

# Cephalasporin Analysis Report

**Analysis Name: Cephalasporin Analysis**

**Principal Analyst:**

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# Communicate

## Communicate Findings and Recommendations

As with this report, an effective means of communication is necessary to get RCA recommendations approved and implemented. This primarily involves communicating the conclusions of the RCA and the recommendations as a result of the RCA.

The elements of this section are intended to communicate the summary of the findings of the RCA for management, as well as the detailed recommendations made by the RCA team members for resolution of the causes identified.

A RCA cannot be successful without the approval and implementation of the analysis recommendations.

## **Event Summary**

This RCA team is chartered to conduct an unbiased Root Cause Analysis concerning the recent allergic reaction that a patient had to Vancomycin. This event resulted in an ADE. All findings and recommendations will be submitted to administration for review, approval and rapid resolution.

## **Summary of Findings**

As a result of this RCA, the following Latent Root Causes were identified; 1) Cost reduction effort forced decision to curb formulary, 2) No input from physicians as to formulary reduction decision and 3) No Quality Control (QC) of the formulary design to prevent such occurrences.

## **PROACT® Description**

PROACT® is a methodology developed by Reliability Center, Inc. (RCI) to help users analyze their organization's most costly problems. The term PROACT® is an acronym for PReserving Failure Data, Ordering the Analysis, Analyzing the Data, Communicating Findings and Recommendations and Tracking for Results.

## Executive Summary Recommendations

Root Cause	Type	Recommendation	Team Member	Estimated Completion Date	Completed
Decision to Curb Scope of the Formulary	Human	Formulary selection algorithm should encompass many criteria, not just the cost of specific medication.	Unknown	10/13/2007	No
No Input Requested From Physicians	Latent	Physicians, Pharmacy and Therapeutics Committee should have input into the selection process for the formulary.	Unknown	10/15/2007	No
No QC Check on Formulary Design	Latent	Use of a quality-based formulary selection algorithm.	Unknown	10/15/2007	No

### Detailed Recommendations

Root Cause	Type	Recommendation	Completed
Decision to Curb Scope of the Formulary	Human	Review the current selection algorithm for the basis of formulary selection. Basis of selection should include factors such as quality, patient safety and efficiency and effectiveness of patient care.	No
No Input Requested From Physicians	Latent	Physicians, Pharmacy and Therapeutics Committee should have input into the selection process for the formulary. They should utilize a multi-factor algorithm that includes quality, patient safety, efficiency and effectiveness of care.	No
No QC Check on Formulary Design	Latent	Use of a quality-based formulary selection algorithm that is based on efficiency and effectiveness, patient safety and evidence-based outcomes.	No

## Acknowledgements

Company	Title	Name	Expertise
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# Analysis-At-A-Glance

## Analysis-At-A-Glance

For the benefit of those that must oversee Root Cause Analysis (RCA) activities from the business perspective, this Analysis-At-A-Glance section provides such information.

In the PROACT® Root Cause Analysis process, there are three points where tasks are assigned to team members, they in:

1. data collection.
2. hypothesis verifications and
3. the development and implementation of recommendations.

At each of these points the analyst is afforded the opportunity to input the number of man-hours it took them to complete the task and to add any other associated costs to complete the task.

Analysis-At-A-Glance is the section where all of this information is brought together in a meaningful fashion. This is the location of where the estimated Return-On-Investment's (ROI-Year 1) reside for both the individual recommendations and the analysis as a whole. The detailed cost breakdowns are also available upon request in this section.

**Executive Summary: Root Cause Action Plan**

Root Cause	Proposed Solution/Action Plan	Metric to Track	Team Member	Estimated Completion Date	Approved	In-Process	Complete
Decision to Curb Scope of the Formulary	Formulary selection algorithm should encompass many criteria, not just the cost of specific medication.	Frequency of Occurrence	Unknown	10/13/2007			
No Input Requested From Physicians	Physicians, Pharmacy and Therapeutics Committee should have input into the selection process for the formulary.	Frequency of Occurrence	Unknown	10/15/2007	√	√	
No QC Check on Formulary Design	Use of a quality-based formulary selection algorithm.	Frequency of Occurrence	Unknown	10/15/2007			

# Analyze

## Analyze the Event Data

Any undesirable outcome is a result of a series of "cause-and-effect" relationships. The data collected in the 5-P's section of this report will ultimately serve as proof (evidence) as to what actually did or did not occur.

