Compounding Errors: Turning Mistakes into Opportunities for Lasting Improvement

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Disclosure Statement

Jacob Deitsch has/have no relevant financial relationship(s) with ineligible companies to disclose.

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None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

At the completion of this activity, the participant will be able to:

- Describe the key components of an effective root cause analysis (RCA) process for compounding errors and understand how to apply them in real-world scenarios
- Explain the principles of a just culture and how they support open reporting and non-punitive response to errors within pharmacy practice
- Identify common contributing factors to compounding errors, including human factors, process design, environmental influences, and communication gaps

Why is This Important?

Errors WILL Happen

29% of pharmacies reported a compounding error impacting patient care within the past five years.

Increased Workload Increased Risk

44% of pharmacies preparing >500 CSPs per day reported an error versus 13% of pharmacies preparing 1-50 CSPs per day.

Compounding is Growing

A majority of systems with more than 100 beds anticipate an increase in compounding volumes over the next year.

The Ripple Effect of Compounding Errors

Patient Impact

Direct harm through adverse drug events

Staff Impact

Psychological burden including fear, guilt, and anxiety

Organizational Impact

Regulatory enforcement actions from FDA or state boards of pharmacy

Case Study 1: A Poke in the Eye

The Background

A 65-year-old female underwent cataract surgery on a complicated by postoperative endophthalmitis. The ophthalmologist ordered vancomycin 1 mg/0.1 mL for intravitreal injection, to be prepared by the hospital pharmacy's sterile compounding service.

The Staffing

One pharmacist and one technician were out on approved leave for the December holiday season, while another pharmacist and technician were absent due to influenza. To help fill the staffing gaps, pharmacy residents were asked to report to the pharmacy to assist. The staff shift was scheduled from 0700 to 1700.

Case Study 1: A Poke in the Eye

The Events

The vancomycin intravitreal injection order was placed in the cleanroom at 1600 for compounding. At the time, the experienced compounder was preparing vancomycin intravenous bags but had to shift to prepare the intravitreal order. During the compounding process, the compounder used a vancomycin 1gm vial instead of the desired 500mg vial for compounding. They did not perform the necessary dilution of the vancomycin and withdrew vancomycin 10 mg/0.1 mL from the vial instead of the intended 1 mg/0.1 mL. A resident pharmacist verified the label and performed a visual inspection of the final product but did not double-check the vials used in the compounding process. The syringe was labeled "Vancomycin 1 mg/0.1 mL intravitreal" but contained 10 mg/0.1 mL (a tenfold overdose).

Case Study 1: A Poke in the Eye

The Outcome

The ophthalmologist administered the injection. Within 24 hours, the patient developed severe ocular inflammation, pain, and loss of light perception. Ophthalmic imaging confirmed retinal necrosis consistent with hemorrhagic occlusive retinal vasculitis (HORV), a complication associated with intravitreal vancomycin toxicity. Despite aggressive management, including corticosteroid therapy, the patient's vision loss was permanent.

Where do we go from here?

Keys to a Successful Investigation

Contributing Factors Identification

- Human factors
- Process design
- Environmental factors
- Communication breakdowns

Just Culture Incorporation

Incorporates an organizational framework that balances:

- Accountability
- Learning

Effective Root Cause Analysis

Systematic approach to problem-solving that focuses on identifying the underlying causes of errors

Common Contributing Factors

Human Factors

- Fatigue and excessive work hours
- Training gaps or inadequate experience
- Distractions and interruptions
- Cognitive biases and mental shortcuts

Process Design Issues

- Unclear or outdated procedures
- Poor workflow design
- Inadequate verification checkpoints
- Look-alike/sound-alike

Environmental Factors

- Inadequate space or cramped conditions
- Poor lighting in critical work areas
- Excessive noise and interruptions
- Temperature/humidity affecting comfort

Communication Breakdowns

- Unclear hand-off procedures
- Documentation gaps or illegible records
- Lack of closed-loop communication
- Hierarchical barriers to speaking up

Case Study 1: A Poke in the Eye

The Staffing

One pharmacist and one technician were **out on approved leave** for the December holiday season, while another pharmacist and technician were **absent due to influenza**. To help fill the staffing gaps, **pharmacy residents** were asked to report to the pharmacy to assist. The staff shift was scheduled from **0700 to 1700**.

