Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

20 YEARS
ADVANCING MEDICATION SAFETY

Table of Contents

Chapter 1. Introduction

It is estimated that the overall dispensing accuracy rate in community pharmacy is 98.3% (77 errors among 4,481 prescriptions).[1] This translates to about 4 errors per day in a pharmacy filling 250 prescriptions daily. Extrapolating these numbers could insinuate that an estimated 51.5 million errors occur during the filling of 3 billion prescriptions annually in America's pharmacies. There is a need for every community/ambulatory pharmacy to find a way to control risk in order to prevent, identify and mitigate harm from these errors.

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a Continuous Quality Improvement (CQI) program in place. Many of the state regulations require a Root Cause Analysis (RCA) in the case of a sentinel event. The Joint Commission defines a sentinel event as an *unexpected occurrence involving death or serious physical or psychological injury or risk thereof*, and recommends completing RCA for all sentinel events that happen in healthcare organizations they accredit. RCA for sentinel events is required in the Center for Pharmacy Practice Accreditation's (CPPA) standards developed by the National Association of Boards of Pharmacy (NABP), American Pharmacists Association (APhA) and American Health System Pharmacy Association (ASHP).

There are several programs and tools available for conducting RCA, but the majority of these focus on acute care settings. Until now, little information existed on how to perform a RCA in a community pharmacy and utilize the results for system improvement.

1.1 Purpose of the Workbook and Associated Tools

1. Describe the root cause analysis (RCA) process in community/ambulatory pharmacy, using a specific set of steps and associated tools, and help the user identify the primary causes of the sentinel event.
2. Prompt the users to create an action plan framework resulting from the RCA, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.
3. Describe common pitfalls when conducting RCA.
4. Provide example of the investigation and analysis of a sentinel event using RCA methodology and the newly developed *ISMP Community Pharmacy Template for Root Cause Analysis and Action Plan*.

This RCA workbook is suitable for use in community pharmacy, mail order pharmacy or other ambulatory pharmacy practice settings that need to investigate a sentinel event.

[1] Flynn et al. National observational study of prescription dispensing accuracy and safety in 50 pharmacies. J Am Pharm Assoc (Wash). 2003 Mar-Apr;43(2):191-200.

Chapter 2. What is RCA?

RCA is a systematic process to identify the causal factors that contributed to the occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant underlying and fundamental systemic conditions that increase the risk of adverse events. These analyses can capture both the big-picture perspective and the details of the error. Implementing effective strategies that target the identified root causes is the best way to prevent similar problems from occurring in the future.

It is important to note that in any organization, top priority should be given to eliminating the need for RCA by designing systems to prevent or attenuate errors through proactive risk assessment. As part of their CQI program, organizations should have access to information published about medication errors that happened at other pharmacies and were reported to national error reporting programs such as the ISMP National Medication Errors Reporting Program and FDA MedWatch Program.

2.1 Characteristics of a Thorough and Successful RCA

- Identifies system and process changes needed to improve performance and reduce the risk of a similar event or close call from recurring.
- Focuses primarily on systems and processes rather than individual performance.
- Provides in-depth understanding of the events being investigated by continuously asking "why did this (or that) happen" until all root causes have been identified.
- Includes participation by leadership of the organization in problem solving and quality and safety improvement (this can range from appointing the RCA team, to direct participation on the RCA team, to participation in the determination of the corrective action plan).
- Includes participation by individuals most closely involved in the processes and systems under review, and who are knowledgeable in human factors and error prevention measures.
- Internally consistent—does not contradict itself or leave obvious questions unanswered.
- Includes consideration of relevant literature. If a similar error was reported and published (e.g., in medication error features in journals, ISMP newsletters or website) consider using identified recommended strategies. If necessary, contact ISMP for assistance in identifying needed information.

2.2 When RCA Is Necessary

Any error defined as a sentinel event requires investigation using the RCA methodology.

Any medication error not defined as a sentinel event should be assessed using case reviews or other investigative techniques. One alternative investigative approach to conducting a full RCA for an incident would be to utilize the *ISMP Assess-ERR™ Community Pharmacy Version*. This simple three step medication system worksheet is designed to assist pharmacists and pharmacy operators in investigating errors, close calls and hazardous conditions. The Assess-ERR™ tool can be found at: www.ismp.org/Tools/Community_AssessERR/default.asp.

Organizations should specify/define which events require RCA. However, they should steer away from putting too much specificity around tying types of events to investigative techniques, as each case is unique.

NOTE: If the event is thought to be the result of a criminal or purposefully unsafe act related to alcohol or substance abuse (i.e., impaired staff), stop the RCA process and refer the issue to organizational leadership.

2.3 Conducting RCA – An Overview

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc.) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA

1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question #2, Table 1 on page 5). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question #3) helps determine the reliability of processes and how often staff cut corners to get the work done.

For each contributing factor identified ask "Why did that happen?" or "Why wasn't it prevented by our process?" This approach is repeated until there are several levels of analysis. As a rule of thumb, it normally takes about 5 rounds of "why" to identify the root cause of a problem, but this is not set in stone—you may sometimes ask "why" more or less than 5 times.[2]

Use the *Assessing Risk and Opportunities for Change* (AROC) document found at www.ismp.org/communityRx/aroc/ to help the team identify several prevention strategies.

The RCA also should include a method to measure the effectiveness of these strategies over time.

2.4 Conducting RCA – A Step-by-Step Approach

See the case example in Section 6 for an illustration of the process outlined below.

NOTE: use the Fact Gathering Worksheet (Appendix F) to record findings from staff interviews, policy and document review, observations and team meetings.

Step 1. Form a team

The RCA team is a group of people selected to analyze the events that led to a sentinel event. Complete Step 1 on the RCA template (Appendix H). The people on the team generally fall into one of the following categories:

- Leadership/owner: organizational leaders who are empowered to make decisions and enact or bring about change must be included on the team.
- Individual knowledgeable about the actual event.
- Front line worker: a colleague familiar with the medication use process at that site.
- (Optional) Technical RCA expert: a colleague familiar with the RCA process.

Step 2. Determine what happened

Describe as accurately as possible what happened in a clear and concise format. Complete Step 2 on the RCA template (Appendix H). Gather information related to the event by:

- Reviewing the documentation (e.g., written prescription, computer data entry, compounding log, counseling log documentation).
- Assessing the physical environment (e.g., workspace, ergonomic factors).
- Reviewing the labeling and packaging of the product.
- Interviewing pharmacy staff involved in the incident to determine the sequence of events.

[2] Dineen, M. Six steps of root cause analysis. UK: Consequence; 2004: 54.

Step 3. Flow chart (i.e., diagram the flow) of the event

- Use the Process Step Descriptions (Appendix C) and Example Prescription Flow Chart (Appendix D) as examples to help create a flow chart or narrative timeline (Step 3 on the RCA template) for the sequence of events gathered in Step 2 above. When charting the flow of events, ask why at each step to identify any contributing or root causes. Any unanswered questions will form the basis for information that team members still need to collect (e.g. by interviewing those involved and witnesses, reviewing documentation).
- Answer "Why did it happen?"question in Step 3 on the RCA template (Appendix H) with findings from flow charting.

Step 4. Identify root causes

- During the RCA meeting, the Fact Gathering Worksheet (Appendix F) can be used to ask and answer questions regarding possible contributing factors and to record the team's comments. Comments from the Fact Gathering Worksheet will be used to complete the RCA template.
- Using the comments from the Fact Gathering Worksheet, identify the proximate (primary contributing) factors. The proximate factor questions on Step 4 of the RCA template are grouped in the same order as the ten key elements of the medication use process and the Fact Gathering Worksheet.
- To inform the team's thought process, review each of the ten key element contributing factors charts in the AROC document found at www.ismp.org/communityRx/aroc/. Also review the definition and examples of trigger question categories found in Appendix A. Strive to take personal bias out of the investigative process.
- Complete the column of findings/proximate factors for each of the ten key elements as applicable (Step 4 on the RCA template, Appendix H).
- Determine if the finding/proximate factor identified is a 'root cause' or 'contributing factor' and check the appropriate box.
  - "Root cause?" should be answered "Yes" or "No" for each finding. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan. Number each finding that is identified as a root cause.
  - "Contributing factor?" should be answered "Yes" or "No" for each finding.
  - "Take action?" should be answered "Yes" or "No" for each finding, including contributing factors.

Step 5. Write root cause statements

- For findings checked off as 'root causes' in Step 4 above, write concise descriptions of the cause-and-effect relationship (Step 5 on the RCA template).
- Read and apply the five rules of causation (Appendix G) when studying the problem. The rules were created in response to the very real biases we all bring to the investigative process and will help the RCA team develop robust contributing factor and root cause statements.
- Ensure that the team has not focused on the actions of individuals or in any way placed blame.

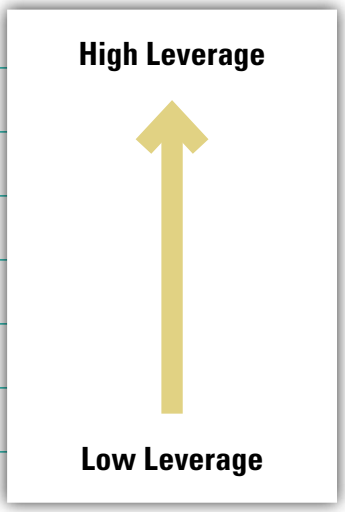
Step 6. Develop action plan and measures

- Form action plan
  - Explore and identify risk-reduction strategies. Review each of the 10 key elements and suggested risk-reduction strategy charts found in the AROC document at: www.ismp.org/communityRx/aroc/.
  - Actions are developed to prevent or minimize future sentinel events or near misses. Actions should include controlling risk by preventing errors, identifying errors that have been made before they reach the patient, or strategies that will mitigate harm if the error reaches the patient. Actions are developed from the RCA team asking:
    - » How can we decrease the chance of the event occurring again?
    - » How can we decrease the degree of harm if the event were to occur again?
    - » What is best practice (when considering changing procedures or rules)?
    - » How can devices, software, work processes or workspace be redesigned using a human factors approach?
    - » How can we reduce reliance on memory and vigilance by improving processes in the workplace?
    - » Is the proposed action achievable within the limitations of the organization's resources?
  - Formulate improvement actions (Step 6 on the RCA template) for each identified root cause in Step 4; each root cause must have an action.
  - Depending on resources (time and money), choose several actionable items. When choosing error-reduction strategies, employ a mix of higher- and lower-leverage strategies (see Table 2) that focus on system issues and address human factors for those who work within that system. For more information about choosing effective error-prevention strategies, read "Selecting the best error prevention tools for the job" at: www.ismp.org/Newsletters/ambulatory/archives/200602_4.asp.
  - Review common pitfalls (Appendix E) as part of a gap analysis before completing the RCA.

- Establish measures—the team should record methods to measure effectiveness of the action plan over time (Step 6 on the RCA template). Measurement ensures recommendations were implemented and are still being followed months and years later.
- Communicate the results—after determining what happened and identifying root causes, the team should provide leadership with its recommendations for improvement and action plan to prevent recurrence of the event. The completed RCA, including risk-reduction strategies or prevention recommendations, should be shared with the entire organization as a learning tool and as a means to create buy-in to proposed system changes. Complete the RCA Summary (Appendix I).

Table 2. Rank Order of Error Reduction Strategies

Fail-safes and constraints
Forcing functions
Automation and computerization
Standardization and protocols
Redundancies
Reminders and checklists
Rules and policies
Education and information



Items at the top of the list, such as fail-safes, forcing functions, and automation, are more powerful strategies because they focus on systems. The tools in the middle attempt to fix the system yet rely in some part on human vigilance and memory. Items at the bottom, such as education, are old, familiar tools that focus on individual performance and therefore are weak and ineffective when used alone.

