Patient Safety Reporting Program

2012 Pharmacy Annual Summary

Report. Learn. Improve Patient Safety.

Bethany Walmsley
Executive Director

Leslie Ray
Patient Safety Consultant

Carrie Parrish
Communications Director

Sydney Edlund
Data Analyst

October 2013

OREGON
PATIENT SAFETY
COMMISSION

Page intentionally left blank

Table of Contents

Executive Summary

Pharmacies participating in the Patient Safety Reporting Program (PSRP) submit adverse event reports about the unintended harm (or potential harm) to patients that occur as a result of medication management in the pharmacy setting. Adverse event is a general term that includes both quality-related events (QRE), adverse drug events (ADE), and medication errors (ME)—terms that are used to describe errors in the medication management process.

Through reporting, pharmacies demonstrate a commitment to building a culture of patient safety that effectively reduces preventable injury and harm. The Oregon Board of Pharmacy recommends that Oregon pharmacies develop procedures for evaluating adverse events and reporting these events to the Commission. The Commission's *Guide to Reporting Adverse Events in Pharmacies* is included in this report to assist pharmacies in their investigations and reporting.

Patient Safety Reporting Program Goals

PSRP focuses on learning from adverse events rather than simply measuring the number of events reported and is:

- Building a strong database for learning
- Identifying best-practices being used in Oregon to prevent adverse events
- Assisting healthcare organizations with setting patient safety priorities and implementing improvement efforts

To date, 17% of Oregon's community pharmacies have committed to building a culture of safety by participating in the Patient Safety Reporting Program; however, only 20% of participants have demonstrated their commitment by reporting adverse events. The Commission reviews submitted reports, provides individual feedback, and analyzes trends and opportunities for improvement.

This is the first annual summary providing a statewide, aggregate analysis of the information reported by pharmacies in 2012. The Commission will be releasing an online reporting system for pharmacies in January 2014. This new online system will allow the Commission to more efficiently and effectively collect information and provide annual summaries to reporting program participants earlier in the year.

Pharmacies can use 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. Primary findings from this analysis include:

- 24 pharmacies submitted 85 reports
- The most commonly reported events were *Incorrect strength* (32%), *Incorrect medication* (24%), and *Incorrect dose* (13%)
- Three-quarters of reported events were harm category C—an event occurred that reached the patient but did not cause patient harm; the majority of those events involved high-alert medications
- Most reported events originated in the entry (39%) or filling (39%) processes
- *Human factors* were the most commonly noted contributing factor

To continue building a culture of safety, pharmacies must learn from, and capitalize on, opportunities to identify and correct the underlying system issues that lead to adverse events. The Commission recommends that pharmacies consider several opportunities for preventing recurrence of similar problems (see box).

Recommendations for Improving Patient Safety in the Pharmacy Setting

- Review steps in the distribution processes for prescription entry and filling to identify vulnerabilities
- Identify specific causes related to human factors that may play a role in adverse events
- Improve management of interruptions and distractions through the use of Institute for Safe Medication Practices recommendations, which may include strategies such as:
  - Identify a “No Interruption Zone”
  - Set aside specific times for answering questions or responding to concerns
  - Use a signal when needing to ask a question rather than interrupting with "Do you have a minute?”
- Post a checklist for high-risk processes (such as prescription entry) to make it easier for a pharmacist or technician to remember where they left off if an interruption occurs
- Consult the Commission's *Guide to Adverse Event Reporting for Pharmacies* to more effectively use the Patient Safety Reporting Program to meet event investigation and reporting needs

The Commission is dedicated to providing value to our Patient Safety Reporting Program participants and encourages reporting with the *Guide to Reporting Adverse Events for Pharmacies* (see page 8), recognition targets to acknowledge leading participants, and the online reporting tool that will be released in January 2014. The Commission appreciates the support of our partners and PSRP participants and is pleased to provide this annual summary to inform efforts throughout Oregon to reduce the risk of serious adverse events and encourage a culture of patient safety.

2012 Pharmacy Reporting

Reporting Overview

Oregon pharmacies have been submitting adverse event reports to the Oregon Patient Safety Commission since 2008. Pharmacy reports submitted to the Commission slowly increased from 2008 to 2011. In 2012, reporting significantly increased. With so few quarters of steady data, the Commission cannot draw conclusions from this rise in reporting other than to infer that pharmacies are becoming more engaged in the Commission's reporting program and contributing to a statewide database for learning. In 2012, 24 pharmacies (20% of participants) submitted one or more reports (see Figure 1 and Figure 2).

Figure 1. Reports Submitted 2009-2012 by Quarter and Cumulatively

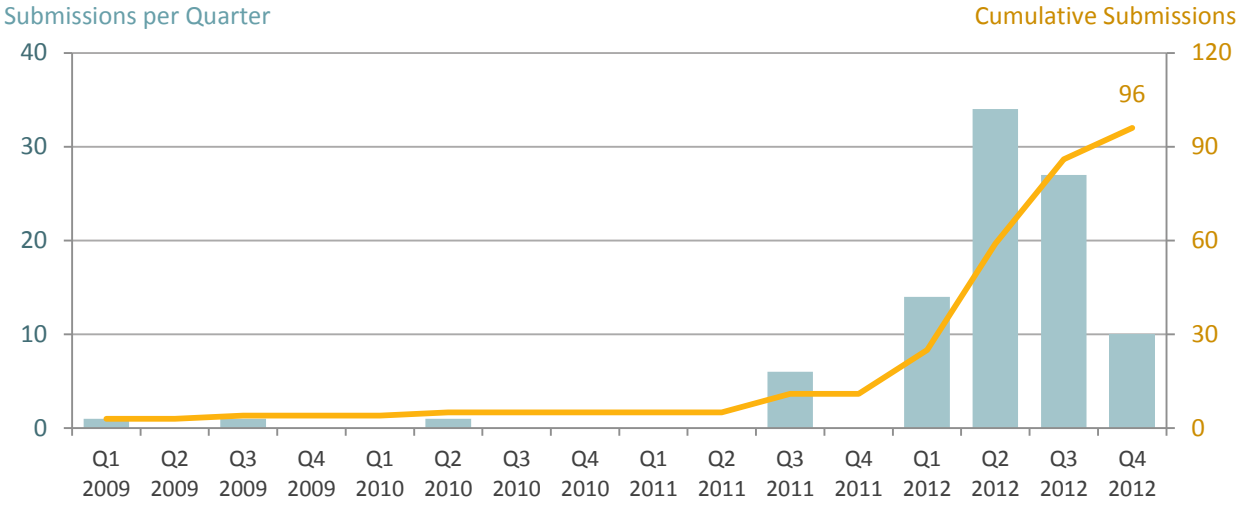
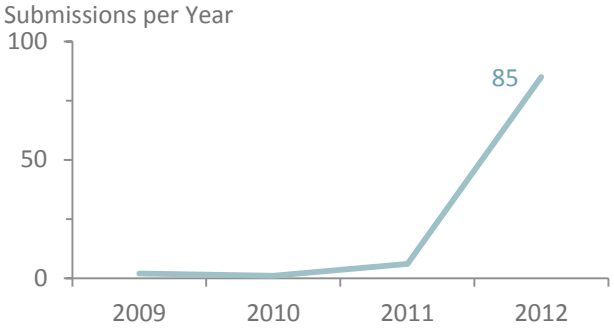