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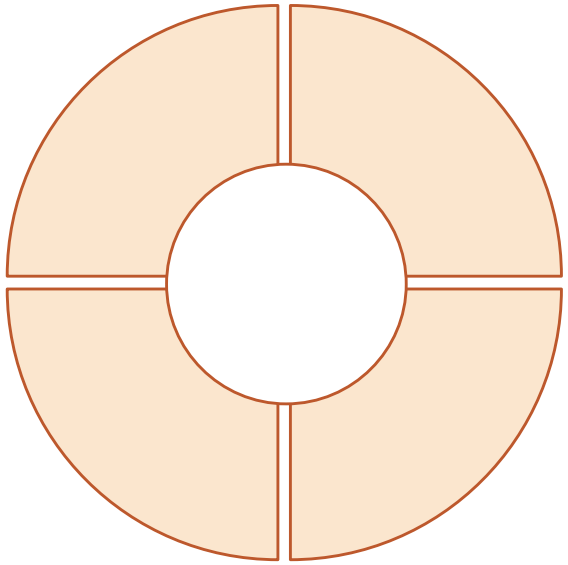
What is Just Culture?

Human Error	At-Risk Behavior	Reckless Behavior
Slips, lapses, mistakes	**Shortcuts, workarounds**	**Conscious disregard of risk**
Response Console, coach, and redesign systems to prevent recurrence.	**Response** Coach on risks and remove system incentives for risky choices.	**Response** Remedial or disciplinary action may be appropriate.
Takeaway These are learning opportunities, not disciplinary matters.	**Takeaway** Understand why the behavior occurred in the first place.	**Takeaway** This represents the small minority of situations.

Breaking Down Barriers to Error Reporting

Fear of Punishment for Reporting

Perception That Nothing Changes



Lack of Feedback Loop or Follow Up

Time Burden and Process Complexity

Takeaway: Addressing these barriers requires intentional leadership commitment, process redesign, and consistent demonstration that reporting leads to meaningful improvement without punishment.

Case Study 2: Fear Silences Safety

The Events

During a busy Monday morning, a pharmacy technician prepared a batch of total parenteral nutrition (TPN) solutions. One of the admixtures contained potassium chloride at 10 times the intended concentration due to a transcription error when entering the formula into the compounding software.

The verification pharmacist, Alex, was covering two hoods due to an absent coworker. Pressed for time, he visually checked the label but did not independently verify the input fields in the compounding software. The error was not detected until the hospital floor called reporting hyperkalemia in a patient.

Case Study 2: Fear Silences Safety

The Response

Upon learning of the incident, the pharmacy manager, under pressure from hospital partners and corporate leadership, immediately suspended the pharmacy technician and issued a formal reprimand to the pharmacist. A brief internal review focused primarily on whether staff had followed the double-check policy. The investigation concluded that the pharmacy technician “failed to pay attention” and that the pharmacist “did not fulfill his verification duty.”

What could have been done differently?

The Just Culture Response

1

Classify the Event Correctly

- Human Error: Pharmacy Technician
- At-Risk Behavior: Pharmacist

2

Addressed System Factors

- Staffing patterns
- Verification design
- Software usability

3

Apply Fair Accountability

Coaching or retraining for Maria and Alex, rather than suspension or reprimand.

4

Encourage Open Reporting

Reinforce that the goal is learning, not punishment.