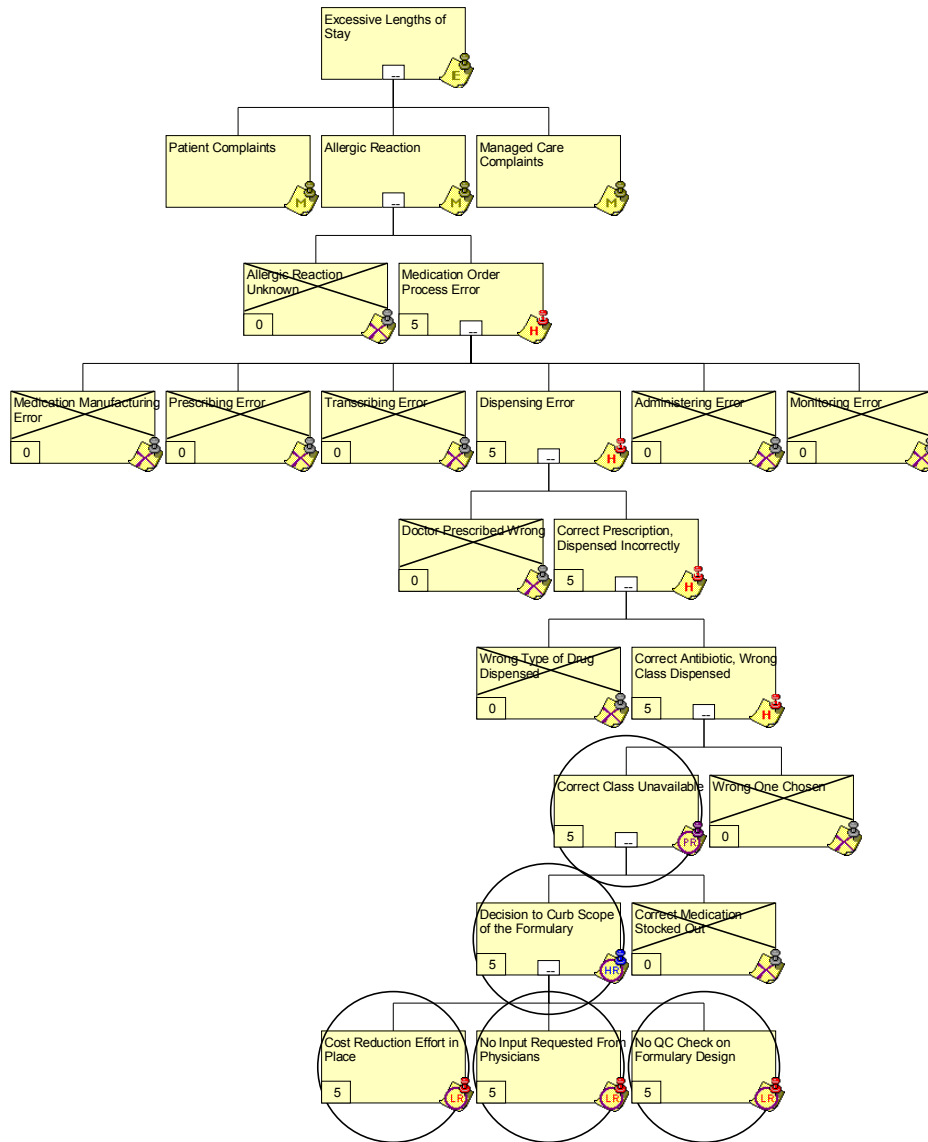
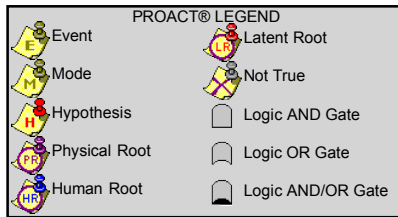
A logic tree will be used in the PROACT® RCA approach to graphically express the "cause-and-effect" relationships discussed earlier. In this approach, the top two levels of blocks represent the Event (Level 1) and the Modes (Level 2). From level to level represents a "cause-and-effect" relationship. These levels specifically represent the "undesirable outcomes" that did occur (facts only)!

From the MODE level, we do not know why they have occurred, just that they did. From this point we become hypothetical and repeatedly ask the question "How Can?".

As hypotheses are developed in this fashion, we use our 5-P's data to verify what is true and what is not true. In this fashion, facts lead our analyses not assumptions. This process is reiterated until we start to uncover the real root causes: the reasons that people make decision errors that lead to undesirable outcome.

