
Executive Summary.....	iv
Introduction	1
OPSC’s Role	2
Lessons from Implementation	4
Challenges to Implementation.....	4
Accomplishments.....	11
EDR Use.....	15
Requests for Conversation.....	15
Event Types.....	17
Conversation and Resolution Information.....	18
Patient Characteristics	23
Patient Representative Characteristics.....	23
Status of the EDR Process	24
Conclusion.....	26
Acknowledgements.....	27
References	28
Appendix I. Important Terms for this Report	31
Appendix II. The Early Discussion and Resolution Process	34
Appendix III. OCCRP Faculty.....	35
Appendix IV. Event Type Categories	37

A Message from the Task Force

Oregon's Early Discussion and Resolution (EDR) program receives oversight from the Task Force on Resolution of Adverse Healthcare Incidents ("Task Force"). The governor-appointed Task Force members include a patient safety advocate, a hospital industry representative, physicians, trial lawyers, and community members.

On behalf of the Task Force, we are pleased to present a report examining the implementation of Oregon's pioneering Early Discussion and Resolution (EDR) program from July 1, 2014 to June 30, 2018: *Lessons from Four Years of EDR Implementation*. The report satisfies the reporting, evaluation, and recommendation requirements of Oregon Laws 2013, Chapter 5, Sections 17(2) and 18.

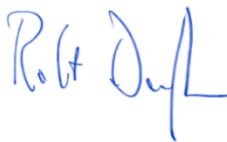
Section 18 of the law requires the Task Force to make recommendations to the Legislature for improvements to the process on or before October 1, 2018.

The Task Force strongly believes in the value of EDR for Oregonians. Ideally any recommendations for change should be based on at least five full years of information about EDR implementation. However, while the EDR program was created by the Legislature on July 1, 2013, Section 21 of the law granted time for the Oregon Patient Safety Commission (OPSC) to develop program infrastructure and administrative rules. The program was first available to Oregonians on July 1, 2014.

We know our recommendations will be stronger if they are informed by conversations with EDR's many Oregon stakeholders, including: consumers of healthcare, healthcare providers, hospitals and other facilities covered by EDR, the liability insurance community, and the legal and mediation community.

We therefore recommend that the Legislature forbear from making changes to the EDR law during the upcoming 2019 session, ask OPSC to continue to collect additional EDR data, and require the Task Force to seek input from key stakeholders and submit recommendations for consideration in a future session.

Respectfully,



Robert Dannenhoffer, MD
Task Force Co-Chair



Richard Lane, JD
Task Force Co-Chair

Task Force Members

Robert Beatty-Walters, trial lawyer
Robert Dannenhoffer, physician
Gayle Evans, patient safety advocate
Richard Lane, trial lawyer
Mary Britton, member at large

John Moorhead, physician
Michelle Graham, hospital industry
Anthony Jackson, member at large
Tina Stupasky, trial lawyer

Executive Summary

Despite the best professional training and intentions of healthcare professionals, things can and do go wrong during healthcare. In cases of serious injury or death there is a constructive way forward. An open conversation about what happened can move both patients and healthcare professionals towards resolution and may promote learning to prevent similar events. Oregon's pioneering Early Discussion and Resolution (EDR) program offers a platform, support, and legal protections for these important communications.

This report, required by Oregon Laws 2013, Chapter 5, Sections 17(2) and 18, examines the implementation of the EDR program from July 1, 2014 to June 30, 2018.

In the four years that EDR has been available to Oregonians, 150 conversations have been requested through the program, with one-third (50) of those requests coming in year four alone. Patients (or their representative) initiated 89% of all requests (134/150). Although less than half of patient EDR Requests for a Conversation were accepted (64/150), 89% of patient requests (119/134) resulted in a conversation that may not have otherwise occurred, some using EDR and some using an alternate method. Participants in 32 EDR conversations reported achieving resolution through the EDR process; resolution may have been reached in other conversations but not reported. We are very encouraged by these early signs that EDR is gaining momentum and helping to increase communication and expedite resolution for Oregonians following unintended patient harm.

As with any new program, continuous learning and improvement are essential to long-term success. Some of our early lessons from implementation include:

- **Culture change takes time:** EDR represents an alternative to the traditional “deny and defend” approach to unintended patient harm. By shining a light on the ethical, psychological, and economic benefits of the communication and resolution approach, we hope to increase the acceptance of EDR by healthcare professionals.
- **The complexity of the healthcare system creates challenges for EDR:** A single unintended harm event may involve multiple players with a variety of employment and indemnification relationships. This creates challenges both for EDR implementation and for Oregon patients seeking to use the program.
- **The asymmetry between patients and healthcare professionals affects the EDR process:** Patients often have less information, medical education, and experience than the healthcare professionals involved in their EDR conversations. Patients also require advocacy support, a service that OPSC, in its neutral role, cannot provide. In addition, we may need to revisit some aspects of the program that make it inaccessible to some patients.

- **Impacts of EDR are difficult to measure at the state level:** The lack of available data hampers our efforts to evaluate the success of EDR.

With guidance from Oregon’s governor-appointed Task Force on Resolution of Adverse Healthcare Incidents (“Task Force”), OPSC has been working to address these challenges. We have focused on developing resources to support healthcare professionals to improve their response to patient harm and make effective use of EDR. We have been working to expedite culture change by convening a statewide learning collaborative, now in its second year. A summary of these and other key EDR accomplishments begins on page 11.

Based on the information in this report, the Task Force has recommended that the Legislature postpone making changes to the EDR law during the upcoming 2019 session, ask OPSC to continue to collect additional EDR data, and require the Task Force to seek input from key stakeholders, and submit recommendations for consideration in a future session.

We are optimistic that EDR is realizing its potential to improve patient safety in Oregon. We are excited to be a part of the national movement promoting communication and resolution following unintended patient harm.

Introduction

*Healthcare professionals*¹ work hard to provide patients the best care every day; however, things can and do go wrong in healthcare. Research estimates that 210,000-400,000 patients die of preventable harm each year in hospitals alone, with serious patient harm occurring much more frequently (James 2013). Harm coupled with a failure of communication may increase the likelihood that patients or their representatives will seek legal advice (Mazor, et al. 2004). Patients are more likely to sue when they feel that their providers have deserted them, discounted their concerns, failed to provide them with adequate information, or did not understand their (or their families') perspectives (Woods and Star 2004).

In 2013, Oregon was the first state in the country to pass a law promoting open communication between patients or their representatives (collectively referred to as “patients” in this report) and healthcare professionals when serious harm or death has occurred as a result of care—what is now called Early Discussion and Resolution (EDR).² EDR provides a constructive way forward after unintended patient harm and promotes learning for improved patient safety.

Oregon remains the only state to allow patients to initiate these types of conversations. When conversations between patients (or their representatives) and healthcare professionals are initiated using EDR, those conversations are protected, allowing healthcare professionals to talk openly with patients about what happened as they explore the best way to reach resolution. (See Appendix II. The Early Discussion and Resolution Process for more detail on the EDR Process.)

An open conversation about what happened using EDR—either in conjunction with a healthcare professional’s own process or independently—can:

- **Prevent an unfortunate situation from escalating.** When a patient (or their representative) does not receive an appropriate and timely response after an unintended harm event, they may file a complaint or lawsuit (Gallagher, et al. 2003, Mazor, et al. 2004). Legal processes can be time-consuming, expensive, and painful for everyone involved. Using EDR to initiate a conversation, and considering fair compensation when appropriate, may avoid litigation and achieve a more positive result for all parties.
- **Maintain the patient-provider relationship.** The relationship between the patient and the individual healthcare provider is the keystone of care

¹ Healthcare professionals are healthcare facilities (or representatives from healthcare facilities), healthcare providers, and employers of healthcare providers. (See Appendix I: Important Terms for this Report.)

² Oregon laws 2013, chapter 5.

www.oregonlegislature.gov/bills_laws/lawsstatutes/2013orLaw0005.pdf

(McCarron, Sheikh and Clement 2017, Committee on Quality Health Care in America 2001), and both can feel great unease when it is compromised. An open conversation about what happened and direct steps toward resolution can restore trust and heal a strained or fractured relationship (Duclos, et al. 2005).

- **Bring greater peace of mind to everyone involved.** Healthcare providers can experience fear, guilt, anxiety, and grief if they have been involved in the serious injury or death of a patient, even if they are not at fault. Patients may be in pain, shock, and grief. They want information about what happened, why it happened, whether it was preventable, what impact it may have on their health, and what is being done to improve care for future patients (Gallagher, et al. 2003, Duclos, et al. 2005). An open conversation and an acknowledgment of the patient's suffering can help the patient heal. It can also be beneficial for the healthcare provider by alleviating feelings of personal and professional distress.
- **Encourage learning from events to improve patient safety.** An open conversation creates an opportunity for healthcare professionals to hear about the event from the patient's perspective. This information may help with event analysis and new learning can be rapidly integrated into the system to improve patient safety. On a broader level, OPSC shares non-identifiable data for statewide learning.