Figure 2. Reporting Frequency by year, 2009-2012*



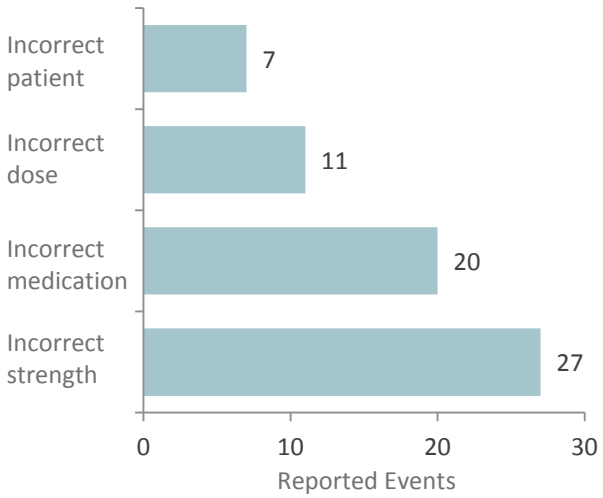
In January 2014, the Commission will release an online system for pharmacies that will allow participants to easily report adverse events. The new tool will also improve the Commission's ability to analyze reports, provide feedback to support participants, encourage learning from adverse events, and improve patient safety.

Recognition Targets

The Commission sets recognition targets to ensure that enough event reports are received to build a strong database for learning and to acknowledge transparency and commitment to patient safety in Oregon healthcare organizations (see page 10). While most pharmacies submitted 1 report in 2012, two pharmacies demonstrated a high commitment to patient safety by exceeding the target for number of reports submitted. The 2013 recognition target for quantity of reports submitted is 1 report per month per pharmacy, or 12 reports per calendar year. Strong reporting by all participating pharmacies will inform prevention strategies and enhance statewide learning.

Reported Adverse Events

Figure 3. Most Frequently Reported Events, 2012



The online reporting form released in January 2014 will include 20 different medication-related adverse events, plus "Other" (see list below). In 2012, pharmacies reported 12 different types of events with the four most frequently reported events noted in Figure 3. *Incorrect strength* was the adverse event reported most frequently by Oregon pharmacists. An *Incorrect strength* event can occur at many places in the pharmacy process. In 2012, most *Incorrect strength* events originated during the entry or filling processes (see Pharmacy Process on page 3).

Reportable Adverse Events for Pharmacies

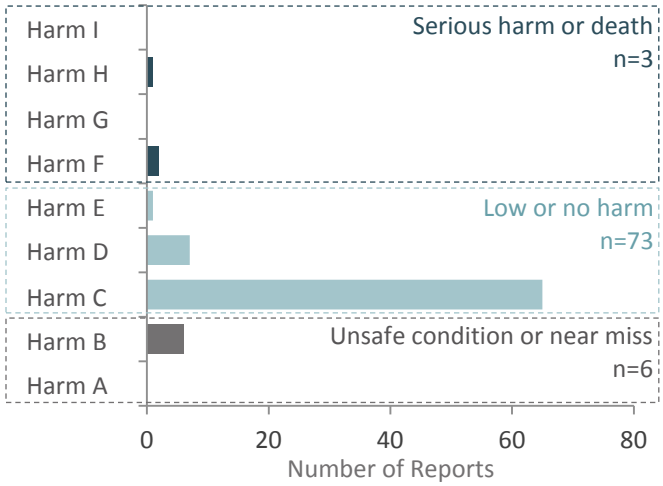
Pharmacy participants are required to report any unanticipated, usually preventable medication or other substance event that results in patient death or serious physical injury. The following list shows 20 of the most commonly reported events.

- Adverse reaction not due to allergy or known contraindication
- Allergic reaction due to unknown allergy
- Brand substitution
- Drug interaction
- Expired medication or substance
- Generic substitution
- Incorrect directions
- Incorrect dosage form
- Incorrect dose
- Incorrect medication or substance
- Incorrect patient
- Incorrect quantity
- Incorrect route
- Incorrect strength
- Incorrect or incomplete labeling
- Medication or substance contraindicated
- Medication or substance taken incorrectly
- Medication or substance omitted
- Oversedation
- Patient counseling omitted
- Other

Harm in Adverse Events

The Commission uses the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) categorization for classifying harm in reported events (see Appendix I). Because opportunities to improve patient safety and prevent the likelihood of future serious adverse events arise from the recognition of unsafe conditions and near misses, community pharmacies are encouraged to submit reports on events in any category of harm.

Figure 4. Number of Reports by Harm Category, 2012 n=82*



** Excludes three reports that did not specify a harm category*

The majority of the 2012 reported events (76%) fell into harm Category C (see Figure 4)—an event occurred that reached the patient, but did not cause harm. A smaller number were Category D, which required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.

Although actual harm from these events was relatively infrequent, the need for continued vigilance in recognizing and addressing patient safety risks remains.

Pharmacy Process

Table 1. Pharmacy Process Origins of Reported Events, 2012

Phase in process*	Number	Percent
Purchasing	0	
Storing or Stocking	2	2%
Prescribing	5	6%
Entry	33	39%
Filling	33	39%
Dispensing (includes reviewing)	2	2%
Distribution or Delivery	6	7%
Administering	2	2%
Monitoring	0	
Counseling or consulting	0	

** There were two reports where phase could not be determined.*

Adverse events can originate in any of the complex steps characterizing medication management in the pharmacy setting (see Appendix II). The Commission identifies 10 steps in a pharmacy process, seven of which were involved in 2012 event reports. In particular, the entry and filling processes were each noted 33 times, respectively, as the origin of the event (see Table 1).

