How to develop a CAPA (Corrective & Preventive Action)

Rose Ermete BSN, RN, OCN, CRN-BC, CCRP
Senior Quality Assurance Nurse Auditor

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What is your current position?

A. Data Management
B. Clinical Research Nurse
C. Regulatory Affairs
D. Quality Assurance
E. Administration
F. Other

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Have you ever developed a formal CAPA?

A. Yes, in current position
B. Yes, at another institution
C. No, I have not
D. What the heck is a CAPA

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Objectives:

- **Explain** – Explain the importance of a Corrective And Preventative Action Plan
- **Describe** – Describe the steps in developing a CAPA
- **Explain** – Explain the importance of measuring results

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Regulatory Documents

- 21CRF parts 50, 56, 312 & 812
- 21CFR part 820
- ICH E6 (Rev2) Guideline for GCP

2009: DHHS – Investigator Responsibilities, Guidance for Industry
2018 : E6(R2) Good Clinical Practice: Integrated addendum to Guidance for Industry
2018: Centerwatch- Expectations for Preventive Action GCP questions: FDA Answers

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Terms

Deficiency – Deviation/Violation from the protocol, regulations or institutional/sponsor policies.

Correction – action to eliminate a detected deficiency.

Corrective Action – Action to eliminate the cause of a deficiency and to prevent its recurrence.

Preventive action- action to eliminate the cause of a potential deficiency or other potential undesirable situation before it happens.

CAPA: A process aimed at correcting and preventing deficiencies from recurring or preventing it from ever occurring.

2015: ISO 9001
2016: Johns & Modi
2016: Lester

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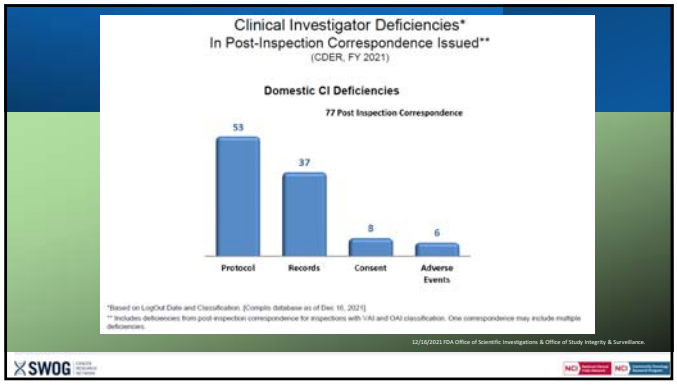
Clinical Investigator Deficiencies*
In Post-Inspection Correspondence Issued**
(CDER, FY 2021)
Domestic CI Deficiencies
77 Post Inspection Correspondence
53
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8
6
Protocol
Records
Consent
Adverse Events
12/16/2021 FDA Office of Scientific Investigations & Office of Study Integrity & Surveillance.
SWOG

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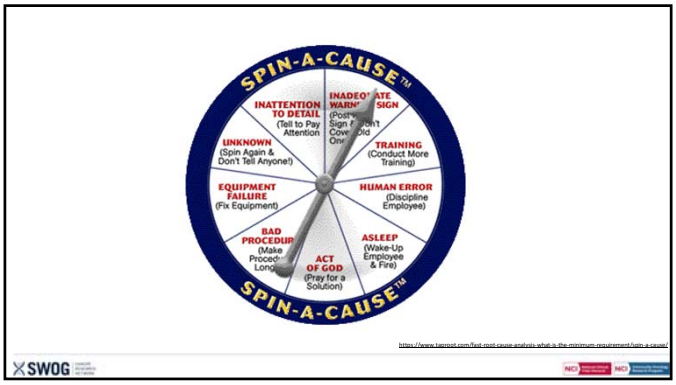
SPIN-A-CAUSE™
INATTENTION TO DETAIL (Tell to Pay Attention)
TRAINING (Conduct More Training)
HUMAN ERROR (Discipline Employee)
ASLEEP (Wake-Up Employee & Fire)
ACT OF GOD (Pray for a Solution)
EQUIPMENT FAILURE (Fix Equipment)
UNKNOWN (Spin Again & Don't Tell Anyone!)
SPIN-A-CAUSE™
SWOG

