

# **Root Cause Analysis Report Vancomycin Allergic Reaction**

**Analysis Name: Vancomycin Analysis**

**Principal Analyst: Bob Latino**

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**Key Note Point Hospital  
401 Downe Road  
Mushaboom, IA 55442**

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## **PROACT® ROOT CAUSE ANALYSIS (RCA) PROCESS DESCRIPTION**

The following Root Cause Analysis (RCA) was conducted to help us determine the "true" root causes of the event analyzed. This PROACT® RCA analysis technique has been field-proven for over thirty years and replicates the tasks involved in any investigative occupation. The analysis was conducted to determine the physical, human and latent root causes associated with the event at hand.

Below is a quick overview of the RCA process used to determine our facility's "Significant Few" events:

1. PReserve Event Data - Outline the measures taken to collect the 5-P's (Parts, Position, People, Paper and Paradigms)
2. Order the Analysis Team - Delineates the formation of the team and its associated structure
3. Analyze the Event Data - The use of a disciplined, logical thought process to draw accurate and comprehensive conclusions based on facts
4. Communicate Findings and Recommendations - The effective and efficient means of getting RCA recommendations implemented through proper communication
5. Tracking for Bottom-Line Results - Ensuring the sustainability of successful outcomes by monitoring performance of implemented recommendations

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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.

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## **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  | Responsible | 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.         | Bob Latino  | 10/13/2002                | Yes       |
| No Input From Physicians                | Latent | Physicians, Pharmacy and Therapeutics Committee should have input into the selection process for the formulary. | Bob Latino  | 10/13/2002                | No        |
| No QC Check on Formulary Design         | Latent | Use of a quality-based formulary selection algorithm.   | Bob Latino  | 10/13/2002                | 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.                                  | Yes       |
| No Input 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        |

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# 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.

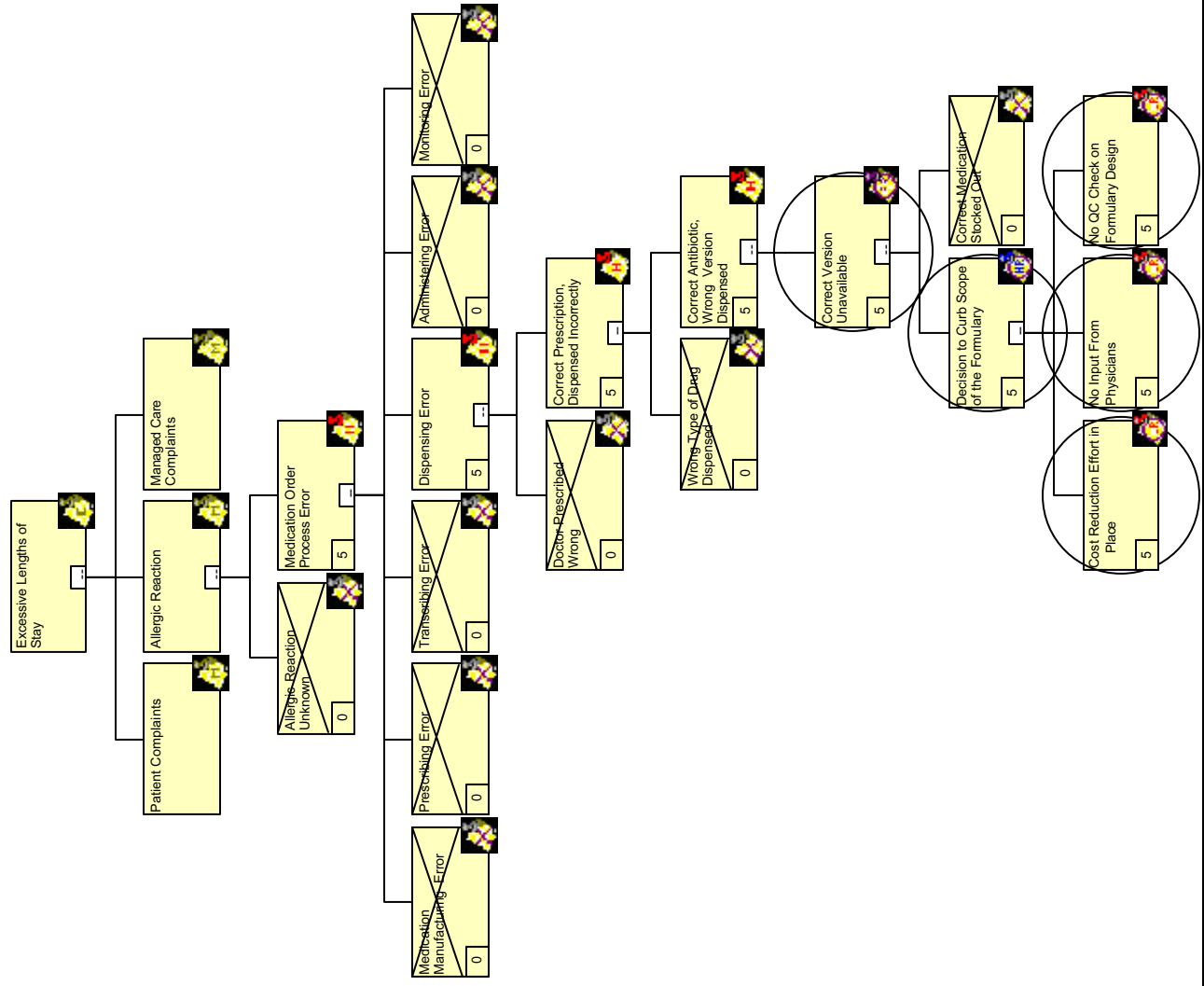
A logic tree will be used in the PROACT® RCA approach to graphically express the "cause-and-effect" relationships discussed earlier. In this approach, the top two levels of blocks represent the Event (Level 1) and the Modes (Level 2). From level to level represents a "cause-and-effect" relationship.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



