WHEN IT ALL GOES WRONG…
Root Cause Analysis Workshop

HCCA™
Health Care Compliance Association

2019 Healthcare Enforcement Compliance Conference

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OBJECTIVES

- **Where do we start when it all goes wrong**
- **Who, What, Where, When, Why & How**
- **What to do with the final answer**

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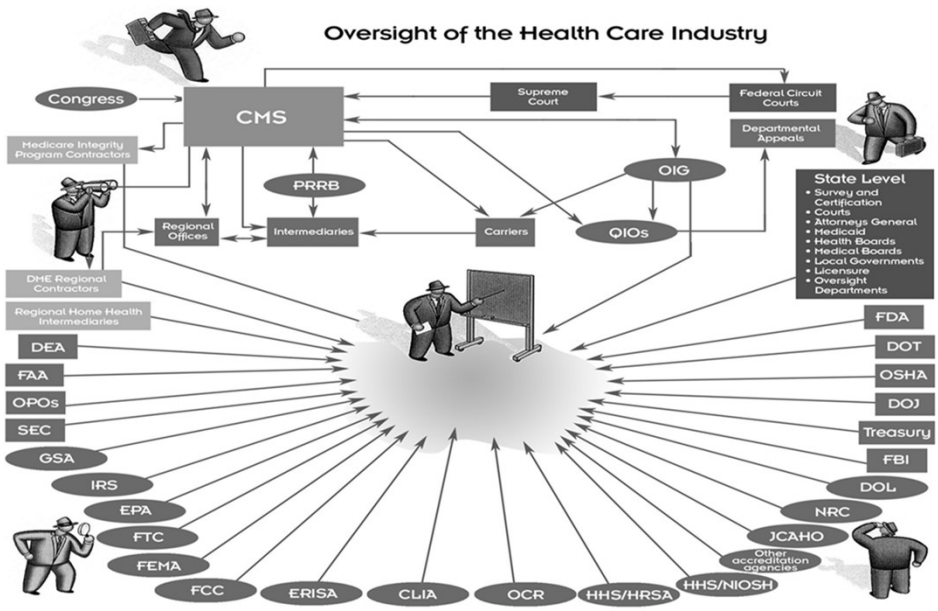
WHO CARES



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WHY

U.S. Department of Justice
Evaluation of Corporate Compliance Programs
(Updated April 2019)

- "A hallmark of an effective compliance program that is working effectively in practice is the extent to which a company is able to conduct a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address root causes."

- "to receive full credit for timely and appropriate remediation" under the FCPA Corporate Enforcement Policy, a company should demonstrate "a root cause analysis" and, where appropriate, "remediation to address the root causes"

https://www.justice.gov/criminal-fraud/page/file/937501/download at p. 16.

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ANALYSIS AND REMEDIATION OF UNDERLYING MISCONDUCT

- **ROOT CAUSE ANALYSIS –** What is the company's root cause analysis of the misconduct at issue? Were any systemic issues identified? Who in the company was involved in making the analysis?
- **PRIOR WEAKNESSES –** What controls failed? If policies or procedures should have prohibited the misconduct, were they effectively implemented, and have functions that had ownership of these policies and procedures been held accountable?
- **PAYMENT SYSTEMS –** How was the misconduct in question funded (e.g., purchase orders, employee reimbursements, discounts, petty cash)? What processes could have prevented or detected improper access to these funds? Have those processes been improved?
- **VENDOR MANAGEMENT –** If vendors were involved in the misconduct, what was the process for vendor selection and did the vendor undergo that process?
- **PRIOR INDICATIONS –** Were there prior opportunities to detect the misconduct in question, such as audit reports identifying relevant control failures or allegations, complaints, or investigations? What is the company's analysis of why such opportunities were missed?
- **REMEDIATION –** What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future? What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?
- **ACCOUNTABILITY –** What disciplinary actions did the company take in response to the misconduct and were they timely? Were managers held accountable for misconduct that occurred under their supervision? Did the company consider disciplinary actions for failures in supervision? What is the company's record (e.g., number and types of disciplinary actions) on employee discipline relating to the types of conduct at issue? Has the company ever terminated or otherwise disciplined anyone (reduced or eliminated bonuses, issued a warning letter, etc.) for the type of misconduct at issue?

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WHAT

Root Cause Analysis (RCA)

is a method of problem solving used for identifying the root causes of faults or problems. A factor is considered a root cause if **removal** thereof from the problem-fault-sequence **prevents** the final **undesirable event from recurring; whereas a causal factor is one that affects an event's outcome, but is not a root cause.** Though removing a causal factor can benefit an outcome, it does not prevent its recurrence with certainty.