Although most reported events occurred at entry and filling, these steps involve multiple actions and are affected by multiple contributing factors. When investigating an event, it is essential to review the distribution process and identify the specific actions leading up to the adverse event (see page 5).

High-Alert Medications

Table 2. High-Alert Medications Involved in Reported Events, 2012

Medication by High Alert Category*	Harm C	Total
Opioid (Narcotic)	19	23
Hydrocodone and acetaminophen	6	6
Oxycodone w/ or w/o acetaminophen	5	5
Morphine	2	4
Fentanyl	2	3
Oxymorphone	2	2
Buprenorphine	1	1
Hydromorphone	0	1
Methadone	1	1
Insulin Formulation	2	3
Liquid Pediatric Medication	2	2
Amoxicillin	1	1
Azithromycin	1	1
Oral Hypoglycemic (Metformin)	2	2
Antithrombotic (Clopidogrel)	1	1
TOTAL	**26**	**31**

* *Based on lists compiled by the Institute for Safe Medication Practices (ISMP)*

In 2012, a third of the reports (28) concerned high-alert medications—medications that are known to pose additional risks. The Institute for Safe Medication Practices has identified a list of high-alert medications for both institutional and community settings. Various formulations of opioids were the primary high-alert medication in reported events (see Table 2).

No specific event type seemed more related to high-alert medications than any other, although both *Incorrect Strength* and *Incorrect Medication* were the most frequent. While the proportion of events involving high-alert medications overall was 33%, the proportion of *Incorrect strength* events involving high-alert medications was 44%. The Commission cannot yet draw conclusions about this data but will be monitoring this relationship over time.

In looking at where high-alert medication events originated in the pharmacy process, over half (54%) originated during the filling process. However, high-alert events were identified in almost every phase of the pharmacy process.

The prevalence of high-alert medication-related adverse event reports emphasizes the value and importance of transparency about these types of events. By reporting high-alert medication-related events, pharmacies can share their lessons learned with others and contribute to shared awareness of best practices and opportunities for improvement.

Contributing Factors

Events rarely have just one identifiable cause. Usually, an adverse event is the end point of a series of actions influenced by individual circumstances, routine organizational practices, workflow processes, and culture. These actions, or factors, contribute to the event and are indicators of the individual and system issues that, if addressed, will reduce the risk of future events.

When released, the Commission's new web-based reporting system for pharmacies will include 61 potential contributing factors organized into eight categories (see Appendix III). The contributing factors are intended to help pharmacies submit in-depth reports with minimum effort.

Table 3. Contributing Factor Categories, 2012 (n=55)

Category	Number (n=55)	Percent
Human or environmental	30	55%
Policy or procedure	20	36%
Computer systems (Health information technology)	14	25%
Organizational	7	13%
Communication	1	2%
Device or supply	1	2%

Fifty-five reports indicated 17 of 61 contributing factors across six of the eight available categories (see Table 3). Some reports submitted using the Commission's reporting form marked no contributing factors; others reports were submitted on pharmacy-specific forms that did not include the same contributing factor options.

The general categories with the most frequently reported factors were *Human or environmental* (55%) and *Policy or procedure* (36%). These two general categories encompassed a number of specific individual and system factors. Drilling down to look for specific factors that played a role in the event is essential.

The purpose of adverse event reporting goes beyond a simple count of events. Reporting is a learning tool. Identifying the specific contributing factors that led to a medication-related event expands the possibilities for prevention. Avoid focusing only on the most apparent factors and think more broadly about the system of care.

A Closer Look at Human Factors

Human factors are the interactions between an individual and the system with which they work (e.g., equipment and environment). When designing work processes, taking human factors into account means considering the human limitations and predispositions that influence outcomes or performance.

Pattern recognition is key to understanding frequently reported human factors seen in pharmacy event reports. In 2012, 30% of reported events that noted a human factor indicated that look-alike/sound-alike medication was involved. To address this issue, human factor designs include the use of tall man (i.e., mixed case) lettering for medication names (see box). Altering the capitalization of medication names helps providers and pharmacists distinguish between medications with similar names or packaging. Efforts to reduce similarity in medication packaging are ongoing and also include 1) separating the location of medications in the pharmacy stock and 2) placing bar codes on medications (an extremely effective strategy because it bypasses human pattern recognition completely).

Examples of Tall Man Lettering for Look-alike/Sound-alike Medications

hydrALAZINE and hydrOXYzine

HYDROcodone and oxyCODONE

traMADol and traZODone

For more information, see the *FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters* available at: https://www.ismp.org/tools/tallmanletters.pdf

Table 4. *Human or Environmental* Factors, 2012

***Human or Environmental* Factors**	**Number** (n=30)	**Percent**
Unspecified human factors	17	57%
Distractions or interruptions	9	30%
Look-alike/sound-alike medications*	9	30%
Production pressure	4	13%
Personnel fatigue	2	7%
Personnel stress	2	7%

* *In the new PSRP online system, Look-alike/sound-alike medications will appear in the Medication Event contributing factors category*

Identifying clear action plans to reduce risk is difficult because the majority of reports (57%) did not specify the human factors involved. Interruptions and distractions were identified in 30% of *Human or environmental* factor-related events (see Table 4). Interruptions and distractions can occur at critical times and may cause pharmacists to incorrectly enter a dose or select the wrong strength drug from the shelf. In the intense dispensing environment, eliminating distractions and interruptions is not always possible; however, several steps can be taken to minimize distractions where possible (see box).

Managing interruptions and distractions is an essential skill for all pharmacy professionals. Pharmacies should improve management of interruptions and distractions by using the Institute for Safe Medication Practices safe practice recommendations, which include strategies such as:

- Identify a No Interruption Zone
- Set aside specific times to answer questions or respond to concerns
- Use a signal when needing to ask a question rather than interrupting with "Do you have a minute?"
- Post a checklist for high-risk processes (such as prescription entry) to make it easier for a pharmacist or technician to remember where they left off if an interruption occurs

Several useful strategies can prevent adverse events due to interruptions and distractions. These strategies range from stronger action plans—a no-interruption zone to prevent distraction altogether—to weaker action plans—checklists that are helpful in prompting memory but do nothing to prevent the interruption. While varying in strength, all of the recommended actions take into account human factor design principles and are likely to result in increased safety.