OPSC's Role

The Oregon Patient Safety Commission (OPSC) administers EDR and is responsible for managing the program infrastructure, connecting patients and healthcare professionals to have conversations, and disseminating best practices for resolving unintended patient harm events.

When unintended harm occurs, either a patient (or their representative) or a healthcare professional can initiate EDR by requesting a conversation through OPSC. Participation in EDR is voluntary for all parties.

We serve in a neutral capacity, offering information that can help both patients and healthcare professionals use the program. If either contact us about EDR, we give them the information they need to decide if EDR is a good fit for their situation (e.g., their event met the criteria to be eligible for EDR and they want to have a conversation about the event with their healthcare professional). If EDR is not a good fit for a patient, our staff may refer them to other resources. To remain effective in our administrative role, we do not provide advice or advocate for either patients or healthcare professionals.

When patients request a conversation, we connect them with involved healthcare professionals. Once a request is made and the involved parties agree to have a conversation, the healthcare professional coordinates the conversation(s).

We provide both parties with information about the practices that contribute to having an effective conversation. We also inform both parties that they have the right to invite others to the conversation for support and that either party may request a mediator.

OPSC is not present for EDR conversations.

After the conversation(s) have concluded, we ask participants to share information about their experience in a voluntary questionnaire called a Resolution Report. We share trends and other aggregated information for statewide learning.

To protect the privacy of all participants in throughout the EDR process, we maintain a secure system for communication and data collection. Information shared with us is confidential.

We also maintain a qualified mediator list. Each mediator on the list meets rigorous 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.

Lessons from Implementation

At OPSC, we are committed to sharing what we learn through the administration of EDR to improve communication and resolution practices in the wake of unintended patient harm. This section describes the challenges we have encountered during the four years of administering this program, and the program accomplishments that addressed these challenges.

Challenges to Implementation

I. Culture Change Takes Time

- **Few healthcare professionals promptly initiate conversations with patients through EDR following unintended harm events.** After a patient's serious injury or death, timely and appropriate communication between the patient (or patient representative) and the healthcare professional can have a significant impact on the patient's experience (Duclos, et al. 2005, Gallagher, et al. 2003, Ock, et al. 2017). No response or a delayed response from a healthcare professional may compound the injury for the patient and family, while proactive communication may help preserve the healthcare relationship and better position everyone for a productive conversation and resolution.

When healthcare professionals do not reach out quickly, patients may feel abandoned and lose trust that a conversation and resolution process will either occur or be beneficial. For example, when a patient requests an EDR conversation and must wait several weeks or even months for a response, the patient may suspect that an organization is hiding something, is indifferent to their well-being, and resistant to learning from the event. During this time, the patient may consider a lawsuit.

Common reasons that healthcare professionals do not reach out to patients include the lack of an internal event reporting system to alert management that a harm event has occurred, fear of litigation, and lack of training in talking with patients about harm events (Mello, et al. 2014, Agency for Healthcare Research and Quality 2017).

Patients initiated 89% of all EDR conversations, and they did so an average of ten and a half months after the harm event occurred. When providers initiated EDR, they did so an average of four and a half months after the event.

Accomplishments that address this challenge: Expanding Oregon's Toolbox for Responding to Unintended Harm (page 12), Convening a Statewide Communication and Resolution Learning Collaborative (page 13)

- **While all Oregon healthcare organizations are concerned with patient safety, not all have the infrastructure in place to respond to unintended patient harm.**

Various studies indicate that unintended patient harm is commonplace across healthcare settings (Classen, et al. 2011, James 2013, Kohn, Corrigan and Donaldson 2000, Levinson 2014, Woods, et al. 2007). In order to implement EDR or other proactive approaches, providers need a certain amount of basic infrastructure. This includes a robust event reporting system, a policy of talking with the patient immediately after an unintended harm event and again after more facts are known, and staff who are skilled communicators (Lambert, et al. 2016, Garbutt, et al. 2007). There should also be a protocol for investigating and analyzing unintended harm events and a system to implement effective improvements in care. The benefits of a structured approach include, but are not limited to, a reduction in rate of claims and lawsuits, a reduction in average total liability per claim, improved patient-physician relationships and patient satisfaction, and a reduction in medical professionals' feelings of guilt related to adverse event (Ock, et al. 2017).

All organizations have limited resources for change and certainly healthcare professionals face many competing demands resulting from changes to healthcare driven by federal and state law.

About 10% of EDR Requests were made by providers. Some providers use their own internal processes to proactively engage with injured patients and choose not to incorporate EDR. However, many healthcare professionals who might be willing to try open communication have indicated to us that they lack the infrastructure to implement EDR or other proactive approaches following patient harm.

Accomplishments that address this challenge: Expanding Oregon's Toolbox for Responding to Unintended Harm (page 12), Convening a Statewide Communication and Resolution Learning Collaborative (page 13)

- **Providers whose own emotional needs have not been met may be less able to support patients and families in the wake of unintended harm.** An unintended serious harm event may be traumatic not only for the patient and family, but also for the healthcare professional (Elwy, et al. 2016). While many healthcare organizations have employee assistance programs or selectively refer providers to mental health professionals, few are equipped to proactively offer peer support to all affected providers immediately following an event. The lack of emotional support is a leading contributor to provider burnout (Sanchez-Reilly, et al. 2013). Leaders in communications and resolution 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 (McDonald 2018).

In the ideal conversation, the healthcare professional will be emotionally attuned to the patient and will not only respond to the patient's factual inquiries but will also demonstrate concern for the patient's well-being (Mazor, et al. 2013). This can be very difficult for providers whose own emotional needs following the harm event have not been met (Gallagher, et al. 2003).

Accomplishments that address this challenge: Expanding Oregon's Toolbox for Responding to Unintended Harm (page 12)

- **Healthcare professionals are reluctant to participate in EDR when patients request conversations.** Fifty-five percent of providers (55/100) and 67% of facilities (70/105) have declined patient Requests for Conversation over the life of the program (see page 16 for further discussion). Some healthcare professionals decline EDR because they prefer to use their own internal grievance or claims processes and do not choose to incorporate EDR. Some are unwilling to engage in conversation regarding a matter if the patient is barred from filing a lawsuit (e.g. the statute of limitations has run). Of note, despite early concerns that healthcare providers would decline EDR due to fear of reporting to the Oregon Medical Board or the National Practitioner Data Bank, neither has been cited as a reason for declining to participate.

Research suggests that healthcare professionals are often uncomfortable openly discussing an adverse event with a patient (Gallagher, et al. 2003). This discomfort may stem from a lack of training in disclosure, and/or a cultural reluctance to admit involvement in unanticipated patient outcomes (Mello, et al. 2014).

Other barriers providers have cited during EDR workshops include:

- Lack of clear policies or guidelines from employer
- Feelings of shame or embarrassment
- Reluctance to involve colleagues
- Concern about exacerbating already strained inter-professional relationships (e.g. a dentist and a hygienist or a nurse and a doctor)
- Low confidence in communication skills
- Lack of awareness about availability of just-in-time communication coaching through employer or insurer
- The providers own unmet need for support following an unintended harm event

Accomplishments that address this challenge: Expanding Oregon's Toolbox for Responding to Unintended Harm (page 12), Convening a Statewide Communication and Resolution Learning Collaborative (page 13)

II. The Complexity of the Healthcare System Creates Challenges for EDR

- **The complexity of the healthcare system has created challenges for Oregonians seeking to use the program.** Depending on the situation, moving a Request for Conversation through the EDR process may require participation on the part of the patient and:
 - The healthcare facility where the event occurred
 - The involved healthcare provider(s)
 - The organization that employs the healthcare provider(s)
 - The liability insurer representing the facility
 - The liability insurer(s) representing the healthcare provider(s)
 - The attorney for any of the above

The patient's experience with EDR may be adversely affected by coordination challenges among these participants. Coordination difficulties may delay both an initial response to a patient's Request for Conversation and the conversation(s) that may take place in response to the request.

One of the primary challenges is related to the employment relationship between healthcare providers and the facilities where they provide care. Among patient requests related to events that occurred at a healthcare facility, more than two-thirds (68%, 91/134) involved providers who were not employed by the facility where the event occurred. Most of these providers were employed by group practices that contract to provide care at the facility where the event occurred. This employment relationship, which is typically unknown to the patient, may result in the facility and the provider each choosing to manage the EDR request independent of the other.

Additionally, participants may have differing philosophies about compensating patients that may affect the likelihood of reaching resolution (Mello, et al. 2014).

