Early Discussion & Resolution

Annual Report

July 2014 – June 2016

A look at the first two years of the Early Discussion & Resolution Program

OREGON
PATIENT SAFETY
COMMISSION
Early Discussion and Resolution

October 2016

The Oregon Patient Safety Commission, 2016

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.

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Executive Summary

Despite the best training and intentions, 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 bring resolution to both healthcare providers and their patients. Oregon's Early Discussion and Resolution (EDR) program offers support and legal protections for these important communications. By encouraging transparency and accountability in health care, EDR also may accelerate implementation of improvements to protect future patients.

This report provides an overview of EDR activity in the first two years, and offers lessons learned during implementation, as well as recommendations for improvement. The report also summarizes the Oregon Patient Safety Commission's ongoing work to ensure the success of EDR.

Over the first two years of EDR, the Oregon Patient Safety Commission has received 67 Requests for Conversation—year two saw a 31% increase in requests over year one. Patients made more than 85% of requests. Although fewer than half of all requests for a formal EDR conversation were accepted, about three-quarters of them resulted in a conversation of some kind. Undoubtedly, the availability of the EDR request process increased communication between patients and providers following an adverse event.

OPSC is committed to sharing what we have learned. In the last year, we have observed the following:

- Organizations that promptly communicate with patients and families following adverse events may more easily reach resolution
- An organizational culture of safety enables implementation of communication and resolution processes
- Coordination between multiple stakeholders adds complexity
- EDR creates opportunities for conversation between patients and their healthcare providers even when the formal EDR process is not used
- Patients may need assistance to advocate for themselves effectively during EDR conversations

A full discussion of these points, as well as recommendations for improvement, may be found in the Lessons Learned section of the report.

Achieving greater transparency and accountability across all settings where Oregonians receive healthcare hinges on long-term culture change among Oregon's healthcare professionals. We are very encouraged by provider and patient engagement in the first two years of EDR. To accelerate that culture change, we are working with partner organizations to convene the Oregon Collaborative on Communication and Resolution Programs (OCCRP). The innovative participants of the OCCRP will spend the next year working together to develop their own robust Communication and Resolution Programs and provide a model for others to follow.

With EDR and the OCCRP, Oregon is an important participant in the larger national conversation about how to improve patient safety by promoting transparency and accountability. EDR is pioneering a statewide approach that may be initiated by patients as well as healthcare professionals. We are proud to advance this important work.

Introduction

Despite the best intentions during healthcare, things don't always go as planned. While the numbers of errors reported in recent articles may be disputed by some (James, 2013; Makary, 2016), there is little disagreement about the fact that too many patients are harmed during care. Early Discussion and Resolution exists to provide a constructive way forward when patients are seriously injured or die during healthcare, and to protect future patients from harm by encouraging healthcare professionals to be transparent and accountable.

In 2013, Oregon was one of the first states in the country to pass a law promoting open, transparent communication with patients and families when serious harm or death occurs as a result of care—what is now called Early Discussion and Resolution (EDR) (see Appendix I for terms and definitions, see Appendix II for history of EDR).[1] When conversations between patients and healthcare professionals occur using EDR, those conversations are protected, allowing healthcare professionals to talk openly with patients about what happened as they explore the best way to move toward resolution and healing. Open communication can diminish a patient's need to seek legal recourse, while also promoting learning for improved patient safety (Boothman, Blackwell, Campbell, Commiskey, & Anderson, 2009).

The Oregon Patient Safety Commission administers EDR and is responsible for managing the program infrastructure, creating materials and guidance for participants, connecting patients and providers to have conversations, and promoting shared learning about best practices for resolution of adverse events.

In only two years of EDR, the Oregon Patient Safety Commission has received 67 Requests for Conversation from patients and healthcare professionals. Nearly 75% of these requests resulted in conversations that may not have otherwise occurred, some using EDR and some using an alternate method. Participants in ten EDR conversations reported achieving resolution through the EDR process. Although there is no way to be sure whether all these situations would have escalated into lawsuits had EDR not been available, it is likely that EDR provided an attractive alternative to litigation. We are very encouraged by these early signs that EDR may help increase communication and expedite resolution for Oregonians following adverse events. We look forward to contributing to the national movement promoting greater transparency in healthcare and principled, consistent, meaningful response to patient harm (Appendix III).

> "Oregon's EDR program represents an important and much needed step towards promoting the transparency and accountability that Oregon citizens deserve after adverse events, an openness that will be critical to improving the quality and safety of healthcare. I hope other states will emulate the thoughtful, inclusive, and patient approach that Oregon is taking to this challenging problem, and I am confident that the building blocks are in place for accelerating adoption of this exceptional program."
>
> **Thomas Gallagher, MD**
> Executive Director, Collaborative for Accountability and Improvement
> Professor, Department of Medicine and Bioethics, University of Washington

[1] Oregon laws 2013, chapter 5. www.oregonlegislature.gov/bills_laws/lawsstatutes/2013orLaw0005.pdf

EDR Overview

EDR Benefits

Despite the professional training and best intentions of healthcare providers, things don't always go as planned. When serious injury or death occurs, patients and their families want acknowledgement, answers, and support so they can move forward. Involved healthcare providers may also need support to move forward, even if they are not at fault. An open conversation about what happened can bring resolution and closure for both healthcare providers and their patients. Used in conjunction with a healthcare organization's internal process or on its own, Early Discussion and Resolution (EDR) can:

Prevent an unfortunate situation from escalating. When patients and families do not receive an appropriate and timely response after a patient is injured or dies, they may file a complaint or lawsuit. Legal processes can be time-consuming, expensive, and painful for everyone involved. Using EDR proactively to initiate a conversation with the patient and/or family, and considering fair compensation when appropriate, may avoid litigation and achieve a more positive result.

Maintain the provider-patient relationship. The relationship between the provider and the patient is the keystone of care, 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.

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 and families 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). An open conversation and an acknowledgment of the patient and family's suffering can help them 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 the healthcare provider to hear about the event from the patient and/or family's perspective. This information may help with the event analysis and new learning from the analysis can be rapidly integrated into the system to improve patient safety. On a broader level, the Oregon Patient Safety Commission (OPSC) analyzes and shares non-identifiable data for statewide learning.

> "While we feel we always strive to have transparent conversations with our patients and families when adverse events occur, the EDR process has further enabled these conversations by providing legal protection."
>
> **Oregon Risk Manager**

OPSC's Role

OPSC plays a dual role related to EDR. On a day-to-day basis, we provide resources to support EDR. We publicize the EDR program and respond to inquiries about it. We connect patients or families to involved healthcare professionals when either requests a conversation. Although OPSC staff are not present at conversations, we provide support for constructive conversation through telephone consultations and written materials.

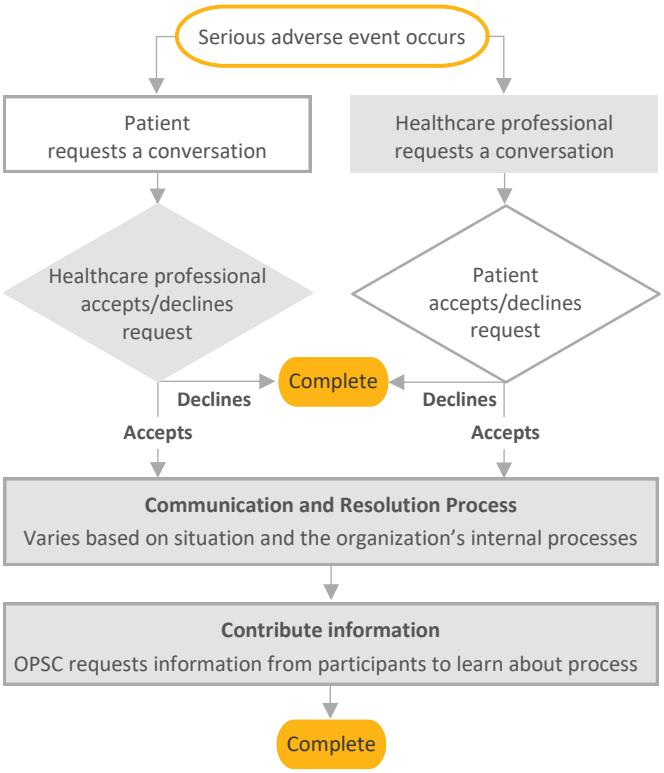
OPSC is also committed to promoting shared learning. Patients and healthcare professionals are asked to complete a voluntary survey after EDR conversations have concluded. We expect this dataset to grow in richness over time, and will use it

to provide guidance on how to more effectively address and resolve adverse events across Oregon.

EDR Process

When a serious adverse event occurs, either a healthcare provider or facility representative ("healthcare professional") or a patient can initiate EDR by requesting a conversation through OPSC (Figure 1). The conversation is an opportunity for healthcare professional(s) and the patient and/or family to talk about what happened and seek resolution. If both parties agree to participate, they come together for a conversation, coordinated by the healthcare professional. The conversation may extend over several meetings. When the conversation is concluded, whether or not resolution was reached, OPSC asks participants to share information about their experience in a Resolution Report. OPSC analyzes non-identifiable data and shares trends and information for statewide learning.

Figure 1. The Early Discussion and Resolution Process*



*See Appendix IV for more detail.

