

Patient Breaks Hip as a Result of Falling at Home After Taking Her Prescribed Nortriptyline Root Cause Analysis Report

Analysis Name: Injury Due to Medication

Printed: 3/15/2011



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Table of Contents

<i>Topic</i>	<i>Page</i>
<i>Preserve (5P's)</i>	<i>3</i>
<i>Data Collection</i>	<i>4</i>
<i>Order</i>	<i>5</i>
<i>Charter</i>	<i>6</i>
<i>Critical Success Factors</i>	<i>6</i>
<i>Analyze</i>	<i>7</i>
<i>Logic Tree (8-1/2 x 11, Best Fit)</i>	<i>8</i>
<i>Verification Logs</i>	<i>10</i>
<i>Communicate</i>	<i>16</i>
<i>Event and Cause Summaries</i>	<i>16</i>
<i>Executive Summary Recommendations</i>	<i>18</i>
<i>Detailed Recommendations</i>	<i>20</i>
<i>Appendices (see attached if applicable)</i>	

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

Category	Data to Collect	Strategy	Team Member	Collection Date	Completed	Hours
Paper	Medical Chart	Obtain from Medical Records and bring to the team for use during the analysis.	Bob Latino	10/18/2010	Yes	0
Paper	Interviews	Interview the attending physician and the patient concerning the events that led up to the incident under investigation and bring the results to the team for correlation with other failure data during the analysis.	Bob Latino	10/18/2010	Yes	0
Parts	Prescription Bottle and Warning Label	Obtain from the patient and bring to the team for use during the analysis.	Bob Latino	10/18/2010	Yes	0

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 (CSF's) - Establishing CSF's that outline how the team will know when they have been successful.

Charter

To identify the root causes of the patient being injured (broken hip) due to Medication side effects. 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 cross-functional section Of personnel/experts will participate In the analysis
- 2 - A disciplined RCA approach will be utilized
- 3 - All analysis hypotheses will be verified Or disproven
- 4 - Management agrees to fairly evaluate the analysis team's findings and recommendations
- 5 - No one will be disciplined for honest mistakes

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.

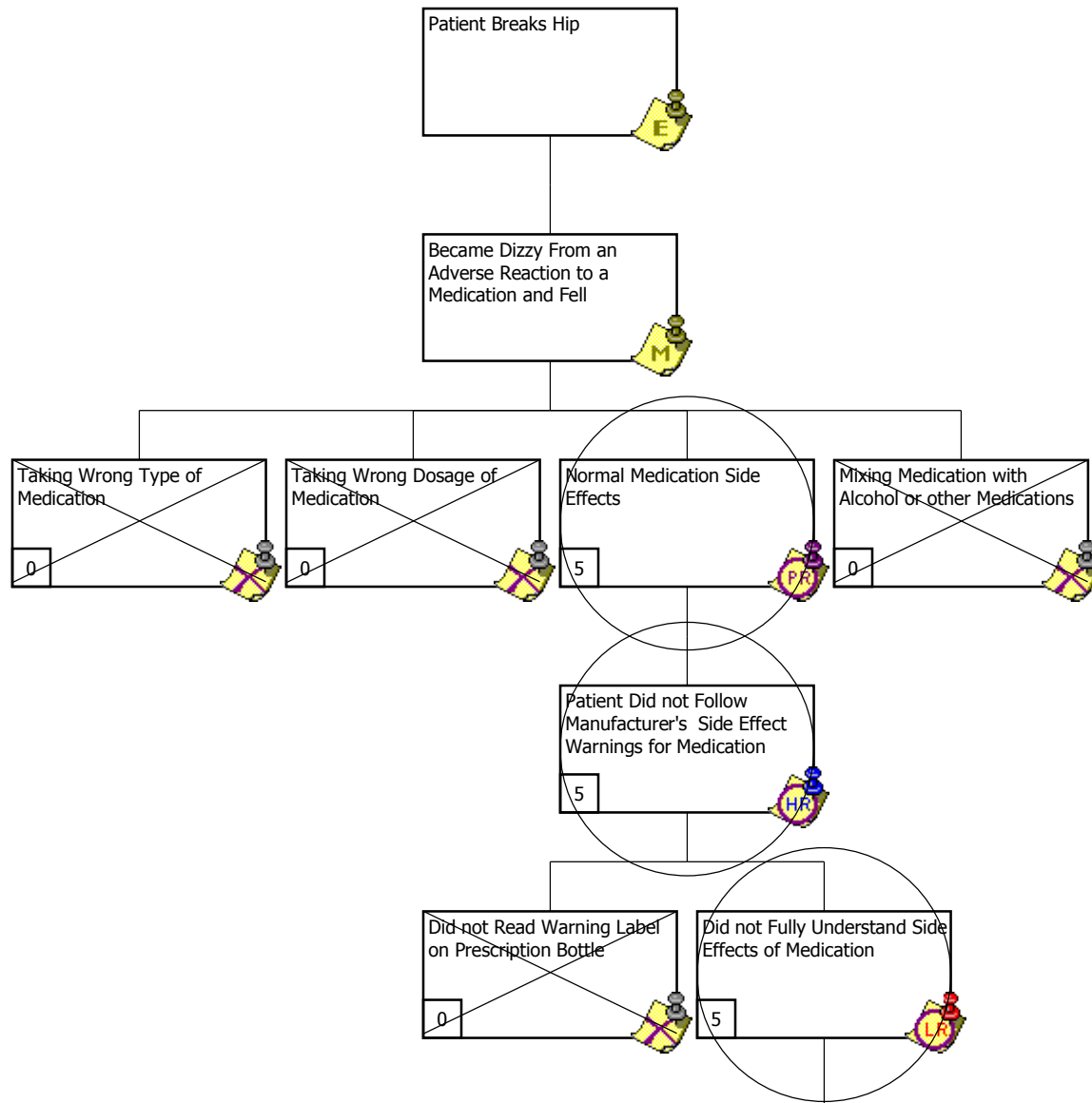
A logic tree will be used in the PROACT® RCA approach to graphically express the "cause-and-effect" relationships discussed earlier. In this approach, the top two levels of blocks represent the Event (Level 1) and the Modes (Level 2). From level to level represents a "cause-and-effect" relationship.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