Accomplishments that address this challenge: Building the Foundation for EDR (page 11), Convening a Statewide Communication and Resolution Learning Collaborative (page 13)

- **It can be challenging to identify, locate, and notify healthcare providers in a timely manner.** When a patient requests a conversation through EDR that names one or more providers, the law requires that we notify each provider directly. It may be challenging to notify a named provider when the provider is not a facility employee but is employed by a group practice and:
 - The patient has incomplete or inaccurate provider information
 - The provider has changed employers or has left the region

- The provider is unfamiliar with us or the EDR program and may be cautious about accepting or returning a call without more information

Although group practices frequently have structures in place to receive and process patient grievances or claims, in accordance with the law (Oregon Laws 2013, Chapter 5, Section 2(3)), we notify providers directly.

In contrast, when a *healthcare facility*³ is involved, all patient EDR Requests for Conversation can be managed centrally, through the organization's established grievance or claims structures. Although we have automated this notification process, it relies on the input of accurate information and must be frequently updated to reflect staffing changes at facilities. In addition, from the patient perspective, some facility locations do not appear to be facilities. For example, an urgent care clinic may be, in fact, a hospital satellite facility. To further complicate matters, some clinics share an address with a facility, information that a patient would not reasonably know.

Accomplishments that address this challenge: Building the Foundation for EDR (page 11)

III. The Asymmetry between Patients and Healthcare Professionals affects the EDR Process

- **Patients often need assistance from OPSC to engage in the EDR process.** At present, most patients who are interested in EDR find the program through internet searches and lawyer referrals. In some cases, the patient has already attempted to speak to their healthcare professional, but more frequently they did not know who to talk to or how to get assistance. Patients who contact us about EDR are often unsure if their situation qualifies for EDR.

For example, one of the qualifying criteria to use EDR is that a patient must have sustained a serious physical injury or death from care. Because patients may have limited medical knowledge, making an independent determination that their situation resulted in serious physical injury by applying a technical definition can be a challenge. In our role as the administrative entity of EDR, we have limited knowledge about an event and must remain neutral. In these situations, we offer the patient information about the definition and answer their questions so that they can decide if they experienced a serious physical injury.

³ A licensed healthcare facility as defined in ORS 442.015. Healthcare facilities are: ambulatory surgery centers, freestanding birthing centers, hospitals (including any licensed satellite facility), nursing facilities, outpatient renal dialysis centers. (See Appendix I: Important Terms for this Report.)

There are additional challenges related to the complexities of the healthcare system that put patients at a disadvantage. These challenges are apparent when a patient must identify the specific location where the event occurred and name the provider(s) involved. When patients describe their situation, they frequently report a cascade of events that transpired over weeks or months and involved multiple visits to healthcare professionals in various care settings. It can be challenging for a patient to pinpoint where EDR-appropriate events occurred. Even when care was provided in a single location, patients may not know the names of the healthcare professionals who provided services. The only information they have may be the “E.R. doctor” or a “nurse named Becky.” Because the goal of EDR is to connect patients with the healthcare professionals involved in the harm event for conversation, knowing the event location and having the name of the professional are essential to making that connection.

Accomplishments that address this challenge: Building the Foundation for EDR (page 11)

- **Patients want OSPC to help them advocate effectively during EDR conversations, a role that we cannot fill.** Research shows that patients harmed by their healthcare who attempt to speak with their healthcare professionals were often unsatisfied with the conversations and left feeling that their concerns had not been addressed (Iedema, et al. 2011, Mazor, et al. 2013). EDR has the potential to offer patients in Oregon a better experience, but there are typically some inherent challenges related to the asymmetry of information, education, and experience between patients and healthcare professionals. Patients may find conversations difficult (Iedema, et al. 2011)—most have never been in a situation like this before and may have limited medical knowledge. In conversations, they are often at the table with experienced healthcare professionals who know how the process should work, have medical knowledge, and have many resources at their disposal.

Over the four years of the program, some patients have expressed discomfort upon learning that OPSC staff would not be attending EDR conversations. While we encourage patients to identify people to accompany them in a support role, community resources for patient advocacy are limited.

Mediators may be a potential resource for patients; however, the cost of a mediator remains a barrier. EDR provides that either party can request a mediator, and both parties must mutually agree on the mediator and split the cost unless they make another agreement (Oregon Laws 2013, Chap. 5, Section 5).

Some communication and resolution models outside Oregon include legal representation for patients, not in anticipation of legal action, but because a lawyer may be able to help a patient understand the process and provide

guidance regarding next steps (Mello, et al. 2014). The Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI) strongly recommends that patients be represented and provides guidance for lawyers participating in the resolution process.

EDR regulations allow a patient to bring anyone, including a lawyer, to an EDR conversation for support. However, it is our experience that healthcare professionals may be less willing to participate if the patient is represented.

Accomplishments that address this challenge: Building the Foundation for EDR (page 11)

IV. Impacts of EDR are Difficult to Measure at the State Level

- **Oregon lacks comprehensive baseline data on the total number of serious adverse events occurring in the state, as well as the number of insurance claims asserted and medical malpractice cases filed related to these events.** Ideally, we would be able to demonstrate the effectiveness of EDR by quantifying annually how many instances of unintended patient harm resulting in serious injury or death were resolved through the EDR process rather than in the courts. However, no state, including Oregon, has a mechanism to accurately capture the total number of qualifying harm events occurring (Classen, et al. 2011, Kohn, Corrigan and Donaldson 2000, Levinson 2012, National Patient Safety Foundation 2015, Shojania and Dixon-Woods 2017, Woods, et al. 2007), the number of statewide claims related to these events, or the number of statewide medical malpractice cases. Neither the Patient Safety Reporting Program,⁴ the National Practitioner Data Bank,⁵ nor the Oregon Medical Board collects comprehensive data that can provide a baseline for any of these measures. Oregon has transitioned to the eCourt system which may allow tracking of medical malpractice lawsuits in the future.⁶ Nevertheless, it will not be possible to measure the impact of EDR on medical malpractice filings because we cannot count lawsuits prevented. Additionally, we will never be able to quantify the number of unintended patient harm events that were prevented because of patient safety improvements made in response to an EDR Request for Conversation.

⁴ The Patient Safety Reporting Program is OPSC's voluntary statewide adverse event reporting program. Learn more at oregonpatientsafety.org.

⁵ NPDB is a limited-access, federal repository containing some information on medical malpractice payments and certain adverse actions related to health care practitioners, entities, providers, and suppliers.

⁶ Oregon eCourt is a statewide web-based courthouse. courts.oregon.gov/oregonecourt/Pages/About.aspx

Accomplishments that address this challenge: Initial Observations on the EDR Value Proposition (page 11), Expanding Oregon’s Toolbox for Responding to Unintended Harm (page 12), The EDR Ripple Effect (page 14)

- **The voluntary nature of Resolution Reports limits our ability to collect complete data.** Much of what can be learned about EDR comes from Resolution Reports, including information about the conversations between patients and healthcare professionals, how events are resolved, and patient demographic information. In accordance with the law, Resolution Reports are voluntary and are not always submitted by EDR participants. Twenty percent of those submitted were incomplete. Additionally, a single EDR Request for Conversation, may generate multiple Resolution Reports with conflicting accounts of what happened (page 21).

Accomplishments

I. Initial Observations on the EDR Value Proposition

- **EDR is gaining momentum:** We have received 150 Requests for Conversation in the four years since the program began on July 1, 2014; 16 (11%) were initiated by healthcare professionals and 134 (89%) by patients. One-third of all Requests for Conversation (50/150) were filed during year four.
- **Patients are initiating EDR:** Oregon is the only state in the nation to allow patients to initiate conversation and resolution with their providers. Although the popularity of the communications and resolution model is growing among healthcare organizations, other programs rely on healthcare professionals to initiate the conversation. We believe that the 89% of EDR requests initiated by patients indicates that patients have a strong desire for communication.
- **EDR fills a gap in our legal system:** Plaintiff lawyers have become EDR’s primary source of patient referrals. Trial lawyers refer patients whose claims are barred by the statute of limitations or by failure to timely file a required notice of claim; as well as clients whose claims are not clear-cut or who’s injuries are not significant enough compared to the expenses associated with pursuing a civil action.

II. Building the Foundation for EDR

- **Stakeholders guided implementation of EDR:** We convened a patient advisory committee and a stakeholder advisory committee to guide the development of EDR administrative rules and program infrastructure.
- **OPSC created a secure online system to manage EDR data and communications:** Anyone with an internet connection can initiate EDR. EDR

data and communications are managed in a secure online system. While telephone and mail-in options are still available as needed, EDR can be initiated any time, even if our staff are not available. Additionally, the system protects the privacy of involved patients and healthcare professionals.

- **Patients and healthcare providers can access EDR information online and over the phone:** We maintain a website with information about EDR (oregonpatientsafety.org). In 2017, the website incorporated usability and accessibility principles, including responsive design to ensure all Oregonians can easily access the content from a variety of electronic devices. We also respond to calls from patients and healthcare professionals and provide assistance on an individualized basis.
- **OPSC developed messaging for key EDR audiences:** Recognizing that the legal language featured in our initial outreach was off-putting to potential users of EDR, we developed a set of key messages for communication with healthcare providers and patients and incorporated them program-wide.