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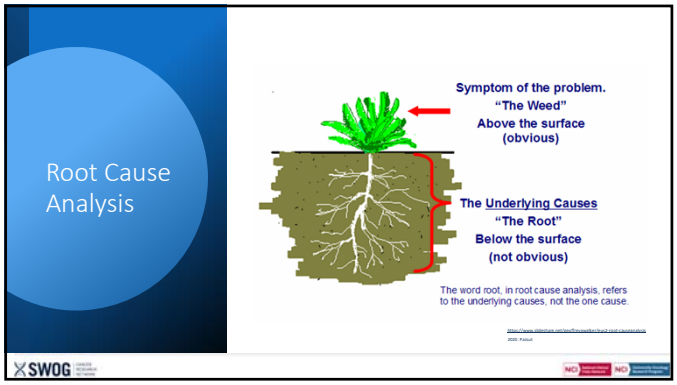
Root Cause Analysis
Symptom of the problem.
"The Weed"
Above the surface
(obvious)
The Underlying Causes
"The Root"
Below the surface
(not obvious)
The word root, in root cause analysis, refers to the underlying causes, not the one cause.
SWOG

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Basic Causes
Physical
Human
Organization
SWOG

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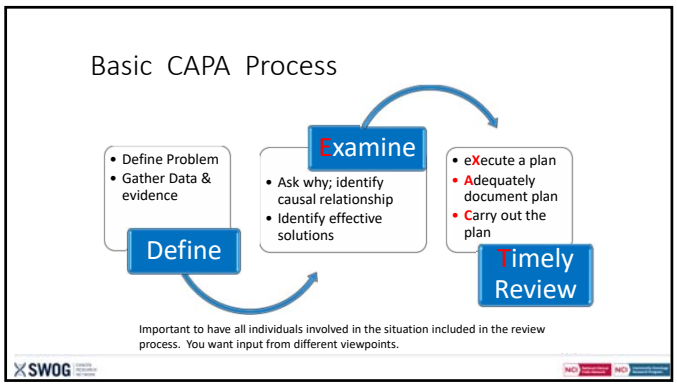
Basic CAPA Process
• Define Problem
• Gather Data & evidence
Define
Examine
• Ask why; identify causal relationship
• Identify effective solutions
• eXecute a plan
• Adequately document plan
• Carry out the plan
Timely Review
Important to have all individuals involved in the situation included in the review process. You want input from different viewpoints.
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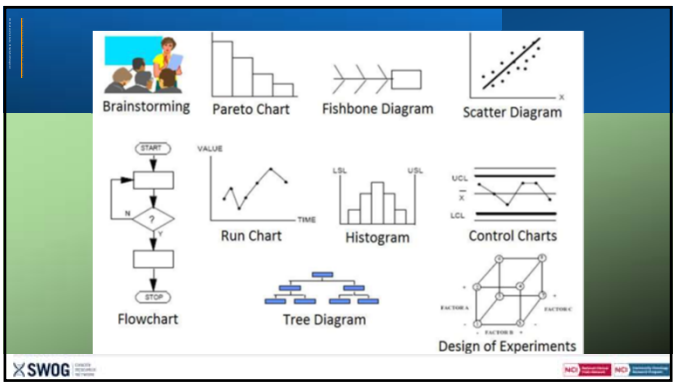
Brainstorming
Pareto Chart
Fishbone Diagram
Scatter Diagram
Run Chart
Histogram
Control Charts
Flowchart
Tree Diagram
Design of Experiments
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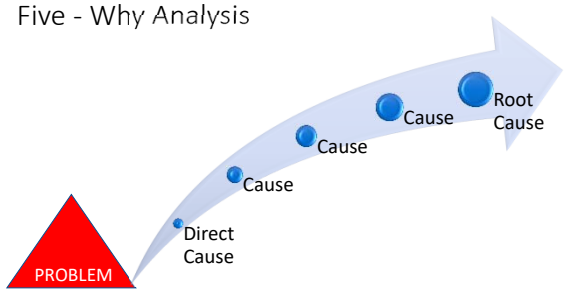
Five - Why Analysis