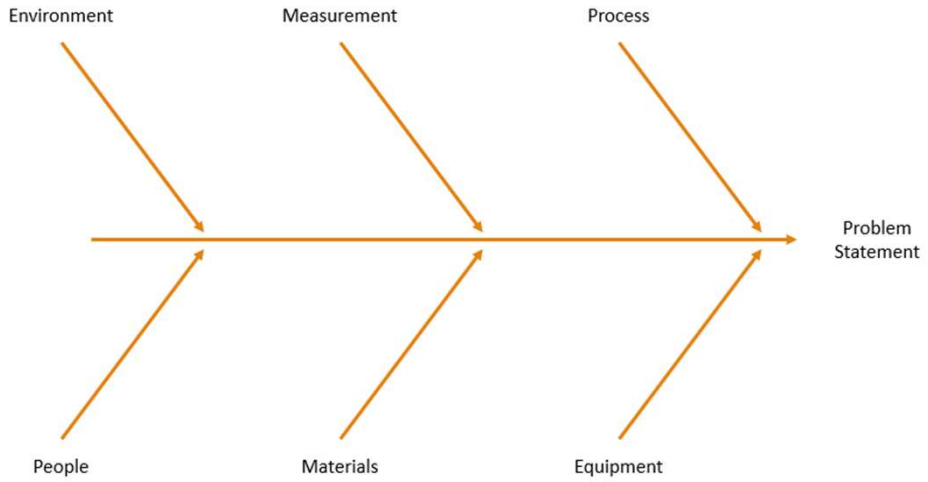
Root Cause Analysis: The Foundation

The Core Purpose

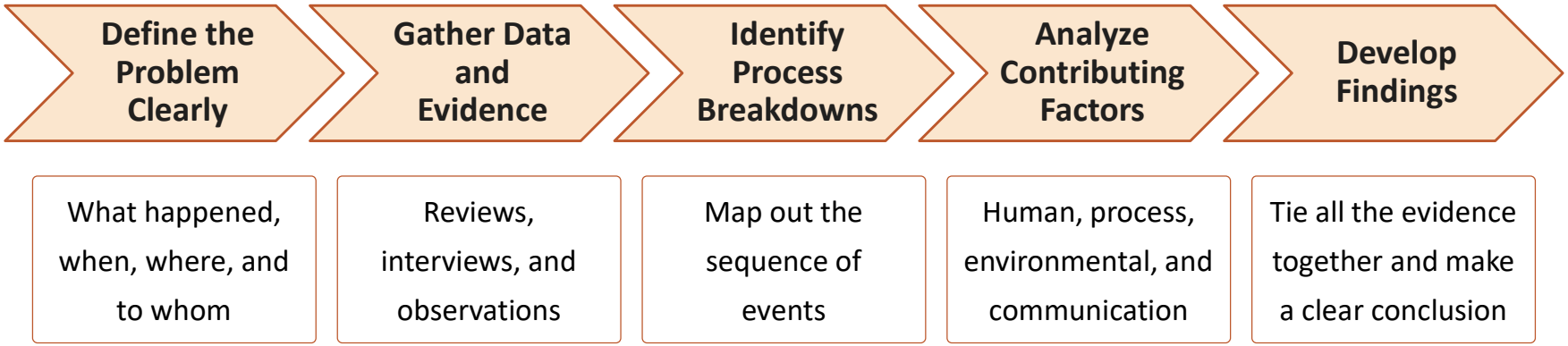
Seeks to answer *why* an error happened, not *who* is to blame.

Essential RCA Tools

- Fishbone Diagram
- 5 Whys Technique
- Process Mapping
- Failure Mode and Effects Analysis (FMEA)



A Systematic RCA Approach



Case Study 1: A Poke in the Eye

Define the Problem Clearly	A patient prescribed intravitreal vancomycin 1 mg/0.1 mL received a syringe containing 10 mg/0.1 mL.
Gather Data and Evidence	• Shift 0700-1700 • Order started 1600 • Short staffing • Residents assisting • Work changed from IV to intravitreal
Identify Process Breakdowns	• Incorrect vial selected for compounding • Dilution omitted during compounding • Source vials not verified during final check
Analyze Contributing Factors	• Human • Environmental • Process • Communication
Develop Findings	Error was caused by the selection of incorrect vials and omission of proper dilution as a result of ineffective verification, workflow design flaws, and staffing pressure

Understanding CAPAs

What Are CAPAs?