III. Expanding Oregon’s Toolbox for Responding to Unintended Harm

- **OPSC educated many stakeholders about EDR:** We have made over twenty presentations about the importance of communication in the wake of unintended harm and the benefits of using EDR to a broad array of stakeholder groups, in locations from Astoria to Pendleton to Roseburg. The most recent presentation was in Spring 2018 to more than 100 dentists.
- **OPSC developed and disseminated a new resource for healthcare professionals who want to have an EDR conversation:** We integrated recommendations from published research about what patients want from a conversation with their providers following unintended harm into a checklist format for healthcare professionals.
- **OPSC published public reports for shared learning:** We have published three reports analyzing deidentified information that we have received through EDR. These reports offered lessons learned during implementation as well as recommendations to healthcare professionals for improving their response to patient harm.
- **OPSC created resources for organizations to implement EDR.** We have responded to stakeholder requests by developing model letters, policies, and evaluation tools for EDR implementation.
- **OPSC informs public about other resources.** As a public agency, when we receive calls from the general public concerning issues not appropriate for EDR, we offer contact information for relevant resources.

IV. Convening a Statewide Communication and Resolution Learning Collaborative

- **OPSC helped Oregon healthcare organizations build their capacity to respond to unintended patient harm:** In September 2016, we convened the Oregon Collaborative on Communication and Resolution Programs (OCCRP) specifically to help build participants' capacity to take a communications and resolution approach integrating Oregon's EDR process to unexpected patient harm.
 - a. OCCRP Cohort One: two critical access hospitals, two large urban medical centers, and two large clinics, serving diverse clients and operating largely in distinct service areas, engaged in a year-long comprehensive exploration of the elements of a communication and resolution program, using the Communication and Optimal Resolution (CANDOR) Toolkit from the Agency for Healthcare Research and Quality (AHRQ) as the base curriculum. Participants learned from national experts (see Appendix III. OCCRP Faculty) and practiced key skills in a workshop setting.
 - b. OCCRP Cohort Two: five hospitals and clinics are focused on developing, implementing, and evaluating the peer support element of a communication and resolution program, and training peer supporters. This effort is ongoing.
- **OPSC conducted organizational assessments:** We have performed confidential assessments for four of the organizations participating in the OCCRP to help each one identify where it should focus resources to bolster its ability to implement a communications and resolution-informed approach to unintended harm events.
- **OPSC brought national communication and resolution experts came to Oregon for OCCRP Learning Sessions:** We have brought some of the foremost patient safety advocates, innovators, and practitioners in the nation to serve as OCCRP faculty and to speak to other interested audiences at public sessions and at our annual Oregon Patient Safety Forum (see Appendix III. OCCRP Faculty).
- **OPSC convened an advisory committee to guide OCCRP work:** We convened an OCCRP Advisory Committee that includes representatives of many key stakeholder groups, including the Oregon Medical Association, the Osteopathic Physicians and Surgeons of Oregon, the Oregon Association of Hospitals and Health Systems, the three major medical liability insurers, two large health systems, and patient advocates. Because of its diverse membership, the Advisory Committee has proven to be very useful for vetting policy and procedural recommendations related to how an organization implements EDR.

V. The EDR Ripple Effect

- **EDR is stimulating conversations beyond the program:** Even when the formal EDR process is not used, EDR has created opportunities for conversations between patients and healthcare professionals. 53% of healthcare professionals who chose not to accept a patient's request to use EDR indicated that they had used or planned to use existing processes to communicate with a patient.
- **EDR promotes improvements to patient safety:** Patients who initiate EDR often express a desire to know how similar events will be prevented. The resolution may include steps healthcare professionals will take to improve care for future patients.
- **Oregon is a part of the national conversation:** Through our work with the Collaborative on Accountability and Improvement (CAI), Oregon is contributing to the national movement towards greater transparency and accountability following unintended patient harm.

EDR Use

What we know about the impact of EDR comes both from our informal communication with patients and healthcare professionals and our structured data collection tools. When someone completes a Request for Conversation or a Resolution Report in the EDR Online System, that information is stored in our secure system.

Requests for Conversation

In the first year of the program, EDR saw a total of 29 Requests for Conversation. In the second year, there was a 31% increase, which plateaued in the third year. In its fourth year, EDR saw 50 requests. Over the four-year period that EDR has been available, a total of 150 requests for conversation have been submitted (Table 1). The majority of Requests for Conversation (89%) have come from patients (Figure 1).

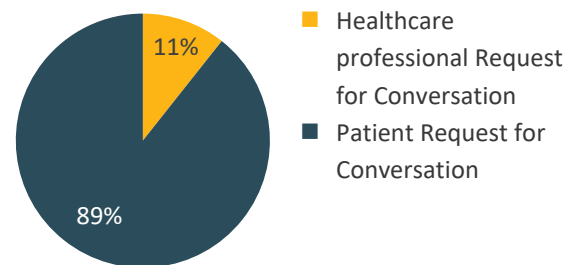
Table 1. Number of Requests for Conversation by year, July 2014-June 2018

(n=150)

	Number of requests
Year 1	29
Year 2	38
Year 3	33
Year 4	50

Figure 1. Requests for Conversation by requester type, July 2014-June 2018

(n=150)

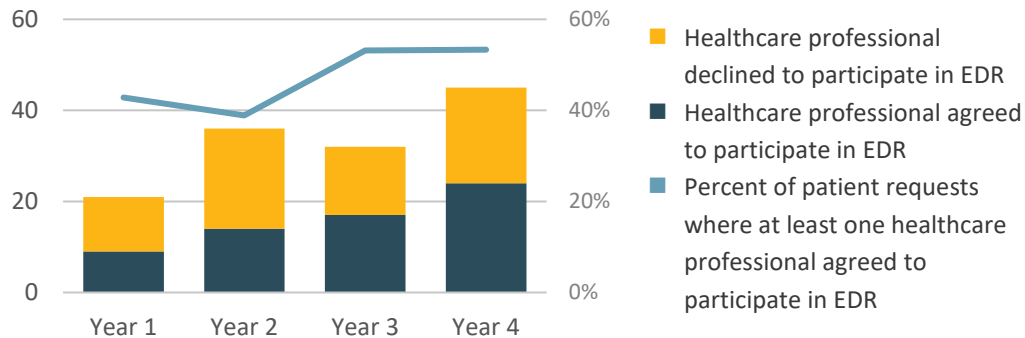


Because EDR is voluntary, participants must agree to engage in EDR and any participant can withdraw at any time. A Request for Conversation submitted by a patient may include multiple healthcare facilities and/or providers. In 64 out of 134 patient Requests for Conversation (48%), at least one of the healthcare professionals named in the request agreed to participate in EDR (Figure 2, page 16).

Figure 2. Accepted and declined patient Requests for Conversation by year, July 2014-June 2018

(n=134)

Number of requests



The acceptance rate for patient Requests for Conversation has increased over time, from 29% in Year 2 to 53% in years 3 and 4.

Reasons Healthcare Professionals Decline Requests

Healthcare professionals (both healthcare facilities and healthcare providers) decline participation primarily because they have elected to use their own internal grievance or claims process and have not integrated EDR into their approach.

Another common reason for healthcare facilities to decline participation is that they determined the event resulted from the actions of a contracted provider, who was in fact employed by a private practice. Individual healthcare providers frequently declined on the recommendation of their liability insurers (Table 2, page 17).

There are also reasons providers decline participation that are included in the *other* category, each occurring fewer than three times. The *other* reasons include the fact that the authority of an individual to serve as a patient’s representative could not be confirmed (see Appendix I. for a description of who can serve as a patient representative), that a healthcare provider had left practice and no longer had access to medical records, or that a provider learned that a facility would not be participating and elected not to participate either.

Table 2. Reasons facilities and providers declined patient Requests for Conversation, July 2014-June 2018

Decline reasons	Number decline reasons from facilities (n=70)	Number of decline reasons from providers (n=59)
I intend to use a different process to address this event, and will not incorporate EDR	28 (40%)	17 (29%)
I have already addressed this event through another process	13 (19%)	11 (19%)
Patient's concerns are exclusive to provider(s)/facility	15 (21%)	2 (3%)
Other	7 (10%)	9 (15%)
Advised against participation by liability insurer	2 (3%)	11 (19%)
I do not believe event meets definition of adverse healthcare event	6 (9%)	5 (8%)
Advised against participation by legal counsel	1 (1%)	6 (10%)
Patient discontinued process	2 (3%)	1 (2%)
Unclear if patient representative had EDR authority	2 (3%)	0 (0%)

Note: Patients can name more than one provider on a Request for Conversation. When the event took place at a healthcare facility, a patient must name the healthcare facility, but naming one or more providers is optional. When the event took place outside a healthcare facility, a patient must name one or more providers. Each facility and provider named in a Request for Conversation may accept or decline the request.