Chapter 3. Key Practice Points

RCA is intended to determine three things:

- What happened?
- Why did it happen?
- What can be done to reduce the likelihood of a reoccurrence?

The RCA framework should be broken down into manageable steps:

- Form a team
- Review all documentation (written prescription, data entry, logs, policies, etc.)
- Review physical environment
- Review product labeling and packaging
- Interview those involved in the incident
- Determine sequence of events through flow charting on the medication use system
- Ask "why?"
- Determine contributing factors and root causes
- Develop an action plan for each identified root cause
- Measure effectiveness of action plan over time
- Communicate results

Chapter 4. Conclusion

Sentinel events are almost never caused by the failure of a single element in the system. More often, there are multiple underlying system failures that lead to the error, many of which can be identified through RCA. The real benefit of RCA only comes when the sentinel events are fully investigated and solutions have been successfully implemented and continually measured over time for effectiveness.

Appendix A. Glossary of Terms[3]

Action plan: The result of RCA, where system and process deficiencies are addressed and improvement strategies are developed and implemented. The plan includes outcome measures to indicate that system and process deficiencies are effectively eliminated, controlled or accepted. The goal of the action plan is to find ways to prevent repeat occurrences of adverse events or close calls.

Adverse events: Untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, pharmacy or other facility. An adverse event results in unintended harm to the patient from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.)

Adverse Drug Events (ADEs): Adverse events specifically associated with medications or therapeutic agents.

Close call: An event, situation, or error that took place but was captured before reaching the patient. Such events have also been referred to as *near miss* incidents. Close calls are opportunities for learning and afford the chance to develop preventive strategies and actions.

Contributing factor: Additional reason, not necessarily the most basic reason, that an event has occurred.

Intentional unsafe acts: Any events that result from:

- A criminal act
- A purposefully unsafe act
- An act related to alcohol or substance abuse
- Impaired provider/staff

Intentional unsafe acts should be dealt with through other methods, i.e., administrative investigation or other administrative channels as determined by the organization and boards of pharmacy.

Medication error: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice; healthcare products, procedures and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use.

Root cause: The most fundamental reason an event has occurred.

[3] US Department of Veterans Affairs. Triage and triggering questions. http://www.patientsafety.gov/CogAids/Triage/index.html?7#page-3. Accessed 5/16/13.

Root cause analysis (RCA): A process for identifying the basic or causal factors that result in variation in performance, including the occurrence or risk of occurrence of a sentinel event or adverse event. RCA is a retrospective investigative process that teaches us what went wrong within any given process.

As a tool, RCA is designed to:

- Describe *what* happened during a particular occurrence
- Determine *how* it happened
- Understand *why* it happened
- Recommend actions to *prevent* it from happening again

Sentinel events: A type of adverse event. Sentinel events, as defined by The Joint Commission, are unexpected occurrences involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. Major permanent loss of function means sensory, motor, physiologic, or intellectual impairment not previously present that requires continued treatment or life-style change. The phrase *risk thereof* includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes. Sentinel events signal the need for immediate investigation and response. Death resulting from a medication error is an example of a sentinel event.

Triggering and triage questions: Questions to bring about discussion (see Appendix F Fact Gathering Worksheet for examples of questions to consider).

Trigger Question categories:

- **Human Factors/Communication:** Questions that help assess issues related to communication, flow of information and availability of information as needed. These questions also reveal the importance of communication in use of equipment and application of policy and procedure, unintended barriers to communication and the organization's culture with regard to sharing information.

  Example of issue involving human factors/communication: A patient who is known to the staff by sight is dispensed the wrong bagged prescription for a person with a similar name. The pharmacy has a policy requiring that the patient's date of birth be asked at every point of sale, but because there is a line forming at the register, the technician dispenses the medication without asking and matching the patient's birthdate to the birthdate on the receipt.

- **Human Factors/Training:** Questions that help assess issues related to routine job training, special training and continuing education, including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment or appropriate manipulation of protective barriers. These questions also focus attention on the interfaces between people, workspace and equipment.

  Example of issue involving human factors/training: After installing an IVR (Integrated Voice Response) system to limit time spent with customer phone calls for routine matters (refill requests, hours of operation, etc.), the phone rings incessantly in the pharmacy. No one picks up the phone because they think it will 'go into voice mail'; they do not realize the customer selected the option to speak to a live person in the pharmacy.

- **Human Factors Fatigue/Scheduling:** Questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, management concern and involvement.

  Example of issue involving human factors fatigue/scheduling: Renovation is taking place in the deli area that adjoins the pharmacy, making it difficult for staff to converse with each other and to hear phone conversations.

- **Environment/Equipment:** Questions to help evaluate factors related to use and location of equipment; fire protection and disaster drills, codes, specifications and regulations; the general suitability of the environment and the possibility of recovery after an error has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions and training needs.

  Example of issue involving environment/equipment: A new pharmacy intern arrives to start a rotation at your pharmacy. A dispensing error occurs when the wrong stock bottle is scanned and the medication is still dispensed because the intern expects to hear a 'beep' if the wrong drug was selected, as it did in the system he worked with previously at another site.

- **Rules/Policies/Procedures:** Questions that help assess the existence and accessibility of directives that should be taken into consideration. These include:
  - Technical information for assessing risk
  - Mechanisms for feedback on key processes
  - Effective interventions developed after previous events
  - Compliance with national policies
  - Usefulness of and incentives for compliance with codes, standards and regulations
  - The qualifications of the facility and employees for the level of care provided
  - Orientation and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness the availability of information to all part time, temporary or voluntary workers and students

  Example of issue involving rules/policies/procedures: An agency technician hired for the day is not familiar with your facility's policy for destroying confidential patient information in compliance with HIPAA.

Appendix B. Research Articles and Resources

For additional reading on RCA, see:

1. Knudsen P, Herborg H, Mortensin AR et al. Preventing medication errors in community pharmacy: root-cause analysis of transcription errors. *Qual Saf Health Care*. 2007;16:285-290.
2. Mills PD, Neily J, Kinney LM et al. Effective interventions and implementation strategies to reduce adverse drug events in the Veterans Affairs (VA) system. *Qual Saf Health Care*. 2008;17(1):37-46.
3. Wichman K, Greenall J. Using root cause analysis to determine the system-based causes of error. *CPJ*. 2006;139(3):63-65.
4. United States Department of Veterans Affairs. Triage and Triggering Questions. http://www.patientsafety.va.gov/CogAids/Triage/index.html#page=page-1. Accessed Dec 26, 2013.
5. VA National Center for Patient Safety. http://www.patientsafety.va.gov/glossary.html. Accessed Dec 26, 2013.
6. Root Cause Analysis. http://www.root-cause-analysis.org/. Accessed May 16, 2013.
7. Dineen, M. *Six steps of root cause analysis*. UK: Consequence; 2004:54.
8. Cohen, M, ed. *Medication Errors*. Washington DC: American Pharmacists Association; 2007:67-86.
9. Smetzer J, Baker C, Byrne D, et al. Shaping systems for better behavioral choices: lessons learned from a fatal medication error. *Jt Comm J Qual Patient Saf*. 2010 Apr;36(4):152-63.
10. Sauer B, Hepler C. Application of system-level root cause analysis for drug quality and safety problems: a case study. *Res Social Adm Pharm*. 2013 Jan-Feb;9(1):49-59.
11. Sadler S, Rodgers S, Howard, R, et al. Training pharmacists to deliver a complex information technology intervention (PINCER) using the principles of educational outreach and root cause analysis. *Int J Pharm Pract*. 2013 Apr 21;1-12.
12. Schafer JJ. Root cause analysis project in a medication safety course. *Am J Pharm Educ*. 2012 Aug 10;76(6):116.
13. Rooney Jj, Vanden-Heuvel Ln. Root cause analysis for beginners. *Quality Progress*. 2004 July;45-53.

For additional reading on error prevention strategies, see:

1. US Food and Drug Administration. MedWatch: the FDA safety information and adverse event reporting program. http://www.fda.gov/Safety/MedWatch/default.htm. Accessed May 16, 2013.
2. *ISMP Medication Safety Alert!*® Community/Ambulatory Care Edition Ambulatory Care Action Agenda. http://www.ismp.org/newsletters/ambulatory/actionagenda.asp. Accessed May 16, 2013.
3. Cohen, M, ed. Medication Errors 2nd Edition. Washington DC: American Pharmacists Association; 2007.

Appendix C. Process Step Descriptions

Typical for most community pharmacies, though some variation will exist.

Process Step 1: Triage, Receipt of Prescription (Rx)

- Order received at the pharmacy via patient, caregiver, fax, phone, electronically or other method (neighbor, mail, transfer, etc.)
- Patient history and demographics obtained, Rx reviewed for completeness; if applicable, Rx scanned into computer system
- If incomplete Rx or patient information, then either the patient or prescriber is contacted. For example:
  - Allergies needed/missing
  - Order clarifications — legibility, readability, missing information
- Issues related to the product not being available arise
- Patient desired pick-up time is noted
- If no scanning capability or if scanning quality is poor, or Rx is for CII product then hard copy prescription moves to next process step—otherwise hard copy is filed

Process Step 2: Order Entry of Prescription

- Order entered into computer system from scanned image or hard copy; prioritized by patient pick-up time and workflow
  - Patient selected from database, local or centralized; if not found, then entered as new patient
  - Drug entered by free text or code
  - Directions entered by free text or code
  - Prescriber selected from database or entered as new if not found
  - Quantity, number of days supply, substitution permission, expiration date of medication entered
  - Date prescription written entered
  - Number of refills entered
- Missing or new patient demographics may be updated at this point

Process Step 3a: Pharmacist Verification I—Data Entry Verification

- Perform order verification by comparing input prescription information to original prescription; necessary changes made
  - Review for correct drug, dose, patient, route, quantity, directions and therapy based on diagnosis or indication

Process Step 3b: Pharmacist Verification I—Pharmacists' Drug Utilization Review (DUR)

- Pharmacist review for interactions, missed allergies
- Resolve non-formulary issues, generic or therapeutic alternatives allowed, severe interactions, refill too soon, duplicate therapy

Process Step 4: Label Print/Stock Selection, Dispensing/Filling the Prescription

- Medication retrieved from robot or shelf for dispensing or use in compounding, selection verified by NDC number or barcode on label/receipt (if CII controlled substance, by law in some states, this step may only be performed by the pharmacist)
  - Stock expiration date checked
  - Quantity of medication indicated on label is counted, poured, etc.
  - Label applied
  - Auxiliary labels applied
  - Initiate extemporaneous compounding if applicable (add diluents)

Process Step 5: Pharmacist Verification II— Product Verification

- Conduct final check to ensure that the product dispensed or packaged is appropriately packaged and labeled; manual verification with stock bottle or use tablet/product imaging technology
- Verify label for proper product, dose, quantity, packaging, labeling, warning labels, route of administration, expiration date; product also verified against the hard copy or scanned prescription
- If issue is identified, labeled product sent back to technician at stock selection (Process Step 4)

Process Step 6a: Delivery Sort and Transfer to Will-Call Area:

- Completed prescription orders bagged and receipts attached to outside of bag
- Labeled prescription(s) and attached receipt(s) are matched
- Consumer medication information produced/retrieved
- Medication guides included as applicable/required
- Bagged prescriptions stocked in will-call area alphabetically by patient last name
- Will-call area routinely scanned for prescriptions filled and not picked up within predetermined timeframe (one week, 10 days, etc.)
- Patient-specific labeled prescriptions needing reconstitution or refrigeration are flagged as such and stored separately