A quality management approach adapted widely across healthcare settings.

CAPAs represent the action phase that follows root cause analysis.

Corrective Action (CA)

Addressing a problem that have already occurred.

Preventative Action (PA)

Addressing the problem before it happens again.

Characteristics of Effective CAPAs

System-Focused

Address process design, environmental factors, and systemic barriers

Measurable and Trackable

Specific metrics and timelines for implementation and effectiveness checks

Address Root Causes

Target the underlying system vulnerabilities rather than surface-level symptoms

Include Follow-Up

Reviews to verify implementation, assess effectiveness, and make adjustments

Using SMART Goals

Specific: Clearly define exactly what will change, who is responsible, and what actions will be taken

Measurable: Establish metrics to assess implementation and effectiveness

Achievable: Ensure the CAPA is realistic given available resources, authority, and organizational constraints

Relevant: Align the CAPA with identified root causes and organizational priorities

Time-Bound: Set clear deadlines for implementation milestones and completion

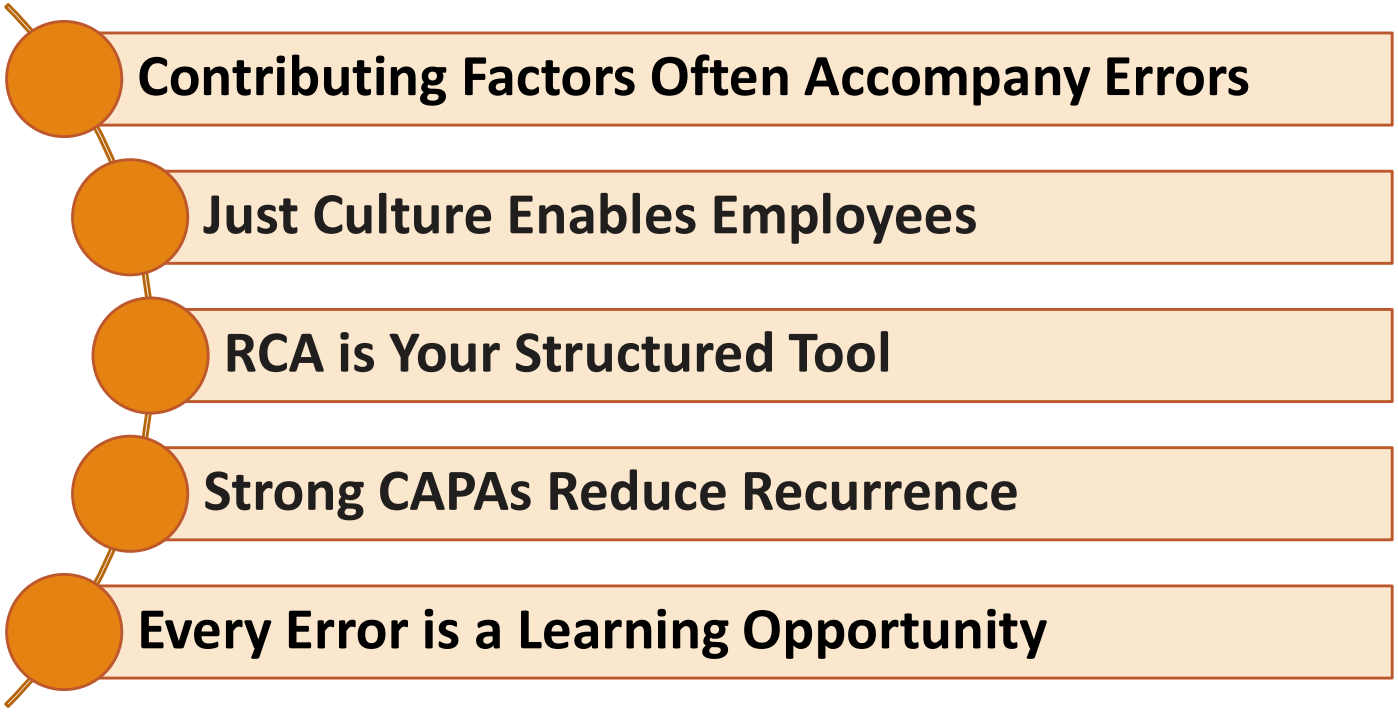
Case Study 1: A Poke in the Eye

Corrective Action				
1.	Staff Training Protocol			
	Action:	All pharmacy personnel involved in verification will complete sterile compounding and intravitreal dosing competency assessments prior to participation. Training will ensure understanding of verification requirements, proper aseptic technique, and adherence to USP <797> standards.		
	Responsible Party:	Pharmacy Manager	Timeline:	30 days
2.	Dual Verification Requirement			
	Action:	Implement a dual verification system requiring two licensed pharmacists, or one pharmacist and one trained technician, to independently verify all calculations, source vials, and final concentrations for intravitreal products.		
	Responsible Party:	Pharmacy Manager	Timeline:	30 days
3.	Shift Coverage Policy			
	Action:	Develop and implement a staffing contingency plan to address holidays and unexpected absences, ensuring adequate coverage and preventing staff overextension during high-risk sterile compounding activities.		
	Responsible Party:	Pharmacy Manager	Timeline:	45 days

Case Study 1: A Poke in the Eye

Preventative Action				
1.	Education and Simulation			