Event Types

Of the 150 Requests for Conversation received, more than two-thirds were related to just two event types: *surgical or other invasive procedure* events (37%) and *care delay* (35%), which includes both delays in diagnosis and delays in treatment (Table 3). While most request included only one type of event (Appendix IV. Event Type Categories), 15 included two distinct event type.

Table 3. Types of events described in Requests for Conversation, July 2014-June 2018

Event Type	Patient Requests (n=134)	Healthcare professional Requests (n=16)	Total (n=150)
Surgical or other invasive procedure	48 (36%)	8 (50%)	56 (37%)
Care delay	46 (34%)	6 (38%)	52 (35%)
Medication or other substance	14 (10%)	1 (6%)	15 (10%)
Other	12 (9%)	0 (0%)	12 (8%)
Product or device	9 (7%)	2 (13%)	11 (7%)
Healthcare-associated infection	9 (7%)	0 (0%)	9 (6%)
Patient protection	3 (2%)	0 (0%)	3 (2%)
Environmental	2 (1%)	0 (0%)	2 (1%)
Fall	2 (1%)	0 (0%)	2 (1%)
Blood or blood product	1 (1%)	0 (0%)	1 (1%)
Obstetrical	0 (0%)	1 (6%)	1 (1%)
Radiologic	1 (1%)	0 (0%)	1 (1%)

Note: Percentages total more than 100 as 15 requests involved more than one event type.

Conversation and Resolution Information

EDR participants are asked to complete a voluntary questionnaire, called a Resolution Report, that serves as our primary window into the conversations that have taken place between patients and healthcare professionals. The Resolution Report includes questions about the number of conversations and who participated in them, the topics included in the conversation, whether an event has been resolved and if so how, the overall satisfaction with the process, and whether a respondent wants to volunteer additional information.

One or more Resolution Reports were completed for 91 of the 150 Requests for Conversation that have been submitted in the four years of the program. In 39 cases, both the patient and at least one involved healthcare professional completed a Resolution Report. In three of those 39 cases, the patient, a facility, and a provider not employed by the facility each completed a resolution report related to the same request for conversation. (A comparison of Resolution Report information from events where multiple reports were received can be found in the discussion of Differences in Perception on page 21.)

Conversation Elements

Resolution Report respondents were asked to indicate the elements included in any conversations that took place from a list of nine discussion elements. The most common elements selected by the 62 patients and healthcare professionals that responded to the question were *information about the event* (55/62, 89%) and *information about why the event happened* (44/67, 71%) (Table 4, page 19).

Table 4. Conversation elements in early discussions, July 2014-June 2018

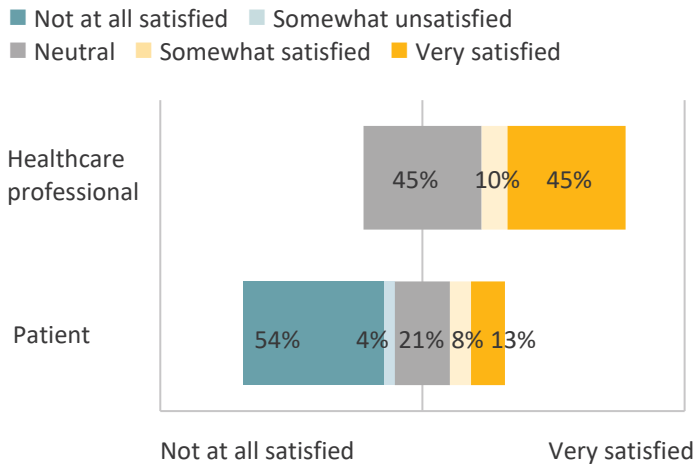
Conversation Element	Patient Resolution Reports (n=23)	Healthcare professional Resolution Reports (n=39)	Total Resolution Reports (n=62)
Information about the event	20 (87%)	35 (90%)	55 (89%)
Information about why the event happened	15 (65%)	29 (74%)	44 (71%)
The possible impact of the event on the patient's health, treatment, and follow-up	10 (43%)	23 (59%)	33 (53%)
Explanation that an error occurred	8 (35%)	19 (49%)	27 (44%)
Explanation that an error did not occur	9 (39%)	16 (41%)	25 (40%)
What actions will be taken to prevent recurrence	4 (17%)	16 (41%)	20 (32%)
An offer of compensation (other than waiver of medical bills)	9 (39%)	10 (26%)	19 (31%)
An offer to waive medical bills	1 (4%)	16 (41%)	17 (27%)
How additional information will be shared with the patient in the future	1 (4%)	15 (38%)	16 (26%)

Note: Percentages add up to more than 100% because users can mark multiple conversation elements in one Resolution Report.

Satisfaction Ratings and Apologies

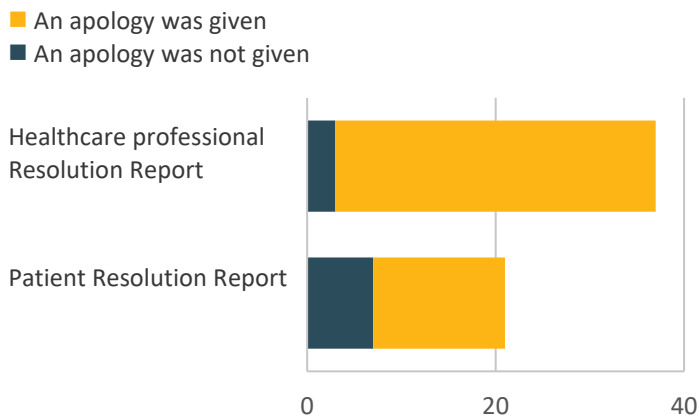
Healthcare professionals and patients often enter conversations about an event with differing expectations and knowledge. We can see evidence of this difference in their reported satisfaction with the resolution process. Respondents indicated their satisfaction using a five-point scale: *very satisfied*, *somewhat satisfied*, *neutral*, *somewhat unsatisfied*, *not at all satisfied*. Of the 41 healthcare professionals and 24 patients that received this question, all but one responded. All of the 40 healthcare professionals who responded to this question indicated that they were *very satisfied*, *somewhat satisfied*, or *neutral*, compared to 10 of 24 patients (42%) (Figure 3).

Figure 3. Respondent satisfaction with the resolution process, July 2014-June 2018
(n=64)



Resolution Report respondents also indicate whether the patient or patient’s representative received an apology (Figure 4, page 10). Of the 41 healthcare professionals and 24 patients that received this question, 58 (89%) responded.

Figure 4. Resolution Report type, was an apology given
(n=58)



Forty-eight of 58 Resolution Report respondents who answered this question (83%) indicated that an apology was given. (A comparison of the perceptions of patients and healthcare professionals as to whether an apology was made can be found on page 22.) Receiving an apology was not correlated with the resolution of the Request for Conversation (Table 5) or either party’s satisfaction with the process (Table 6).

Table 5. Resolution Report type by Resolution Report status, was an apology given

	An apology was given	An apology was NOT given
Patient Resolution Reports (n=21)		
Issue was resolved in discussion	5 (24%)	1 (5%)
Issue was unresolved	8 (38%)	6 (29%)
Other Resolution Report status	1 (5%)	0 (0%)
Healthcare professionals Resolution Reports (n=37)		
Issue was resolved in discussion	17 (46%)	2 (5%)
Issue was unresolved	12 (32%)	1 (3%)
Other Resolution Report status	5 (14%)	0 (0%)

Note: Further discussion of Resolution Report statuses can be found on page 24.

Table 6. Resolution Report type by satisfaction with the process, was an apology given

	An apology was given	An apology was NOT given
Patient Resolution Reports (n=21)		
Very or somewhat satisfied	4 (19%)	1 (5%)
Neutral	3 (14%)	1 (5%)
Somewhat unsatisfied or not at all satisfied	7 (33%)	5 (24%)
Healthcare professionals Resolution Reports (n=37)		
Very or somewhat satisfied	18 (49%)	2 (5%)
Neutral	16 (43%)	1 (3%)
Somewhat unsatisfied or not at all satisfied	0 (0%)	0 (0%)

The Resolution Reports also show that resolution may be reached during a conversation even when no apology is made.

Differences in Perception

In cases where we have multiple resolution Reports related to one Request for Conversation, we sometimes see differences between what was reported by patients and healthcare professionals. These differences may be related to a variety of factors, such as:

- Patient and healthcare professionals may submit Resolution Reports at different times
- Patient and healthcare professionals may not have a shared understanding of which conversation was the “initial conversation”
- Patient and healthcare professionals may have a difference in interpretation of Resolution Report questions and/or answer options

Conversation Elements

Fourteen Requests for Conversation had an associated Resolution Report from both a patient and a healthcare professional, that also included a response to the question about what elements were included in a conversation. (This question is only offered when the respondent indicates that a conversation took place and was not asked on all Resolution Reports.) Although in all but one case, patients and healthcare professionals agreed on at least one reported conversation element, there was only one situation in which all identified conversational elements matched (1/14, 7%). The most commonly shared element was *information about the event* (12/14, 86%). The conversation elements most frequently reported by the healthcare professionals only were *the possible impact of the event on the patient’s health, treatment, and follow-up* and *explanation that an error occurred* (each 5/14, 36%).