EDR Use

Much of what the Oregon Patient Safety Commission (OPSC) knows about the impact of Early Discussion and Resolution (EDR) comes from our informal communication with patients, family members, healthcare providers, healthcare facility representatives, and legal representatives. On the other hand, most of what we can definitively say about EDR comes from structured data collection tools. When someone completes a Request for Conversation in the EDR Online System, that information is stored in our secure system for future analysis.

There is the potential to learn much more from the Resolution Reports that OPSC asks people to complete 180 days after a Request for Conversation has been submitted. These reports include questions about whether an event has been resolved and if so how, the number of conversations and who participated in them, the topics included in the conversation, the overall satisfaction with the process, and whether a respondent wants to volunteer additional information. However, Resolution Reports were only completed 35% of the time, and one-third of those reports were submitted with incomplete information. This may result from our initial program design. There may be a significant time lag between the date the conversation takes place and the 180 day mark when the request to complete a Resolution Report is issued by our system. By law, completion of this report is voluntary. In addition, to ensure that excessive paperwork was not a barrier to participation in EDR, we made many elements of the report optional. Because incomplete data hampers our ability to learn from people's experiences, we are re-evaluating the choice to make most elements optional.

Data Limitations

Limited Resolution Report data. Much of what can be learned about the resolution status and process comes from Resolution Reports. In accordance with the law, Resolution Reports are voluntary and requested from participants 180 days after the date the notice was filed. While 67 Requests for Conversation were submitted in the first two years of the program, we only received Resolution Reports related to 36 of those requests. Two thirds of these included responses to all questions. Until we have more data, it will be difficult to draw conclusions.

Limited patient demographic data. To ensure that paperwork would not be a barrier to participation, the process of filing a notice was greatly simplified. As a result, patient demographic data is primarily collected in Resolution Reports and these fields have frequently been skipped by respondents. Limited demographic data is available for analysis.

Lack of baseline or malpractice data. There is currently no mechanism to capture the total number of serious adverse events occurring in Oregon, the number of statewide claims related to events, or the number of statewide medical malpractice cases.

Neither the Patient Safety Reporting Program,[2] the National Practitioner Data Bank,[3] nor the Oregon Medical Board collect comprehensive data that can provide a baseline for any of these measures. Oregon has newly transitioned to the eCourt system which may allow tracking of medical malpractice lawsuits in the future.[4] Without a baseline for comparison, data trends will take years to assess.

[2] The Patient Safety Reporting Program is OPSC's voluntary program for Oregon healthcare facilities to report adverse event investigation findings and action plans; non-identifiable data is analyzed and shared for statewide learning. oregonpatientsafety.org

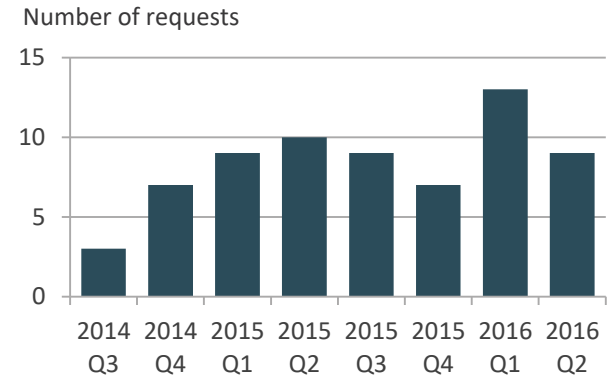
[3] NPDB is a limited-access, federal repository containing some information on medical malpractice payments and certain adverse actions related to health care practitioners, entities, providers, and suppliers.

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

Requests for Conversation

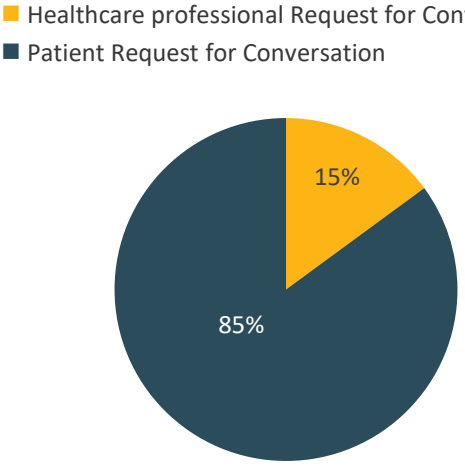
In the first year of the program, EDR saw a total of 29 Requests for Conversation, with an average of 7.5 requests per quarter. In the second year, we saw a 31% increase, receiving 38 Requests for Conversation with 9.5 requests per quarter (Figure 2). Our experience with OPSC's voluntary Patient Safety Reporting Program has taught us that slow, incremental growth builds a strong, sustainable program.

Figure 2. Number of Requests for Conversation by quarter, July 2014-June 2016
(n=67)



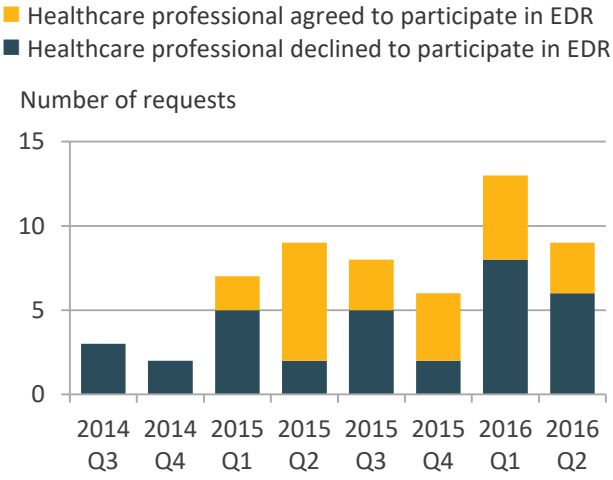
The majority of Requests for Conversation (85%) have come from patients or their representatives (Figure 3). This is a statistic that we hope will change in the coming years, as more conversations are proactively intiated by healthcare professionals.

Figure 3. Requests for Conversation by requester type, July 2014-June 2016
(n=67)



Because EDR is voluntary, all participants must agree to engage in EDR and any participant can withdraw at any time. At least one involved healthcare professional accepted the patient's request to participate in EDR in 24 out of 57 patient Requests for Conversation (42%) (Figure 4).

Figure 4. Accepted and declined patient Requests for Conversation by quarter, July 2014-June 2016
(n=57)



"Oregon has done admirable work building momentum toward transparent communication in the state. It takes hard work and time to convince those who are used to the status quo of 'deny and defend' to change their minds and see that there is a better way to reach reconciliation after adverse events, and they are diligently carving a path out for healthcare facilities, attorneys, and insurers to follow."

Melinda B. Van Niel, MBA, CPHRM
Project Manager, MACRMI
Beth Israel Deaconess Medical Center

A Request for Conversation submitted by a patient may include multiple healthcare facilities and/or providers, each of which has the option to accept of or decline the request. The acceptance rate for patient Requests for Conversation has remained stable at 42% for the first two years; increasing this rate is a priority for us. Healthcare facilities decline participation primarily because they have elected to use their own internal approach to resolution and have not integrated EDR into that approach. Healthcare facilities also decline participation when they determine the event resulted from actions of a non-employed healthcare provider (Figure 5 on page 6).

Healthcare providers who decline are most likely to do so because, like many healthcare facilities, they are using a resolution process that does not incorporate EDR or because their liability insurers have recommended that they decline (Figure 6 on page 6).

There are many reasons for declining participation included in the *other* category, each occurring fewer than three times. The *other* reasons include the fact that the authority of a patient representative could not be confirmed, that a healthcare provider had left practice and no longer has access to medical records, or that a provider learned that a facility would not be participating and elected not to participate either.

Despite early concerns that providers would decline EDR due to fear of reporting to the Oregon Medical Board or the National Practitioner Data Bank, no one has cited either as a reason for declining to participate.

Figure 5. Reasons facilities declined patient Requests for Conversation
(n=29)