Process Step 6b: Delivery to Patient

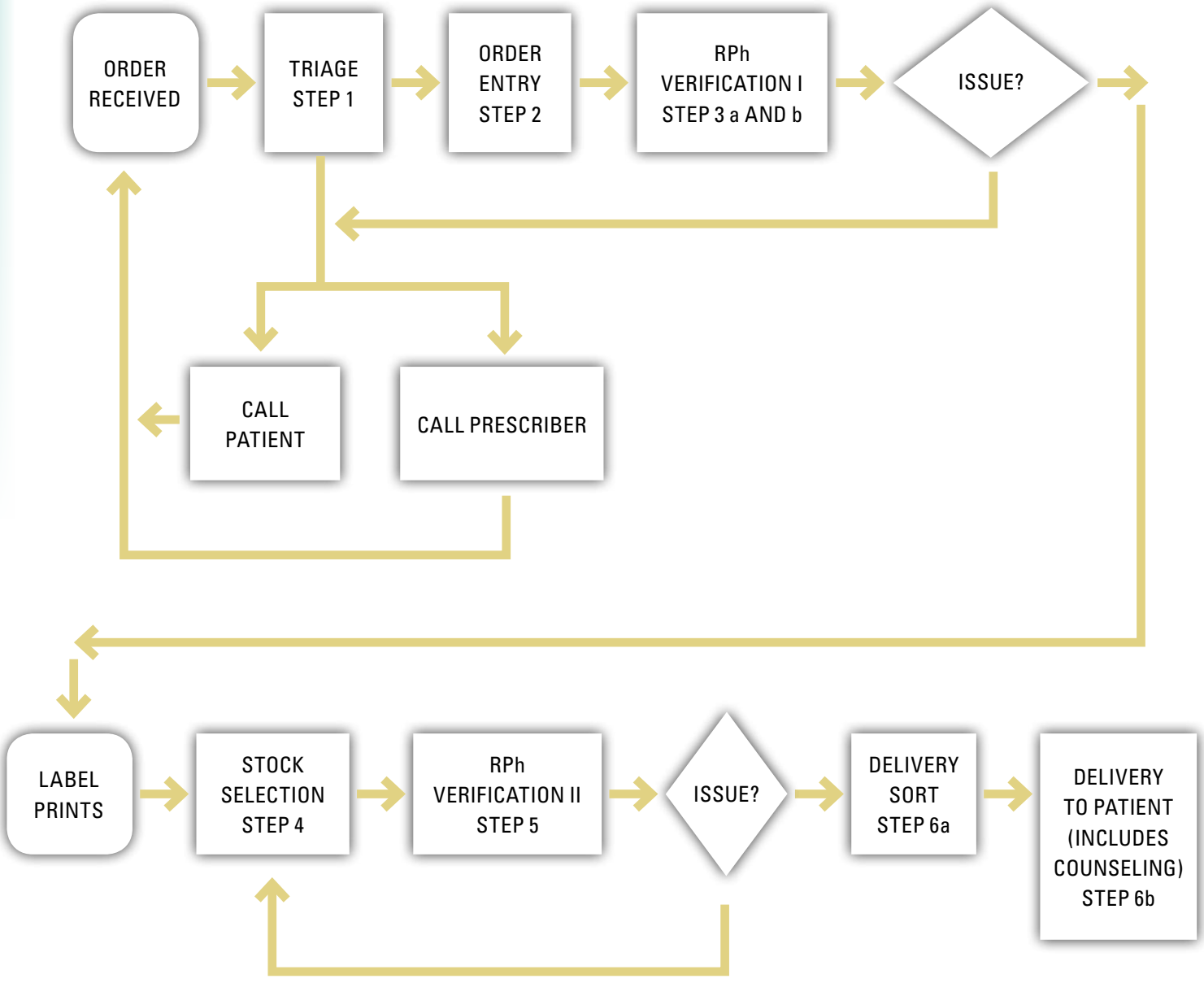
- Technician asks patient or caregiver for two different patient identifiers at point of sale
- Refrigerated or reconstituted items retrieved from specific area and given to pharmacist to verify/ reconstitute

- Offer made to patient for counseling on all new prescriptions (and sometimes refills, depending on state regulations)
- Technician directs patient to private consultation area when prescription receipt indicates mandatory counseling by pharmacist or when patient accepts offer
- Patient counseling (some computer systems will capture counseling notes and keep them in the patient's profile)
  - Conversation between pharmacist and patient or caregiver may include:
    - The name and description of the medication and known indications
    - Dosage form, dosage, route of administration and duration of drug therapy
    - Special directions and precautions for preparation, administration and use by the patient
    - Common severe side effects, adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur
    - Techniques for self-monitoring drug therapy
    - Proper storage
    - Prescription refill information
    - Action to be taken in the event of a missed dose

Appendix D. Prescription Flow Chart

Typical for most community pharmacies, though some variation will exist.

Tip: When developing your own flow chart of events, don't jump to conclusions. It is essential to stay focused on what **actually** happened – not what the team **thinks** happened. Construct a basic "time series" of the facts leading up to and including the adverse outcome.



Appendix E. Common Pitfalls

Some of the most common errors in RCA include the following.

Skipping the chronology

Many RCAs do not include a sequence of events, flow chart and/or narrative that adequately describes what actually happened. To be effective, RCA must start with an accurate sequence of events and timeline to help uncover all the gaps where human error or unsafe behavioral choices were made. This helps define the problems that need to be addressed, understand the relationship between contributory factors and the underlying causes and ensure that all aspects of the event are analyzed. Although developing an event chronology is time consuming, it is a step that should not be skipped despite time constraints and a desire to quickly "get to the bottom" of the event.

Reliance on policies and procedures

Some RCAs fail to uncover "real life" conditions that led to an event because the team relies too much on what is written in policies and procedures to illustrate what actually happens when care is provided. ISMP has observed over-reliance on policies and procedures by some regulatory and licensing agencies that investigate events. When these agencies issue no citations because the policies and procedures look great on paper, the organization or RCA team may feel compelled (or find it easier) to stand behind the finding of "no system issues."

Failure to conduct at-risk behavior investigation

RCAs often fail to closely examine the behavioral components of an error, which is an important omission. When an event involves staff who cut corners, breach a policy or did not follow a procedure, the conditions that led to these at-risk behaviors need to be investigated. It is necessary to uncover incentives that encourage the behavior, the unintended consequences that discourage safe behavior, or why the risks associated with the task have faded to allow these at-risk behaviors to occur. Most often, the investigation stops with the identification of the cut corner or breached policy, which frequently results in punitive action for the involved individuals. Each at-risk behavior should always be investigated further to determine its causes, which most often reside in the organization's culture or design of systems.

Failure to identify deep-seated, latent failures

Many RCAs do not dig far enough to uncover the deep system-based causes of events, or latent failures. To learn about latent failures, probing questions must be systematically asked about how the organization was managing information, the environment, human resources, equipment/technology and associated human factors at the time of the event. The process of repeatedly asking "why" when a system or human factor has been identified as contributory leads to uncovering more latent failures in the system.

Failure to conduct human error/human factors investigation

The investigation of an event sometimes ends when "human error" has been identified as the cause. However, a human-error investigation should always occur to uncover any preexisting performance shaping factors (e.g., task complexity, workflow, time availability/urgency, process design, experience, training, fatigue, stress) or other environmental conditions, system weaknesses or equipment design flaws that allowed the error to happen and reach the patient. The investigation is incomplete if it ends with human error as the root cause because it fails to uncover how human errors get through the system and reach patients—information that is crucial when planning the redesign of systems.

Failure to seek outside knowledge

RCA teams may get so involved in analysis of the specific event that they fail to recognize the value of looking outward for similar occurrences or related literature to see what could be learned. A search of internal error databases might uncover related events that have not led to harm, which can help identify and clarify risks. Also, professional literature, including research and anecdotal case reports, often helps in the analysis of the event and the selection of high-leverage, evidence-based, risk-reduction strategies. Examination of applicable regulations, standards and professional guidelines as well as consultation with clinical and safety experts can greatly enhance the RCA process and lead to greater success with interventions.

Not linking the causation to the actions

The RCA action plan sometimes fails to clearly show a link between the proposed actions and the causative factors. To achieve buy-in for the action plan, it is important for administration and staff to be able to follow the logic of the RCA team. Each intervention should be clearly linked to one or more causative factors. Another potential issue is the veil of secrecy under which RCAs are performed. Although confidentiality is important during a RCA, enough information needs to be shared with staff for them to understand the purpose and importance of implementing change.

Selecting weak risk-reduction strategies

The most effective risk-reduction strategies involve redesigning systems to make them more resistant to human error, and enabling staff to make safe behavioral choices by removing the system- and cultural-based incentives for cutting corners. Yet, developing new rules and educating staff—weaker interventions—are among the most common risk-reduction strategies found in RCAs. Next in line is often a manual downstream double-check that does little to prevent the errors upstream. Strategies that rely heavily on human memory and vigilance are much weaker than strategies that prevent staff from carrying out tasks the wrong way, "force" them to carry out tasks the correct way or involve automation to provide just-in-time decision support, verify accuracy and halt progress when errors are likely to be made. Layering action plans with multiple strategies also helps ensure success. See AROC document found at: www.ismp.org/communityRx/aroc/.

Failure to carry out the action plan and measure success

A RCA is only useful if it results in positive change. Yet we sometimes encounter RCA action plans with critical interventions that have not been implemented or do not have realistic plans for future implementation. In those cases, progress in reaching goals has not been monitored and a structured format does not exist to support implementation of the action plan and monitor accountability. Some changes that have been implemented often are later abandoned because they were designed without consideration of the workflow, barriers were encountered and not addressed, the reason for change was not clearly communicated to staff or measures were not in place to quantify and monitor the scope of change and its effect on patient safety. Staff require motivation to initially change and data that links the change to positive patient outcomes in order to sustain that change.

Unjust punitive action

Some RCAs have been weakened by unjust punitive action taken against involved practitioners shortly after the event, largely due to hindsight bias and a prevailing but unfair outcome-based justice system in healthcare where the patient's outcome dictates the degree of punishment. Due to punitive action, individuals involved in the event may not be available to provide important details during the analysis, often leading to inaccurate assumptions.

Appendix F. Fact Gathering Worksheet

The RCA team leader may use this optional tool as a method to systematically investigate the event and to record findings and observations gathered during staff interviews, policy and document review, observations and team meetings. This document may be used as a single tool to record all findings and observations or duplicated to individually record the findings from multiple interviews. Once the investigation is complete, findings/descriptions from this working document can be used to complete the ISMP Community Pharmacy Template for Root Cause Analysis and Action Plan (Appendix H).

Date/Time Range of Event:

Problem Statement:

Team Members

Team leader:

Individual with knowledge about the event:

Frontline worker familiar with process (but not directly involved with the event):

RCA expert (optional: someone who works in medication safety such as a risk manager, an outside consultant or a respected pharmacist from another pharmacy who can look at this objectively to properly guide this process):

1. Record the name of the Interviewee. If this form is used for more than one person, then use the associated numbers to attribute the comments to the correct individual.

Name of Interviewee #1 _____ Role: _____

Name of Interviewee #2 _____ Role: _____

Name of Interviewee #3 _____ Role: _____

Name of Interviewee #4 _____ Role: _____

2. Begin the Investigation:
   a. Ensure that the RCA team leader is familiar with the process being investigated. Setting the tone for the interview/investigation is VERY important to its success.
   b. It is important to use a non-judgmental/system based approach to the investigation to gain the most information about the event. Ideally, one can begin by getting the individual(s) involved to describe what they remember or know about the event. Make sure that they understand that there is no "right or wrong answer," and that the best way to learn about what happened is to provide as much detail as possible—including why they may have taken certain steps. Also, as the description of the process is given, ask periodically if this is the usual way it is done, or was something altered during this circumstance.
   c. Open-ended questions that engage staff in describing their routine practices and procedures may be helpful in soliciting all necessary information. Investigators should avoid leading conversations and arriving at premature conclusions when interviewing staff.
   d. It will likely be important as the investigation unfolds to ask a series of "why" questions, in order to establish the root causes and contributing factors of the event. Notes below should only include facts gathered from documents and interviews.

