OREGON PATIENT SAFETY COMMISSION

2010 Ambulatory Surgery Center Report

Reporting Summary & Tools for Improvement

Bethany Higgins
Administrator

Valerie Van Buren
Patient Safety Consultant

Sydney Edlund
Data Analyst

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A Message from the Director

The Patient Safety Commission established an adverse event reporting program for Oregon Ambulatory Surgery Centers (ASCs) in 2007. As a participant, your organization is receiving the *2010 Ambulatory Surgery Center Report: Reporting Summary & Tools for Improvement*. This report shares aggregate data obtained from participating ASCs in the state from 2010 and preceding years and offers applicable tools to guide improvement efforts. Please utilize the information in this report as a resource to strengthen your organization's culture of patient safety.

As an ASC, you are an important participant of our adverse event reporting system. Your participation in our reporting program demonstrates your commitment to patient safety and demonstrates to the public that your organization is committed to safe care. To improve, we must commit to transparency to reduce preventable injury and harm. By reporting, we learn from the opportunities we have to identify and correct underlying system failures. It is the very cornerstone of creating a culture of safety. Oregon is unique with a voluntary reporting system and it can be preserved by your full participation.

Please consider the Commission to be your partner in patient safety. We are committed to providing resources and support so you can provide high-quality, reliable and safe care for your patients. Some examples include:

1. Offering guidance through the adverse event reporting process.
2. Providing meaningful feedback to your organization, and the ASC community, in order to prevent recurrence of the same problem.
3. Developing an industry specific model infection control program toolkit that can be modified for implementation in all ASCs.

Valerie Van Buren is your contact at the Commission for the ASC adverse event reporting program (503.227.2632 or val.vanburen@oregonpatientsafety.org). Please email or call Valerie with any questions regarding this report. We welcome your thoughts and ideas about how we can best support you in the coming year.

Sincerely,

Bethany A. Higgins
Administrator

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2010 Ambulatory Surgery Center Report

Reporting Summary & Tools for Improvement

Oregon ambulatory surgery centers (ASCs) have been submitting adverse event reports to the Oregon Patient Safety Commission since 2007. This report summarizes those submissions and provides a platform to share aggregate data with participating ASCs across the state. It is our goal that ASCs will utilize the information in this report as a tool, in conjunction with evidence-based best practices and quality improvement tools, to build and strengthen their organization's culture of patient safety.

Oregon's Adverse Event Reporting Snapshot

The following section offers a high-level overview of participating Oregon ASCs' adverse event reports to the Patient Safety Commission with an event date in 2010 and offers some comparison of reporting to previous years.

232
Reports submitted in 2010

With
257
Events

Reporting (2007-2010)

Reports submitted to the Commission saw a steady climb from 2007 through 2009 but have seen a leveling off in 2010. We interpret the initial rise not as an increase in the number of reportable events occurring, but rather as improvement on the part of Oregon ASCs in recognizing and reporting adverse events. Reports of adverse events may be higher in facilities that are vigilant in searching for potential problems. In fact, those facilities may be safer than facilities that do not look diligently for problems. An ASC's commitment to identify, submit and learn from adverse events, demonstrates a commitment to patient safety.

Because it is possible for multiple events to be included in one adverse event report (e.g., a perforation that resulted in both a blood transfusion as well as admission to the hospital), the total number of events is greater than the number of reports. Take note of the difference, as both are used throughout this report.

Table 1: Adverse Event Reporting 2007-2010: Submitted Reports vs. Events

	2007	2008	2009	2010	Total
Submitted reports	22	87	223	232	**564**
Events	26	101	257	257	**641**

Reporting Frequency

Overall, there has been an increase in reporting from year to year. A closer look at reporting frequency throughout 2010 shows that, while the first half of the year saw an increase in reporting, the second half has seen a tapering off. As previously mentioned, the initial increase is interpreted as diligence on the part of Oregon ASCs in recognizing and reporting adverse events. Similarly, we interpret the decrease in the second half of 2010, not as a decrease in number of reportable events but as a decrease in the reporting of events. The Patient Safety Commission encourages consistent reporting of all event types to allow individual ambulatory surgery centers to monitor their performance over time in relation to specific patient safety goals.

