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 quide this process):	

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 Findin
What was the actual sequence of events? (complete a flowchart)	Create own flow chart Ask why for key findings on the flowchart
What events were involved in (contributed to) the event?	Determine which steps were involved or directly contributed to the adverse outcome
Why did it happen?	

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?				

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

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
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?				

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
IX. Patient Education Was the patient provided education about his/her prescriptions?				
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 (<u>Appendix G</u>). 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?	OVERFLOW
	PAGE NEEDED

Question	Finding Findin
Continued from:	
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Continued from:	

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
Continued from:				
Continued from:				

Continued from:

Root Cause #	Statement of Cause

Continued from:

Root Cause #	Risk-reduction Strategy	Measure of Effectiveness

Continued from:

Contributing Factors	Risk-reduction Strategy	Measure of Effectiveness

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