By contrast, the conversation element most frequently reported by the patient only was *an explanation that error did not occur* (5/14, 36%). In fact, in two of those four cases, the provider reported contradictory information (*explanation that an error occurred*).

Apologies

There were 12 cases where both a patient and a healthcare professional responded to the question regarding the offer of an apology. In 11 of 12 cases, the healthcare professionals reported offering an apology, but only seven of the patients reported receiving an apology.

While we don’t know the reasons for these differences in perception, research shows that when healthcare professionals apologize to patients, they may not include all the characteristics of a full apology; therefore, these partial apologies may not be perceived as an apology by patients (Mazor, et al. 2013, Levinson, Yeung and Ginsburg 2016, Prothero and Morse 2017, Robbennolt 2009).

Resolution

There were four situations in which the healthcare professional indicated that resolution had been reached during the discussion, but the patient reported that no resolution had been reached. All of these situations involved a facility and a contracted healthcare provider, not employed by the facility. In each, the patient perceived that the individual provider had shown an insufficient degree of accountability or respect.

Patient Characteristics

Patients who either requested a conversation or were engaged in a conversation by a healthcare professional were more likely to be female than male (Figure 5) and were most likely to be between the ages of 50 and 69 (59%, Figure 6).

Figure 5. Patient gender
(n=150)

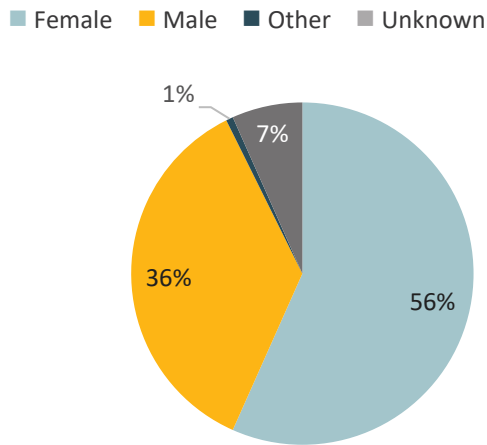
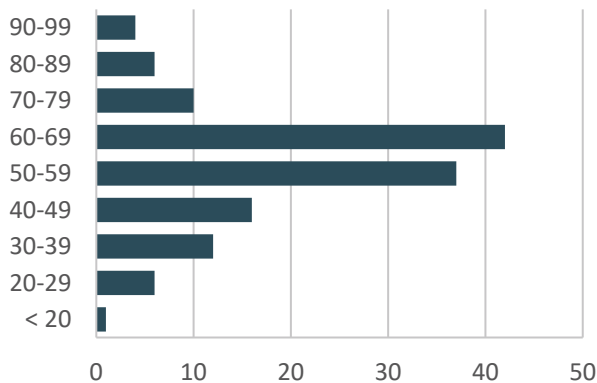


Figure 6. Patient age by age groups
(n=134)



Note: Dataset excludes healthcare professional Requests for Conversation

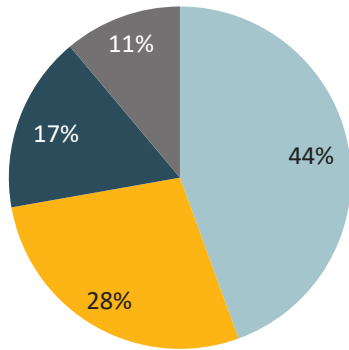
Patient Representative Characteristics

Nineteen Requests for Conversation were submitted by patient representatives (see Appendix I for a description who can serve as a patient representative). Sixty-eight percent were the adult child or spouse of the patient (Figure 7). Fourteen of the 19 patient representatives were so authorized because the patient had died. In one of the other cases, the representative was the parent of a child under the age of 18. In the

other four, the patient's doctor determined that the patient was incapable of making decisions related to EDR.

Figure 7. Type of patient representative
(n=19)

■ Adult child ■ Spouse ■ Guardian ■ Parent



Status of the EDR Process

Patients and healthcare professionals can complete Resolution Reports even if no conversation occurred. The Resolution Report asks the status of the EDR process at the point in time the report is made. More than half (41/75, 55%) of the Resolution Reports submitted by providers followed a discussion. Half (21/41, 51%) of the healthcare professional Resolution Reports following a discussion indicated that the discussion resulted in resolution, compared to less than a fifth (6/31, 19%) of those where a discussion did not take place (Table 7).

Twenty-four of the 44 Resolution Reports completed by patients (55%) followed an EDR discussion. A third of the patient Resolution Reports completed following an EDR discussion indicated that the discussion resulted in resolution (8/24, 33%). In patient Resolution Reports where no EDR discussion took place, no resolution was reached (0/18, 0%).

Overall, 27 of the 75 Resolution Reports from healthcare professionals (36%) and eight of the 44 Resolution Reports from patients (18%) indicated that the parties reached resolution.

Table 7. Resolution report statuses by EDR discussion occurrence, July 2014-June 2018

	An EDR discussion took place	An EDR discussion did not take place	Question unasked or unanswered	Total
Patient Resolution Reports	24 (55%)	18 (41%)	2 (5%)	n=44
Reached resolution	8 (33%)	0 (0%)	0 (0%)	8 (18%)
Did not reach resolution	16 (67%)	14 (78%)	0 (0%)	30 (68%)
Discontinued process, declined process, or handed off to other parties	0 (0%)	4 (22%)	2 (100%)	6 (14%)
Healthcare professionals Resolution Reports	41 (55%)	31 (41%)	2 (3%)	n=75
Reached resolution	21 (51%)	6 (19%)	0 (0%)	27 (36%)
Did not reach resolution	17 (41%)	19 (61%)	2 (100%)	38 (51%)
Discontinued process, declined process, or handed off to other parties	3 (7%)	6 (19%)	0 (0%)	9 (12%)

Note: *Reached resolution* includes selection of one of the following answer options: “Resolved during discussions between patient/patient’s representative and facility/healthcare provider,” “Resolved during mediation,” and “Other: resolved with liability insurer.”

Did not reach resolution includes selection of one of the following answer options: “Not settled and no claim or lawsuit filed,” “Not settled, no claim or lawsuit asserted,” “Other: Considering legal action,” “Other: unknown,” “Other: not settled, tort claim notice filed,” “Still pending in litigation.”

Discontinued process, declined process, or handed off to other parties includes selection of one of the following answer options: “Patient discontinued process,” “Other: Provider declined participation,” “Other: claimant died prior to completion,” “Other: handed off to insurer,” “Other: Handed off to corporate,” “Other: patient declined participation.”

It is important to note that because Resolution Reports are submitted a point in time, we do not know if the reported status changed following submission. Additionally, it will not be possible to measure the impact of EDR on medical malpractice filings because we cannot count lawsuits prevented.

Conclusion

EDR is the first statewide program of its kind in the country, and the only one to support initiation by patients as well as healthcare professionals. Still in its infancy, EDR is gaining visibility and acceptance across Oregon. We are encouraged by the number of people who have employed EDR to seek resolution following unintended patient harm.

We are optimistic that EDR has the potential to increase communication and improve patient safety.

We support the recommendations of the Task Force. We will be in a better position to confer with the Task Force about potential EDR changes to the Task Force after we have collected at least five years of data and received input from key stakeholders.

Acknowledgements

We are grateful for the dedicated stakeholders and community leaders who contributed to the design and implementation of EDR. The hard work of so many highlights the growing desire for a new and better approach to resolving serious adverse events.