54% of Oregon's ASCs are participants in the Patient Safety Commission's adverse event reporting program; however, only 61% of those submitted a report in 2010.

For questions about your ASC's participation, contact Valerie Van Buren (503.227.2632 or val.vanburen@oregonpatientsafety.org)

Figure 1: Reporting Frequency 2007-2010

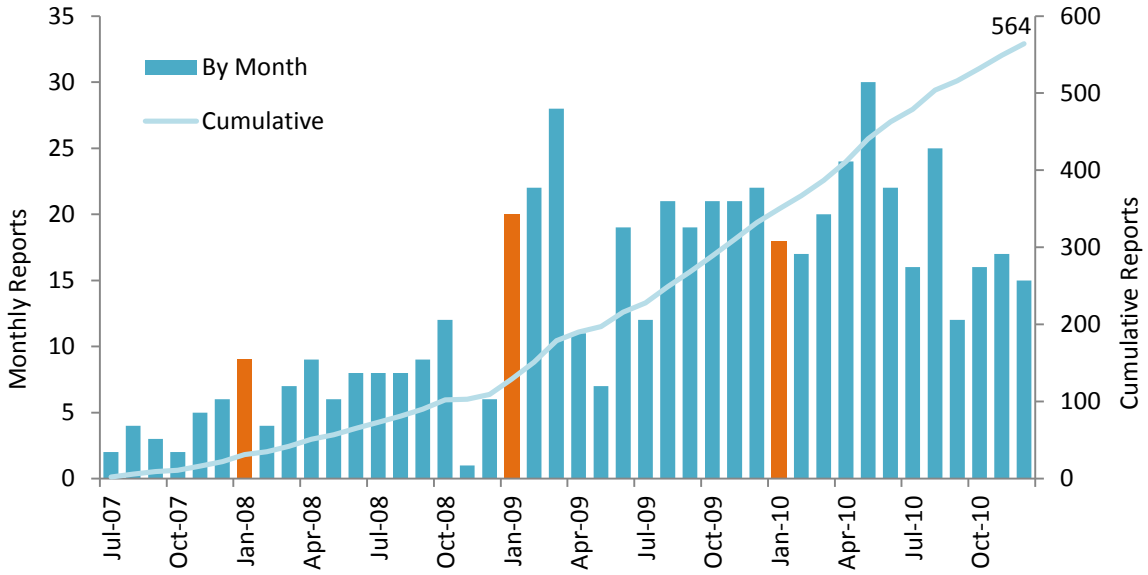
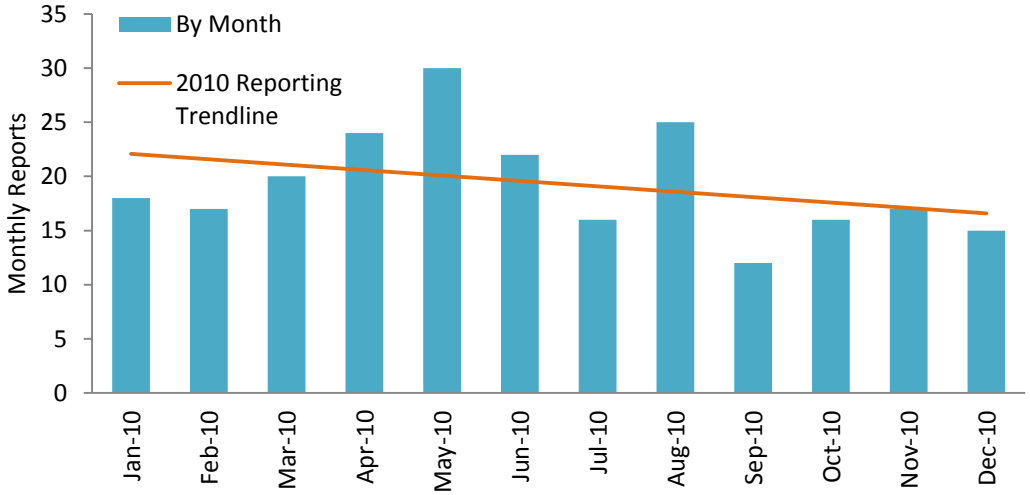