In general the most desirable safety strategy is one that makes an adverse event impossible. Knowing that one of the most critical human limitations in healthcare is memory and attention span, practices and procedures that eliminate reliance on these factors are essential. Unfortunately, a common response to adverse events is to implement a strategy of "pay more attention." This continued reliance on human memory and attention disregards the human factors principles and is ineffective. Calling on staff to "pay more attention" has no impact on improving safety as human beings will buckle under the pressure of competing demands and time constraints. Pharmacies should look deeper into processes to identify the specific human factors that may play a role in adverse events (e.g., lighting, clutter, speed, interruptions/distractions) and implement strategies to improve the environment or work flow and give staff the best opportunity to provide safe medication management.

Resources

Patient Safety Reporting Program: Recognition Targets for 2013

Oregon Board of Pharmacy, Medication Error Reduction Research Council (2008). Recommendations for Optimizing Patient Safety and Reducing Medication Errors

ISMP Medication Safety Alert. (2012). ISMP Side Tracks On The Safety Express. Interruptions Lead To Errors And Unfinished…Wait, What Was I Doing?

The Patient Safety Reporting Program

A Guide to Reporting Adverse Events in Pharmacies

The Patient Safety Reporting Program (PSRP) is an external reporting system that collects reports of adverse events from healthcare organizations throughout Oregon. Although each adverse event may have unique characteristics, reporting to PSRP allows for commonalities among the events to be identified. Aggregate analysis is able to detect trends and patterns that may otherwise go unnoticed. The program provides expertise and shares lessons learned with the larger healthcare community to promote learning, improve safety, and prevent the recurrence of adverse events.

> An *adverse event* is an event resulting in unintended harm or creating the potential for harm that is related to any aspect of a patient's care (by an act of commission or omission) rather than to the underlying disease or condition of the patient; adverse events may or may not be preventable.

How healthcare organizations respond to adverse events is representative of their culture of safety. The cornerstone of a strong culture of safety is transparency about adverse events. By reporting adverse events, organizations are able to learn and improve their complex systems. A good pharmacy-level reporting system is an essential element in a robust quality improvement program. The reporting system can help identify potential risks, promote learning from experiences, and play a role in monitoring the progress of improvement efforts. Sharing lessons among internal staff and teams is only the first step. Lessons learned can be shared externally through the PSRP so that other organizations can benefit as well.

What to Report

Pharmacies report adverse events ranging from near miss or no harm events to serious events. While the Commission encourages reports of all adverse events, Table 5 shows 20 of the most commonly reported adverse event types.

Table 5. Pharmacy Adverse Event Types

Adverse reaction not due to allergy or known contraindication	Incorrect patient
Allergic reaction due to unknown allergy	Incorrect quantity
Brand substitution	Incorrect route
Drug interaction	Incorrect strength
Expired medication or substance	Incorrect/incomplete labeling
Generic substitution	Medication or substance contraindicated
Incorrect directions	Medication taken incorrectly
Incorrect dosage form	Oversedation
Incorrect dose	Patient counseling omitted
Incorrect medication or substance	Other

Conducting an Effective Investigation

A majority of the factors that lead to adverse events are systemic and are not the result of poorly performing individual pharmacists, technicians, or other staff members. Adverse events are simply the symptoms or indicators that problems exist somewhere in the system. When an adverse event occurs, it offers organizations the opportunity to understand what occurred and why, which allows for system-level improvements to prevent recurrence. An adverse event serves as the starting point for a more in-depth investigation to identify the system-level contributing factors and root cause(s) and develop action plans to prevent recurrence of similar events.

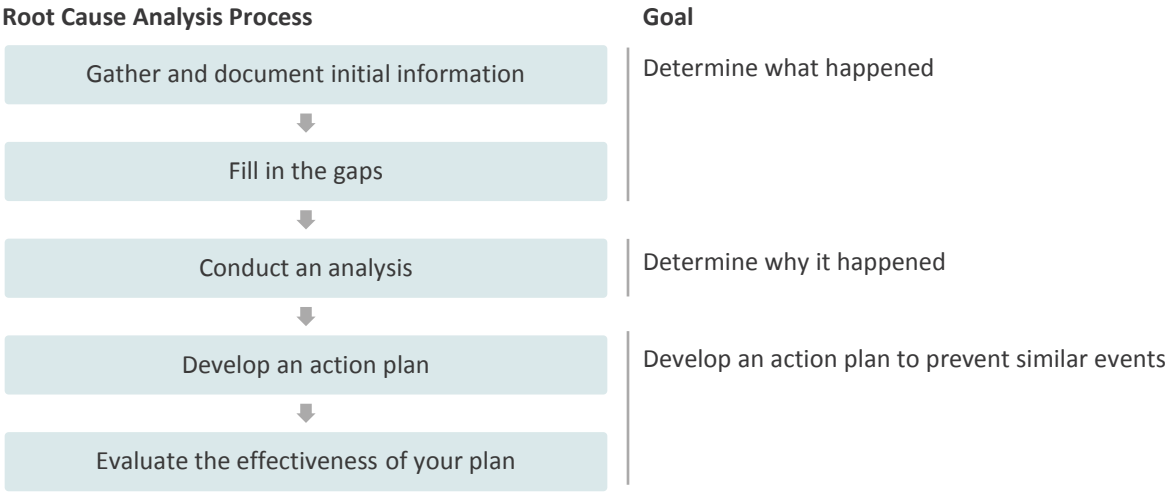
Root Cause Analysis

To better understand why adverse events occur, the Patient Safety Reporting Program is based on root cause analysis (RCA). RCA requires a systematic, in-depth review to learn the most basic reasons why an adverse event occurred. The goal is to understand the problem in sufficient depth to effectively eliminate the chance of future occurrence. Adverse event investigators can use the RCA process to determine what happened, why it happened, and develop an action plan to prevent similar events (see Figure 5).

Avoid Common RCA Pitfalls

1. Prematurely jumping to solutions
2. Spending too much time on what happened rather than why
3. Getting distracted by minor or moderate details of the event
4. Focusing on shortcomings of people rather than systems and processes

Figure 5. Root Cause Analysis Process and Goals



Root cause analysis guides the investigation process to help organizations learn from adverse events for improved patient safety.

Recognition Targets

The Commission established Patient Safety Reporting Program (PSRP) recognition targets to ensure that enough adverse event reports are received to build a strong database for learning, encourage effective investigations, and to recognize healthcare organizations for their transparency efforts and commitment to patient safety (see Table 6). Targets are designed to change each year as organizations build their reporting programs to meet the State of Oregon's reporting requirements (Oregon Revised Statute 442.820-442.835, Oregon Administrative Rules 325).

Each year, the Commission identifies leading PSRP participants and issues awards to the top performers based on established recognition targets. The Commission's website identifies all pharmacies that meet or exceed recognition targets. The recognition targets focus on the *quantity* of reports submitted as well as the *quality* and *timeliness* of those reports.