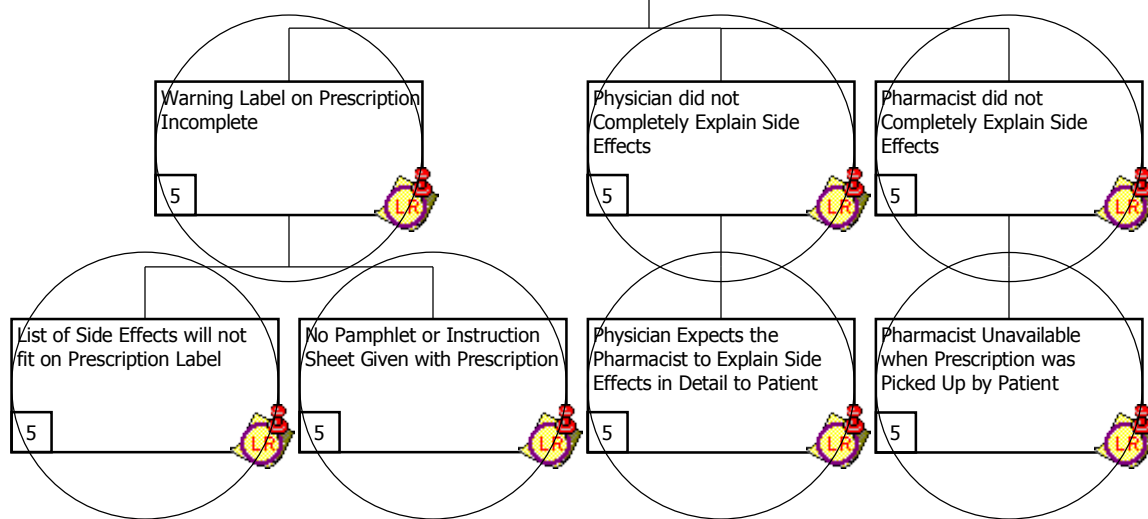
From the MODE level, we do not know why they have occurred, just that they did. From this point we become hypothetical and repeatedly ask the question "How Can?".

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
Did not Fully Understand Side Effects of Medication	~	Unknown	Interview the patient to see if she fully understood the side effects from taking an alpha blocker such as nortriptyline.	The patient read the warning label which stated " May Cause Dizziness" but did not understand that this meant at any time during the day. The physician instructed the patient not to get out of bed too quickly in the morning and to sit on the side of the bed for a few minutes before attempting to stand up. Although this is good advice, it does not convey to the patient that postural changes at any time during the day can trigger orthostatic hypotension, especially at initiation of treatment or following a recent dose increase.
Did not Read Warning Label on Prescription Bottle	~	Unknown	Interview the patient to see if she read and understood the warning label on the prescription.	The patient read the warning label. The label simply says "May Cause Dizziness."
List of Side Effects will not fit on Prescription Label	~	Unknown	Look at the Label on the Prescription and determine if all the side effects will fit on the label.	The label is approximately 1" x 3" as does not provide enough room to list all the potential side effects of the medication prescribed.