Figure 2: Reporting Frequency 2010

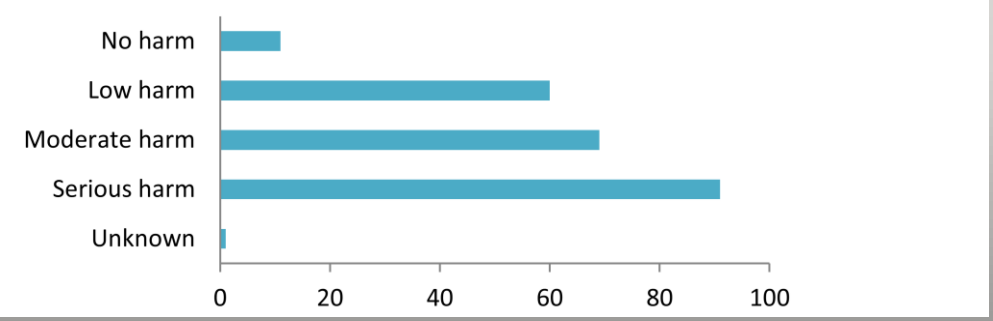


Harm Level Classification (2010)

Participating ASCs report all adverse events listed on the reporting form along with any serious adverse event (i.e., harm level of 7, 8 or 9) that is not listed on the reporting form. Reporting on lower level harm events is encouraged as well. Each one of these events offers an opportunity for investigation and root cause identification, process improvements, and shared learning to improve patient safety —without waiting for serious harm to occur.

Through the assignment of harm levels we are able to better understand events and the impact to the patient. Upon review of reported harm levels, it was noted that the Commission's interpretation of harm level definitions was not consistent with that of the ASCs. For example, 17% of reports submitted with a harm level of 2 (no harm) were reviewed by the Commission as a harm level of 7 (serious harm). Given the unique environment ASCs operate within (e.g., short window of patient interaction, logistically complex coordination of care, etc.) coupled with needed clarity of harm level definitions, the Commission is currently working towards a solution to enable increased accuracy with harm level application, by way of a reporting program redesign (see below). Figure 3 shows harm levels for 2010 events based on the Commission's interpretation of the guideline definitions.

Figure 3: Harm Levels (2010)



Reporting Program Redesign

to Include Revision of Harm Levels

The Oregon Patient Safety Commission is in the process of a major redesign to optimize the adverse event reporting program. In order to develop a more intuitive model that meets the latest industry standards, the commission will be transitioning to the NCC MERP (National Coordinating Council for Medication Error Reporting and Prevention) index for harm level categorization. With the healthcare industry's familiarity with the NCC MERP categories and with an awareness of the value of standardization, the Commission is hopeful that this will be a welcome change. We are committed to supporting our participants through this transition and with the application of the revised harm levels.

Adverse Event Reporting in Oregon ASCs

RCA can be used to analyze a single event as well as to look at multiple events in order to identify trends and make system-wide changes if necessary.

To guide your organization's adverse event investigation process, the Patient Safety Commission uses root cause analysis (RCA) as the foundation for its reporting program. RCA provides a systematic, in-depth review to learn the most basic reasons for adverse event. The goal is to understand the problem in sufficient depth to effectively eliminate the chance of future occurrence. The adverse event report walks the investigator though the RCA process in order to:

1. Determine **what** happened.
2. Determine **why** it happened.
3. Develop an **action plan** to prevent similar events.