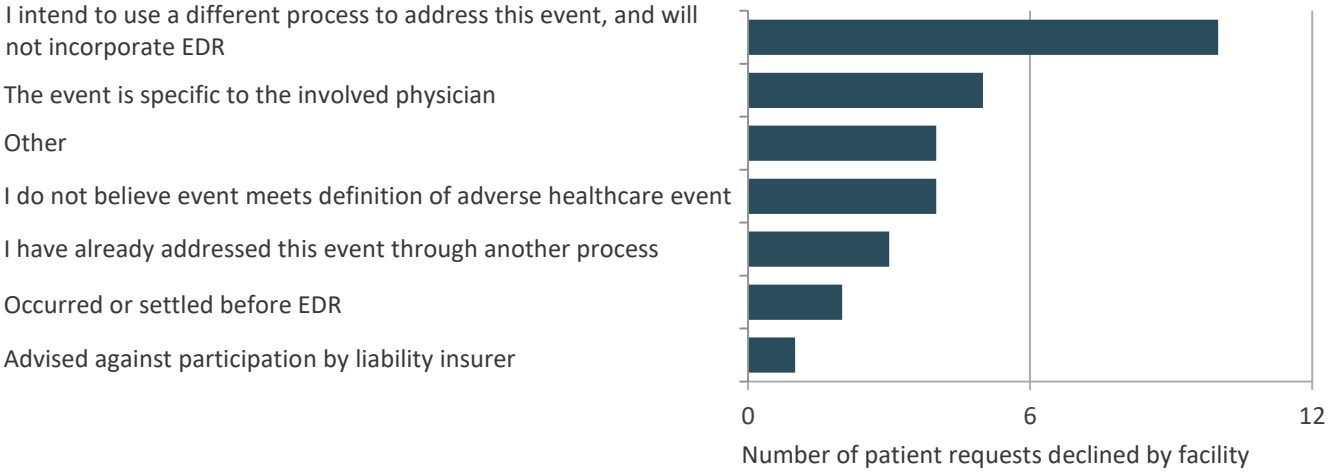
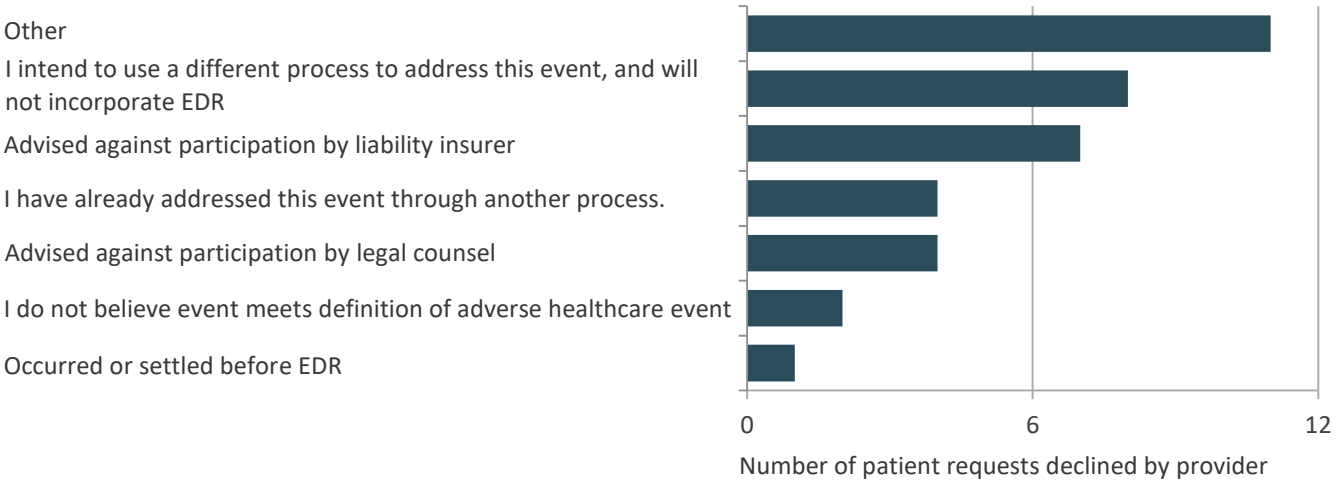


Figure 6. Reasons providers declined patient Requests for Conversation
(n=37)



Early Progress at Beth Israel Deaconess Medical Center

To better understand the early stages of adoption of a new approach to resolution of adverse events, we look to Beth Israel Deaconess Medical Center (BIDMC), a founding member of the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI). At BIDMC, there was a core group who strongly favored transparent communication with patients. With the support of enabling legislation in 2012, they began to apply the concepts of Communication, Apology, and Resolution (CARe) in advance of full implementation of the program. However, without infrastructure and buy-in fully in place, it was very challenging to use the new approach extensively, and only five events went through CARe prior to the launch of the program. Once CARe was fully in place, BIDMC used the program for 120 events in the first year.

To accelerate the adoption of a communication and resolution process approach in Oregon healthcare facilities, OPSC is leading the Oregon Collaborative on Communication and Resolution Programs, beginning in September 2016 (Appendix III).

Event Types

From the 67 Requests for Conversation received, we identified 69 event types (see Appendix V for a list of event types); two Requests each described two distinct event types. Nearly two thirds of the Requests for Conversation were related to *surgical or other invasive procedure* events (43%). The second most common event type was *care delay* (27%), which includes both delays in diagnosis and delays in treatment (Table 1).

Table 1. Types of events described in Requests for Conversation, July 2014-June 2016

Event Type	Patient Requests (n=57)	Healthcare Professional Requests (n=10)	Total (n=67)
Surgical or other invasive procedure	22 (39%)	7 (70%)	29 (43%)
Care delay	16 (28%)	2 (20%)	18 (27%)
Healthcare-associated infection	4 (7%)		4 (6%)
Medication or other substance	4 (7%)		4 (6%)
Other	4 (7%)		4 (6%)
Patient protection	3 (5%)		3 (4%)
Product or device	2 (4%)	1 (10%)	3 (4%)
Radiologic	1 (2%)		1 (1%)
Fall	1 (2%)		1 (1%)
Environmental	1 (2%)		1 (1%)
Obstetrical		1 (10%)	1 (1%)

Note: percentages may total more than 100 as two requests involved more than one event type.

Resolution Information

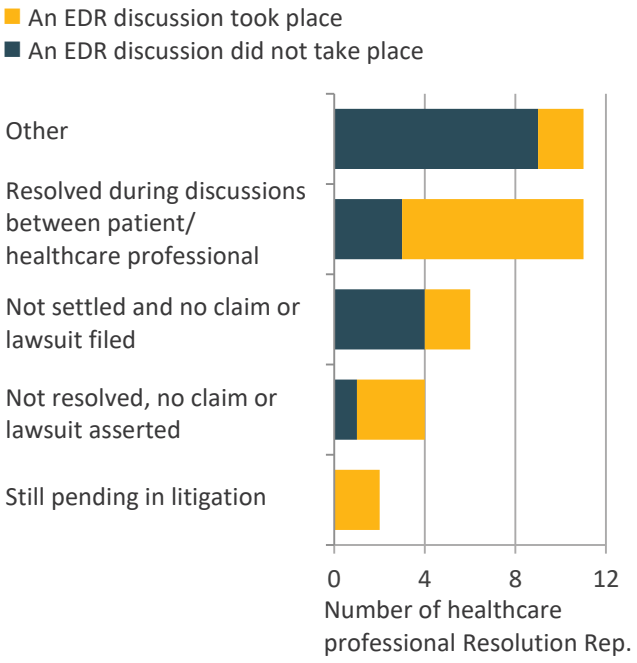
OPSC's role in EDR is limited; OPSC staff do not attend EDR conversations. The Resolution Reports completed by EDR participants serve as our primary window into the conversations that have taken place between patients and healthcare professionals. Completing a Resolution Report is voluntary, in accordance with law, and during the first and second years of the EDR program, many of the fields within the Report were optional. While we acknowledge that our dataset is not complete, and caution against broad generalizations, there are some pearls of knowledge contained in the data that we are able to share.

We have received one or more Resolution Reports for 36 of the 67 Requests for Conversation submitted in the first two years of the program. In nine cases, we received Resolution Reports from both the patient and one involved healthcare professional, and in one case we received a Resolution Report from the patient, facility, and a non-employed provider, resulting in a total of 43 Resolution Reports related to 36 original Requests 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 10.

Status of the EDR Process

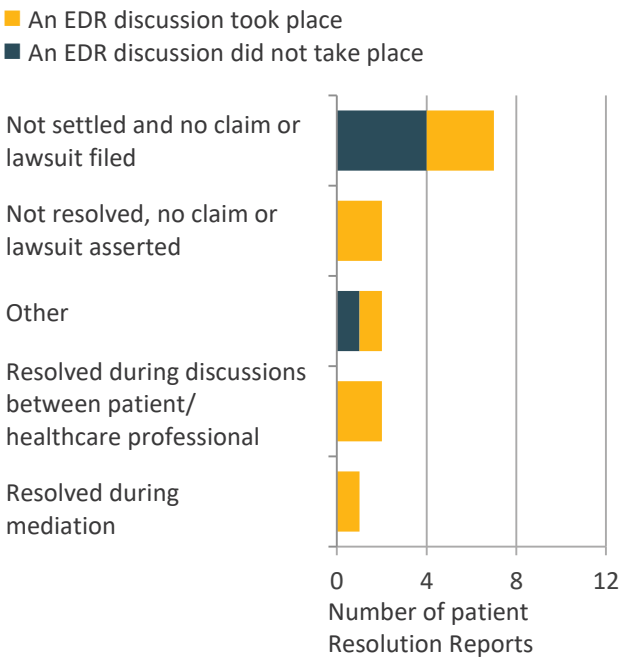
Patients and providers can complete Resolution Reports even if no conversation occurred. The Resolution Report asks the status of the EDR process at the point in time the Report is made. Half of the Resolution Reports submitted by providers followed a discussion. Almost half (47%) of the provider Resolution Reports following a discussion indicated that the discussion resulted in resolution, compared to less than a fifth (18%) of those where a discussion did not take place (Figure 7 on page 8). When no resolution was reported, the respondent frequently chose to provide a very specific explanation about the status of the EDR process, outside of the standard categories provided; in these cases, the status is represented in the *other* category.

Figure 7. Healthcare professional Resolution Report statuses, July 2014-June 2016
(n=34)



Nine of the 14 Resolution Reports submitted by patients followed an EDR discussion. A third of the patient Resolution Reports following an EDR discussion indicated that the discussion resulted in resolution. In patient Resolution Reports where no EDR discussion took place, no resolution was reached (Figure 8).

Figure 8. Patient Resolution Report statuses, July 2014-June 2016
(n=14)



Overall, 11 of the 34 Resolution Reports from healthcare professionals (32%) and three of the 14 Resolution Reports from patients (21%) indicated that the parties arrived at resolution.