Note: The questions below are organized by *Key Elements of the Medication Use Process*™. Detailed descriptions of the key elements and how they relate to ambulatory/community pharmaceutical care can be found in the AROC document at www.ismp.org/communityRx/aroc/. It is very likely that some areas will not be relevant to the event, while others will solicit a great deal of discussion. Remember, these questions are by no means an exhaustive list of those that may be asked during the investigation.

Question to consider	Questions to Comments/Description of answers
I. Patient Information *Was the patient properly identified?* (e.g., at least two identifiers used when prescription entered into patient profile, at pick-up when prescriptions and patient identification are matched, etc.) *Was critical patient information available?* (e.g., age, weight, allergies, diagnoses, pregnancy status)	
II. Drug Information *Was critical drug information available when needed?* (e.g., was up-to-date drug information easily and readily available to staff through text references, was computerized drug information available, was the patient's medication profile available, was clinical decision support from the pharmacy information system available if needed?)	
III. Communication of Drug Orders *Was communication between physicians and pharmacy staff adequate?* (e.g., is there a standard process for receiving prescription orders and was it followed? Were there issues with ambiguous handwriting or directions, incomplete prescriptions, dangerous abbreviations and dose expressions, prescription readability? Were there challenges receiving and interpreting electronic prescriptions? Consider verbal communications such as telephone conversations or voicemail messages) *Was communication between pharmacy staff adequate?* (e.g., were there any barriers to communication or teamwork? Is there a standard process for communication during order processing and communication handoffs for meal breaks or end of shift?)	

Was communication between pharmacy staff and the patient adequate? (e.g., were there any barriers to patient communication due to disability and/or need for translator?)	
IV. Drug Labeling, Packaging, and Nomenclature *Was the prescribed drug easily identified/selected by staff?* (e.g., was labeling and packaging or drug name clear? Consider look- and sound-alike names, look-alike packaging, ambiguous drug packaging, pharmacy labeling issues, labels that obscure information, labels not visible, warning labels missing or inconsistently applied, NDC or barcode not available)	
V. Drug Standardization, Storage, and Distribution *Were drugs stored, dispensed, and returned to stock safely?* (e.g., consider whether drugs were stocked incorrectly. Were there crowded shelves, overflowing bins, look-alike products stored next to each other, adult dosage forms stored next to pediatric dosage forms, hazardous drugs and chemicals safely sequestered, same drug stored in multiple locations, filled prescriptions not returned to stock in timely manner or not returned in a standard manner, recalled and discontinued drugs not segregated from active stock, no shelf talkers used for high-alert or look-alike drug products?)	
VI. Medication Device Acquisition, Use, and Monitoring *Was the proper equipment utilized?* (e.g., automated dispensing devices, barcode scanners, scanners, fax machines, telephones, copiers, robotics, counting machines, keyboard functions) *Was the utilized equipment properly maintained?* (e.g., consider if the equipment is calibrated, maintained, or cleaned. Consider scanners, fax machines, telephones, copiers, robotics, counting machines, keyboard functions, barcode scanners, automated dispensing devices. Is there a standard process in place for preventative maintenance?) *Was equipment safety properly assessed prior to purchase?* (e.g., automated dispensing devices, barcode scanners, counting machines) *Were necessary medication delivery devices dispensed to patient?* (e.g., oral syringes for oral liquid medications)	

VII. Environmental Factors, Workflow, and Staffing Patterns

Was the work environment (either physical or ergonomic) appropriate? (e.g., temperature, noise, poor lighting, construction projects, interruptions, cluttered work space)

Was the pharmacy appropriately staffed for the volume of prescriptions processed? (e.g. lack of necessary staff, excessive workload, no breaks)

Were standard work processes clearly established? (e.g. placement/ storage of inventory, workflow, placement of equipment; designated roles versus overlapping roles and responsibilities? Consider physical limitations to workflow such as staff height vs storage location)

VIII. Staff Competency and Education

Are all appropriate personnel trained to operate the equipment? (e.g. staff using equipment have all been trained, workarounds such as scanning only one stock bottle during product verification has been discussed as a risky behavior)

Is there a program to orient and train staff? (e.g., consider if staff was trained prior to performing new roles such as data entry or barcode scanning)

Is there ongoing assessment of all staff members' baseline competencies and education about new medications and/or processes? (e.g., consider how new information is shared and competency ensured)

IX. Patient Education

Was the patient provided education about their prescriptions? (e.g., consider offer to counsel, location to counsel, printed information available, non-adherence, whether patient is encouraged to ask questions, lack of investigation of patient inquiries, physical patient barriers, complex drug regimen, medication reconciliation problem, health literacy, language barrier or other communication problem, patient intimidation by staff, mental health issues)

X. Quality Processes and Risk Management

Was there a system for identifying, reporting, analyzing and reducing the risk of medication errors? (e.g., do all staff know when and how to report an event or hazardous condition, and is it documented? Is there a formal process in place for review of those reports? Are system-based changes made to identify and correct error-prone processes?)

Was there a culture of safety established to encourage candid disclosure of errors (including close calls) in order to identify system-based solutions? (e.g., Is there a culture of safety present? Is there a fear of error reporting, lack of analysis of system-based causes, lack of equipment quality control checks, focus on productivity and volume, financial resources or constraints, conflicting organizational structure and priorities, technology workaround and/or malfunction, design flaw, technology user error, technology and devices not meeting needs)

3. Review the policies/procedures/staff training documentation/quality improvement documents that may be associated with the event and make notations below. Attach these documents to the final report.

Appendix G. The Five Rules of Causation[4]

Review these rules before determining the action plan and submitting the final RCA document to leadership.

Rule 1 - Causal Statements must clearly show the "cause and effect" relationship.

This is the simplest of the rules. When describing why an event has occurred, you should show the link between your root cause and the bad outcome, and each link should be clear to the RCA team and others. Focus on showing the link from your root cause to the undesirable patient outcome you are investigating. Even a statement like **"technician was fatigued"** is deficient without your description of **how and why this led to a slip or mistake**. The bottom line: the reader needs to understand your logic in linking your causes to the outcome.

Wrong: Pharmacist was fatigued.

Correct: Pharmacists are routinely scheduled for 12 hour work days; as a result, the level of pharmacist fatigue increased the likelihood of the instructions being misread, which led to incorrect data entry and subsequent incorrect labeled instructions for patient on prescription vial.

Rule 2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements.

As humans, we try to make each job we have as easy as possible. Unfortunately, this human tendency works its way into the documentation process. We may shorten our findings by saying **"policy and procedure manual was poorly written"** when we really have a much more detailed explanation in our mind. **To force clear cause and effect descriptions (and avoid inflammatory statements), we recommend against the use of any negative descriptor that is merely the placeholder for a more accurate, clear description.** Even words like "carelessness" and "complacency" are bad choices because they are broad, negative judgments that do little to describe the actual conditions or behaviors that led to the mishap.

Wrong: Poorly written manual.

Correct: The training manual was not indexed, used a font that was difficult to read, and did not include any technical illustrations; as a result, the manual was rarely used and did not improve performance by the technicians.

Rule 3 - Each human error must have a preceding cause.

Most of our mishaps involve at least one human error. Unfortunately, the discovery that a human has erred does little to aid the prevention process. You must investigate to determine WHY the human error occurred. It can be a system-induced error (e.g., step not included in the dispensing procedure) or an at-risk behavior (completing a task by memory, instead of using a checklist). **For every human error in your causal chain, you must have a corresponding cause.** It is the cause of the error, not the error itself, which leads us to productive prevention strategies.

Wrong: The technician made a dosage error.

Correct: Due to lack of automated software to check the dosage limits (teaspoonful entered and should have been mL), there was a likelihood of this dosing error, which resulted in five times the appropriate level of antibiotic suspension being administered.

Rule 4 - Each procedural deviation must have a preceding cause.

Procedural violations are like errors in that they are not directly manageable. Instead, it is the cause of the procedural violation that we can manage. If a pharmacist is violating a procedure because it is the local norm, the incentives that created the norm will have to be addressed. If a technician is missing steps in a procedure because he or she is not aware of the formal checklist, work on education.

Wrong: The techs did not follow the procedure for barcode scans.

Correct: Noise and confusion in the production area and pressures to quickly complete dispensing increased the probability of bypassing the barcode scan protocol; this resulted in the wrong dose being dispensed.

Rule 5 - Failure to act is only causal when there is a pre-existing duty to act.

We can all find ways in which our investigated mishap would not have occurred—but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in the system as it is designed today. The duty to perform may arise from standards and guidelines for practice, or other duties to provide patient care.

Wrong: The clerk did not call the pharmacist to the out window to counsel the patient when the high-alert mediation was being dispensed.

Correct: The absence of an established procedure insisting on mandatory counseling for patients receiving high-alert medications or for patients considered to be high-risk, resulted in the patient not realizing heating pads should not be used with fentanyl patches.

Appendix H. ISMP Community Pharmacy Template for Root Cause Analysis and Action Plan

This template is provided as an aid to organizing/displaying the steps in a RCA. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest to identify root causes, contributing factors and associated risk reduction strategies.

Step 1 - RCA Title:

Date/Time Range of Event:

Problem Statement:

Team Members

Team leader:

Individual with knowledge about the event:

Frontline worker familiar with process (but not directly involved with the event):

RCA expert (optional: someone who works in medication safety such as a risk manager, an outside consultant or a respected pharmacist from another pharmacy who can look at the event objectively to properly guide this process):

Step 2 - What Happened

Question	Finding
When did the event occur? (e.g., time period—date(s), day of week, time of day)	
What are the details of the event? (i.e., full event description)	

Step 3 – Flowchart Steps in the Process

Develop a flowchart to illustrate the process steps involved in the event. Construct a basic "time series" of the steps/facts beginning with the initial cue to fill the prescription and then recording all steps leading up to and including the adverse outcome.

Tip: When developing the flowchart of events, do not jump to conclusions. It is essential to stay focused on what **actually** happened – not what the team **thinks** happened.

Question	Finding
What was the actual sequence of events? (complete a flowchart)	Attach process flowchart to template Ask why for key findings on the flowchart
What events were involved in (contributed to) the event? *Why did it happen?*	Determine which steps were involved or directly contributed to the adverse outcome

Step 4 – Identify Proximate (Primary Contributing) Factors and Root Causes

As an aid to avoiding "loose ends," the last three columns on the right are provided to be checked off for later reference:

- "Root Cause?" should be answered "Yes" or "No" for each finding. Each finding that is identified as a root cause should have an assigned action plan (Step 6 on this form). Number each finding that is identified as a root cause so that it can be correlated to specific strategies.
- "Contributing Factor?" should be answered "Yes" or "No" for each finding. Consider how it relates to the event and create action plans as appropriate.
- "Take Action?" should be answered "Yes" for each finding of a root cause or contributing factor that can reasonably be assigned a risk reduction strategy.

Tip: Root causes and contributing factor statements must clearly address why something has occurred and there must be a clear focus on process and system vulnerabilities, never on individuals.