The following section addresses these three areas as they relate to adverse event reports from Oregon ambulatory surgery centers.

Types of Adverse Events

The "Event Type" answers the most basic question about an adverse event: "What happened?" The ASC adverse event report contains 25 different Event Types (including "Other"). Table 2 offers an overview of the most common adverse events Oregon ASCs have reported.

Table 2: 2007-2010 Most Common Reported Event Types

Event Types	2007	2008	2009	2010	Total Events	% of Events	% of Reports
Unplanned hospital or ED admission (within 48 hrs.)	8	48	140	150	346	54%	61%
Surgical infection	4	13	39	41	97	15%	17%
Other	3	15	28	10	56	8%	10%
Medication error	3	5	10	10	28	4%	5%
Postoperative bleeding	1	2	12	9	24	4%	4%
Fall	1	7	5	9	22	3%	4%
Thrombosis	3	1	8	10	22	3%	4%
Transfusion	1	3	1	6	11	2%	2%
Burn		1	4	5	10	2%	2%
Equipment malfunction/misuse	2	1	2	2	7	1%	1%
Wrong procedure		1	3	2	6	1%	1%

Unplanned hospital and ED admissions were the most commonly reported event type. Due to differences in services provided by reporting ASCs, factors associated with admissions were variable. Tools and resources are offered in the following sections which individual facilities can use in guiding an analysis of their own hospital/ED admission data to identify trends and inform decisions for their organization.

The second most common reported event type was surgical infection. As of last May, Medicare-certified ASCs across the country were required to comply with CMS's new Conditions for Coverage for infection control. This is now a required component of an ASC's Quality Assurance and Performance Improvement (QAPI) program (as set forth at 42 C.F.R. 416, Subpart C). According to Susan Lautner, RN, BSN, MSHL, an accreditation specialist for quality and patient safety at the Healthcare Facilities Accreditation Program, "Infection control requirements are becoming more stringent due to recent incidents, such as the Nevada ASC incident [during which poor infection control practices led to a hepatitis C scare]."

"The ambulatory care setting, such as an ASC, presents unique challenges for infection control, because: patients remain in common areas, often for prolonged periods of time; surgical prep, recovery rooms and ORs are turned around quickly; patients with infections/communicable diseases may not be identified; and there is a risk of infection at the surgical site."

State Operations Manual, CMS.

Coming Soon!

A Model Infection Control Program

for ASCs

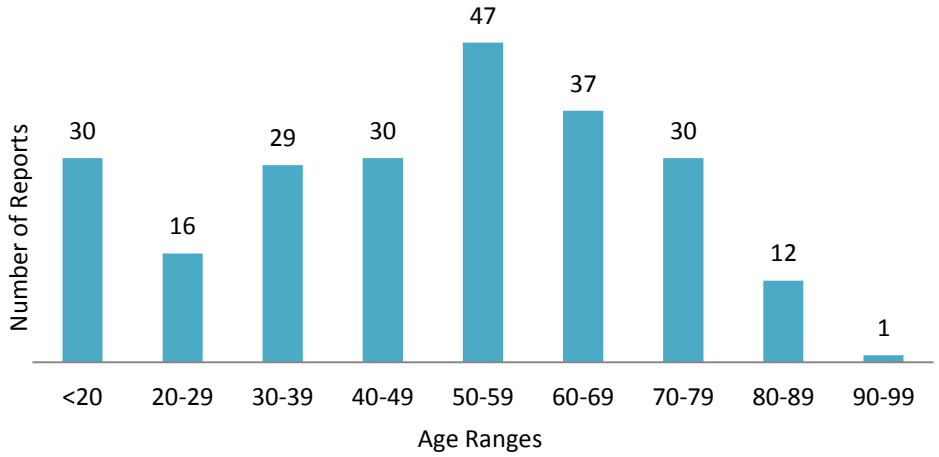
The Commission is working to support all Oregon ASCs with effective management of infection control processes and to comply with the Centers for Medicare and Medicaid Services (CMS's) infection control program standards as outlined in Medicare's Conditions for Coverage. The development of industry specific tools and resources is currently underway and will include:

1. A model infection control program toolkit that can be modified for implementation in all ASCs
2. A pilot of the model infection control program in at least five Oregon ASCs
3. Five training seminars offered around the state
4. Individual consultation and quality improvement support on how best to implement the Infection Control Program

For additional information, contact Mary Post, Infection Prevention Specialist at 503.227.3059 or mary.post@oregonpatientsafety.org

Characteristics of Reported Events for 2010

Figure 4: Adverse Events by Age Range



A patient's preoperative physical condition is determined using the American Society of Anesthesiologists' (ASA) Physical Status Classification System. It is often regarded by health care organizations as a scale to predict risk, although there are other factors that impact operative risk (e.g., age and obesity of the patient, the nature and severity of the operative procedure, selection of anesthetic techniques, the competency of the surgical team {surgeon, anesthesia providers and assisting staff}, duration of surgery or anesthesia, etc.) While there are six ASA classes, ASCs typically see ASA class one through three.

ASA 1: A normal healthy patient

ASA 2: A patient with mild systemic disease

ASA 3: A patient with severe systemic disease

Of the adverse event reports submitted to the Commission in 2010, 228 (of 232 reports) indicated an ASA classification; roughly half of those were identified as ASA class 2 patients. Overall for all reporting years (2007-2010), the Commission has seen a similar number of reports for ASA class 1 and 2; with ASA class 3 patients identified on far fewer reports (see Table 3 for details).

Table 3: Adverse Event Reports by ASA Class

	2007-2010		2010	
ASA Class	Number of Reports	% of Total Reports	Number of Reports	% of Total Reports
ASA 1	215	44 %	80	35%
ASA 2	262	47%	118	51%
ASA 3	36	6 %	28	10%
Total	513	91%	228	95%

Note: Because number of reports includes only reports indicating ASA class, totals (which are calculated using total number of reports) may not equal 100%.

Contributing Factors Cited in Reports

Identifying the factors that may have contributed to an event, and those that ultimately caused the event —the root cause(s)— helps us understand "Why the event happened." The adverse event report lists 51 potential contributing factors which are grouped into eight categories (see Table 4). In 2010, 310 contributing factors were identified on 232 reports. While multiple contributing factors within a category could be selected, Table 4, for comparison purposes, counts a category only once per report (e.g., two communication contributing factors identified on a single report are counted one time under communication). Table 5 takes a more detailed look at the total number of contributing factors identified for the three most common contributing factor categories.

There are typically multiple contributing factors for a single adverse event. Identifying and understanding them is critical in action planning for improvement.

Table 4: Contributing Factors (2010) (n=232)

Category	Number of Reports	% of Reports
Patient factors	112	48%
Patient management	98	42%
Communication	30	13%
Policies & procedures	13	6%
Training & supervision	10	4%
Work area/environment	8	3%
Equip. software, material defects	4	2%
Organization factors	4	2%

Table 5: Top Three Contributing Factors by Sub-Category (2010)

Category	Contributing Factor	Total	% of Category
Patient factors (n=112)	Other patient factor	105	94%
	Behavioral status	9	8%
	Family dynamics/relationships	6	5%
	Mental status	6	5%
	Language/culture	1	1%
Patient management (n=98)	Response to changing condition	51	52%
	Other patient management factor	39	40%
	Initial diagnosis	8	8%
	Tracking or follow-up	6	6%
	Care plan	2	2%
	Delegation of clinical care	1	1%
Communication (n=30)	Among healthcare personnel	14	47%
	Between center personnel & patient/family	7	23%
	Other communication factor	6	20%
	Available information	4	13%
	Look-alike/sound-alike drug	1	3%

Contributing Factor Identification is Only the First Step

"While the tendency to blame an individual is a strong one—and a very natural one—it is unhelpful, and actually counterproductive for a number of reasons. Whatever role that the "blamed" health-care worker (or patient) may have had in the evolution of the incident, it is very unlikely that their course of action was deliberate in terms of patient harm."

