What Went Wrong and How To Fix It

(AKA Conducting a Root Cause Analysis and Creating an Effective CAPA Plan)

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Objectives

- Define RCA and CAPA
- Identify different types of RCA
- Recognize an effective CAPA plan

What is a Root Cause Analysis (RCA)?

- A systematic method of problem solving used for identifying the origin of an issue leading to noncompliance
- It usually takes a team to conduct
- Outcome is usually process related

How is an RCA used in Clinical Trials?

- Determines where in a process a breakdown has occurred leading to noncompliance with regulations:
  - Federal
  - State
  - Local
  - Institutional

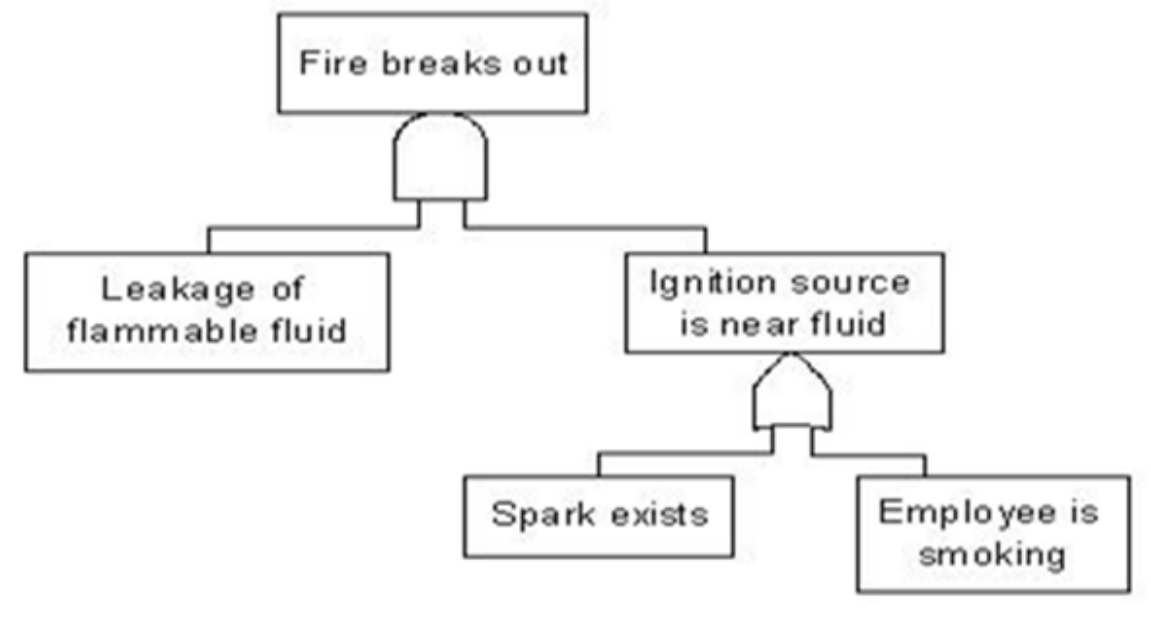
How Can an RCA Help Me?

- Conducting an RCA can help to drill down and find the most basic reason for the failure in the process allowing for an understanding of where/what in the process should be changed

- An RCA is also helpful in creating a plan to correct the issue and to prevent future occurrences (CAPA plan)