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# Preserve

## **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

| Category | Data   | Strategy   | Team Member | Date      | Completed | Hours |
|----------|--|--|-------------|-----------|-----------|-------|
| Paper    | Patient Medical History                        | Obtain patient medical history and review for any past allergic reactions to vancomycin.   | Bob Latino  | 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.                                       | Bob Latino  | 8/14/2001 | Yes       | 5     |
| Parts    | Dispensed Vancomycin                           | Obtain samples of the dispensed Vancomycin and have lab tested to assure that the actual medication is as certified.   | Bob Latino  | 8/14/2001 | Yes       | 4     |
| People   | Pharmacist                                     | Interview with pharmacist to determine the possibility of a transcribing error.  | Bob Latino  | 8/14/2001 | Yes       | 4     |
| People   | Prescribing Physician                          | Interview prescribing Physician to determine if the ordered medication was what he intended to prescribe.  | Bob Latino  | 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.   | Bob Latino  | 8/14/2001 | Yes       | 4     |
| 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.                                     | Bob Latino  | 8/14/2001 | Yes       | 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. | Bob Latino  | 8/14/2001 | Yes       | 0     |
| People   | Pharmacist                                     | Ask the Pharmacist, "How could the correct prescription have been ordered and the wrong medication dispensed?"   | Bob Latino  | 8/14/2001 | Yes       | 0     |

| Category | Data                      | Strategy   | Team Member | Date      | Completed | Hours |
|----------|---------------------------|--|-------------|-----------|-----------|-------|
| People   | Pharmacist                | Interview Pharmacist and ask, "What the correct version of the medication available in the pharmacy at that time?"   | Bob Latino  | 8/14/2001 | Yes       | 4     |
| 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. | Bob Latino  | 8/14/2001 | Yes       | 0     |
| People   | Physicians                | Interview Physicians to see they had been asked to participate in any decisions to change the Vancomycin formulary.  | Bob Latino  | 8/14/2001 | Yes       | 0     |
| People   | P&T Committee Chairman    | Interview P&T Committee Chairman about the quality control checks in place to oversee any changes in formulary.  | Bob Latino  | 8/14/2001 | Yes       | 0     |
| People   | Pharmacist                | Interview with Pharmacist to determine if the correct medication was "stocked out".  | Bob Latino  | 8/14/2001 | Yes       | 0     |
| Paper    | Pharmacy Procedures       | Request from management all procedures and policies related to the pharmacy.   | Bob Latino  | 8/14/2001 | Yes       | 0     |
| Paper    | Pharmacy Procedures       | Have the Pharmacy manager provide.   | Bob Latino  | 8/14/2001 | Yes       | 0     |
| People   | Pharmacist                | Interview  | Bob Latino  | 8/14/2001 | Yes       | 0     |
| People   | Pharmacist                | Interview  | Bob Latino  | 8/14/2001 | Yes       | 2     |