Table 6. Pharmacy Recognition Targets, Individual Pharmacies

Quantity	1 report per month (12 annually)
	In 2011, the Commission established annual quantity targets for the first time. The target is designed to increase the number of reports submitted each year to ensure that the Commission has enough adverse event reports to build a strong database for learning.
Quality	25% of reports meet acceptable quality criteria
	The quality of submitted adverse event reports are evaluated by the Commission using four Joint Commission criteria to determine if reports meet acceptable quality criteria: *complete*, *thorough*, *credible*, and having *effective action plan(s)* (See High-Quality Investigations on the next page). Participants are required to earn specific points in each of the four criteria.
Timeliness	50% submitted within 45 days
	After an adverse event, an immediate response is needed to collect full and reliable information on the circumstances surrounding the event. Timeliness is defined as the amount of time that passes between the date an event was discovered and the date a report is submitted to the Oregon Patient Safety Commission. The State of Oregon requires that pharmacies submit a completed adverse event report within 45 calendar days of discovery of a reportable serious adverse event (Oregon Administrative Rules, 325-015-0025(3) (2006)). This standard promotes timely responses to adverse events in an effort to aid the development of preventative plans.

High-Quality Investigations

High-quality reports play a vital role in the success of the Patient Safety Reporting Program (PSRP) and have the greatest potential to contribute to shared learning across healthcare organizations. Program consultants evaluate reports submitted to the Commission for acceptable quality. The intent of evaluation is to support healthcare organizations in conducting in-depth investigations that focus on preventing future events. Acceptable quality is determined using four criteria (outlined in OAR 325-010-0035) (see Table 7).

Table 7. PSRP Acceptable Quality Criteria

Complete	Report provides all information pertinent to understanding what happened
Thorough	Report represents an analysis that considered system-level contributing factors and identified root cause(s)
Credible	Report contains evidence that the investigation included leadership participation and was internally consistent
Effective action plan(s)	Report includes system-level plans that address identified causes and are likely to decrease the risk of future occurrences

The quality criteria serve as an indicator that organizations conduct effective investigations using root cause analysis to prevent similar adverse events and improve safety.

Complete

Report provides all information pertinent to understanding what happened

Quality Measures	Characteristics of Complete Investigations
■ Sequence of actions and relevant surrounding circumstances/conditions	• Provides information pertinent to understanding what happened
□ Relevant clinical information	• Provides only clinical information that is relevant to understanding the event

Legend: ■ Measure required for acceptable quality score □ Measure not required for acceptable quality score

Sequence of Actions and Relevant Circumstances/Conditions

Providing a clearly understandable description of the event ensures the information shared can be used for learning beyond the walls of the pharmacy that submitted the report (see box). Summarize the sequence of activities and circumstances leading up to the event in a way that someone unfamiliar with the event could easily understand. Include details about identified contributing factors along with decisions and other rationale that influenced the occurrence of the event.

Strategies for
Submitting a Complete Report

- Start from the adverse event and work backwards to retrace the sequence of action leading up to the event
- Include those closest to the event on the review team
- Include information related to identified contributing factors and causes identified during the investigation process to help paint a clear picture about what happened

One example of a *complete* report is available on page 18 and can be used to inform a pharmacy's reporting process.

Thorough

Report represents an analysis that considered system-level contributing factors and identified root cause(s)

Quality Measures	Characteristics of Thorough Investigations
■ System-level contributing factors directly associated with the event ■ At least one relevant root cause identified ☐ Presence of additional root or proximal causes	• Identifies the factors most directly associated with the event and the related process(es) and systems • Does not focus on individual performance • Identifies risks and their potential contributions to the event • Analyzes the underlying systems through a series of why questions to determine where changes might reduce risk

Legend: ■ Measure required for acceptable quality score ☐ Measure not required for acceptable quality score

System-Level Contributing Factors

Typically, multiple system-level contributing factors can be identified for a single adverse event if a thorough investigation is conducted. Contributing factors, as defined by the Agency for Healthcare Research and Quality, are circumstances that are retrospectively determined to have increased the likelihood of an adverse event. Contributing factors are generally external to the patient and frequently relate to the physical environment or to the care delivery system.

Root Cause(s)

Adverse event reports should identify at least one relevant root cause—the most basic reason for why an adverse event occurred, which, if adequately addressed, will prevent or minimize recurrence of similar events. Root causes can be identified by examining specific contributing factors more thoroughly. Once contributing factors have been identified, an organization must continue the investigation until the root cause(s) have clearly been identified (see box). Ultimately, a successful investigative process can provide meaningful information about root causes that can be translated into ongoing system-level improvements.

Strategies for
Identifying System-Level Contributing Factors and Relevant Root Causes

- **Use the Five Whys** – To uncover the contributing factors and root causes of an event, continue to ask "why" until it is no longer reasonable.
- **Clearly show a cause and effect relationship** – Ask, if you eliminate this cause, will you minimize/prevent future events?
- **Identify the preceding causes, NOT the "human error" or potential policy/procedure violations** – Seek to understand why a "human error" or mistake was made or why a policy/procedure was not followed.

Credible

Report contains evidence that the investigation included leadership participation and was internally consistent

Quality Measures	Characteristics of Credible Investigations
■ Participation by senior management either through notification of individual/aggregate events, as a member of review team, or in a post-review briefing (only for serious harm events; i.e., F, G, H, and I)	• Includes participation by leadership and by the individuals most closely involved in the processes and systems • Is internally consistent; i.e., does not contradict itself or leave obvious questions unanswered
■ Less than four inconsistencies	

Legend: ■ Measure required for acceptable quality score ☐ Measure not required for acceptable quality score

Participation by Senior Management

One of the keys to conducting a credible investigation is engagement and support of pharmacy senior management following an adverse event. Leadership can set the tone that patient safety is a priority by encouraging a culture of learning and improvement when adverse events occur. Participation by senior leadership is also essential to ensure appropriate resource allocation in addressing adverse events and in managing the response to adverse events in the larger organization context (see box).