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
I. Patient Information *Was the patient correctly identified?* *Was critical patient information available?*				
II. Drug Information *Was critical drug information available when needed?*				

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
III. Communication of Drug Orders *Was communication between physicians and pharmacy staff adequate?* *Was communication between pharmacy staff adequate?* *Was communication between pharmacy staff and the patient adequate?*				
IV. Drug Labeling, Packaging, and Nomenclature *Was the prescribed drug easily/correctly identified/selected by staff?*				
V. Drug Standardization, Storage and Distribution *Were drugs stored, dispensed and returned to stock safely?*				
VI. Medication Device Acquisition, Use and Monitoring *Was the proper equipment utilized?* *Was the equipment properly maintained?* *Was equipment safety properly assessed prior to purchase?* *Were necessary medication delivery devices dispensed to patient?*				

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
VII. Environmental Factors, Workflow and Staffing Patterns *Was the work environment (either physical and/or ergonomic) appropriate?* *Was the pharmacy appropriately staffed for the volume of prescriptions processed?* *Were standard work processes clearly established?*				
VIII. Staff Competency and Education *Are all appropriate personnel trained to operate the equipment?* *Is there a program to orient and train staff?* *Is there ongoing assessment of all staff members' baseline competencies and education about new medications and/or processes?*				
IX. Patient Education *Was the patient provided education about his/her prescriptions?*				

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
X. Quality Processes and Risk Management *Was there a system for identifying, reporting, analyzing and reducing the risk of medication errors?* *Was there a culture of safety established to encourage candid disclosure of errors (including close calls) in order to identify system-based solutions?*				

Step 5 – Root Cause Statements

Create a causation statement for each root cause using the findings identified in Step 4 above and Five Rules of Causation (Appendix G). Write concise descriptions of the cause-and-effect relationship between the findings and the error. Ensure that the team has focused on the system-based causes and not on the actions of individuals or in any way placed blame on the individuals.

Tip: To determine whether a statement is effective, ask, "If this is corrected, will it significantly reduce the likelihood of another adverse event?" The answer should be yes.

Root Cause #	Statement of Cause

Step 6 – Action Plan

Root Causes

For each of the root causes identified in Step 4 above, assign at least one strategy. To be most effective, choose strategies based on the rank order of error reduction strategies. Once strategies are identified, develop measures that will provide strategy effectiveness over time. Some measures will be easy (something is completed or not completed by a particular date), while others may require several steps. Interim dates for substep completion should be established. If a decision is made not to implement an action for a particular root cause, indicate the rationale for not taking action at this time.

Tip: Discuss the proposed risk reduction strategies with those involved with the event to see if they believe that the RCA team is on the right track.
Ask: If these recommendations were in place at the time of the incident, do you think it likely that the incident may have been prevented from occurring? If the answer is no, it is likely the team has not actually identified the root cause or may not have selected effective strategies.

Root Cause #	Risk-reduction Strategy	Measure of Effectiveness

Contributing Factors

For each of the contributing factors identified in Step 4 above as needing an action, complete the following table. To be most effective, choose strategies based on the rank order of error reduction strategies. Once strategies are identified, develop measures that will provide strategy effectiveness over time. Some measures will be easy (something is completed or not completed by a particular date), while others may require several steps. Interim dates for substep completion should be established. If a decision is made not to implement an action for a particular contributing factor, indicate the rationale for not taking action at this time.

Contributing Factors	Risk-reduction Strategy	Measure of Effectiveness

Cite any books/journal articles/resources that were considered in developing this analysis and action plan:

Determine the frequency with which this plan will be re-visited/re-evaluated.

By whom?

Appendix I. RCA Summary

The RCA team leader may use this optional tool as a method to disseminate the results of a completed RCA (root causes and action plan risk reduction strategies) to frontline staff and others in the organization. The real benefit of RCA only comes when solutions have been successfully implemented and continually measured over time for effectiveness. Although strategies for implementation can be written down, it is a team effort to actually make these changes. Without harmonious efforts between frontline staff and organizational leadership to execute the risk-reduction tactics, they will not work. Therefore, communication of the desired risk reduction strategies is important to the success of the RCA.

Organization Name:

Root Cause Analysis Title: Refer to Appendix H, Step 1: RCA Title.

Incident Date: Date the incident occurred.

Root Cause Analysis Author: The author of this RCA.

Synopsis of Events: Include a summary paragraph describing what happened. Refer to Appendix H, Step 2: What Happened?

Root Cause(s): Describe the root cause(s) identified as the cause of the event. What specifically is the process error or system error identified? Refer to Appendix H, Step 5: Root Cause Statements.

Corrective Actions to Prevent Recurrence: Describe what is being done (or what will be done) to prevent similar incidents from occurring in the future. Describe how compliance with any changes will be monitored. Will this become a temporary or long-term quality indicator for the department? What are your compliance goals? By when? Refer to Appendix H, Step 6: Action Plan.

Case Study

The Error

(Based on a real error reported to the ISMP National Medication Errors Reporting Program [ISMP MERP]): Patient received four vials of Lantus (insulin glargine) instead of three vials of Apidra (insulin glulisine) and one vial of Lantus. Three of the Lantus cartons were labeled as Apidra and one was labeled as Lantus. The patient did not recognize the error and injected himself with Lantus (a basal insulin normally given once daily at night) four times a day. He did not receive the Apidra as prescribed. Since this could have resulted in serious patient harm or even death from hypoglycemia, RCA was performed.

The prescriptions were written as:

Rx:	*Lantus*
Sig:	*20 units at bedtime*
Dispense:	*1 vial*
Refills:	*1*

Rx:	*Apidra*
Sig:	*Use as directed per sliding scale*
Dispense:	*3 vials*
Refills:	*1*

Fact Gathering Worksheet

The RCA team leader may use this optional tool as a method to systematically investigate the event and to record findings and observations gathered during staff interviews, policy and document review, observations and team meetings. This document may be used as a single tool to record all findings and observations or duplicated to individually record the findings from multiple interviews. Once the investigation is complete, findings/descriptions from this working document can be used to complete the *ISMP Community Pharmacy Template for Root Cause Analysis and Action Plan* (Appendix H).

Date/Time Range of Event: *Feb 6-8, 20XX*

Problem Statement: *Patient severely hypoglycemic due to pharmacy error—injected Lantus instead of Apidra 4 times a day*

Team Members

Team leader: *Ross Geller, District Manager*

Individual with knowledge about the event: *Chandler Bing, CPhT*

Frontline worker familiar with process (but not directly involved with the event): *Rachel Green, RPh*

RCA expert (optional: someone who works in medication safety such as a risk manager, an outside consultant or a respected pharmacist from another pharmacy who can look at this objectively to properly guide this process): *Joseph Tribianni, RPh*

1. Record the name of the Interviewee. If this form is used for more than one person, then use the associated numbers to attribute the comments to the correct individual.
2. Begin the Investigation:
    a. Ensure that the RCA team leader is familiar with the process being investigated. Setting the tone for the interview/investigation is VERY important to its success.

b. It is important to use non-judgmental /system based approach to the investigation to gain the most information about the event. Ideally, one can begin by getting the individual(s) involved to describe what they remember or know about the event. Make sure that they understand that there is no "right or wrong answer," and that the best way to learn about what happened is to provide as much detail as possible—including why they may have taken certain steps. Also, as the description of the process is given, ask periodically if this is the usual way it is done, or whether something was altered in this circumstance.

c. Open-ended questions that engage staff in describing their routine practices and procedures may be helpful in soliciting all necessary information. Investigators should avoid leading conversations and arriving at premature conclusions when interviewing staff.

d. It will likely be important as the investigation unfolds to ask a series of "why" questions, in order to establish the root causes and contributing factors of the event. Notes below should only include facts gathered from documents and interviews.

Name of Interviewee #1 *Technician A* **Role:** *greet, data entry*

On a Monday evening, a man came into a community pharmacy with two prescriptions. The prescriptions were: Apidra, use as directed per sliding scale, dispense three cartons; and Lantus, use as directed at bedtime, dispense 1 carton. The technician working at the drop-off counter took the prescriptions and typed them as they were written.

Name of Interviewee #2 *Technician B* **Role:** *cash register and dispensing/production area*

The prescriptions were filled by a technician working at production. The pharmacy was short staffed that night, so the technician at production rotated between filling prescriptions and taking care of the register. The technician left the register, obtained the labels at the production station and went to the refrigerator to retrieve the Apidra and Lantus cartons to fill the prescriptions. Instead of grabbing three cartons of Apidra and one carton of Lantus, she grabbed four cartons of Lantus. The technician did not scan the barcode on the cartons to verify the products before applying the labels. She labeled one of the cartons correctly with the Lantus label, and labeled the other three Lantus cartons incorrectly with the Apidra labels. Unfortunately the technician covered all relevant drug information on the front and sides of the cartons (drug name, NDC number) when she applied the labels. The counter was covered with prescriptions to be filled. Customers were standing at both sides of the pharmacy waiting for their prescriptions to be finished. The phone was ringing constantly. The patient was in a hurry to leave, and paid for his prescriptions and went home without being counseled.

Name of Interviewee #3 *Pharmacist A* **Role:** *verification (Monday)*

The pharmacist was on the phone waiting to speak with an insurance company representative. He began verifying the prescriptions because the patient was standing at the register (the patient had been told that it would take 20 minutes because they were busy, yet he went to the register after leaving the drop-off counter). The pharmacist checked the directions on the labels against the prescriptions. As he began to examine the cartons, the insurance company representative became available on the phone. He put all four cartons in the bag and handed the sealed bag to Technician B to be rung up at the register.

Name of Interviewee #4 *Pharmacist B* **Role:** *verification (Wednesday)*

On Wednesday afternoon, the patient called to ask a question about insulin and possible side effects. He explained that he had been feeling dizzy, shaky, and weak and that morning he had been sweating. The pharmacist verified that the patient was using the insulin as per instructions provided by the physician, to which he replied, "I have been pretty good about my dose, but I did forget to use it yesterday morning." The pharmacist explained that his symptoms sounded like he was hypoglycemic. She asked him if he had a blood glucose meter at home to check his blood sugar, which he did. He took his blood sugar and told the pharmacist that it was 57. The pharmacist instructed him to drink orange juice and suggested he contact his physician. Instead, the patient came into the pharmacy. The pharmacist saw the cartons and realized they all contained Lantus. The patient had been using the Lantus four times daily. The pharmacist noticed the error, explained it to the patient, notified the physician and correctly dispensed the Apidra. The District Manager was informed. Luckily the patient experienced no further hypoglycemic episodes or harm from this error.

Note: The questions below are organized by *Key Elements of the Medication Use Process*™. Detailed descriptions of the key elements and how they relate to ambulatory/community pharmaceutical care can be found in the AROC document at www.ismp.org/communityRx/aroc/. It is very likely that some areas will not be relevant to the event, while others will solicit a great deal of discussion. Remember, these questions are by no means an exhaustive list of those that may be asked during the investigation.