Curriculum Guide for Medical Schools, World Health Organization

Patient factors (48%) and patient management (42%) were the most frequently identified contributing factors on submitted reports. While recognizing these factors is a critical step, more in depth investigation must follow to identify system-level root causes and action plans. Submitted reports did not consistently reflect this further level of investigation, as seen in investigation findings that assigned blame to the healthcare worker most directly involved, or to the patient. For example, reports indicating a patient factor tended to focus on patient fault as the root cause (i.e., patient did not follow discharge instructions, the patient had developed a tolerance to pain medication, patient was overweight, etc.).

With a systems perspective, organization can begin to think about how they are able to impact processes, and ultimately outcomes. Looking at patient factors, ASCs can start by framing improvement efforts around questions such as, "How can we modify processes to account for human factors?" For example, the patient assessment and care planning processes could be enhanced to help safeguard against common issues a facility observes in their case mix. Or, best-practice teaching and learning principles might be incorporated into the discharge instruction process for improved patient understanding.

While the Commission recognizes that patient factors often play a role in adverse events, identification is only the first step. Further analysis is needed to better understand system-level causes, or issues will not be resolved. The following section offers insight into the analysis process to better understand why adverse events occur.

A System-Level Solution for Improved Communication

The Safe Surgical Checklist developed by the World Health Organization (WHO) is an evidence-based best practice tool to decrease postoperative complications. The checklist reinforces accepted safety practices and fosters better communication and teamwork between clinical disciplines.

An adapted version of the checklist, along with an ASC pilot version, is available on the Commission's website at www.oregon.gov/OPSC/. The original WHO checklist along with tools and resources for implementation can be found at IHI.org.

Identifying Root Causes

The root causes, or the most basic reason(s) for the event, are those that, if corrected, will minimize the recurrence of that event. Because root causes have the potential to be so diverse, they are individually identified by the reporting facility in the "Findings" section of the adverse event report and have not been categorized. Use the following tips as guidance for identifying root causes.

Tips for identifying Root Causes

1. **Use the 5 Whys** (a question-asking method to uncover underlying causes of an event; continue to ask "why" until it is no longer reasonable)
2. **Clearly show a cause and effect relationship** (i.e., if you eliminate this cause/contributing factor, will you minimize/prevent future events?)
3. **Identify the preceding causes, NOT the "human error"**
4. **Identify the preceding causes of procedure violations** (i.e., "why was the procedure not followed?" → Distractions, workarounds, time-management, knowledge, etc.)
5. **Failure to act is only causal when there is a pre-existing duty to act** (i.e., was there a procedure in place to justify an expectation?)

Using RCA as a Foundation for QAPI Programs

Because RCA is a tool for identifying system level causes, it is a natural fit for an ASC's Quality Assessment and Performance Improvement Program (QAPI), which is a Medicare Condition for Coverage (CfC) (as set forth in 42 C.F.R. §416.43). The interpretive guideline states:

> *"The QAPI CfC presumes that ASCs employ a systems approach to evaluating their systems and processes, identifying problems that have occurred or that potentially might result from the ASC\'s practices and getting to root causes of problems rather than just superficially addressing one problem at a time."*

Action Plans to Prevent Recurrence

Action plans are the critical component of the RCA. Strong and well-crafted actions plans have a clear link to the root causes or contributing factors and are easily understood. Action plans have been identified as an area for improvement in Oregon ambulatory surgery centers, based on submitted adverse event reports in 2010. The most prominent issue noted with RCAs was the superficial analyses— only uncovering surface-level causes to adverse events. A failure to ask "why" questions led to action plans that did not reflect an in-depth level of analysis.