These include, but are not limited to:

- The Task Force on Resolution of Adverse Healthcare Incidents
- The Advisory Committee to the Oregon Collaborative on Communication and Resolution Programs
- The Oregon Patient Safety Commission Board of Directors
- Members of the healthcare community
- 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 serious adverse events

References

- Agency for Healthcare Research and Quality. 2017. *Communication and Optimal Resolution (CANDOR) Toolkit*. Accessed September 13, 2018.
<https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/introduction.html>.
- Classen, David C, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C Whittington, Allan Frankel, Andrew Seger, and Brent C James. 2011. "'Global Trigger Tool' Shows That Adverse Events in Hospitals May Be Ten Times Greater Than Previously Measured." *Health Affairs* 30 (4): 581-589. Accessed September 13, 2018.
<https://www.healthaffairs.org/doi/10.1377/hlthaff.2011.0190>.
- Committee on Quality Health Care in America, Institute of Medicine. 2001. *Crossing The Quality Chasm : a New Health System for the 21st Century*. Washington, D.C.: National Academy Press.
- Duclos, Christine W, Mary Eichler, Leslie Taylor, Javan Quintela, Deborah S Main, Wilson Pace, and Elizabeth W Staton. 2005. "Patient perspectives of patient-provider communication after adverse events." *Journal for Quality in Health Care* 17 (6): 479-486.
- Elwy, A. Rani, Kamal M. F. Itani, Barbara G. Bokhour, Nora M. Mueller, Mark E. Glickman, Shibe Zhao, Amy K. Rosen, et al. 2016. "Surgeons' Disclosures of Clinical Adverse Events." *JAMA Surgery* 151 (11): 1015-1021.
doi:10.1001/jamasurg.2016.1787.
- Gallagher, Thomas H., Amy D. Waterman, Alison G. Ebers, Victoria J. Fraser, and Wendy Levinson. 2003. "Patients' and physicians' attitudes regarding the disclosure of medical errors." *JAMA* 289 (8): 1001-1007.
- Garbutt, Jane, Dena R. Brownstein, Eileen J. Klein, Amy Waterman, Melissa J. Krauss, Edgar K. Marcuse, Erik Hazel, Wm Claiborne Dunagan, Victoria Fraser, and Thomas H. Gallagher. 2007. "Reporting and Disclosing Medical Errors: Pediatricians' Attitudes and Behaviors." *Archives of Pediatric and Adolescent Medicine* 161: 179-185.
- Iedema, Rick, Suellen Allen, Kate Britton, Donella Piper, Andrew Baker, Carol Grbich, Alfred Allan, et al. 2011. "Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study." *BMJ* 343: d4423. Accessed September 13, 2018.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3142870/>.

- James, John T. 2013. "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care." *Journal of Patient Safety* 9 (3): 122-128. Accessed September 13, 2018.
https://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx.
- Kohn, Linda T, Janet M Corrigan, and Molla S Donaldson, . 2000. *To err is human : building a safer health system*. Washington, DC: National Academy Press.
- Lambert, Bruce L, Nichola M Centomani, Kelly M Smith, Lorens A Helmchen, Dulal K Bhaumik, Yash J Jalundhwala, and Timothy B McDonald. 2016. ""The "Seven Pillars" response to patient safety incidents: Effects on medical liability processes and outcomes." *Health Services Research* 51 (S3): 2491-2515.
- Levinson, Daniel R. 2014. "Adverse Events In Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries." (US Department of Health and Human Services, Office of Inspector General). Accessed September 13, 2018.
<https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>.
- Levinson, Daniel R. 2012. "Hospital Incident Reporting Systems Do Not Capture Most Patient Harm." (US Department of Health & Human Services, Office of Inspector General). Accessed September 13, 2018. <https://oig.hhs.gov/oei/reports/oei-06-09-00091.asp>.
- Levinson, Wendy, Jensen Yeung, and Shiphra Ginsburg. 2016. "Disclosure of Medical Error." *JAMA* 316 (7): 764-765.
- Mazor, Kathleen M, Steven R Simon, Robert A Yood, Brian C Martinson, Margaret J Gunter, George W Reed, and Jerry H Gurwitz. 2004. "Health Plan Members' Views about Disclosure of Medical Errors." *Annals of Internal Medicine* 140: 482-483.
- Mazor, Kathleen M., Sarah M. Greene, Douglas Roblin, Celeste A. Lemay, Cassandra L. Firreno, Josephine Calvi, Carolyn D. Prouty, Kathryn Horner, and Thomas H. Gallagher. 2013. "More Than Words: Patients' Views on Apology and Disclosure When Things Go Wrong in Cancer Care." *Patient Education and Counseling* 90 (3): 341-346.
- McCarron, Tamara L, Manal S Sheikh, and Fiona Clement. 2017. "The Unrecognized Challenges of the Patient-Physician Relationship." *JAMA Internal Medicine* 177 (11): 1566-1567.
- McDonald, Tim. 2018. "Essential Tools and Practices for Every Healthcare Setting." *7th Annual Oregon Patient Safety Forum*. Portland, OR: Oregon Patient Safety Commission. Accessed September 13, 2018.

https://oregonpatientsafety.org/docs/resources/2018_Patient_Safety_Forum_Main_Slide_Deck.pdf.

Mello, Michelle M, Richard C Boothman, Timothy McDonald, Jeffrey Driver, Alan Lembitz, Darren Bouwmeester, Benjamin Dunlap, and Thomas Gallagher. 2014. "Communication-and-resolution programs: the challenges and lessons learned from six early adopters." *Health Affairs* 33 (1): 20-29. Accessed September 13, 2018. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0828>.

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

Ock, Minsu, So Yun Lim, Min-Woo Jo, and Sang-il Lee. 2017. "Frequency, Expected Effects, Obstacles, and Facilitators of Disclosure of Patient Safety Incidents: A systematic Review." *Journal of Preventive Medicine & Public Health* 50: 68-82.

Prothero, Marie M., and Janice M. Morse. 2017. "Eliciting the Functional Processes of Apologizing for Errors in Health Care: Developing an Explanatory Model of Apology." *Global Qualitative Nursing Research* 4: 1-9.

Robbennolt, Jennifer K. 2009. "Apologies and Medical Error." *Clinical Orthopaedics and Related Research* 467: 376-382.

Sanchez-Reilly, Sandra, Laura J Morrison, Elise Carey, Rachelle Bernacki, Lynn O'Neill, Jennifer Kapo, Vyjeyanthi S Periyakoil, and Jane deLima Thomas. 2013. "Caring for oneself to care for others: physicians and their self-care." *Journal of Supportive Oncology* 11 (2): 75.

Shojania, Kaveh G, and Mary Dixon-Woods. 2017. "Estimating deaths due to medical error: the ongoing controversy and why it matters." *BMJ Quality and Safety* 26: 423-428. doi:10.1136/bmjqs-2016-006144.

Woods, Donna M, Eric J Thomas, Jane L Holl, Kevin B Weiss, and Troyen A Brennan. 2007. "Amulatory care adverse events and preventable adverse events leading to a hospital admission." *Quality and Safety in Health Care* 16: 127-131.

Woods, Michael S, and Jason Isaac Star. 2004. *Healing words: The power of apology in medicine*. Oak Park, IL: Doctors in Touch.

Appendix I. Important Terms for this Report

Term	Definition
Serious adverse event (also called adverse healthcare incident*)	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: <ul style="list-style-type: none"> • Is life threatening; or • Results in significant damage to the body; or • Requires medical care to prevent or correct significant damage to the body.
Apology	In the book <i>Healing Words: The Power of Apology in Medicine</i> , Michael Woods describes an effective apology, acknowledging that the “requirements for an effective apology will vary from case to case, depend on the injured person’s hopes, needs, and fears, and the relationship between the two parties...broadly speaking an authentic apology is likely to include the following five elements: <ol style="list-style-type: none"> 1. Recognition of the event that caused harm 2. An expression of regret and sympathy (the partial apology) 3. An acknowledgement of responsibility—where appropriate—once the facts are fully understood (the full apology) 4. Effective reparation 5. One or more opportunities to meet again after a period of reflection”⁷
Confidentiality	Confidentiality applies to discussion communications for Early Discussion and Resolution (Oregon Laws 2013, chapter 5, section 4). All written and oral communication is confidential, may not be disclosed, and is not 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.
Communication and resolution process	A process used by healthcare professionals to communicate with patients who have been harmed by their healthcare. The goal is to seek resolution and address the quality and safety gaps that contribute to events.
Healthcare professionals	Includes <i>healthcare facilities</i> (or representatives from <i>healthcare facilities</i>), <i>healthcare providers</i> , and employers of

⁷ Woods, M. S., & Star, J. I. (2004). *Healing words: The power of apology in medicine*. Doctors in Touch.

healthcare providers

Healthcare facility*	A licensed healthcare facility as listed in Oregon Laws 2013, chapter 5. Healthcare facilities are: <ul style="list-style-type: none">• Ambulatory surgery centers• Freestanding birthing centers• Hospitals (including any licensed satellite facility)• Nursing facilities• Outpatient renal dialysis centers
Healthcare provider*	A licensed healthcare provider as listed in Oregon Laws 2013, chapter 5. Healthcare providers are: <ul style="list-style-type: none">• 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	A patient or a patient's representative
Patient advocate	A person whose role is to support the patient and family in a healthcare setting, and to ensure that their voices are heard. Patient advocates may work for the organizations that are directly responsible for the patient's care, for an outside organization, or may be independent. Most are laypeople but some are trained medical professionals. Responsibilities may include: <ul style="list-style-type: none">• Personalizing and humanizing the healthcare experience• Explaining policies, procedures and services• Acting as a liaison between patients and medical providers• Ensuring that care is culturally appropriate and accessible• Providing access to resources for individual needs and questions• Providing access to information regarding sensitive healthcare questions

- Supporting the exercise of autonomy on medical decision-making
- Serving as the point of contact for concerns, complaints, and grievances

Patient advocates with specialized training may also provide medical guidance, insurance or financial guidance, and legal or ethical advocacy.

