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?)	

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Question to consider	Questions to Comments/Description of answers
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?)	

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Question to consider	Questions to Comments/Description of answers
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?)	

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Question to consider	Questions to Comments/Description of answers
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)	

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Question to consider	Questions to Comments/Description of answers
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)	

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Question to consider	Questions to 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 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)	

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Question to consider	Questions to Comments/Description of answers
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)	

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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.

Question to consider	Questions to Comments/Description of answers
Continued from:	
Continued from:	

Question to consider	Questions to Comments/Description of answers
Continued from:	
Continued from:	