Question to consider	Comments/Description of answers
I. Patient Information *Was the patient properly identified?* (e.g., at least two identifiers used when prescription entered into patient profile, at pick-up when prescriptions and patient identification are matched, etc.) *Was critical patient information available?* (e.g., age, weight, allergies, diagnoses, pregnancy status)	*No issues*
II. Drug Information *Was critical drug information available when needed?* (e.g., was up-to-date drug information easily and readily available to staff through text references, was computerized drug information available, was the patient's medication profile available, was clinical decision support from the pharmacy information system available if needed?)	*No issues*
III. Communication of Drug Orders *Was communication between physicians and pharmacy staff adequate?* (e.g., is there a standard process for receiving prescription orders and was it followed? Were there issues with ambiguous handwriting or directions, incomplete prescriptions, dangerous abbreviations and dose expressions, prescription readability? Were there challenges receiving and interpreting electronic prescriptions? Consider verbal communications such as telephone conversations or voicemail messages)	*Reviewed two handwritten prescriptions:* *Apidra (use as directed per sliding scale) dispense 3 vials* *Lantus (use as directed at bedtime) dispense 1 vial* *No issues with prescription orders*

Question to consider	Comments/Description of answers
Was communication between pharmacy staff adequate? (e.g., were there any barriers to communication or teamwork? Is there a standard process for communication during order processing and communication handoffs for meal breaks or end of shift?) *Was communication between pharmacy staff and the patient adequate?* (e.g., were there any barriers to patient communication due to disability and/or need for translator?)	
IV. Drug Labeling, Packaging, and Nomenclature *Was the prescribed drug easily identified/selected by staff?* (e.g., was labeling and packaging, or drug name clear? Consider look- and sound-alike names, look-alike packaging, ambiguous drug packaging, pharmacy labeling issues, labels that obscure information, labels not visible, warning labels missing or inconsistently applied, NDC or barcode not available)	*Both insulin cartons were the same size (10 mL cartons)* *Both insulin cartons have similar labeling (same manufacturer)* *Not a lot of color differentiation between insulin types*
V. Drug Standardization, Storage, and Distribution *Were drugs stored, dispensed, and returned to stock safely?* (e.g., consider whether drugs were stocked incorrectly. Were there crowded shelves, overflowing bins, look-alike products stored next to each other, adult dosage forms stored next to pediatric dosage forms, hazardous drugs and chemicals safely sequestered, same drug stored in multiple locations, filled prescriptions not returned to stock in timely manner or not returned in a standard manner, recalled and discontinued drugs not segregated from active stock, no auxiliary warnings used for high-alert or look-alike drug products?)	*Refrigerator: small, cramped, crowded, extra stock of insulin due to new clinic opening, no shelf dividers, no shelf labels, product intermingled (wrong place), dark (light bulb missing)*
VI. Medication Device Acquisition, Use, and Monitoring *Was the proper equipment utilized?* (e.g., automated dispensing devices, barcode scanners, scanners, fax machines, telephones, copiers, robotics, counting machines, keyboard functions)	*Not enough scanners, scanners do not retain charge for entire shift, staff need to borrow scanners from other staff/stations when battery runs out* *Scanners not returned to charge station per manual instructions*

Question to consider	Comments/Description of answers
Was the utilized equipment properly maintained? (e.g., consider if the equipment is calibrated, maintained, or cleaned. Consider scanners, fax machines, telephones, copiers, robotics, counting machines, keyboard functions, barcode scanners, automated dispensing devices. Is there a standard process in place for preventative maintenance?) *Was equipment safety properly assessed prior to purchase?* (e.g., automated dispensing devices, barcode scanners, counting machines) *Were necessary medication delivery devices dispensed to patient?* (e.g., oral syringes for pediatric medications)	
VII. Environmental Factors, Workflow, and Staffing Patterns *Was the work environment (either physical or ergonomic) appropriate?* (e.g., temperature, noise, poor lighting, construction projects, interruptions, cluttered work space) *Was the pharmacy appropriately staffed for the volume of prescriptions processed?* (e.g. lack of necessary staff, excessive workload, no breaks) *Were standard work processes clearly established?* (e.g. placement/ storage of inventory, workflow, placement of equipment; designated roles versus overlapping roles and responsibilities? Consider physical limitations to workflow such as staff height vs storage location)	*Data entry and drop off occur at same terminal* *Pick up window and counter for assembling prescriptions not near each other—working both stations can be exhaustive* *Pharmacy verification area is small, crowded, cluttered* *Pharmacist interrupted during verification process; insurance representative became available for different patient and required pharmacist's attention* *Basket system used but baskets piled high during busy times* *Second pharmacist verification area available but not used if only one pharmacist on duty* *Staffing schedule for Monday:* *Regular staff except one technician called in sick and not replaced* *Alternate/substitute tech contact sheet not found/available to be used* *Staff felt tired due to running between stations; no meal breaks* *High volume/many patients waiting/phone ringing constantly*

Question to consider	Comments/Description of answers
VIII. Staff Competency and Education *Are all appropriate personnel trained to operate the equipment?* (e.g. staff using equipment have all been trained, workarounds such as scanning only one stock bottle during verification is discussed as a risky behavior) *Is there a program to orient and train staff?* (e.g., consider if staff was trained prior to performing new roles such as data entry or barcode scanning) *Is there ongoing assessment of all staff members' baseline competencies and education about new medications and/ or processes?* (e.g., consider how new information is shared and competency ensured)	*Pharmacy system documentation:* *Entered by technician A, verified by pharmacist; documentation that barcoding was skipped* *Barcode scanning policy and barcode scanning bypass policy were not enforced* *Technicians routinely workaround scanning because of scanner non-reliability* *Noise and confusion in the production area and pressures to quickly complete dispensing increased the probability of bypassing the barcode scan protocol; this resulted in the wrong labels being applied* *Value of barcode scanning to reduce errors not emphasized with staff during training* *NDC numbers on carton not verified with pharmacy-generated computer label* *Training did not include how to label unit of use stock bottles. The names and NDC numbers on the insulin cartons were covered by the prescription labels, leaving only the top of the cartons visible* *Drug images did come up on the verification screen but the prescription labels covered the carton panels*
IX. Patient Education *Was the patient provided education about their prescriptions?* (e.g., consider offer to counsel, location to counsel, printed information available, non-adherence, whether patient is encouraged to ask questions, lack of investigation of patient inquiries, physical patient barriers, complex drug regimen, medication reconciliation problem, health literacy, language barrier or other communication problem, patient intimidation by staff, mental health issues)	*Reviewed patient counseling log:* *No documentation of counseling; patient declined offer* *Patient not encouraged to engage in counseling/education with pharmacist* *Absence of an established procedure to insist on mandatory counseling.*

Question to consider	Comments/Description of answers
	No mandatory education policy for patients receiving high-alert medications or for patients considered to be high-risk; resulted in the patient not realizing he was injecting the wrong insulin 4 times a day *Bag not opened at point of sale–current procedures only call for bag to be opened during patient counseling*
X. Quality Processes and Risk Management *Was there a system for identifying, reporting, analyzing and reducing the risk of medication errors?* (e.g., do all staff know when and how to report an event or hazardous condition, and is it documented? Is there a formal process in place for review of those reports? Are system-based changes made to identify and correct error-prone processes?) *Was there a culture of safety established to encourage candid disclosure of errors (including close calls) in order to identify system-based solutions?* (e.g., Is there a culture of safety present? Is there a fear of error reporting, lack of analysis of system-based causes, lack of equipment quality control checks, focus on productivity and volume, financial resources or constraints, conflicting organizational structure and priorities, technology workaround and/or malfunction, design flaw, technology user error, technology and devices not meeting needs)	*The pharmacist was distracted and concerned about 'wait time' and volume of prescriptions to be verified within promised time* *The pharmacist was aware barcoding had been bypassed but did not foresee or grasp repercussions of this workaround* *Previous errors involving barcode scanning bypass were not discussed with staff*

3. Review of policies/procedures/staff training documentation/quality improvement documents that may be associated with the event and make notations below. Attach these documents to the final report.

Team reviewed:

1. Policy and procedure manual for barcode scanning, labeling
2. Training manual for production area

Review of the Event: Process Flow/Steps (attach to RCA template)

ISMP Community Pharmacy Template for Root Cause Analysis and Action Plan

This template is provided as an aid to organizing/displaying the steps in a RCA. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest to identify root causes, contributing factors and associated risk reduction strategies.

Patient brings two prescriptions to the pharmacy: 1 for a vial of Lantus and 1 for 3 vials of Apidra

The patient is informed that the wait will be approximately 20 minutes.

Patient proceeds to register to wait.

Technician A at drop-off enters the prescriptions as written

Technician B leaves the register to go to dispensing area and obtain the labels

WHY?
Pharmacy was short staffed that night, so the technician at dispensing rotated between filling prescriptions and taking care of the register

WHY?
Technician C called out sick and no replacement found

WHY?
Replacement unable to be located

Technician B retrieves four cartons of Lantus and none of Apidra

WHY?

Cartons of Lantus and Apidra intermingled

WHY?

Refrigerator crowded

WHY?
Insulin prescription volume recently increased

WHY?
New diabetes clinic recently opened next door

No shelf dividers

Lantus cartons stocked in incorrect location

WHY?
Shelf tags/ labels not present for all products

WHY?
Not ordered for new products

Main panels of all cartons not faced forward

WHY?
Not included in technician training

"Grab and go." No routine process to read label at time of drug selection

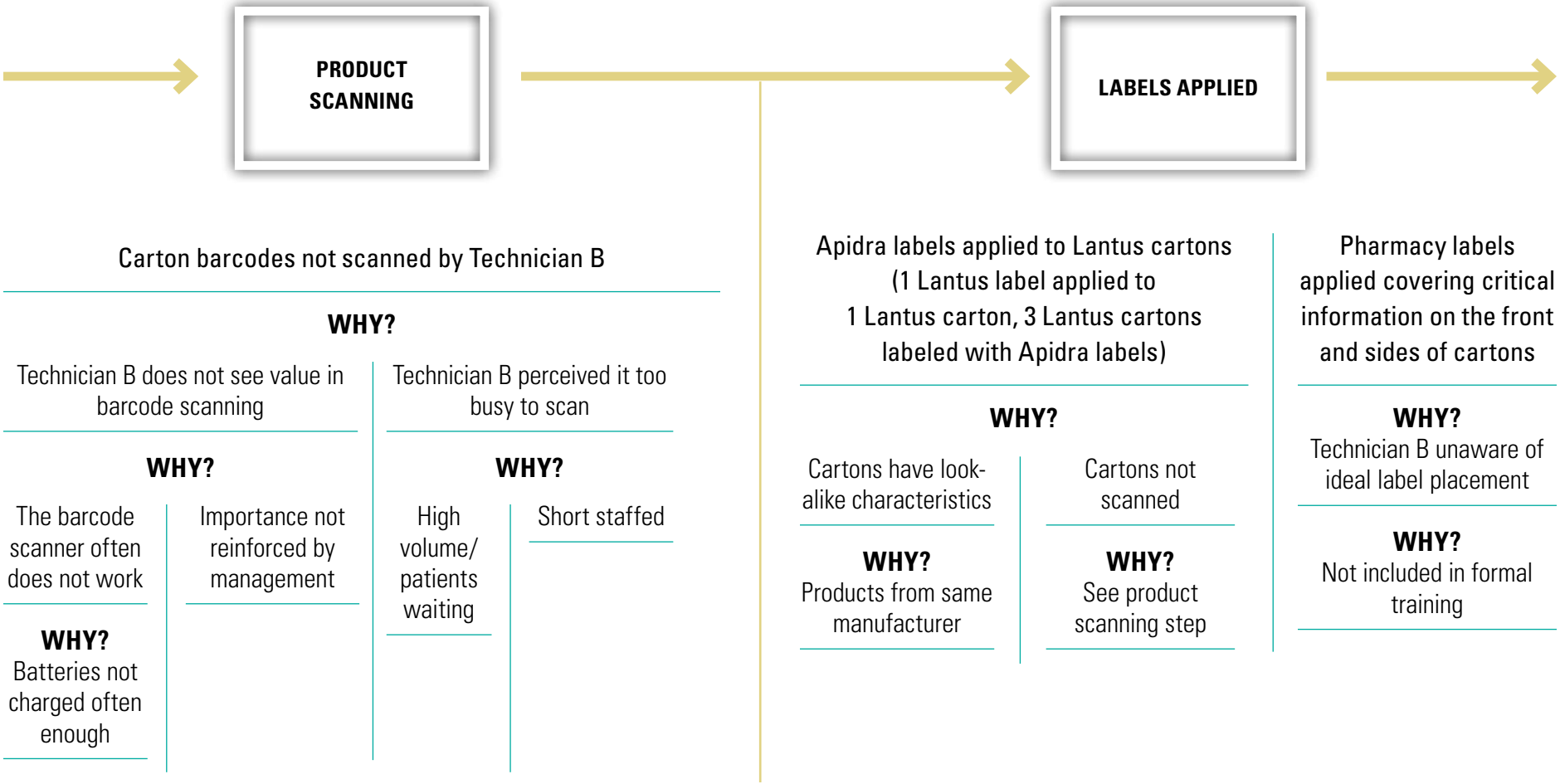
Color differentiation on cartons not seen