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. Patients selected an average of 2.8 conversation elements (range 1-4) while providers selected an average of 4.6 elements (range 1-7). The most common element selected by the 23 patients and providers that responded to the question was *information about the incident* (18 of 23, 78%). For providers, there were three other frequently selected elements: *information about why the event happened*, *information about an error that occurred*, and *the possible impact of the event on the patient's health, treatment, and follow-up* (each selected by ten of 14 respondents, 71%). For patients, the second most frequently selected element was *an offer of compensation (other than waiver of medical bills)* (five of nine respondents, 56%) (Table 2 on page 9).

Table 2. Conversation elements in early discussions, July 2014-June 2016

Conversation Element	Patient Resolution Reports (n=8)	Provider Resolution Reports (n=14)	Total Resolution Reports (n=22)
Information about the event	7 (88%)	12 (86%)	19 (86%)
Information about why the event happened	4 (50%)	11 (79%)	15 (68%)
The possible impact of the event on the patient's health, treatment, and follow-up	2 (25%)	10 (71%)	12 (55%)
Information about an error that occurred	1 (13%)	11 (79%)	12 (55%)
An explanation that error did not occur	4 (50%)	4 (29%)	8 (36%)
How additional information will be shared with the patient in the future		7 (50%)	7 (32%)
An offer of compensation (other than waiver of medical bills)	4 (50%)	2 (14%)	6 (27%)
What actions will be taken to prevent recurrence	1 (13%)	5 (36%)	6 (27%)
An offer to waive medical bills		5 (36%)	5 (22%)

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

Satisfaction Ratings and Apologies

Resolution Report respondents indicate their satisfaction with the EDR process using a 5-point scale: very satisfied, somewhat satisfied, neutral, somewhat unsatisfied, not at all satisfied. Of the 17 healthcare professionals and nine patients that received this question, all but one responded. Fifteen healthcare professionals who responded to this question indicated that they were very satisfied, somewhat satisfied, or neutral. Patient experiences, on the other hand, varied widely, from very satisfied to not at all satisfied (Figure 9).

Resolution Report respondents also indicate whether the patient or patient's representative received an apology (Figure 10 on page 10).

Figure 9. Respondent satisfaction with EDR process, July 2014-June 2016
(n=25)

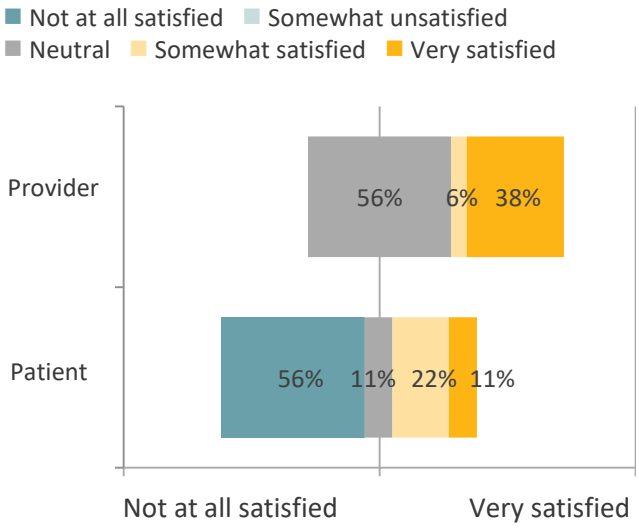
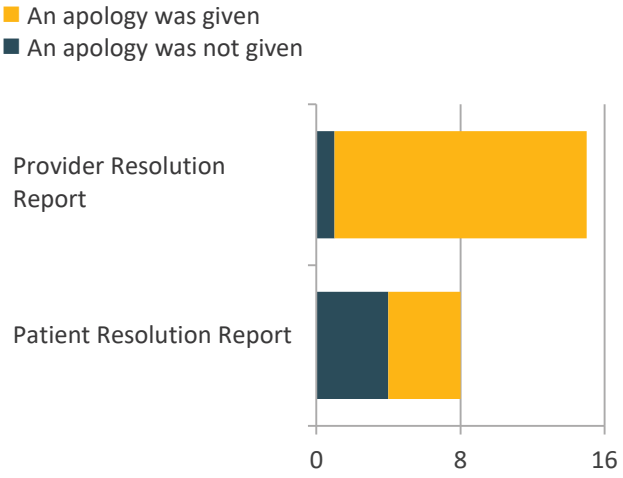


Figure 10. Resolution Report type, was an apology given (n=23)



Eighteen of 23 Resolution Report respondents who answered this question (78%) 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 11. Receiving an apology was not correlated with the resolution of the request for conversation (Table 3) or either party's satisfaction with the process (Table 4).

Table 3. Resolution Report type by Resolution Report status, was an apology given

	An apology was given	An apology was NOT given
Patient Resolution Reports (n=8)		
Issue was resolved in discussion	2 (25%)	1 (13%)
Issue was unresolved	2 (25%)	3 (38%)
Other Resolution Report status	0 (0%)	0 (0%)
Provider Resolution Reports (n=15)		
Issue was resolved in discussion	6 (40%)	1 (7%)
Issue was unresolved	6 (40%)	0 (0%)
Other Resolution Report status	2 (13%)	0 (0%)

Table 4. Resolution Report type by Resolution Report status, satisfaction with the process

	An apology was given	An apology was NOT given
Patient Resolution Reports (n=8)		
Very or somewhat satisfied	2 (25%)	1 (13%)
Neutral	0 (0%)	1 (13%)
Somewhat unsatisfied or not at all satisfied	2 (25%)	2 (25%)
Provider Resolution Reports (n=15)		
Very or somewhat satisfied	6 (40%)	1 (7%)
Neutral	8 (53%)	0 (0%)
Somewhat unsatisfied or not at all satisfied	0 (0%)	0 (0%)

In fact, patients who reported being somewhat unsatisfied or not at all satisfied with the process were evenly split between those who had received an apology and those who had not (Table 4). The Resolution Reports also show that resolution may be reached during a conversation even when no apology is made.

Differences in Perception

Resolution Report status. There were two cases in which the provider or facility indicated that resolution had been reached during the discussion but the patient reported that no resolution had been reached. Both cases involved a facility and a non-employed healthcare provider, and in both the patient perceived that one of the two had shown a lack of accountability or respect. These cases suggest the importance of securing the participation of both facilities and providers in the conversation where possible. Refusal by one healthcare professional to participate in a conversation can compromise the ability to achieve a full resolution satisfactory to the patient.

Conversation elements. OPSC received responses to the question about conversation elements in 22 out of the 24 Resolution Reports in which it was asked.

They represent the results of 15 Requests for Conversation, with seven requests resulting in Resolution Reports from both provider or facility and patient. Although in every case, patients and medical professionals agreed on at least one reported conversation element, there was only one case that had exactly matching conversational elements (1/7, 14%). The most commonly shared element was *information about the event* (6/7, 86%). The conversation element most frequently reported by the healthcare professional only was *the possible impact of the event on the patient's health, treatment, and follow-up* (4/7, 57%). By contrast, the conversation element most frequently reported by the patient only was *an explanation that error did not occur* (3/7, 43%). In fact, in two of those three cases, the provider reported the exact opposite (*information about an error that occurred*).

There are several reasons perceptions may differ. Professionals may be reporting on what they intended to cover, rather than what was actually discussed. Professionals may use technical language in the conversation that patients do not understand. Professionals may continue on script even when a patient is experiencing strong emotion and is temporarily unable to listen (Kessels, 2003). It may be helpful for healthcare professionals to ask about patient's key goals and concerns at the start of a conversation, and to check in during the conversation to ensure that the patients have understood the information shared with them. It may also be helpful to encourage patient questions, and summarize the conversation at the end, perhaps in writing.

Apologies. There are six cases where OPSC has responses from both a patient and a healthcare professional to the question regarding the offer of an apology. In every case, the healthcare professional reported offering an apology, but only three of the patients reported receiving an apology. In fact, healthcare professionals reported offering apologies in a total of 12 of 15 Resolution Reports (80%) while patients reported receiving them in four of eight Resolution Reports (50%). Based on conversations with both patients and healthcare professionals throughout these processes, as well as the additional information provided in the open text fields in the Resolution Reports, we believe that this misalignment may be the result of different understandings of what constitutes an apology.

As we receive more Resolution Reports in the coming year, and obtain more complete data from respondents, we hope to glean and share more recommendations and points of interest.

Patient Characteristics

Patients who either requested a conversation or were engaged in a conversation by a healthcare professional were equally likely to be male or female (Figure 11) and were most likely to be between the ages of 50 and 69 (63%, Figure 12).