	Action:	Conduct semiannual simulation training focused on intravitreal compounding to reinforce proper dilution, labeling, and verification practices. Use simulated error scenarios to assess and strengthen staff response and process reliability.		
	Responsible Party:	Staff Development Coordinator	Timeline:	90 days
2.	Implement Barcode Verification			
	Action:	Introduce barcode scanning systems for all high-risk sterile preparations, including intravitreal doses, to minimize human error in product identification, labeling, and verification steps.		
	Responsible Party:	IT and QA Pharmacist	Timeline:	120 days
3.	Ongoing Quality Audits			
	Action:	Integrate ophthalmic compounding verification into quarterly QA audits. Focus audits on calculation accuracy, documentation completeness, and compliance with compounding procedures. Use audit findings to guide continuous process improvement		
	Responsible Party:	QA Pharmacist	Timeline:	Ongoing

Summary of Key Points



References

1. *Pharmacy Purchasing & Products'* State of Pharmacy Compounding 15th Annual National Survey. *Pharmacy Purchasing & Products*. April 2022;19(4):s1–60.
2. Institute for Safe Medication Practices (ISMP). *Medication Errors Involving Intravitreal Injections.* ISMP Medication Safety Alert! Acute Care Edition, 2021.
3. American Society of Health-System Pharmacists (ASHP). *Guidelines on Compounding Sterile Preparations. Am J Health-Syst Pharm.* 2014;71(2):145–166.
4. Agency for Healthcare Research and Quality (AHRQ). *Root Cause Analysis (RCA) Toolkit.* Rockville, MD: U.S. Department of Health and Human Services.
5. Marx D. *Patient Safety and the "Just Culture": A Primer for Health Care Executives.* New York: Columbia University, 2001.

References

6. *Institute for Safe Medication Practices (ISMP). Principles of Designing a Safe Medication Use System. ISMP; 2020.*
7. *Packer M, et al. "Toxicity of Intravitreal Vancomycin: Case Series and Review." Ophthalmology. 2019;126(4):534–541.*
8. *Flynn EA, Pearson RE, Barker KN. "Sterile Compounding Errors in Hospitals: Causes and Prevention Strategies." Am J Health-Syst Pharm. 2018;75(4):e88–e97.*
9. *Reason J. Human Error. Cambridge University Press; 1990.*
10. *Institute for Healthcare Improvement (IHI). Framework for Safe, Reliable, and Effective Care. Boston, MA: IHI, 2015.*

Need More Information?

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