Strategies for
Senior Management Participation Following Adverse Events

- Review, track, and trend adverse events on a continuous basis (this can be of aggregate information); leadership review of aggregate information satisfies the criteria for participation by senior management (e.g., review of aggregate quarterly event data or report)
- Promote open communication about safety concerns
- Empower staff to identify and address safety hazards and risks
- Allocate adequate safety resources
- Measure the effect of what has been done (e.g., data collection) to ensure patient safety efforts are having the intended impact

Effective Action Plan(s)

Report includes system-level plans that address identified causes and are likely to decrease the risk of future occurrences

Quality Measures	Characteristics of Effective Action Plans
■ A system-level action plan that decreases the likelihood of such events in the future*	• Includes participation by leadership and by the individuals most closely involved in the processes and systems
☐ Additional system-level action plans or action plans that fit the description of stronger actions*	• Is internally consistent; i.e., does not contradict itself or leave obvious questions unanswered
☐ Plans clearly link to the identified cause	

Legend: ■ Measure required for acceptable quality score ☐ Measure not required for acceptable quality score

*Based on the VA National Center for Patient Safety's root cause analysis tools, *Recommended Hierarchy of Actions*. The VA categorizes action plans into three categories based on their likelihood of reducing vulnerability: stronger, intermediate, and weaker. http://www.patientsafety.va.gov/CogAids/RCA/index.html

System-Level Action Plans

Action plans outline the steps an organization will take to prevent future adverse events and are a critical component of the root cause analysis. Many action plans do not effectively address the root cause(s) of an adverse event because they are focused on individual-level actions and not system-level actions. Strong, system-level action plans have a clear link to an event's root cause(s) and contributing factors, are easily understood, and are more likely to be successful in achieving system-level changes (see box and Table 8).

Strategies for
Developing Effective Action Plans

- Address the identified root cause(s)/contributing factors
- Focus on systems, not on individuals
- Be specific and concrete
- Include stronger actions, which are more likely to eliminate or greatly reduce the likelihood of an event

Table 8. Stronger, Intermediate, and Weaker Action Plans

Stronger Action Plans	Actions that do not depend on staff to remember to do the right thing; the action may not totally eliminate the vulnerability but provides very strong controls (uses system fixes)	• Simplify the process and remove unnecessary steps • Standardize equipment or process • Tangible involvement and action by leadership in support of patient safety • Forcing functions* • New device with usability testing before purchasing • Architectural/physical plant changes	
Intermediate Action Plans	Actions are somewhat dependent on staff remembering to do the right thing, but they provide tools to help staff to remember or to promote clear communication	• Increase in staffing/decrease workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look-alikes and sound-alikes • Read back • Independent verification • Enhanced documentation/communication • Redundancy	
Weaker Action Plans	Actions depend on staff to remember their training or remember what is written in the policy	• Training/education • Additional study/analysis • New policy/memorandum • Double checks • Warnings and labels	*Weaker action plans alone DO NOT meet the acceptable quality criteria*

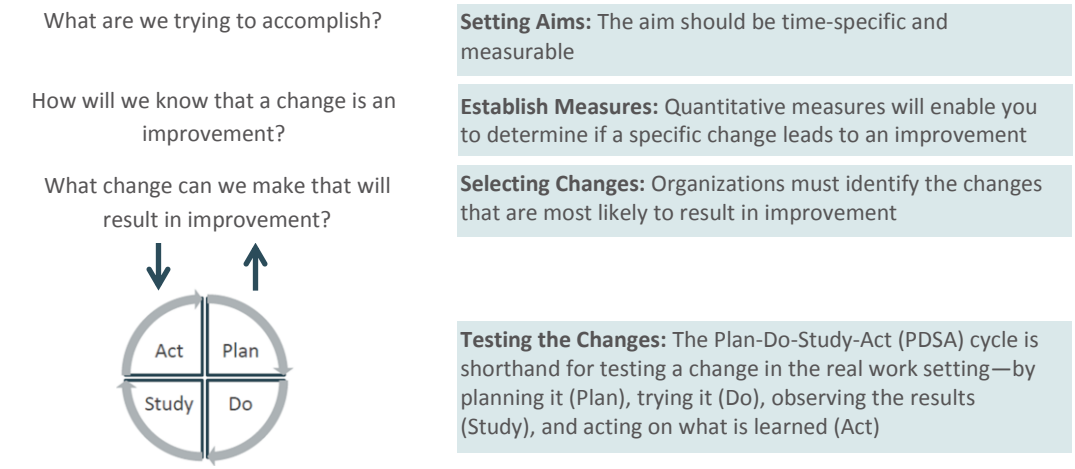
The VA National Center for Patient Safety's root cause analysis tools. Available at: http://www.patientsafety.gov/CogAids/RCA/index.html#page-14

*An aspect of a design that prevents an unintended or undesirable action from being performed or allows its performance only if another specific action is performed first (e.g., a single dose vial)

Testing an Action Plan

Once the decision has been made to implement an action plan, purposeful planning will help guide effective implementation. Organizations can use the Model for Improvement, a simple tool that serves as a roadmap for improvement, to structure this process. The Model for Improvement is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. Hundreds of healthcare organizations have used this model to improve many different healthcare processes and outcomes (Langley, Nolan, Nolan, Norman, and Provos, 2009). As shown in Figure 6, the Model for Improvement has two parts: 1) three fundamental questions and 2) the Plan-Do-Study-Act (PDSA) cycle to test and implement change.

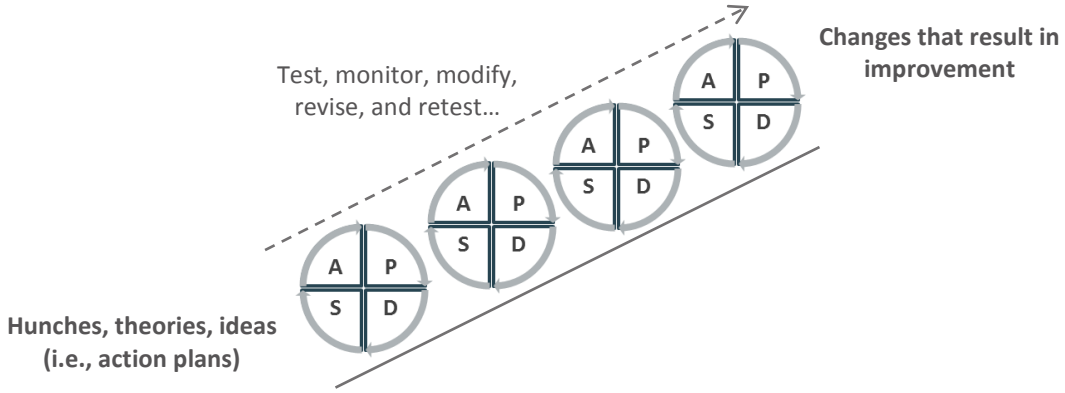
Figure 6. The Model for Improvement



(Langley et al., 2009)

When testing the change, the PDSA cycle helps guide the test to determine if the change is an improvement. The PDSA cycle is used to test change on a small scale (e.g., with one patient) multiple times in order to learn and make necessary modifications before implementing changes on a large scale (e.g., pharmacy-wide) (see Figure 7).