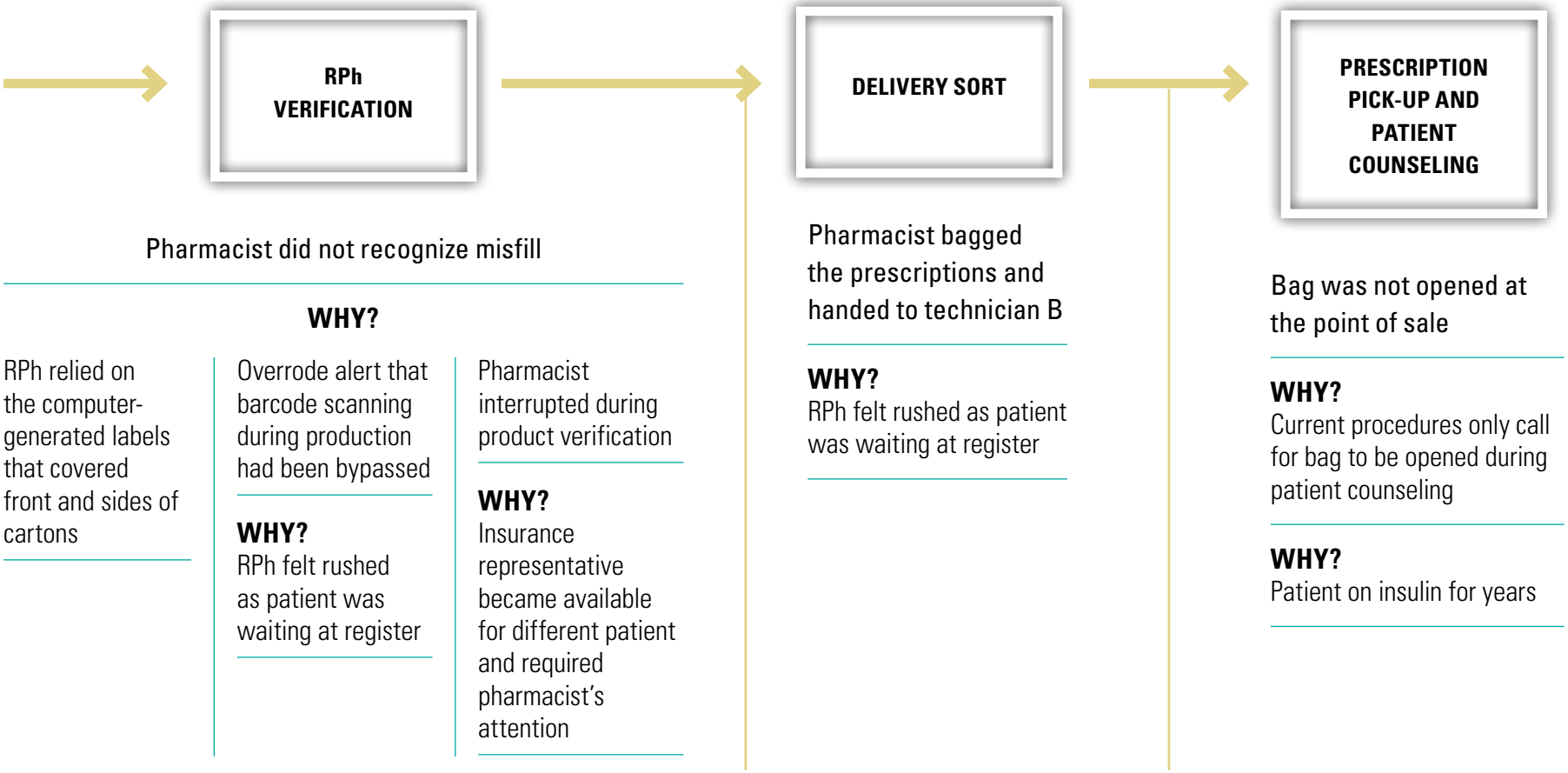
WHY?
Refrigerator dark

WHY?
Light bulb not working

Cartons have look-alike characteristics

WHY?
Products from same manufacturer


PRODUCT SCANNING
LABELS APPLIED
Carton barcodes not scanned by Technician B
WHY?
Technician B does not see value in barcode scanning
WHY?
The barcode scanner often does not work
WHY?
Batteries not charged often enough
Importance not reinforced by management
Technician B perceived it too busy to scan
WHY?
High volume/ patients waiting
Short staffed
Apidra labels applied to Lantus cartons (1 Lantus label applied to 1 Lantus carton, 3 Lantus cartons labeled with Apidra labels)
WHY?
Cartons have look-alike characteristics
WHY?
Products from same manufacturer
Cartons not scanned
WHY?
See product scanning step
Pharmacy labels applied covering critical information on the front and sides of cartons
WHY?
Technician B unaware of ideal label placement
WHY?
Not included in formal training


RPh VERIFICATION
DELIVERY SORT
PRESCRIPTION PICK-UP AND PATIENT COUNSELING
Pharmacist did not recognize misfill
WHY?
RPh relied on the computer-generated labels that covered front and sides of cartons
Overrode alert that barcode scanning during production had been bypassed
WHY?
RPh felt rushed as patient was waiting at register
Pharmacist interrupted during product verification
WHY?
Insurance representative became available for different patient and required pharmacist's attention
Pharmacist bagged the prescriptions and handed to technician B
WHY?
RPh felt rushed as patient was waiting at register
Bag was not opened at the point of sale
WHY?
Current procedures only call for bag to be opened during patient counseling
WHY?
Patient on insulin for years

Step 1 - RCA Title: Apidra Labeled as Lantus

Date/Time Range of Event: *2/6-8/20XX*

Problem Statement: *Patient severely hypoglycemic due to pharmacy error—injected Lantus instead of Apidra 4 times a day*

Team Members

Team leader: *Ross Geller, District Manager*

Individual with knowledge about the event: *Chandler Bing , CPhT*

Frontline worker familiar with process (but not directly involved with the event): *Rachel Green, RPh*

RCA expert (optional: someone who works in medication safety such as a risk manager, an outside consultant or a respected pharmacist from another pharmacy who can look at this objectively to properly guide this process): *Joseph Tribianni, RPh*

Step 2 - What Happened

Question	Finding
When did the event occur? (e.g., time period—date(s), day of week, time of day)	*Monday evening 2/6/20XX and Wednesday 2/8/20XX* *Prescriptions dispensed Monday evening. Patient returned to the pharmacy and the error was discovered Wednesday afternoon*
What are the details of the event? (i.e., full event description)	*On a Monday evening, a man came into a community pharmacy with two prescriptions. The prescriptions were written as:* **Rx:** *Lantus* **Sig:** *20 units at bedtime* **Dispense:** *1 vial* **Refills:** *1* **Rx:** *Apidra* **Sig:** *Use as directed per sliding scale* **Dispense:** *3 vials* **Refills:** *1* *Technician A, working at the drop-off counter, received the prescriptions from the patient and entered them into the pharmacy computer system as they were written.* *The prescriptions were filled by Technician B working at the prescription preparation area. The pharmacy was short staffed that night, so Technician B rotated between filling prescriptions at the dispensing area and working the cash register. Technician B left the register, obtained the labels, and went to the refrigerator to retrieve the insulin glulisine (APIDRA) and insulin glargine (LANTUS) cartons to fill the prescriptions. Instead of retrieving three cartons of Apidra and one carton of Lantus, she inadvertently grabbed four cartons of Lantus. Technician B did not scan the barcodes on the cartons in order to match them with the computer generated labels before applying the labels. She labeled one of the cartons correctly with the Lantus label, and labeled the other three Lantus cartons incorrectly with the Apidra labels.*

Question	Finding
	Technician B covered all relevant drug information on the front and sides of the insulin cartons (drug name, NDC number) with the labels when she applied them. *The counter was covered with other prescriptions to be reviewed. Patients were standing at the pharmacy area waiting for their prescriptions to be finished. The phone was ringing constantly.* *The only pharmacist on duty was on hold waiting to speak with an insurance company representative when Technician B handed the prescriptions to him for immediate verification since the patient was waiting.* *The pharmacist checked the directions on the labels against the prescriptions. Just as he began to examine the cartons, the insurance company representative came on the phone. During the conversation, the pharmacist put all four cartons in a bag to be rung up at the register and handed the sealed bag to Technician B. The patient was in a hurry to leave, paid for his prescriptions, and went home after declining the offer for patient counseling.* *On Wednesday afternoon, the patient called to ask a question about insulin and possible side effects. He was unaware that the two different insulins he was supposed to be getting should have looked different. He explained that he had been feeling dizzy and weak with perfuse sweating. The pharmacist accessed the patient's profile and verified with the patient that he was using the insulin as per instructions on the labels. The pharmacist explained that his symptoms sounded like he was hypoglycemic. He took his blood sugar which he reported to her as 57 mg/dL. The pharmacist instructed him to drink orange juice and suggested he contact his physician immediately. Instead, the patient came into the pharmacy with his insulin cartons in hand. The pharmacist reviewed the cartons and labels and realized that all four cartons contained Lantus, and that the patient was inadvertently self-administering Lantus in place of Apidra. The pharmacist explained the error to the patient, notified the patient's physician, and correctly dispensed the Apidra.* *During the investigation and interviews with staff it was discovered that similar selection errors with insulins had happened in the past. However, no changes were implemented in response to these events.*

Step 3 – Flowchart Steps in the Process

Develop a flowchart to illustrate the process steps involved in the event. Construct a basic "time series" of the steps/facts beginning with the initial cue to fill the prescription and then recording all steps leading up to and including the adverse outcome.

Tip: When developing the flowchart of events, do not jump to conclusions. It is essential to stay focused on what **actually** happened – not what the team **thinks** happened.

Question	Finding
What was the actual sequence of events? (complete a flowchart)	*See attached flow chart and WHY? questions*
What events were involved in (contributed to) the event? *Why did it happen?*	*Steps involved* *Technician pulls four cartons of Lantus from the refrigerator to fill the prescriptions* *Technician labels one carton correctly and labels the other three cartons of Lantus with the Apidra labels* *Pharmacist verifies the directions with the written prescriptions but fails to verify the contents of the cartons* *Pharmacist on the phone with an insurance company at the time of verification* *The pharmacy labels covered the entire outside of the carton, leaving only the tops exposed* *Patient picks up the prescriptions and declines offer for counseling*

Step 4 – Identify Proximate (Primary Contributing) Factors and Root Causes

As an aid to avoiding "loose ends," the last three columns on the right are provided to be checked off for later reference:

- "Root Cause?" should be answered "Yes" or "No" for each finding. Each finding that is identified as a root cause should have an assigned action plan (Step 6 on this form). Number each finding that is identified as a root cause so that it can be correlated to specific strategies.
- "Contributing Factor?" should be answered "Yes" or "No" for each finding. Consider how it relates to the event and create action plans as appropriate.
- "Take Action?" should be answered "Yes" for each finding of a root cause or contributing factor that can reasonably be assigned a risk reduction strategy.

Tip: Root causes and contributing factor statements must clearly address why something has occurred and there must be a clear focus on process and system vulnerabilities, never on individuals.