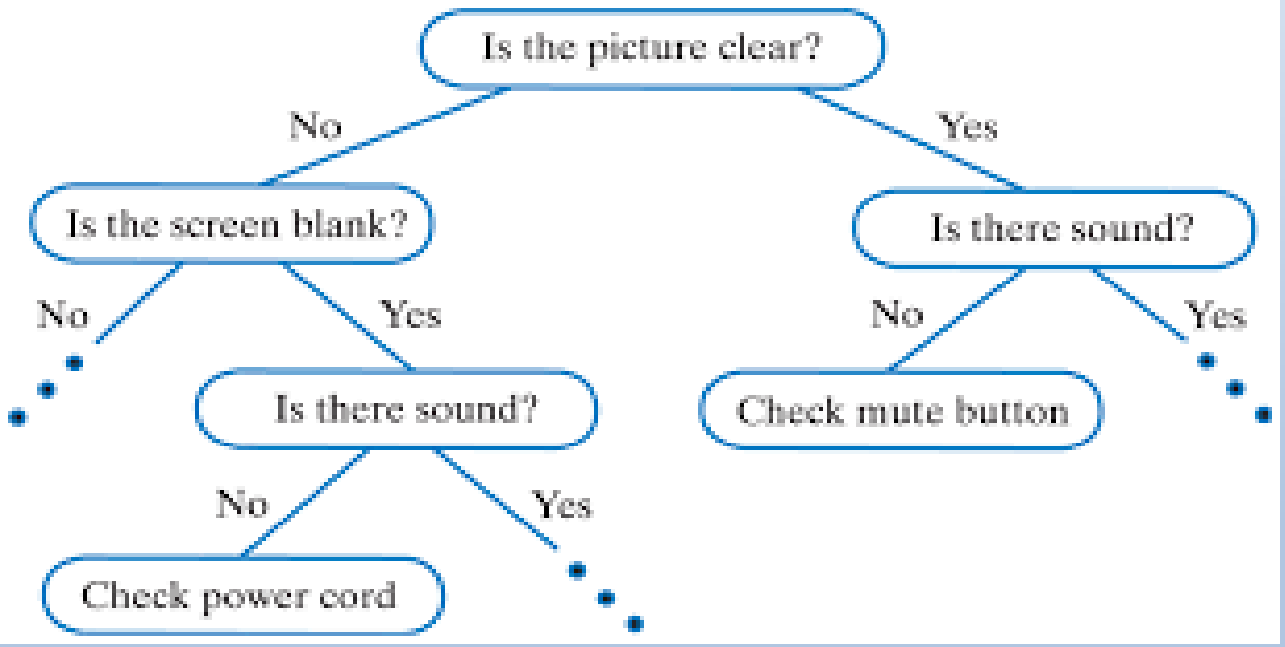
Methods of Conducting an RCA

- Causal Tree



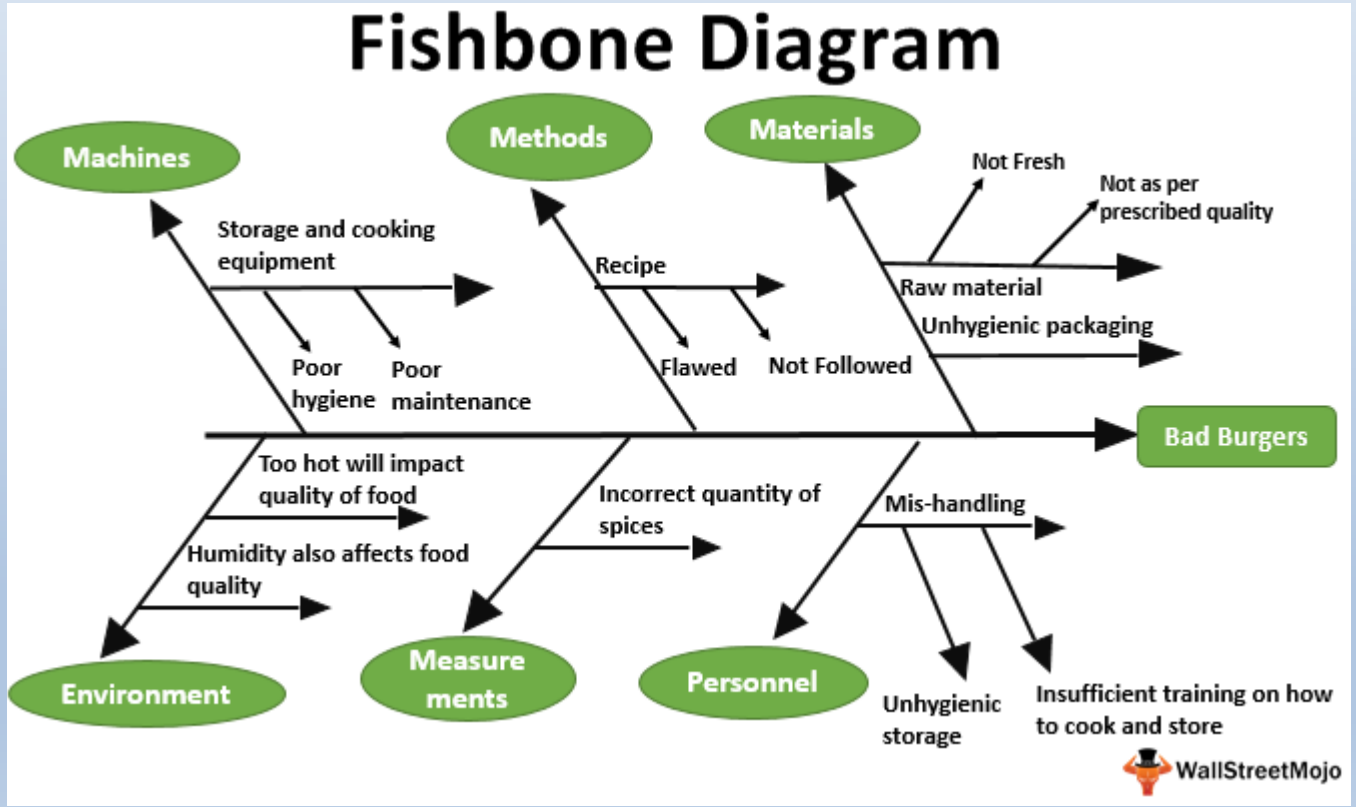
Methods of Conducting an RCA

- Decision Tree



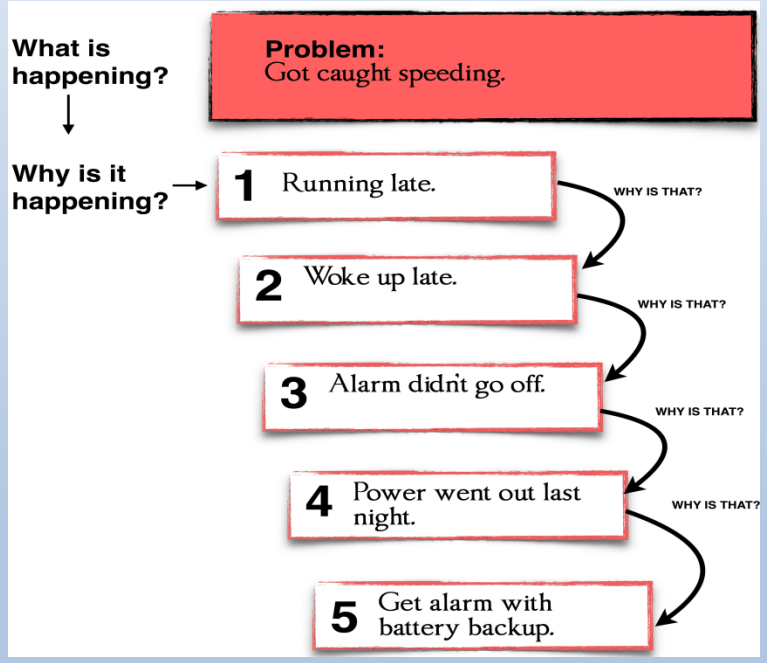
Methods of Conducting an RCA

- Fishbone Diagram



Methods of Conducting an RCA

- 5 Whys



What Might an RCA look like for a Clinical Trial?

Event:

- A protocol amendment (#1) was received by the site on March 1, 2019, but was never submitted to the IRB. This amendment had changes to the informed consent document, which included new risk information and was provided in the form of an addendum for previously enrolled subjects.

- An additional protocol amendment (#2) was received by the site on September 1, 2019 and also had changes to the consent document; again via an addendum, which included additional procedures to be conducted during the protocol. This protocol amendment was received by the IRB and was approved on September 30, 2019.

What Went Wrong???

- Previously enrolled subjects signed the 2nd addendum, but never signed the 1st addendum.

- Previously enrolled subjects were not made aware of new information (risks) that might affect their willingness to continue to participate in the trial.

Using the 5 Why's to Determine the Root Cause of this Event

- 1st Why: Why wasn't the protocol amendment #1 submitted to the IRB for review/approval?

- Answer: It was never received by the person on the research staff responsible for submitting information to the IRB

- 2nd Why: Why didn't that person receive the protocol amendment?

- Answer: The document was sent to the SC by the sponsor who then forwarded the email to the responsible team member
- However, the SC did not know that person was out on an extended leave of absence and his/her duties were reassigned to a different person .

3rd Why

- Why didn't the SC follow up with the responsible person?

- Answer: the process in place at the time of the event was to email any new information related to that protocol to a specific person.

4th Why

- Why didn’t the SC know that person was out on leave?

- Answer: There was no communication to the research staff informing them of the changes in personnel.

5th Why

- Why wasn't there any communication by management to the staff regarding the change in personnel?

- Answer: There wasn't a process in place to address changes to study personnel.

Root Cause

- The root cause of this event, based on the prior questions, is:

There is no formal process to inform research staff of changes to workflow/study personnel.