Hypothesis	Description	Team Member	Verification Method	Outcome
Mixing Medication with Alcohol or other Medications	~	Unknown	Interview the patient to see if she was mixing her medication with any other substances.	The patient was not drinking alcohol or any other substances prior to or at the time of the incident under investigation.
No Pamphlet or Instruction Sheet Given with Prescription	~	Unknown	Interivew the patient and pharmacist to find out if a pamphlet or instruction sheet was provided with the medication.	No pamphlet or other instructional materials on the medication were provided with the prescription.
Normal Medication Side Effects	~	Unknown	Look at the potential side effects of nortripyline and see if it can cause dizziness.	Nortripyline can cause dizziness due to postural changes at any time triggering orthostatic hypotension, especially at initiation of treatment or following a recent dose increase.

Hypothesis	Description	Team Member	Verification Method	Outcome
Patient Did not Follow Manufacturer's Side Effect Warnings for Medication	~	Unknown	Interview the patient to see if she followed the manufacturer's warning concerning the use of nortriptyline 75 mg.	The patient read the warning label which stated " May Cause Dizziness" but did not understand that this meant at any time during the day. The physician instructed the patient not to get out of bed too quickly in the morning and to sit on the side of the bed for a few minutes before attempting to stand up. Although this is good advice, it does not convey to the patient that postural changes at any time during the day can trigger orthostatic hypotension, especially at initiation of treatment or following a recent dose increase.
Patient Did not Follow Manufacturer's Side Effect Warnings for Medication	~	Unknown		
Pharmacist did not Completely Explain Side Effects	~	Unknown	Interview the Pharmacist concerning what instructions were provided to the patient about the prescribed medication.	The pharmacist was unavailable at the time the prescription was filled and only the warning label provided instructions.
Pharmacist Unavailable when Prescription was Picked Up by Patient	~	Unknown	Interview the Pharmacist concerning what instructions were provided to the patient about the prescribed medication.	The pharmacist was unavailable at the time the prescription was filled and only the warning label provided instructions.

Hypothesis	Description	Team Member	Verification Method	Outcome
Physician did not Completely Explain Side Effects	~	Unknown	Interview the physician concerning instructions provided to the patient about the medication prescribed.	<p>The physician instructed the patient not to get out of bed too quickly in the morning and to sit on the side of the bed for a few minutes before attempting to stand up.</p> <p>Although this is good advice, it does not convey to the patient that postural changes at any time during the day can trigger orthostatic hypotension, especially at initiation of treatment or following a recent does increase.</p> <p>The physician was counting on the pharmacist to provide this information during an anticipated patient counseling session when she picked up the prescription.</p>

Hypothesis	Description	Team Member	Verification Method	Outcome
Physician Expects the Pharmacist to Explain Side Effects in Detail to Patient	~	Unknown	Talk with the physician concerning what instructions were provided to the patient about the medication being prescribed.	<p>The physician instructed the patient not to get out of bed too quickly in the morning and to sit on the side of the bed for a few minutes before attempting to stand up.</p> <p>Although this is good advice, it does not convey to the patient that postural changes at any time during the day can trigger orthostatic hypotension, especially at initiation of treatment or following a recent does increase.</p> <p>The physician was counting on the pharmacist to provide this information during an anticipated patient counseling session when she picked up the prescription.</p>
Taking Wrong Dosage of Medication	~	Unknown	Compare the Medication being taken to what was prescribed by the physician.	The physician prescribe nortriptyline 75 mg to be taken once a day at bedtime. This is what is being taken and at the correct interval and amount.
Taking Wrong Type of Medication	~	Unknown	Review Medical Records and Compare with the Medication being Taken	The physician prescribe nortriptyline 75 mg to be taken once a day at bedtime. This is what is being taken and at the correct interval and amount.

Hypothesis	Description	Team Member	Verification Method	Outcome
Warning Label on Prescription Incomplete	~	Unknown	Look at the prescription label to see if all known warnings are listed.	The warning label reads "May Cause Dizziness." This is incomplete because it does not specify under what circumstances that Dizziness may occur.

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

A 68 year old female in good health is seen by her family physician following the death of her husband. The patient reports feelings of loneliness, difficulty concentrating, sleep disturbances, decreased appetite and generalized feelings of depression. The physician decides to try the patient on a short course of tricyclic antidepressant medication and prescribes nortriptyline 75 mg at bedtime. The physician instructs the patient not to get out of bed too quickly in the morning and to sit on the side of the bed for a few minutes before attempting to stand up.