Figure 7. The PDSA Cycle, Testing Action Plans Using Small Tests of Change



Example of High-Quality Adverse Event Report

The following example is based on an actual adverse event report received by the Commission and provides guidance on completing a high-quality PSRP report. The example includes a majority of information the Commission uses to determine if reports meet the acceptable quality criteria: *complete*, *thorough*, *credible*, and having *effective action plan(s)*.

✓Sequence of actions and relevant surrounding circumstances/conditions

Complete account: Rx for Alprazolam 0.5mg was phoned into pharmacy on Friday, 11-16-2012 during a typical busy time and was initially transcribed correctly by the pharmacist on a handwritten Rx log; however, when the same pharmacist entered the Rx into the pharmacy computer system an hour later, the Rx was entered incorrectly as Alprazolam 0.25mg. Review of the log showed easily recognizable strength. Pharmacist does not recall any specific interruptions or distractions at the time, but it is not uncommon for the pharmacist to stop in the middle of a prescription to answer questions or field a phone call. The directions were correctly captured as one tablet 3 times daily as needed for anxiety.

✓ System-level contributing factors directly associated with the event

When the patient received the Rx on Tuesday 11-20-12, she noticed the Rx was labeled with Alprazolam 0.25mg mg and that the bottle contained the 0.25mg strength, not the 0.5mg strength desired. (Patient has taken the 0.5mg strength routinely and has ordered this med from this pharmacy since 2004). The patient contacted the pharmacy on 11-20-12 to inquire about the discrepancy and inquired if she could take 2 of the 0.25mg tablets.

✓ Relevant clinical information

The pharmacist who entered the Rx incorrectly handled this call from the patient on 11-20 and upon a review of the Rx detail, recognized the error. The prescriber was contacted and the agreed upon course was for the patient to finish this prescription by taking 2 of the 0.25mg tablets 3 times per day as needed to equal the prescribed dose. A subsequent Rx for the correct strength (0.5mg) was issued and dispensed correctly. Patient was understanding and appreciated the quick resolution of the problem.

✓ At least one relevant root cause identified

A review of each of the steps for entering a prescription was conducted to determine if there was a system or process related problem. No clearly discernible problem was identified in the prescription entry process. Internal review of the events was documented and staff were counseled regarding greater attention to detail to ensure prescriptions are entered correctly.

Cause 1: Probable distraction or interruption in the midst of entering Rx from handwritten log due to need for pharmacist to respond to questions.

Through this investigation, the pharmacy was able to identify a probable system-level cause related to current process(es) and systems even though the time lapse between the event and its discovery hindered the ability to identify the cause with 100% certainty. This investigation is critical for the development of strong action plans that are more likely to effectively prevent the recurrence of similar events.

✓ System-level solutions that decrease the likelihood of such events in the future

Action Plan 1: Develop interruption management plan that includes identifying times when the pharmacist may be interrupted.

✓ Plans clearly link to the identified cause

This action plan focused on process and system improvements that decrease the likelihood of similar events in the future; however, a stronger action plan

would have described the specific plan. While this action plan may not completely eliminate the vulnerability, it uses system fixes rather than relying on human memory and attention.

Action Plan 2: Counsel staff regarding greater attention to detail to ensure prescriptions are entered correctly.

This action plan is unlikely to prevent future occurrences; however, recognizing human limitations in dealing with distractions is an important step to developing an interruption management plan. In addition to making system changes (as above), providing a prescription entry checklist to assist the pharmacist in recalling where in the process he/she was when interrupted would be useful.

Using Your Patient Safety Consultant

The patient safety consultant, a resource available to all pharmacy participants, offers support and consultation for using PSRP as well as for conducting effective investigations (e.g., using root cause analysis). Pharmacies can contact their consultant at any point in the reporting process for assistance. The consultant also reviews and evaluates reports submitted to PSRP for acceptable quality with the intent of supporting pharmacies in conducting in-depth investigations that focus on prevention of future events. Pharmacies are encouraged to review consultant feedback of submitted reports for future learning.

Contact Your Patient Safety Consultant

Leslie Ray
Email: leslie.ray@oregonpatientsafety.org
Tel: 503.224.9227

References

Langley GL, Nolan KM, Nolan TW, Norman CL, Provos LP. (2009). The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd edition). San Francisco: Jossey-Bass Publishers.

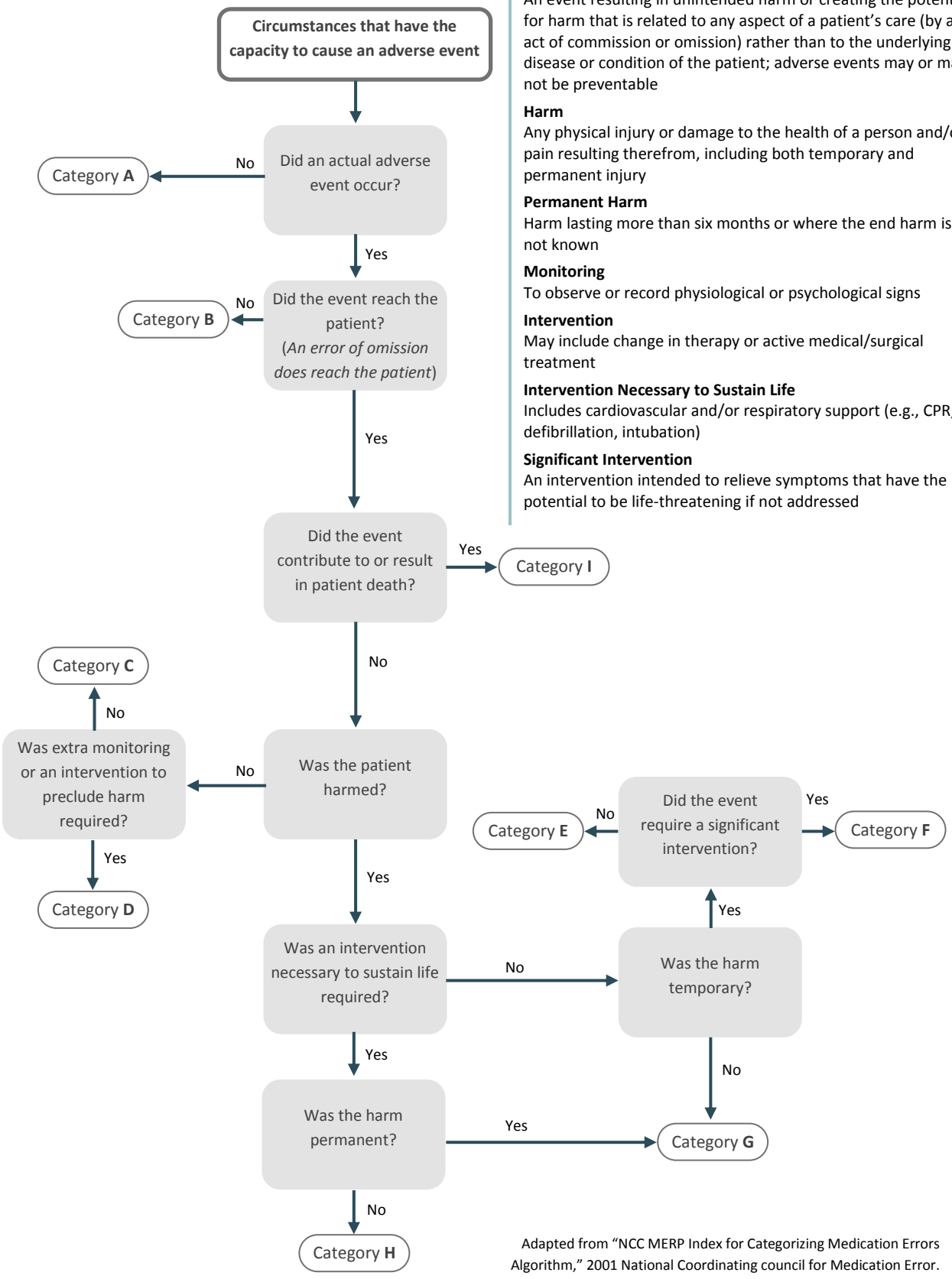
Appendix I. Harm Categories and Algorithm