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## Data Collection File Links

| Category | Data       | Team Member | Location                                | Name       |
|----------|------------|-------------|---|------------|
| People   | Pharmacist | Bob Latino  | C:\Program Files\RC\PROACT3\FileLinks\4 | doctor.jpg |
| People   | Pharmacist | Bob Latino  | C:\Program Files\RC\PROACT3\FileLinks\4 | doctor.jpg |
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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 implement 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.

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## PROACT® RCA Analysis-At-A-Glance Overview

### ANALYSIS AND TEAM DATA

|                            |  |
|----------------------------|--|
| Analysis Name:             | Vancomycin Analysis  |
| Principal Analyst:         | Bob Latino   |
| Team Members:              | Ken Latino, Julie Clarke   |
| Team Charter:              | To identify the root causes of the <<FILL IN INFORMATION HERE>>. 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:  | <ul style="list-style-type: none"><li>- Comply with NYPORTS Analysis Requirements</li><li>- No one will be disciplined for honest mistakes</li><li>- A disciplined RCA approach will be utilized</li></ul>                                     |
| Start Date:                | 4/23/2003 9:07:59 PM   |
| Estimated Completion Date: | 4/23/2003 9:07:59 PM   |
| Estimated Cost of Event:   | \$500,000.00   |

### STATUS OF PRESERVE

|   |     |
|---|-----|
| Number of Data Collection Tasks Assigned: | 18  |
| Number of Data Collection Tasks Complete: | 6   |
| % of Data Collection Tasks Completed:     | 33% |

### STATUS OF ANALYZE

|                                    |      |
|------------------------------------|------|
| Number of Hypotheses:              | 18   |
| Number of Verifications Assigned:  | 18   |
| Number of Verifications Completed: | 18   |
| % of Verifications Completed:      | 100% |

### STATUS OF COMMUNICATE

|                                     |     |
|-------------------------------------|-----|
| Number of Root Causes Identified:   | 5   |
| Number of Recommendations Proposed: | 3   |
| Number of Recommendations Approved: | 2   |
| % of Recommendations Approved:      | 67% |

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**NUMBER OF RECOMMENDATIONS**

|             |   |     |
|-------------|---|-----|
| Approved:   | 2 | 67% |
| In-Process: | 1 | 50% |
| Completed:  | 1 | 50% |

**ESTIMATED RETURN-ON-INVESTMENT (Year 1)**

|  |                              |
|--|------------------------------|
| Estimated Cost of Event/Benefit Derived if Eliminated: | \$500,000.00                 |
| Cost of Root Cause Analysis and Recommendations:       | \$21,188.94 (see<br>Details) |
| Estimated Return on Investment (Year 1) (%):           | 2360%                        |

## Executive Summary: Root Cause Action Plan

| Root Cause                              | Suggested Resolution/<br>Action Plan  | Metric to Track         | Responsible | Estimated<br>Completion<br>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 | Bob Latino  | 10/13/2002                      | v        |            | v        |
| No Input From Physicians                | Physicians, Pharmacy and Therapeutics Committee should have input into the selection process for the formulary. | Frequency of Occurrence | Bob Latino  | 10/13/2002                      | v        | v          |          |
| No QC Check on Formulary Design         | Use of a quality-based formulary selection algorithm.   | Frequency of Occurrence | Bob Latino  | 10/13/2002                      |          |            |          |



**Executive Summary: Estimated Return-On-Investment (Year 1)**

| Est. % of Annual Loss | Root Causes Identified                  | Annual Losses (Potential Benefit) | Sum of Recommendations | Estimated ROI (Year 1) |
|-----------------------|---|-----------------------------------|------------------------|------------------------|
| 30%                   | Decision to Curb Scope of the Formulary | \$150,000.00                      | \$3,817.31             | 3929%                  |
| 45%                   | No Input From Physicians                | \$225,000.00                      | \$12,048.08            | 1868%                  |
| 25%                   | No QC Check on Formulary Design         | \$125,000.00                      | \$2,163.46             | 5778%                  |

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