Root causes originate from flawed systems in which people depend on to make informed decisions. We call these Latent Root Causes or Organizational Root Causes. Flawed organizational systems lead to poor decisions being made by well-intentioned individuals. We call these the Human Root Causes. Decision errors lead to Physical Root Causes, or events or conditions that are visible.

Only when we uncover the Latent Roots or Organizational System Roots are we actually conducting a "real" ROOT CAUSE analysis.



## Verification Logs

Hypothesis	Description	Team Member	Verification Method	Outcome
Administering Error		Unknown	Interview with nurse.	Nurse administered the medication using the correct procedure.
Allergic Reaction Unknown		Unknown	Check this particular patient history for past allergic reactions to this drug	Past history indicates that such a medication had been taken by patient and no allergic reaction was observed.
Correct Antibiotic, Wrong Class Dispensed		Unknown	Interview the Pharmacist.	Pharmacist confirmed he had limited antibiotic formulary without first consulting pharmacy and therapeutics committee and did not communicate the change to staff physicians.  Computerized order entry system programmed to default to least expensive member of class of antibiotics.
Correct Class Unavailable		Unknown	Interview with Pharmacist.	Interview reveals that versions of the antibiotic typically used in the past had been eliminated from the formulary.
Correct Medication Stocked Out		Unknown	Interview with Pharmacist.	Pharmacist indicates that there was no stock out.
Correct Prescription, Dispensed Incorrectly		Unknown	Interview with Pharmacist.	Pharmacist confirms that he consciously dispensed the version of drug that he intended to, not realizing that the ADE would occur.

Hypothesis	Description	Team Member	Verification Method	Outcome
Cost Reduction Effort in Place		Unknown	Interview with CFO.	CFO confirms all department heads were told to achieve a 10% cost reduction.
Decision to Curb Scope of the Formulary		Unknown	Interview with Pharmacist.	Pharmacist confirms due to the pressures to reduce cost and a well intentioned effort to contribute to "perceived" continuous improvement, a conscious decision was made to reduce the number of versions of the drug to reduce cost.
Dispensing Error		Unknown	Interview with Pharmacist that dispensed the drug in this particular situation.	Pharmacist confirms that the drug he dispensed was the one that he intended to dispense. While the family of drugs dispensed was correct, the version was apparently incorrect for this patient.
Doctor Prescribed Wrong		Unknown	Interview with prescribing Physician.	Interview confirms that Physician prescribed the drug that he intended for this patient.
Medication Manufacturing Error		Unknown	Review and test dispensed drug from pharmacy by an outside, independent laboratory.	There is no indication that there was a problem with the medication received from the manufacturer.
Medication Order Process Error		Quality Management Coordinator	test	
Monitoring Error		Unknown	Interview with nurse.	Nurse observed patient 30 minutes after administering medication and found symptoms of allergic reaction.

Hypothesis	Description	Team Member	Verification Method	Outcome
No Input Requested From Physicians		Unknown	Interview with Pharmacist.	Interview reveals that decision was made unilaterally and without the knowledge of staff Physicians.
No QC Check on Formulary Design		Unknown	Interview with Chairman of P&T committee.	Interview reveals no oversight on selection of antibiotic medications maintained in the hospital pharmacy.
Prescribing Error		Unknown	Interview Physician who prescribed medication.	Interview confirms that the Physician ordered the medication that he intended to prescribe.
Transcribing Error		Unknown	Interview with Pharmacist.	Interview confirms that there was no transcription. Physician used computerized order entry.
Wrong Type of Drug Dispensed		Unknown	Interview the Pharmacist.	Interview confirms that the correct antibiotic was dispensed, but wrong version.

# Order

## Ordering the Analysis Team

Another prerequisite to the PROACT® RCA approach is that an appropriate team be formed for the analysis at hand. Such an effort involves the following:

1. Providing an unbiased team facilitator - Assigning a person to lead the analysis who has nothing to gain or lose by the outcome; an expert in the facilitation of the PROACT® RCA methodology.
2. Amassing a team of cross-functional members - Ensuring that the team itself is not biased with one perspective; allowing team members to be experts as well as objective observers.
3. Establishing a Team Charter (Terminal Objective) for the analysis - Gaining consensus on a one (1) paragraph statement that outlines the reason the team is together.
4. Establishing Critical Success Factors (CSFs) - Establishing CSFs that outline how the team will know when they have been successful.