A few days later, the patient is lying on a chase lounge by her swimming pool enjoying the sun. She decides to check her mailbox. After a few steps she gets dizzy and falls on the concrete apron surrounding the pool breaking her hip.

It was determined by the medical staff that a need for a formal analysis to uncover the Root Cause(s) of this incident be conducted at this time.

Summary of Findings

The root causes of this incident can be directly attributed to the patients inability to determine the potential side effects of the prescribed medication. This can be further attributed to the limitations of the amount of information that can be put on prescription labels as well as the lack of other types of materials such as pamphlets and instructions sheets. Also the instructions provided to the patient by the pharmacist and the physician were less than adequate to prevent potential mishaps that could occur due to a lack of knowledge concerning the potential side effects of the prescribed medication.

PROACT® Description

PROACT® is a methodology developed by Reliability Center, Inc. (RCI) to help users analyze their most important problems. The term PROACT® is an acronym for:

- PR - Preserving Failure Data
- O - Ordering the Analysis
- A - Analyzing the Data
- C - Communicating Findings and Recommendations
- T - Tracking for Results.

Executive Summary Recommendations

Root Cause	Type	Recommendation	Team Member	Estimated Completion Date	Completed
Pharmacist Unavailable when Prescription was Picked Up by Patient	Latent	Make sure that someone is available to brief the patient when the medication is given.	Unknown	10/21/2010	No
Pharmacist did not Completely Explain Side Effects	Latent	Make sure that someone is in the pharmacy to explain side effects of medications.	Unknown	10/21/2010	No
Normal Medication Side Effects	Physical	Make sure patient understands all the potential side effects of prescribed medications.	Unknown	10/21/2010	No
Physician Expects the Pharmacist to Explain Side Effects in Detail to Patient	Latent	Physician has a duty to warn their patient of any potential adverse drug reactions and should fully explain all the potential side effects of any medication prescribed to the patient.	Unknown	10/21/2010	No
No Pamphlet or Instruction Sheet Given with Prescription	Latent	Make sure that either the prescription label completely denotes possible adverse reactions to prescribed medications and when applicable a pamphlet or instruction sheet (package insert) is provided if needed.	Unknown	10/21/2010	No
Physician did not Completely Explain Side Effects	Latent	Physician to completely explain side effects of medications at the time they are prescribed and tell the patient to call when anything unusual or unexpected occurs.	Unknown	10/21/2010	No

Root Cause	Type	Recommendation	Team Member	Estimated Completion Date	Completed
No Pamphlet or Instruction Sheet Given with Prescription	Latent	Provide instructions sheets or information pamphlets for required medications.	Unknown	10/21/2010	No
List of Side Effects will not fit on Prescription Label	Latent	Provide an instruction sheet or information pamphlet for medications whose warnings and precautions can not fit on the prescription label.	Unknown	10/21/2010	No
Warning Label on Prescription Incomplete	Latent	Provide an instruction sheet or information pamphlet for medications whose warnings and precautions can not fit on the prescription label.	Unknown	10/21/2010	No

Detailed Recommendations

Root Cause	Type	Recommendation	Completed
Pharmacist Unavailable when Prescription was Picked Up by Patient	Latent		No
Pharmacist did not Completely Explain Side Effects	Latent	Make sure the patient is aware and completely understands the side effects of prescribed medications as detailed in the package insert or in other respected medical or pharmacology textbooks.	No
Normal Medication Side Effects	Physical		No
Physician Expects the Pharmacist to Explain Side Effects in Detail to Patient	Latent		No
No Pamphlet or Instruction Sheet Given with Prescription	Latent		No

Root Cause	Type	Recommendation	Completed
Physician did not Completely Explain Side Effects	Latent	<p>Clearly explain all the potential side effects of prescribed medications and point out the additional instructions and warning that may be contained in the package insert (pamphlet or instruction sheet) as well as respected medical or pharmacology textbooks. As minimum provide the following information:</p> <ol style="list-style-type: none"> 1. The name of the proposed treatment or procedure. 2. A description of any reasonably foreseeable material risks or discomforts (including the incidence or likelihood of occurrence, if known). 3. A description of the anticipated benefits. 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous. 5. Any foreseeable risks should the patient become pregnant. 6. Ask patient to repeat any special or critical instructions. 7. Ask the patient if he/she has any questions. 	No
No Pamphlet or Instruction Sheet Given with Prescription	Latent		No
List of Side Effects will not fit on Prescription Label	Latent		No
Warning Label on Prescription Incomplete	Latent		No