There can be multiple root causes for a noncompliance issue

- A different set of questions for the event could start with:
  - Why didn't the SC realize an approved addendum with the relevant information was never given back so subjects could be consented?
  - Why didn't a monitor pick up on the absence of subjects' signed addendums in the study record?
  - Why didn't the responsible person have an out of office message indicating who should be contacted in their absence?

Corrective and Preventive Action Plan (CAPA)

- Created based on the outcome of the RCA
- Helpful to have quantifiable actions
  - Training – can measure how many were trained prior to "go live" on the SOP
- Have a clear and complete path forward –
  - i.e., revise the SOP, but also need to have training completed for those involved and then an effective date for the SOP

- Include an expected completion date for each item associated with the CAPA
- Assign a responsible party (not necessarily the person/team making the changes)
- Review for effectiveness – is there still an issue with subjects not having new information that may affect their willingness to continue participation
- Close out

Considerations

- K.I.S.S.

- Determine prior to the RCA whether or not it was just a “one off”
  - the situation only happened once
    - keep in mind the severity of the situation – even though it’s a “one off,” may still need an RCA/CAPA plan

CAPA

Example of CAPA for the previous RCA:

Corrective Action – submit Amendment 1 and associated consent addendum to the IRB ASAP (include a date!)

Preventive Action –

- create/revise the SOP related to submission of documents to the IRB to be completed by XX/XX/XXXX.
- include a requirement that everyone must have an out of office message with information on who should be contacted in their absence
- Retrain all pertinent staff on the new/revised SOP by XX/XXX/XXXX. New/revised SOP will then become effective on XX/XX/XXXX

Wrap Up

- The majority of root causes most likely are attributed to a break down in a process; NOT an individual
- An RCA is a step by step process and should involve management and staff who have direct knowledge of the process being discussed
- The CAPA should be reflective of the root cause
- Keep in mind that you may not be able correct the problem, but you can prevent/mitigate future occurrences
- The OCT CTQA Program staff is available to assist with initiating and conducting a root cause analysis and helping to develop a CAPA plan

Thank you!