Figure 11. Patient gender
(n=67)

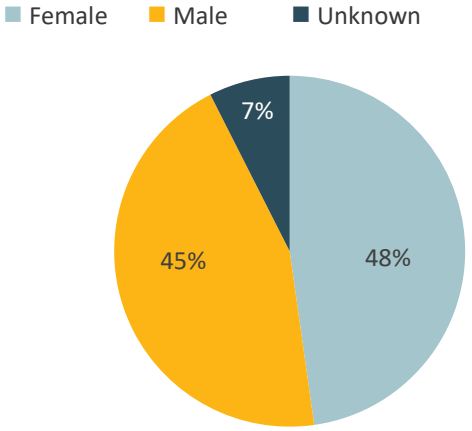
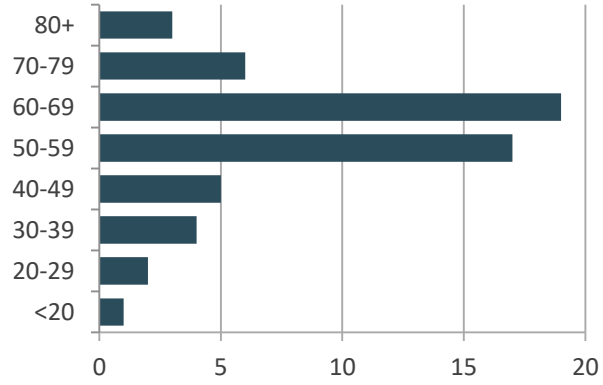


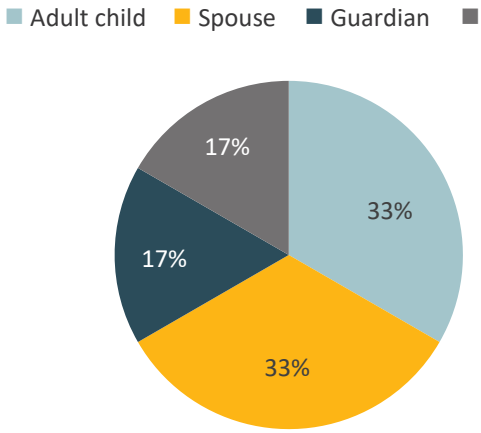
Figure 12. Patient age by age groups
(n=57)



Patient Representative Characteristics

Twelve Requests for Conversation were submitted by patient representatives (see Appendix I for a description of patient representative). Two-thirds were the adult child or spouse of the patient (Figure 13). All but one of the patient representatives were so authorized because the patient had died. The other was the parent of a child under the age of 18. The requirements for who may serve as a patient representative are clearly defined by statute (Oregon Laws 2013, Chapter 5, section 8).

Figure 13. Type of patient representative
(n=12)



Lessons Learned

The Oregon Patient Safety Commission is committed to learning as much as possible from the administration of Early Discussion and Resolution (EDR). We intend to model transparency by sharing what we have learned, in order to improve communication and resolution of serious adverse events in Oregon. Our key lessons from the second year of this program, as well as our efforts to address identified needs, are described in this section.

I. Organizations that promptly communicate with patients and families following adverse events may more easily reach resolution.

After a patient's serious injury or death, timely and appropriate communication between the patient and/or family and their healthcare provider can make a difference in the patient's experience of resolution and response to the provider's or facility's efforts. An organization may need a month or more to conduct an event analysis and come to full understanding of an event. A provider may need approval from their insurer before communicating with patients about an adverse event. However, it is important to understand that when organizations or providers do not reach out quickly, patients and/or family members may lose trust that a resolution process can be beneficial.

For example, when patients request conversations through EDR and wait several weeks for a response, they may suspect that an organization is hiding something or that a provider is just waiting for them to go away. During this time, they may consider a lawsuit and may become wary of heading into conversations in the future.

Recommendation: Healthcare organizations and providers should engage with patients and families as quickly as possible, ideally within 72 hours of learning about an adverse event. An initial conversation might simply include an acknowledgement that this was not the desired outcome and a commitment to learn more and share new information. At the end of the initial conversation, schedule a follow-up conversation. This will ease a patient's anxiety, providing reassurance that they have not been forgotten while they wait for further communication.

Recommendation: Healthcare facilities should designate EDR Managers—individuals who can quickly submit a Request for Conversation or be

automatically notified if a patient submits a Request about an event that happened at their facility. EDR Managers are currently designated in 83% of hospitals, 26% of ASCs, 12% of nursing facilities, and lower percentages of dialysis facilities and birthing centers.

Healthcare professionals working in other healthcare settings can submit or view a Request from any computer with internet access.

OPSC Targeted Efforts

Infrastructure support. To support success with EDR, we help organizations develop the process infrastructure, including policies and protocols, to enable prompt response to patients and families following adverse events. While many organizations already have processes in place to respond to adverse events, they may not yet include tight timelines for response or ensure a consistent response. Integrating EDR into policies can prepare an organization to initiate or respond to an EDR Request, thereby ensuring that patients and families experience the organization as communicative and responsive.

Beginning in Fall 2016, we will provide 12 months of intensive support to a cohort of six organizations as they develop robust Communication and Resolution Programs through the Oregon Collaborative on Communication and Resolution Programs (OCCRP) (Appendix III). This collaborative is convened by OPSC in partnership with the Oregon Medical Association, the Osteopathic Physicians and Surgeons of Oregon, and the Oregon Association of Hospitals and Health Systems. The foundational curriculum of the OCCRP was also shared with other interested organizations and providers in a Fundamentals of Communication and Resolution Programs training course. We will repeat this offering as interest grows.

II. An organizational culture of safety enables implementation of communication and resolution processes.

A strong culture of safety is needed to support and sustain open communication with patients and families following serious adverse events. A culture of safety is one in which healthcare professionals are encouraged to report safety events and near misses, where everyone knows how to report such events and can do so without fear of reprisal, and where the organization commits to learning from events by sharing the results of the analysis into what happened and improving patient care to prevent a recurrence. These elements are interconnected and all must be present to achieve a culture of safety.

An organization that values transparency and learns from adverse events will find that adopting a policy of communicating with patients and families consistently and openly following an adverse event using EDR will fit naturally into its culture.

Recommendation: An organization looking to implement a communication and resolution approach should cultivate a culture of safety that will support and sustain it. Much can be learned by conducting a Patient Safety Culture survey of staff, made available by the Agency for Healthcare Research and Quality (AHRQ).

For more on a culture of safety, see *Culture of Safety: The Foundation of Patient Safety Improvement* in Appendix VI.

OPSC Targeted Efforts

OPSC is committed to supporting healthcare organizations to develop a culture of patient safety through a variety of initiatives. Over the past year, we have worked to provide the healthcare community with education to support safety culture development through publications, conference exhibits and presentations, and these OPSC sponsored trainings:

- Avoid Band-Aid Solutions: Strengthening Adverse Event Investigations
  (Offered quarterly since October 2014)
- Speak Up for Patient Safety: Communicating Before, During, and After and Adverse Event
  (First offered August 2016)
- Fundamentals of Communication and Resolution Programs
  (First offered September 2016)

OPSC will continue to seek out best practices and other patient safety innovations to share with healthcare professionals to strengthen the culture of safety within their organizations.

III. Coordination between multiple stakeholders adds complexity.

When multiple stakeholders are associated with a serious adverse event, EDR may require additional preparation and coordination.

Depending on the unique situation, the stakeholders may include:

- The healthcare facility where the event occurred
- The liability insurer representing the facility
- The involved healthcare professional(s)
- The liability insurer(s) representing the healthcare professional(s)
- The organization that employs the healthcare professional(s)

Coordination among stakeholders may be necessary to deciding whether to use EDR for a given event, conducting the event analysis into what happened and why, and working towards resolution. In situations where multiple stakeholders share responsibility for the event, one or more may be reluctant to acknowledge its role. If it appears that care was not reasonable or did not meet institutional standards, stakeholders' differing philosophies about restitution may affect the likelihood of reaching resolution. When stakeholder perspectives do not align, coordinating EDR can be a challenge. Yet, lack of coordination can delay a prompt response to a patient's request for conversation, inflaming an already difficult situation.

Recommendation: Organizations should proactively coordinate with potential stakeholders before an event ever occurs. Having plans and protocols in place for a coordinated stakeholder response, should an event occur, may create a better experience for the patient who was harmed, and may lead to more successful resolution for everyone involved.

OPSC Targeted Efforts

We continue to engage healthcare professionals and insurers, encouraging them to work through potential challenges to an aligned response in anticipation of future adverse events. We also continually seek ideas for how best to bring differing stakeholders together around the complexities of communication and resolution following adverse events.

IV. EDR creates opportunities for conversation between patients and their healthcare providers even when the formal EDR process is not used.

Patients and their families contact OPSC regularly with patient safety questions or concerns. Using criteria provided by OPSC, patients and their families may decide EDR is not appropriate for their situation, or they may simply decide not to pursue EDR. Regardless of the situation, OPSC provides these callers with other resources. When appropriate, we encourage patients and families to contact a provider or facility directly; we provide contact information for the individual or department (e.g., customer relations) best suited to respond to the caller's needs. While we rarely hear back from these callers, we hope that this practice opens the door for needed communication.

When patients do use EDR to request conversations, providers and facilities may choose not to engage in discussions. Of 57 patient requests, 25 (44%) were accepted and moved forward with EDR discussions. An additional 16 EDR requests (28%) were declined, but nevertheless resulted in a conversation using an organization's existing communication processes, whether formal or informal. Thus, 72% of patient Requests for Conversation resulted in direct communication between patients and their providers. We believe many of these conversations would not have taken place at all had EDR not offered a constructive way forward for patients harmed during healthcare.

We believe that direct, open communication is important for both patients and providers after adverse events. We readily acknowledge that there are some situations where engagement would not be beneficial, e.g. where the patient and provider have already had extensive conversations. There are also some situations that do not meet the criteria for EDR. In most instances, however, communication offers significant potential benefit, and we hope to increase the percentage of requests that result in conversation. We would of course like to see more requests result in formal EDR conversations because we believe that the EDR program has features that enhance the likelihood of a constructive conversation, such as legal protection for conversation communications, the right to bring a support person to the conversation, conversation guidance materials, and the availability of mediation. However, a more important measure of our success may be whether a request initiated through EDR results in direct communication between patient and provider, on any platform.