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

Request for Conversation

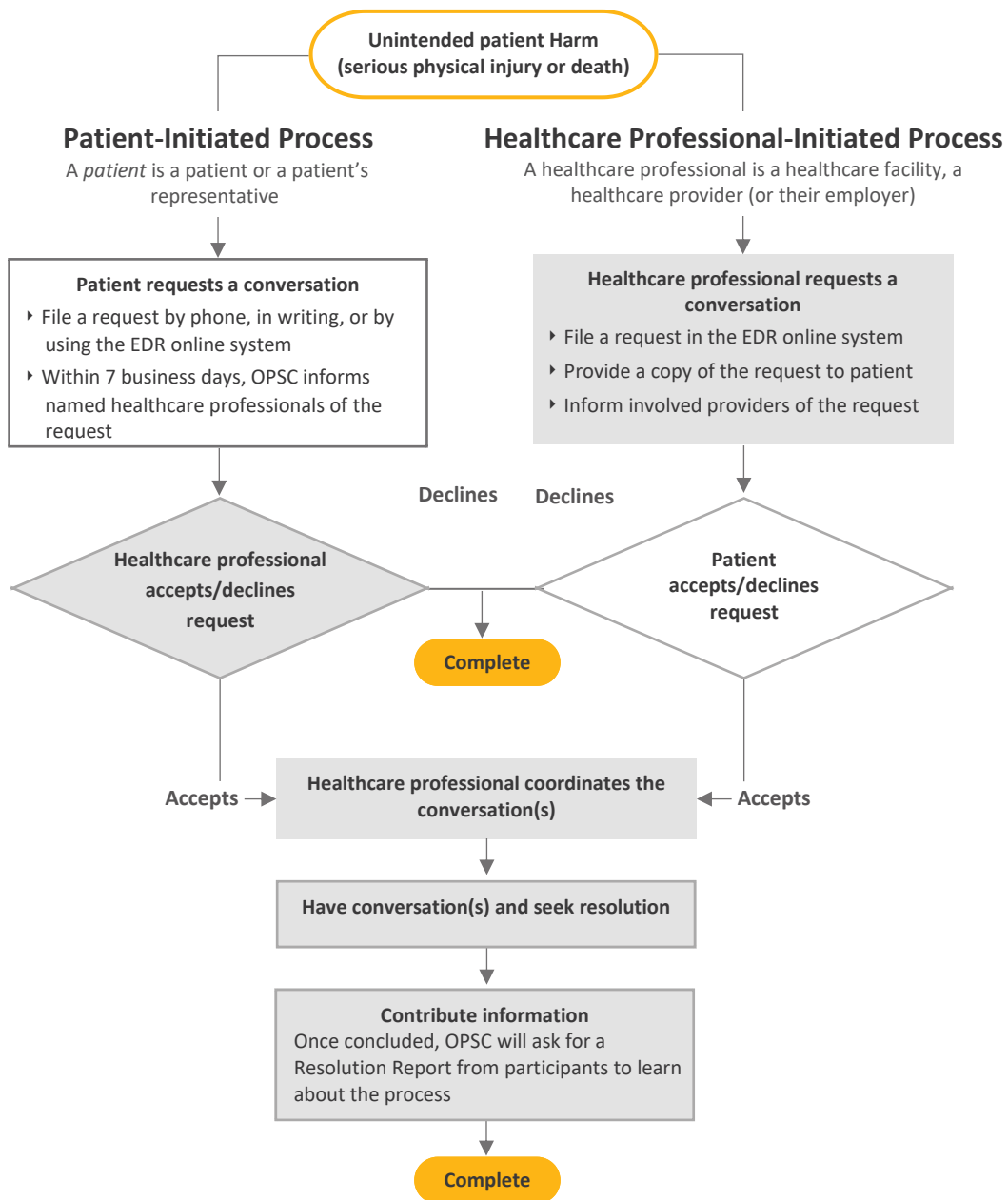
A Request for Conversation is a brief form that includes information about a specific physical injury or death (serious adverse event). A notice can be filed by a patient, a patient’s representative (in certain circumstances), a healthcare facility representative, or a healthcare provider. Submitting a Request for Conversation starts the Early Discussion and Resolution process. The request lets the other party know that the filer would like to talk to them about what happened. (Termed “Notice of Adverse Healthcare Incident” in Oregon Administrative Rule 325-035-0001 through 325-035-0045)

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

Appendix II. The Early Discussion and Resolution Process

When a serious adverse event occurs, either a patient or a healthcare professional can initiate EDR by completing a Request for Conversation, through 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 using the healthcare professional’s communication and resolution process.

- Patient-specific
- Healthcare professional-specific
- Patient and healthcare professional



Appendix III. OCCRP Faculty

The Oregon Collaborative on Communication and Resolution Programs (OCCRP) expert faculty

Rick Boothman, JD

Principal, Boothman Consulting Group LLC | Adjunct Assistant Prof, University of Michigan Medical School, Dep't of Surgery | Visiting Scholar, Vanderbilt University Medical School, Center for Patient and Professional Advocacy

Nikki Centomani, RN, BSN, ARM, MJ

Director, Office of Patient Safety, Loyola University

Julie Duncan, BN, MN, CPHQ

Director, Center for Clinical Excellence, University of Washington Medical Center

Thomas Gallagher, MD

Executive Director, Collaborative for Accountability and Improvement | Professor and Associate Chair of Medicine, University of Washington School of Medicine | Director, University of Washington School of Medicine Center for Scholarship in Patient Care Quality and Safety

Carol Gunn, MD, CIH

Member, OCCRP Advisory Committee | Patient Advocate | Internist and Occupational Physician

Claire Hagan, MHL

Member, OCCRP Advisory Committee | Manager of Risk Management Programs at Providence Health & Services

Carole Hemmelgarn, MS, MS

Patient Advocate, The Risk Authority, Stanford

Sam Imperati, JD

Executive Director, The Institute for Conflict Management, Inc.

Lorie Larsen-Denning, RN, MBA, CPCU, RPLU, DFASHRM

Member, OCCRP Advisory Committee;
Senior Vice-President, Marsh USA, Inc.

Bruce L. Lambert, PhD

Director, Institute for Public Health and Medicine – Center for Communication and Health, Northwestern University | Professor, School of Communication and Medical Social Sciences, Northwestern University

Timothy McDonald, MD, JD

Director, Center for Open and Honest Communication, MedStar Institute for Quality and Safety

Marcia Rhodes

Director, UW Medicine and Health Sciences Risk Management and Manager UW
Medicine CQIP at University of Washington

Susan Scott, PhD, RN, CPPS

Manager of Patient Safety and Risk Management, University of Missouri Health Care
System

Jo Shapiro, MD

Chief, Division of Otolaryngology, and Director, Center for Professionalism and Peer
Support, Brigham and Women's Hospital

John Westphal

Chief Advisor, Outcome Engenuity

Heather Wong, JD, MBA

Assistant Vice President of Claims & Litigation at The Risk Authority, Stanford

Appendix IV. Event Type Categories

Event type categories are based on definitions used by the OPSC’s Patient Safety Reporting Program and informed by the Agency for Healthcare Research and Quality’s Common Formats and the National Quality Forum’s Serious Reportable Events.^{8,9}

Event Type Category	Description
Blood product	Serious physical injury or death of a patient associated with unsafe administration of blood products (e.g., hemolytic reaction, mislabeled blood, incorrect type, incorrect blood product, expired blood product).
Care delay	Serious physical injury or death associated with a delay in care, treatment, or diagnosis.
Environmental	Serious physical injury or death of a patient associated with electric shock, oxygen or other gas related event, burns, restraint or bed rail related events.
Fall	Serious physical injury or death of a patient associated with a patient fall.
Healthcare-Associated Infection	Serious physical injury or death of a patient associated with an infection acquired while being cared for in a healthcare setting.
Medication	Serious physical injury or death of a patient associated with the administration of a medication; includes medication omissions.
Obstetrical	Serious physical injury or death of a patient associated with childbirth and the processes associated with it.
Patient protection	Serious physical injury or death of a patient associated with elopement, suicide, attempted suicide, or self-harm.
Pressure ulcer	Serious physical injury or death of a patient associated with a pressure ulcer.
Product or device	Serious physical injury or death of a patient associated with contaminated drugs devices or biologics, use or function related events, or intravascular air embolisms.
Radiologic	Serious physical injury or death of a patient associated with the introduction of a metallic object in the MRI area.
Surgical or other invasive procedure	Serious physical injury or death of a patient associated with a surgical or other invasive procedure (including anesthesia).

⁸ Agency for Healthcare Research and Quality’s Common Formats (common definitions and reporting formats) support healthcare professionals to uniformly report patient safety events and prevent future harm.

⁹ The National Quality Forum’s Serious Reportable Events list is a compilation of serious, largely preventable, and harmful clinical events, designed to help healthcare professionals assess, measure, and report performance in providing safe care.

Event Type Category	Description
Other	Serious physical injury or death of a patient associated with any other event type that does not fit into one of the defined event type categories.