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
I. Patient Information *Was the patient correctly identified?* *Was critical patient information available?*	*None*			
II. Drug Information *Was critical drug information available when needed?*	*None*			
III. Communication of Drug Orders *Was communication between physicians and pharmacy staff adequate?* *Was communication between pharmacy staff adequate?*	*None*			

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
Was communication between pharmacy staff and the patient adequate?				
IV. Drug Labeling, Packaging, and Nomenclature *Was the prescribed drug easily identified/selected by staff?*	*Both insulin cartons were the same size (10 mL cartons)*	*Yes (1)*		*Yes*
	Both insulin cartons have similar labeling	*Yes (2)*		*Yes*
	The names and NDC numbers on the insulin cartons were covered by the prescription labels, leaving only the top of the cartons visible	*Yes (3)*		*Yes*
	Drug images did come up on the verification screen, but the prescription labels covered the carton panels		*Yes*	*Yes*
	Barcodes not scanned		*Yes*	*Yes*
	NDC numbers on carton not verified with pharmacy computer label		*Yes*	*Yes*
V. Drug Standardization, Storage and Distribution *Were drugs stored, dispensed and returned to stock safely?*	*Both drugs were stocked in the same (dark) refrigerator*	*Yes (4)*		*Yes*
	The drugs are stored on the same shelf in the refrigerator	*Yes (5)*		*Yes*
	The shelves in the refrigerator were crowded	*Yes (6)*		*Yes*
	There were no dividers to separate the insulin cartons and prevent them from getting mixed up	*Yes (7)*		*Yes*

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
VI. Medication Device Acquisition, Use and Monitoring *Was the proper equipment utilized?* *Was the equipment properly maintained?* *Was equipment safety properly assessed prior to purchase?* *Were necessary medication delivery devices dispensed to patient?*	*Not enough scanners; scanners do not retain charge for entire shift*		*Yes*	*Yes*
	Staff need to borrow scanners from other staff/stations when battery runs out		*Yes*	*Yes*
VII. Environmental Factors, Workflow and Staffing Patterns *Was the work environment (either physical and/or ergonomic) appropriate?* *Was the pharmacy appropriately staffed for the volume of prescriptions processed?* *Were standard work processes clearly established?*	*The pharmacy was busy (Monday night)*		*Yes*	*Yes*
	The pharmacy was short staffed		*Yes*	*Yes*
	The technician working at the production station was also working the cash register (forced to run between the two locations)		*Yes*	*Yes*
	The counter was covered with prescriptions to be filled and stock bottles		*Yes*	*Yes*
	Customers were standing at both sides of the pharmacy waiting for their prescriptions to be finished.		*Yes*	*Yes*
	The phone was ringing		*Yes*	*Yes*
	The pharmacist was on hold with the insurance company when he began verifying the prescriptions		*Yes*	*Yes*
	He began speaking to insurance agent during the verification process		*Yes*	*Yes*
	None of the staff had a break that night		*Yes*	*Yes*

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
VIII. Staff Competency and Education *Are all appropriate personnel trained to operate the equipment?* *Is there a program to orient and train staff?* *Is there ongoing assessment of all staff members' baseline competencies and education about new medications and/or processes?*	*No policy for mandatory counseling of high-alert drugs*		*Yes*	*Yes*
IX. Patient Education *Was the patient provided education about his/her prescriptions?*	*The patient was not counseled*		*Yes*	*Yes*
	The patient was in a hurry to get home		*Yes*	*No*
	No policy for mandatory counseling with high-alert medications		*Yes*	*Yes*
X. Quality Processes and Risk Management *Was there a system for identifying, reporting, analyzing and reducing the risk of medication errors?* *Was there a culture of safety established to encourage candid disclosure of errors (including close calls) in order to identify system-based solutions?*	*The pharmacist was distracted and concerned about 'wait time' and volume of prescriptions to be verified within promised time*		*Yes*	*No*
	The pharmacist was aware barcoding had been bypassed but did not foresee or grasp repercussions of this workaround		*Yes*	*Yes*
	Previous errors involving barcode scanning bypass were not discussed with staff		*Yes*	*Yes*

Step 5 – Root Cause Statements

Create a causation statement for each root cause using the findings identified in Step 4 above and Five Rules of Causation (Appendix G). Write concise descriptions of the cause-and-effect relationship between the findings and the error. Ensure that the team has focused on the system-based causes and not on the actions of individuals or in any way placed blame on the individuals.

Tip: To determine whether a statement is effective, ask, "If this is corrected, will it significantly reduce the likelihood of another adverse event?" The answer should be yes.

Root Cause #	Statement of Cause
1-3	*Technician pulled wrong cartons of insulin due to look alike packaging from manufacturer*
4-7	*Extra insulin inventory due to increased prescription volume led to overcrowding and misplacement of stock*

Step 6 – Action Plan

Root Causes

For each of the root causes identified in Step 4 above, assign at least one strategy. To be most effective, choose strategies based on the rank order of error reduction strategies. Once strategies are identified, develop measures that will provide strategy effectiveness over time. Some measures will be easy (something is completed or not completed by a particular date), while others may require several steps. Interim dates for substep completion should be established. If a decision is made not to implement an action for a particular root cause, indicate the rationale for not taking action at this time.

Tip: Discuss the proposed risk reduction strategies with those involved with the event to see if they believe that the RCA team is on the right track. **Ask:** If these recommendations were in place at the time of the incident, do you think it likely that the incident may have been prevented from occurring? If the answer is no, it is likely the team has not actually identified the root cause or may not have selected effective strategies.

Root Cause #	Risk-reduction Strategy	Measure of Effectiveness
1-3	*Inform ISMP re: look-alike packaging*	*ISMP to report back*
4-7	*Invest in larger refrigerator, apply shelf labels, maintain working light bulbs and obtain dividers*	*Add 'check storage areas for proper use of dividers' to supervisor or auditor's check list; review at each store visit*

Contributing Factors

For each of the contributing factors identified in Step 4 above as needing an action, complete the following table. To be most effective, choose strategies based on the rank order of error reduction strategies. Once strategies are identified, develop measures that will provide strategy effectiveness over time. Some measures will be easy (something is completed or not completed by a particular date), while others may require several steps. Interim dates for substep completion should be established. If a decision is made not to implement an action for a particular contributing factor, indicate the rationale for not taking action at this time.

Contributing Factor	Risk-reduction Strategy	Measure of Effectiveness
Drug images did come up on the verification screen, but the prescription labels covered the carton panels *Barcodes not scanned* *NDC numbers on carton not verified with pharmacy computer label*	*Develop and implement a standard process when barcode scanning has been bypassed*	*Pharmacy manager and field supervisor to periodically run barcode scanning reports (scanning rates, measure bypass reports and wrong scan reports)*
Not enough scanners; scanners do not retain charge for entire shift *Staff need to borrow scanners from other staff/stations when battery runs out*	*Invest in more scanners or scanners with longer battery life*	*Pharmacy manager and field supervisor to periodically run barcode scanning reports (scanning rates, measure bypass reports and wrong scan reports) to ensure scanners are being used*
The pharmacy was busy (Monday) *The pharmacy was short staffed* *The technician working at the production station was also working the cash register (forced to run between the two locations)* *The counter was covered with prescriptions to be filled and stock bottles* *The phone was ringing* *The pharmacist was on hold with the insurance company when he began verifying the prescriptions* *He began speaking to insurance agent during the verification process*	*Consider centralize triage of incoming phone calls*	*Not implemented at this time due to cost* *Review in 6 months during budgeting session*

Contributing Factor	Risk-reduction Strategy	Measure of Effectiveness
Customers were standing at both sides of the pharmacy waiting for their prescriptions to be finished.	*Remodel workflow with signage prompting customers to wait in either pick up or drop off line*	*Periodically observe wait lines in front of pharmacy for sign effectiveness*
No policy for mandatory counseling of high-alert drugs *The patient was not counseled*	*Institute a policy for mandatory education, which includes opening the bag and showing medication to patient when high alert medications dispensed*	*Review sign off sheets indicating completion of mandatory education policy and procedure training*
None of the staff had a break that night	*Address staffing issues to include meal and rest breaks*	*Periodically run 'Average wait time per prescription' reports to adjust daily/hourly staffing schedules*
The pharmacist was aware barcoding had been bypassed but did not foresee or grasp repercussions of this workaround *Previous errors involving barcode scanning bypass were not discussed with staff*	*Convene a medication event team to routinely review and analyze errors, identify system-based causes and facilitate implementation of system-based enhancements*	*Pharmacy Manager and field supervisor to review minutes of medication event team meetings and review effectiveness of implemented error prevention recommendations on quarterly basis*

Cite any books/journal articles/resources that were considered in developing this analysis and action plan:

Corporate CQI manual, ISMP Medication Safety Alert *Community/Ambulatory care edition volume 7, issue 5, May 2008: Workflow by Design Part III*

Determine the frequency with which this plan will be re-visited/re-evaluated

Quarterly with CQI meetings

By whom?

Pharmacy Manager

Root Cause Analysis Summary

The RCA team leader may use this optional tool as a method to disseminate the results of a completed RCA (root causes and action plan risk reduction strategies) to frontline staff and others in the organization. The real benefit of RCA only comes when solutions have been successfully implemented and continually measured over time for effectiveness. Although strategies can be written down to implement, it is a team effort to essentially put forth these changes. Without harmonious efforts between front line staff and organizational leadership to execute the risk-reduction tactics, they will not work. Therefore, communication of the desired risk reduction strategies is important to the success of the RCA.

Organization Name: *XYZ Pharmacy*

Root Cause Analysis Title: *Apidra labeled as Lantus*

Incident Date: *2/6-8/20XX*

Root Cause Analysis Author: *Ross Geller, District Manager*

Synopsis of Events:

Patient received four vials of Lantus (insulin glargine) instead of three vials of Apidra (insulin glulisine) and one vial of Lantus. Three of the Lantus cartons were labeled as Apidra and one was labeled as Lantus.

Root Cause (s):

Technician pulled wrong cartons of insulin due to look alike packaging from manufacturer

Extra insulin inventory due to increased prescription volume led to overcrowding and misplacement of stock

Corrective Actions to Prevent Re-occurrence: *See following tables*

Risk-reduction Strategy	Measure of Effectiveness
Inform ISMP re: look-alike packaging	*ISMP to report back*
Invest in larger refrigerator, apply shelf labels, maintain working light bulbs and obtain dividers	*Add 'check storage areas for proper use of dividers' to supervisor or auditor's check list; review at each store visit*
Develop and implement a standard process when barcode scanning has been bypassed	*Pharmacy manager and field supervisor to periodically run barcode scanning reports (scanning rates, measure bypass reports and wrong scan reports)*
Invest in more scanners or scanners with longer battery life	*Pharmacy manager and field supervisor to periodically run barcode scanning reports (scanning rates, measure bypass reports and wrong scan reports) to ensure scanners are being used*
Consider centralized triage of incoming phone calls	*Not implemented at this time due to cost* *Review in 6 months during budgeting session*
Remodel workflow with signage prompting customers to wait in either pick up or drop off line	*Periodically observe wait lines in front of pharmacy for sign effectiveness*
Institute a policy for mandatory education, which includes opening the bag and showing medication to patient when high alert medications dispensed	*Review sign off sheets indicating completion of mandatory education policy and procedure training*
Address staffing issues to include meal and rest breaks	*Periodically run 'Average wait time per prescription' reports to adjust daily/hourly staffing schedules*
Convene a medication event team to routinely review and analyze errors, to identify system-based causes and facilitate implementation of system-based enhancements	*Pharmacy Manager and field supervisor to review minutes of medication event team meetings and review effectiveness of implemented error prevention recommendations on quarterly basis*

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Educating the healthcare community about safe medication practices

200 Lakeside Drive, Suite 200
Horsham, PA 19044
Phone: 215-947-7797
Fax: 215-914-1492

www.ismp.org
www.facebook.com/ismp1
twitter.com/ismp1
www.consumermedsafety.org

nabp

Developed through grant support from the **National Association of Boards of Pharmacy Foundation**