Recommendation: Healthcare organizations with a preferred contact for patients who have concerns about their care should provide OPSC with that contact information,[5] along with guidance about when it would be appropriate for OPSC to share that information with patients.

OPSC Targeted Efforts

Seeking more comprehensive resolution information. Initially, information about conversations resulting from EDR Requests for Conversation was only collected in a Resolution Report if the conversations used EDR. This limited our ability to collect complete information about resulting conversations that did not use EDR. While Resolution reports remain voluntary, going forward, we will request Resolution Reports following all Requests for Conversation. Every conversation is a learning opportunity.

Providing communication tools. Research suggests that healthcare professionals are often uncomfortable openly discussing an adverse event with a patient. 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). To help prepare providers for these conversations, we have created Conversation Guidance as a resource for providers and facility representatives to support effective communication with patients about adverse events (Appendix VII). The resource, which is based on research from leaders in the healthcare communication and resolution field, includes information about what patients are likely to want from a conversation, how to prepare for the initial and subsequent meetings, and what to cover during each stage of the conversation.

Encouraging use of EDR. With guidance from communications professionals, OPSC has taken a strategic approach to increasing knowledge about and use of the EDR program. We have replaced legal jargon with simple, friendly, and

[5] Contact OPSC staff at edr@oregonpatientsafety.org.

inclusive language. This year, we have focused outreach primarily on the provider community. Since EDR is a voluntary program, provider participation is essential for it to succeed.

We have leveraged OPSC's relationships with the Oregon Medical Association, the Osteopathic Physicians and Surgeons of Oregon, the Oregon Association of Hospitals and Health Systems, the Oregon Society of Healthcare Risk Managers, major insurers (CNA, the Doctors Company, Physicians Insurance), and provider organizations across Oregon to promote EDR, by speaking at their meetings, running articles in their newsletters, and connecting with their leaders and members.

We are reaching out to the plaintiff's bar to make them aware of the program and increase referrals to it.

We will be reaching out to Oregon's trial courts to remind them to inform parties to medical malpractice suits about the availability of EDR, as required by law. We will prepare a sample notice that they can easily adapt for use.

V. Patients may need assistance to advocate for themselves effectively during EDR conversations.

At present, most patients who submit Requests for Conversation do so an average of 6 months after an adverse event has occurred. They find EDR through internet searches, lawyer referrals, or newspaper articles, often after they've become desperate for help. In some cases, the patient has already attempted to speak to a provider or facility administrator, but more frequently they did not know who to talk to or how to get help.

Even if they had talked to a provider or administrator, they left unsatisfied. They may not have known what questions to ask, or they may not have understood the provider or facility's process. They left frustrated, feeling that their concerns had not been addressed.

We would like EDR to offer patients a better experience, but there are some inherent challenges. Patients find conversations difficult—most have never been in a situation like this before and never will be again. They may not be able to understand or interpret medical records and other information furnished by the healthcare organization. They typically do not have access to an expert who can advise them whether the standard of care was met. They are often speaking with experienced risk managers or facility administrators who know exactly how the process should work and have many resources at their disposal.

We know from our Resolution Reports and from phone conversations with patients, providers, and facilities during the EDR process that this mismatch can lead to miscommunication, frustration, and confusion. A well-intentioned risk manager may adopt a professional tone and focus on compensation out of a sincere desire to reach a quick and fair resolution. The patient may interpret this as a refusal to disclose information about what happened, disinterest in improving care for future patients, and a lack of empathy.

EDR provides that either party can request a mediator, and that the parties must split the cost unless they make another agreement. We believe that using a mediator could promote resolution by ensuring that common patient questions, such as what happened, why it happened, and whether it was preventable, are addressed before any restitution is discussed. However, the cost of a mediator remains a barrier. Further, a request for a mediator to help them be heard and understood can sound to a healthcare professional like the precursor to a demand for compensation.

Patients need help advocating for themselves effectively. Several patients have told us that they expected that OPSC staff would participate in EDR conversations as their advocate, and one

patient decided not to use the EDR process when informed that staff would not be present.

Some communication and resolution programs recommend that all patients be represented by legal counsel, not in anticipation of further legal action, but because a lawyer may be able to help a patient understand the process and provide guidance regarding next steps. 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.[6] EDR rules allow a patient to bring a lawyer to an EDR conversation for support. However, we know facilities and providers can be less willing to participate if the patient is represented. EDR rules currently require that a patient be advised of their legal right to consult an attorney only when an offer of restitution is made.

Recommendations: Patients participating in EDR should feel free to ask that mediators be hired to participate in the process. They should also feel free to ask that a patient advocate be present. Healthcare professionals participating in EDR should consider these requests to be in service of the process, rather than a threat to it. A mediator, patient advocate, or attorney may be able to provide guidance and insights that keep conversations on track and result in resolutions that are satisfying to all involved, avoiding litigation.

OPSC Targeted Efforts

OPSC intends to more actively engage the legal community in the coming year to increase the number of plaintiff lawyers who are familiar with a lawyer's role in the EDR process and might be willing to represent patients in EDR. However, the cost of retaining a lawyer may be a barrier for some patients.

OPSC also intends to begin to explore what other resources for patient advocacy might be available through healthcare organizations, non-profits, and other entities.

OPSC Activity

Facility Preparation

The Oregon Patient Safety Commission (OPSC) seeks to support healthcare facilities to integrate EDR into their current processes. To that end, we have asked all hospitals, nursing facilities, ambulatory surgery centers, dialysis facilities, and free-standing birthing centers to designate staff to serve as the facility's EDR Manager. In our on-line system, a designated EDR Manager is able to act on behalf of their facility to initiate EDR or respond to patients Requests for Conversation. We strive to educate all designated EDR Managers about how best to use the program and how to align their internal processes with EDR guidelines for communicating with patients following adverse events.

In addition, we have created targeted guidance on how to align with EDR for nursing facilities, ambulatory surgery centers, and outpatient medical practices. These resources are available on our website and distributed at conferences.

EDR Insider

The OPSC monthly newsletter has a recurrent segment called the EDR Insider which shares resources, strategies, new tools, and general guidance for users of EDR. All EDR Insiders are available on our website.

Mediator List Maintenance

Per Oregon Laws 2013, Chapter 5, we maintain a qualified mediator list. This list currently includes 18 mediators. As a group, they can provide mediation services to EDR participants in every Oregon county. Each mediator meets rigorous standards for education and experience developed by members of the Oregon Mediation Association and the

[6] Guidance for lawyers from MACRMI is available at http://www.macrmi.info/attorneys/#sthash.J9yQ6Ej5.mTNJZecG.dpbs.

Alternative Dispute Resolution section of the Oregon Bar Association. Annually, we contact mediators on our list and ask that they update or confirm their qualifications. This allows us to be sure that we are maintaining a current and accurate list of mediators who are interested in supporting EDR.

EDR participants are also free to retain mediators who are not on this list.

We have no way of knowing whether mediators are engaged in the process of resolution unless the fact is mentioned in a Resolution Report. We believe the list is a valuable resource that, over time, will help many in their effort to reach resolution.

Conclusion

Early Discussion and Resolution (EDR) is new to Oregon, and is gaining visibility and acceptance by a growing number of patients and healthcare professionals in our state. The Oregon Patient Safety Commission (OPSC) is encouraged by the numbers of people who have used EDR to seek open communication toward resolution of adverse events.

Because it is the first statewide program of its kind in the country, and the only one to support initiation by patients and/or family members as well as healthcare professionals, many eyes are on EDR. What we learn will contribute to the national conversation about communication and resolution processes. In the interests of transparency and continuous learning, we share these key recommendations from our first two years of administering EDR.

- Communication with patients and families after adverse outcomes should happen as soon as possible, even when investigations have not yet determined whether the event was preventable.
- A culture of patient safety is essential for healthcare organizations to implement communication and resolution processes. The culture should be monitored through regular surveys and actively promoted through participation in initiatives like Just Culture, High Reliability, and the Oregon Collaborative on Communication and Resolution Programs.
- Having plans and protocols in place for a coordinated stakeholder response, should an event occur, may create a better experience for the patient who was harmed, and may lead to more successful resolution for everyone involved.
- While we hope to see more organizations integrate EDR into their communication strategies, we recognize that many healthcare providers and healthcare facilities already engage in transparent communication with patients even when not using EDR. OPSC applauds this.
- Patients and/or family members need assistance to advocate for their needs and participate productively in conversations with healthcare professionals. More resources should be made available to them, whether through healthcare facility employees or through referrals.

The governor-appointed Task Force on Resolution of Adverse Healthcare Incidents provides key input into the ongoing development of this program and will continue to consider improvements and new directions. The Patient Safety Commission is honored to support Early Discussion and Resolution. We are committed to continuously learning about how healthcare professionals and patients use EDR to support transparent communication following adverse events, and to making ongoing improvements to the EDR infrastructure and support services. We look forward to continued, and new, collaborations as we work to foster a culture of patient safety in Oregon. We are optimistic that with increased participation, Early Discussion and Resolution will improve patient safety and transparency in healthcare and strengthen the relationship between the Oregon healthcare community and the population it serves.

Acknowledgements

The Oregon Patient Safety Commission is 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

References

Boothman, R. C., Blackwell, A. C., Campbell Jr, D. A., Commiskey, E., & Anderson, S. (2009). A better approach to medical malpractice claims? The University of Michigan experience. *J Health Life Sci Law*, 2(2), 125-159..