## **Charter**

To identify the root causes of the Extended Lengths of Stay (ELOS) due to an Allergic Reaction. This includes identifying deficiencies in or lack of management systems. Appropriate recommendations for root causes will be communicated to management for rapid resolution.

## **Critical Success Factors**

- 1 - A disciplined RCA approach will be utilized
- 2 - Comply with NYPORTS Analysis Requirements
- 3 - No one will be disciplined for honest mistakes

# Preserve (5P's)

## Preserve Event Data

As in any investigative occupation, it is a REQUIREMENT that data (evidence) be collected from the scene and preserved in such a fashion as is appropriate for further analysis. As with the detective at a crime scene, the area is roped off and the scene preserved for the professionals who will come in and collect the necessary data.

PROACT® utilizes a data collection technique called the 5-P's. The 5-P's stand for the following five (5) data categories:

1. Parts – Physical or tangible evidence. Examples include process equipment, diagnostic equipment, fluid samples, etc.
2. Paper – Documentation. Examples include procedures, specifications, records, policies, test results, literature searches, etc.
3. Positional - Elements of time and space. Examples include times of occurrences, location of occurrences, frequency of occurrences, etc.
4. People - People sought to be interviewed regarding an event. Examples include management, administration, witnesses, engineers, hourly personnel, purchasing, etc.
5. Paradigms - People's belief systems that contribute to decision errors. "Cost reduction is #1". "It's the manufacturer's fault". "Poor design". etc.

## Data Collection

Data Category	Data To Collect	Collection Strategy	Team Member	Date	Completed	Hours
Paper	Patient Medical History	Obtain patient medical history and review for any past allergic reactions to vancomycin.	Unknown	8/14/2001	Yes	3
Paper	Medication Order Process Procedure	Obtain and review the work process flow of the medication order process procedure. Search for any deviations from the correct procedure.	Unknown	10/12/2007	Yes	10
Paper	Formulary Scope Histories	Obtain the mix of the family of vancomycin medication over the past three years and search for any changes consistent with the time frame of the allergic reaction. Also check for other allergic reactions during and since the time period for a possible correlation.	Unknown	8/14/2001	No	0
Paper	Pharmacy Procedures	Request from management all procedures and policies related to the pharmacy.	Unknown	10/30/2001	No	0
Paper	Pharmacy Procedures	Have the Pharmacy manager provide.	Unknown	5/30/2002	No	0
Paper	Patient Record	Have nurse obtain from records	Unknown	2/19/2004	No	0
Parts	Dispensed Vancomycin	Obtain samples of the dispensed Vancomycin and have lab tested to assure that the actual medication is as certified.	Unknown	8/14/2001	Yes	4
People	Pharmacist	Interview with Pharmacist to determine if the drug he intended to dispense was actually the the drug that was dispensed.	Unknown	8/14/2001	Yes	3
People	Phamracist	Interview	Unknown	4/21/2003	Yes	2
People	Pharmacist	Interview	Unknown	8/28/2003	Yes	2
People	Pharmacist	Interview with pharmacist to determine the possibility of a transcribing error.	Unknown	8/14/2001	No	0

Data Category	Data To Collect	Collection Strategy	Team Member	Date	Completed	Hours
People	Prescribing Physician	Interview prescribing Physician to determine if the ordered medication was what he intended to prescribe.	Unknown	8/14/2001	No	0
People	Nurse that Administered Medication	Interview nurse on duty that administered the medication to this patient to determine if she understands and applied the proper procedure.	Unknown	8/14/2001	No	0
People	Nurse on Duty During Time of Allergic Reaction	Interview nurse to determine when the patient was monitored and the time difference between the detection of the allergic reaction and the time the medicine was administered.	Unknown	8/14/2001	No	0
People	Pharmacist	Ask the Pharmacist, "How could the correct prescription have been ordered and the wrong medication dispensed?"	Unknown	8/14/2001	No	0
People	Pharmacist	Interview Pharmacist and ask, "What the correct version of the medication available in the pharmacy at that time?"	Unknown	8/14/2001	No	0
People	Physicians	Interview Physicians to see they had been asked to participate in any decisions to change the Vancomycin formulary.	Unknown	8/14/2001	No	0
People	P&T Committee Chairman	Interview P&T Committee Chairman about the quality control checks in place to oversee any changes in formulary.	Unknown	8/14/2001	No	0
People	Pharmacist	Interview with Pharmacist to determine if the correct medication was "stocked out".	Unknown	8/14/2001	No	0