When pharmacies report adverse events, they assess harm related to the event. In 2012, the Commission adopted formally validated national harm categories established by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) (see Table 9). Adoption of the national NCC MERP harm categories improves the Commission's ability to interpret the impact of adverse events in a standardized way. Reporters follow an algorithm embedded in the adverse event report and answer a series of yes/no questions to assign an appropriate harm category (See Figure 8).

Table 9. NCC MERP Harm Categories

Category A	Circumstances that have the capacity to cause an adverse event	**No adverse event**
Category B	An event occurred that did not reach the patient (an "error of omission" does reach the patient)	**Adverse event, no harm**
Category C	An event occurred that reached the patient but did not cause patient harm *Harm is defined as "any physical injury or damage to the health of a person requiring additional medical care, including both temporary and permanent injury"*	
Category D	An event occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm *Monitoring is defined as "to observe or record physiological or psychological signs"*	
Category E	An event occurred that may have contributed to or resulted in temporary harm to the patient but did not require a significant intervention *A significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"*	**Adverse event, harm**
Category F	An event occurred that may have contributed to or resulted in temporary harm to the patient and required a significant intervention *A significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"*	
Category G	An event occurred that may have contributed to or resulted in permanent patient harm *Permanent harm is defined as "harm lasting more than 6 months, or where end harm is not known ('watchful waiting')"*	
Category H	An event occurred that required intervention necessary to sustain life *An intervention necessary to sustain life is defined as including "cardiovascular and/or respiratory support (e.g., CPR, defibrillation, intubation)"*	
Category I	An event occurred that may have contributed to or resulted in patient's death	**Adverse event, death**

Figure 8. Harm Category Algorithm



Adapted from "NCC MERP Index for Categorizing Medication Errors Algorithm," 2001 National Coordinating council for Medication Error.

Appendix II. Pharmacy Process

Table 10. Pharmacy Process Origins of All Reported Events, 2012

Phase of origin	Purchase	Store, stock	Prescribe	Enter	Fill	Dispense	Distribute, deliver	Administer	Monitor	Consult, counsel	Unknown, other	Grand total
Incorrect strength			1	9	17							**27**
Incorrect medication		1	1	10	9						1	**22**
Incorrect dose			1	7			2	1				**11**
Incorrect patient			1	2			4					**7**
Incorrect dosage form				4	1							**5**
Incorrect directions				2		2						**4**
Incorrect or incomplete labeling		1			3							**4**
Incorrect amount, quantity or size					3							**3**
Contraindicated			1									**1**
Incorrect time											1	**1**
Adverse reaction, unexpected											1	**1**
Allergic reaction, unknown allergy								1				**1**
Grand total	**0**	**2**	**5**	**34**	**33**	**2**	**6**	**2**	**0**	**0**	**3**	**87**

Appendix III. List of Contributing Factors

The Commission's web-based reporting system for pharmacies will include 61 potential contributing factors organized into eight categories. The contributing factors are intended to help pharmacies submit in-depth reports with minimum effort.

Communication (n=10)

- Among pharmacy staff
- Between manager or pharmacist and staff
- Hard to read fax or handwriting
- Unclear prescription
- With prescribing provider or other outside organizations
- Between staff and patient
- Culture
- Language
- Misinterpreted directions
- Other

Device or Supply (n=6)

- Availability
- Design
- Function (including device failure)
- Maintenance
- User error
- Other

Computer system (health information technology) (n=9)

- IVR (Integrated voice response)
- Bar-coding
- Electronic prescribing
- Integrated health record (including EHR/EMR)
- Robot or autofill system
- Patient profile incomplete or inaccurate
- Software
- Telepharmacy
- Other

Human or environmental (n=9)

- Clutter
- Interruptions or distractions
- Lighting
- Noise
- Personnel fatigue
- Personnel health issues
- Personnel stress
- Work area design and specifications
- Other

Organizational (n=13)

- Assignment or work allocation
- Culture of safety
- Internal reporting
- Job orientation or training
- Management or leadership skills
- Patient waiting
- Prescription backlog
- Staff competencies
- Staffing levels
- Supervision
- Systems to identify risk
- Temporary or new staff
- Other

Policy or procedure (n=7)

- Clarity of policy or procedure
- Policy or procedure absent
- Pharmacist, technician or staff unfamiliar with policy or procedure
- Policy or procedure unrealistic
- Policy or procedure too cumbersome
- Work-around more efficient
- Other

Patient (n=7)

- Behavioral status
- Family dynamics or relationships
- Fragile health status
- Mental status
- Sensory impairment
- Physical limitations
- Other