Gallagher, T. H., Waterman, A. D., Ebers, A. G., Fraser, V. J., & Levinson, W. (2003). Patients' and physicians' attitudes regarding the disclosure of medical errors. *Jama*, 289(8), 1001-1007.

James, J.T. (2013). A new, evidence-based estimate of patient harms associated with hospital care. *The Journal of Patient Safety*, 9(3), 122-128. doi: 10.1097/PTS.0b013e3182948a69.

Kessels, R. P. (2003). Patients' memory for medical information. *Journal of the Royal Society of Medicine*, 96(5), 219-222.

Makary, M. A., & Daniel, M. (2016). Medical error—the third leading cause of death in the US. *BMJ*, 353, i2139.

Mello, M.M., Boothman, R.C., McDonald, T., Driver, J., Lembitz, A., Bouwmeester, D., Dunlap, B., & Gallagher, T.H. (2014). Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters. *Health Affairs, 33(1)*, 20-29. doi: 10.1377/hlthaff.2013.0828.

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: • 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 *Healing Words: The Power of Apology in Medicine*, 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: 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 *healthcare facilities (*or representatives from *healthcare facilities*), *healthcare providers*, employers of *healthcare providers*, and liability insurers
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

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

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	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: • 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. History of Early Discussion & Resolution

July 2012
Original workgroup formed

The governor formed the Patient Safety and Defensive Medicine Workgroup with the goal of recommending a legislative concept for medical liability reform. The Workgroup's efforts were guided by the following principles: improving patient safety, effectively compensating injured individuals, and reducing medical liability system costs.

March 2013
Law signed

The legislation was signed into law March 18, 2013 with overwhelming bipartisan support,[8] and established the Early Discussion and Resolution (EDR) process.

The law charged the Oregon Patient Safety Commission (OPSC) with administration of the EDR process. OPSC was a natural fit to administer the process because of its mission to improve patient safety in Oregon and its substantial experience with sharing learning statewide for patient safety improvement.

October 2013
1st Task Force meeting

The law established the Task Force on Resolution of Adverse Health Care Incidents to provide oversight for the EDR process. The Task Force meets quarterly with OPSC to provide input on the EDR process and related activities, and reports annually to the Legislative Assembly on the progress of EDR.

June 2014
Rules approved

OPSC developed EDR administrative rules with feedback from OPSC's Board of Directors, the Task Force, the EDR Patient Advisory Group, the EDR Stakeholder Advisory Group, and a month-long public comment period.

July 2014
Law in effect

The administrative rules and the EDR process went into effect on July 1, 2014.[9]

[8] Oregon Laws 2013, chapter 5. www.oregonlegislature.gov/bills_laws/lawsstatutes/2013orLaw0005.pdf
[9] Oregon Administrative Rules 325-035-0001- 325-035-0045. arcweb.sos.state.or.us/pages/rules/oars_300/oar_325/325_035.html

Appendix III. Oregon Collaborative on Communication and Resolution Programs

There is a better way to respond to patients who are harmed during medical care

Despite the best training and intentions, things can and do go wrong during healthcare. By initiating a transparent conversation with patients and their families about what went wrong, providers can move toward resolution and closure for themselves and their patients. While healthcare organizations in Oregon may widely agree about the effectiveness and ethical imperative of transparent communication when things go wrong, the practicalities of ensuring the use of such an approach can be daunting. In coordination with the Collaborative for Accountability and Improvement, the Oregon Collaborative on Communication and Resolution Programs (OCCRP) will launch in September 2016 to support six healthcare organizations in developing robust, multi-faceted programs that are capable of achieving a consistent, systematic approach to patient harm.

The Oregon Patient Safety Commission, the Oregon Medical Association, the Oregon Association of Hospitals and Health Systems, and the Osteopathic Physicians and Surgeons of Oregon are partnering to convene this 12-month collaborative. The pioneering members of the collaborative are:

- Columbia Memorial Hospital
- Grande Ronde Hospital
- Providence St. Vincent Medical Center
- Salem Hospital
- The Oregon Clinic
- Women's Healthcare Associates, LCC

Collaborative members come together with a shared commitment to improve processes and outcomes. The success of any collaborative comes partly from the evidence-based ideas and expert advice provided by faculty, and partly from the group learning fostered by the collaborative—participants teach what they know and learn what they need. This will be true for this collaborative as well.

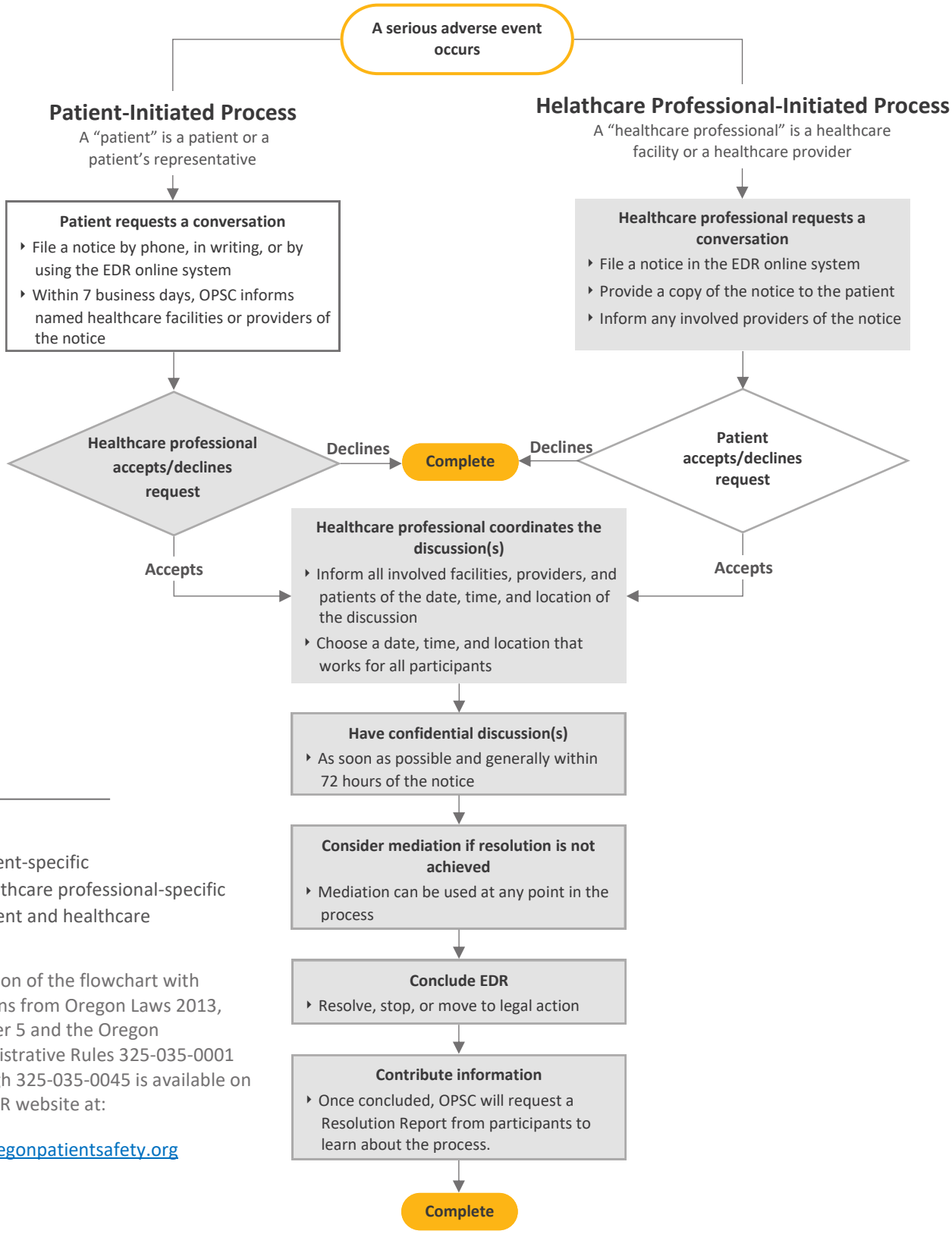
At the conclusion of the collaborative, in September 2017, we hope to form an ongoing consortium of committed organizations with robust CRPs at the same time as we launch a second cohort of the OCCRP.

CRP Core Commitments

- Being transparent with patients around risks and adverse events.
- Analyzing adverse events using human factors principles, and implementing action plans to prevent recurrences.
- Supporting the emotional needs of the patient, family, and care team affected by the event.
- Proactively and promptly offering financial and non-financial resolution to patients when adverse events were preventable.
- Educating patients or their families about their right to seek legal representation at any time.
- Working collaboratively with other organizations and insurers to respond to events involving multiple parties.
- Assessing the effectiveness of the CRP program using accepted, validated metrics.

Appendix IV. The Early Discussion & Resolution Process

When a serious adverse event occurs, either a healthcare professional or a patient can initiate Early Discussion and Resolution (EDR) by filing a notice with the Oregon Patient Safety Commission (OPSC). The notice represents a request from the filer to talk to the other party about what happened to reach resolution. If both parties agree to participate, they will come together for an open conversation using the healthcare professional's communication and resolution process.



A version of the flowchart with citations from Oregon Laws 2013, Chapter 5 and the Oregon Administrative Rules 325-035-0001 through 325-035-0045 is available on the EDR website at:

edr.oregonpatientsafety.org

Appendix V. Event Type Categories

Event type categories are based on definitions used by the Oregon Patient Safety Commission'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.[10, 11]

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).
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.