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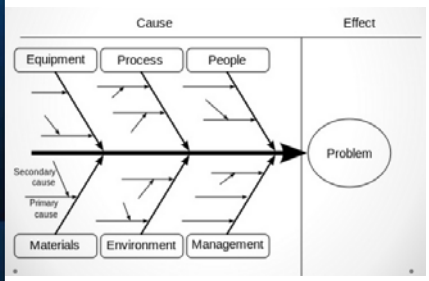
Fishbone Diagram



https://www.slideshare.net/geoffreywalker/eu2-root-causeanalysis
2016: Leister
2019: Nikityuk, Karamavrova & Lebedynets

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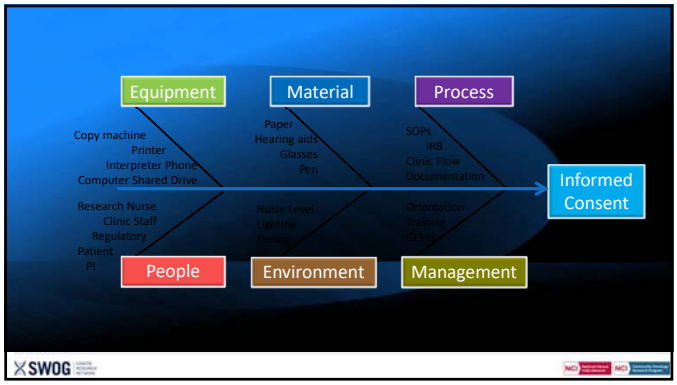

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The Preventative Action Plan

- Preventative actions focus on preventing future deviations based upon the root cause analysis.
- Single issue vs. multiple occurrences.
- Documentation

et. al
2019: Song, et. al.

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Drug infused over wrong time?

Who do you think should be on the team to evaluate the problem?

A. Infusion Nurse
B. Laboratory
C. Data Management
D. Research Nurse
E. PI
F. Pharmacy
G. All of the above
H. A, C, D, E & F

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Drug infused over wrong time?

What would be a good preventative action:

A. Re-educate the infusion nurses to always stop the drug at 30 minutes, whether or not it is finished.
B. Have all team members re-read the protocol.
C. The data manager will remain in the clinic during the infusion to assure it goes in over the correct time.
D. Have the pharmacy include the total volume on the infusion bag.
E. The PI will infuse the drug per protocol

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Evaluation

- What will be measured?
- What is an acceptable rate?
- How will it be measured?
- How often & for how long will it be measured?

2014: Singleton, DeBastiani, Rose, Kahn

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Documentation Example

https://www.iacrn.org/Templates-documents
https://www.smartsheet.com/corrective-and-preventive-action
https://safetyculture.com/checklists/capa-report/

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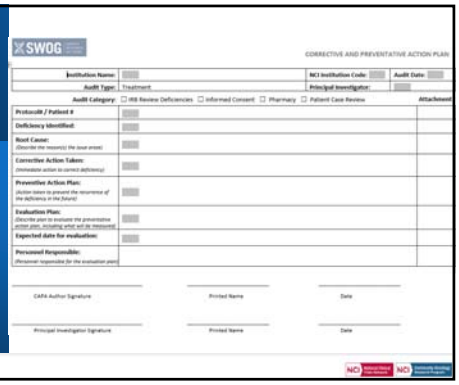
Documentation Example



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"Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it."

— H. James Harrington

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