Effective Action Plan Criteria

- Addresses the root cause(s)/contributing factors
- Focuses on systems, not on individuals
- Is specific and concrete
- Can be understood and implemented by a "cold reader"
- Is tested prior to full implementation (***Plan-Do-Study-Act**)
- Consults process owners

**More information on Plan-Do-Study-Act can be found in the following section.*

Additionally, some action plans are stronger than others. The stronger the action plan, the more likely it is to be successful in accomplishing system-level changes .The strongest, most effective actions re-design processes, devices, software, and workspaces rather than trying to change individual memory or vigilance. The table below presents categories and types of actions that might be considered.

Weak Action Plans	Intermediate Action Plans	Strong Action Plans
• Double checks • Warnings and labels • New policy/procedure • Training/education • Additional study/analysis	• Increase in staffing/decrease workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look/sound-alikes • Read back • Enhanced documentation/ communication • Redundancy	• Simplify the process and remove unnecessary steps • Standardize equipment or process • Tangible involvement and action by leadership in support of patient safety • New device with usability testing before purchasing • Architectural/physical plant changes

NCPS Root Cause Analysis Tools, The VA National Center for Patient Safety

Implementing Action Plans and Sustaining Improvement

Once the decision has been made to implement a change, purposeful planning will help guide effective implementation. One tool that can provide structure to this process is the Model for Improvement, a simple tool which serves as a roadmap for improvement. It is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. This model has been used very successfully by hundreds of health care organizations to improve many different health care processes and outcomes.

The Model for Improvement has two parts:

1. Three fundamental questions (can be answered in any order)
2. The Plan-Do-Study-Act (PDSA) cycle to test and implement change. The PDSA cycle helps guide the test to determine if the change is an improvement.

For more information on the Model for Improvement visit the Institute for Healthcare Improvement at: www.ihi.org

Model for Improvement

What are we trying to accomplish?

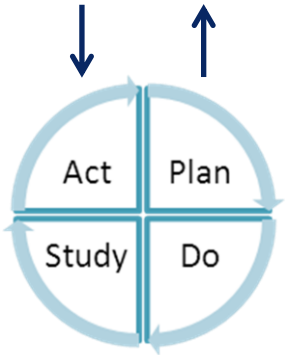
Setting Aims: The aim should be time-specific and measurable (use SMART to help set your aim).

How will we know that a change is an improvement?

Establish Measures: Quantitative measures will enable you to determine if a specific change actually leads to an improvement.

What change can we make that will result in improvement?

Selecting Changes: Organizations must identify the changes that are most likely to result in improvement.



Testing the Changes: The Plan-Do-Study-Act (PDSA) cycle is shorthand for testing a change in the real work setting — by planning it (Plan), trying it (Do), observing the results (Study), and acting on what is learned (Act). Use the PDSA to test change on a small scale (multiple times, in order to learn and make modification before implementing changes on a large scale (i.e., facility-wide).

After testing your change on a small scale, learning from each test, and modifying the change through several PDSA cycles, you can implement the change on a broader scale. Once implemented, it is important to make sure your change continues to have the intended impact (i.e., are you still meeting your aim?). Monitor your progress by tracking your measure. You may find that you need to modify your approach over time using the PDSA cycle. It is also possible for your aim to change, in which case you can begin the Model for Improvement again by asking the three fundamental questions.

Information presented in this report is based on data submitted to the Commissions through the adverse event reporting program for ASCs. While a great deal can be learned from the adverse events that occur, it is important to note that without true denominators (e.g., for the number of patients receiving services in ASCs, the number of specific surgical procedures, etc.) it cannot be used to draw conclusions about all Oregon ASCs nor should it be compared to other healthcare settings. The Commission encourages ASCs to use reporting as a tool to monitor their performance over time in relation to specific patient safety goals.

Resources

Centers for Medicare and Medicaid Services (CMS). *State Operations Manual Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers*. CMS publication 42 C.F.R. § 416. www.cms.gov/GuidanceforLawsandRegulations/02_ASCs.asp. Accessed May, 2011.

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