[10] 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.

[11] 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.

Appendix VI.

Culture of Safety: The Foundation of Patient Safety Improvement

A culture of safety is comprised of three components: a *learning culture*, a *just culture* and a *reporting culture*. The three components are interconnected—all must be present to achieve a culture of safety—and share common characteristics (e.g., transparency, accountability, committed leadership). Having a culture of safety is foundational to implementing organizational efforts to improve patient safety. Organizational efforts can be enhanced by engaging in supportive patient safety activities, such as the Oregon Patient Safety Commission's (OPSC) programs highlighted below.

Communication and Resolution Process

When something goes wrong during care, the organization has a process to have an open conversation with the patient about what happened and to explore the best way to move toward resolution.

Early Discussion and Resolution (EDR)

When serious physical injury or death occurs, EDR enhances the organization's process by providing confidentiality to encourage open communication creating an environment of trust, diminishing the need for lengthy lawsuits, and fostering learning and improvement.

Adverse Event Analysis Process

When adverse events or safety issues are identified, the organization has a structured process to conduct an in-depth analysis and implements system-level action plans to prevent future occurrences.

Patient Safety Reporting Program

Organizations report their adverse event investigation findings and action plans to OPSC, which are analyzed, de-identified, and shared for statewide learning. Organizations receive consultation and support on adverse event investigation.

Patient Safety Initiatives

The organization is actively working to improve patient safety in targeted areas.

Improvement Collaborative

Through shared learning, teams from different organizations work to rapidly test and implement changes that lead to improvement.

Learning Culture	Just Culture	Reporting Culture
A willingness and competence to learn from safety information systems and the will to implement change as needed.	An atmosphere of trust in which people are encouraged to provide essential safety-related information, while maintaining professional accountability.	An organizational climate which encourages and facilitates the reporting of adverse events and safety issues.

Appendix VII. Early Discussion and Resolution Conversation Guidance

When healthcare did not go as planned and a patient has experienced serious injury or death, an open conversation between healthcare providers and the patient or their family offers a constructive way forward, even if the care met professional standards. When a conversation is initiated under the Early Discussion and Resolution (EDR) program, communications are protected under Oregon law.

You may need several conversations to achieve resolution. This document offers general guidance for both the initial conversation and follow-up conversations, based on research from leaders in the healthcare communication and resolution field (see References). Every conversation is unique and you should adjust your approach in consultation with your liability insurer.

Nothing in this document is intended as legal advice.

The Initial Conversation

The initial conversation with the patient or family should take place as soon as reasonably possible, even if your event analysis (e.g., investigation, inquiry, root cause analysis, or event review) is in an early stage.

Goals

- **Rebuild trust** with the patient or their family
- **Acknowledge** the patient or family's experience
- **Respond** to questions you can answer
- **Ensure the patient or family can contribute** to the event analysis
- **Set the stage for future discussions** with the patient or family

Guidance

Get ready

- ☐ Review the event, with team members as appropriate, so that you are familiar with information relevant to the **Five Questions the Patient and Family Will Likely Have About the Event**

5 Questions the Patient and Family Will Likely Have About the Event

1. What happened?
2. Was it preventable?
3. Why did it happen?
4. What impact will there be on my health, treatment, and follow-up care?
5. What is being done to improve care for future patients?

- ☐ Know the timeline for completing the event analysis
- ☐ Prepare yourself emotionally
  - Consider your own feelings and seek support as needed
  - Anticipate the patient or family's emotional response and plan how you will respond empathetically
- ☐ Decide who should be included in the discussion with the patient
  - Consider bringing one or more team members with you as well as a patient advocate, if your organization has one
  - Limit the size of your team—too large a team may overwhelm the patient or family member and put them on the defensive
- ☐ Rehearse the discussion, choosing a rehearsal partner who will be able to protect the confidentiality of your discussion, such as your liability insurer or risk manager
- ☐ Decide if a mediator would be helpful
- ☐ Hold all bills and donation requests until the matter is resolved

Frame the conversation and begin to rebuild the relationship

- ☐ Give the patient or family your full and undivided attention (no phones or beepers)
- ☐ Introduce everyone and explain their role
- ☐ Remind everyone that all communications are protected under law
- ☐ Describe the purpose of the conversation and check in with the patient or family to understand their goals and key concerns
- ☐ Ask the patient or family how they are doing, actively listen, and respond with empathy
- ☐ Validate the patient or family's feelings
- ☐ Express personal regret, and apologize as appropriate

Explain and confirm the facts as known, while remaining emotionally attuned

- ☐ Answer the **Five Questions the Patient and Family Will Likely Have About the Event** (see p.1) to the extent that the facts are known—do not require the patient or family to dig for vital information
  - Use plain language, avoid jargon, and check for understanding throughout
  - Do not speculate—incomplete information can create the wrong impression and it may be impossible to correct
  - You can have follow-up conversations when more is known
- ☐ Confirm your understanding of the event
  - If the patient or family has not been interviewed, ask for their account of the event
  - If the patient or family has been interviewed, ask if they have information to add
- ☐ Explain your role in the event and, if appropriate, accept responsibility—avoid blaming others or "the system"

Close the initial conversation and communicate next steps

- ☐ If needed, plan for a follow-up conversation
- ☐ Ask the patient or family if they have any other questions
- ☐ Designate a contact person whom the patient or family can reach with questions or concerns

Follow-up Conversation(s) and Resolution

After the initial conversation with a patient or family, it may be appropriate to have one or more follow-up conversations.

Goals

All the goals for the initial conversation still apply. Additional goals include:

- **Fully inform** the patient or family about the findings of your event review
- **Offer financial or non-financial restitution** if you conclude that care did not meet standards
- **Engage the patient and family** in patient safety improvement activities when and if they are willing

Guidance

Assess progress of the conversation to date, and prepare for the upcoming conversation(s)

- ☐ Review the initial conversation with your team
  - Identify what worked, what didn't work, and any outstanding questions
  - If communication was especially challenging, consider hiring a mediator

- [ ] Look over the completed event analysis
    - Determine if medical error occurred or if the event was an adverse outcome that occurred despite care that met professional and institutional standards
    - If there is any question, seek the assessment of impartial clinicians
- [ ] Prepare an offer of financial and non-financial restitution if the care did not meet professional and institutional standards
    - Work with your team to value the event fairly
    - Ask the patient or family for information you may need to assemble your offer (e.g., out of pocket expenses or lost wages)
    - Put all offers in writing—consider including the offer as part of a letter describing what happened
    - When you make the offer, advise the patient or family of their right to consult an attorney

Note: Generally it is better to separate the conversation about what happened from the discussion of restitution. Discuss the event analysis at one meeting, and schedule another to talk about compensation.

- [ ] Rehearse the upcoming discussion, choosing a rehearsal partner who will be able to protect the confidentiality of your discussion, such as your liability insurer or risk manager

Frame the conversation

- [ ] Give the patient or family your full and undivided attention (no phones or beepers)
- [ ] Re-introduce everyone
    - If you have new team members, explain their roles
- [ ] Ask how the patient or family has been since you last met, actively listen, and respond with empathy
- [ ] Bring everyone onto the same page: summarize where things stood at the end of the previous conversation, describe the purpose of the conversation, and check in with the patient or family to see if they have anything to add

Update your explanation of the facts based on the complete event analysis

- [ ] Use plain language, avoid jargon, and check for understanding throughout
- [ ] If the event occurred despite reasonable care, explain how the care met professional standards
- [ ] If the injury or death resulted from care that did not meet professional or institutional standards, tell the patient or family what should have happened
- [ ] Express personal regret, and apologize as appropriate
- [ ] Tell the patient or family what will be done differently to improve care for future patients

Conclude the conversation

- [ ] Identify next steps and plan for additional conversations if needed, including any discussion of restitution
- [ ] Express your appreciation for the patient or family's participation in the conversation process
- [ ] At the final conversation, invite the patient or family to participate in patient safety activities when and if they are interested, and let them know who to contact

Learn more: To get additional information to support your communication and resolution work, including care for the caregiver and event analysis, contact the Oregon Patient Safety Commission or visit us online, oregonpatientsafety.org.

References

Early Discussion and Resolution Statute: Oregon Laws 2013, Chapter 5

Boothman, RC, Imhoff, SJ, Campbell Jr., DA. (2012). Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk through Disclosure: Lessons Learned and Future Direction. *Frontiers of Health Services Management*, 28.3, 13-28.

Coulehan, JL, Platt, FW, Egener, B, Frankel, R, Lin C, Lown, B, Salazar, WH. (2001). "Let Me See if I Have This Right . . . ": Words that Build Empathy. *Annals of Internal Medicine*, 124.3, 221-228.

Gallagher, TH. Training Doctors to Disclose Unanticipated Outcomes to Patients: Randomized Trial. AHRQ Grant #1RO1HS016506.

Scott, S. (2011). The Second Victim Phenomenon: A Harsh Reality of Health Care Professions. *AHRQ Patient Safety Network Perspectives on Safety,* May 2011.

Scott, SD, Hirschinger, LE, Cox, KR, McCoig, M, Hahn-Cover, K, Epperly, KM, Phillips, EC, Jall, LW. (2010). Caring for Our Own: Deploying a Systemwide Second Victim Rapid Response Team. *The Joint Commission Journal on Quality and Patient Safety*, May 2010, 36.5, 233-40.