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Investigation

(Fact Finding)

RCA

(Cause)

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PROCESS

- WHO • Why
- WHAT • Why
- WHERE • Why
- WHEN • Why
- WHY • Why
- HOW • Why

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RCA STEPS

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CHARTER

- **What is an RCA?**
- **What is the role of the RCA team?**
- **Who is on the Base Team?**
- **Process for identifying additional team members?**
- **What is the size of the team?**
- **How to determine facilitator?**

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BASE TEAM

- **Compliance**
- **Risk Management**
- **Legal Counsel (attorney client privilege)**
- **Quality**
- **Administration Representative**
- **Chief Medical Officer**

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SELECT THE EVENT TO BE INVESTIGATED AND GATHER PRELIMINARY INFORMATION

- **Gather documents (investigation report, hotline, policies, ect.)**
- **Start with problem not solution**
- **What went wrong not why or how**
- **Focus on process/system**

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SELECT TEAM FACILITATOR AND TEAM MEMBERS

- **Base team**
- **Charter**
  - **review with full team**
- **Identify facilitator**
- **Members determined by problem (personal knowledge of the problem)**

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PRELIMINARY STEPS

- **Describe What Should Have Happened**
  - **Existing Policy, Procedure, SOP**
  - **Existing Unwritten Process**
- **Describe What Actually Happened**
  - **Document the Timeline of Events**
  - **Be Complete**
  - **Don't Skip Steps**

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What Expected Steps did not Occur?

- Why?
- Outdated Policy/Procedure/SOP/Process?

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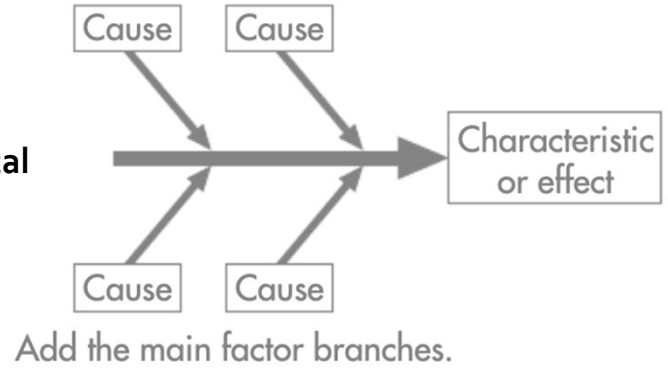
DETERMINE POTENTIAL CAUSES BASED ON WHAT HAPPENED

- **Human Factors?**
  - **Failure to follow policy/procedure?**
  - **Trust?**
- **Controllable Environmental Factors?**
  - **Security**
- **Other Factors**
  - **Lack of Adequate Controls**



https://www.researchgate.net/publication/42831418_Root_Cause_Analysis_A_Framework_for_Tool_Selection

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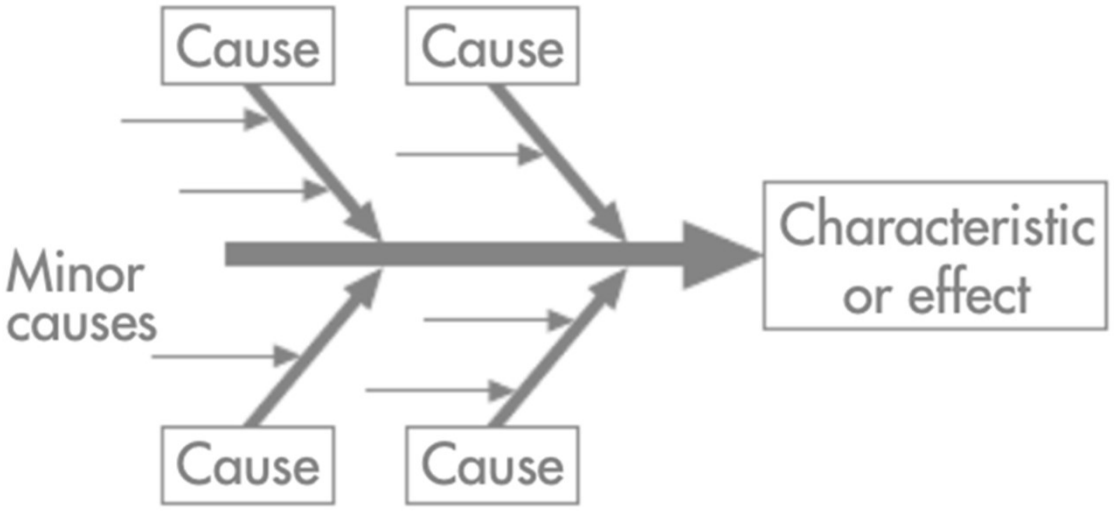
IDENTIFY ADDITIONAL CONTRIBUTING FACTORS



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IDENTIFY THE ROOT CAUSES

- **Why? Why? Why?**
- **All incidents have a direct cause**
- **Cause versus contributing factor**
- **Ask**
  - **Would the event have occurred if this cause had not been present**
  - **Will the problem recur if this cause is corrected or eliminated**
  - **To what extent does the organization's culture support compliance risk reduction?**
  - **What communication barriers exist to communiating compliance concerns?**
- **Don't judge individuals**
- **Frank and open discussion of cause and event**

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DESIGN AND IMPLEMENT CHANGES TO ELIMINATE TO ROOT CAUSES

- **Evaluate each root cause**
  - **Choose action(s) to address each identified root cause**
  - **Develop a measure of success**
    - **How will you know if your action is working?**
- **Short term solutions**
  - **Fix contributing factor**
  - **Rarely fix the cause**

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MEASURE THE SUCCESS OF CHANGES

- **Did corrective action get implemented timely**
- **Has education been provided**
- **Are people complying with changes**
- **Have changes made a difference**
- **Measure over time**
- **Confident change is permanent**

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CORRECTIVE ACTIONS

Root Cause	Corrective Action(s)	Responsible Individual/Group	Completion Deadline	Measure of Success	Re-Audit Timeline

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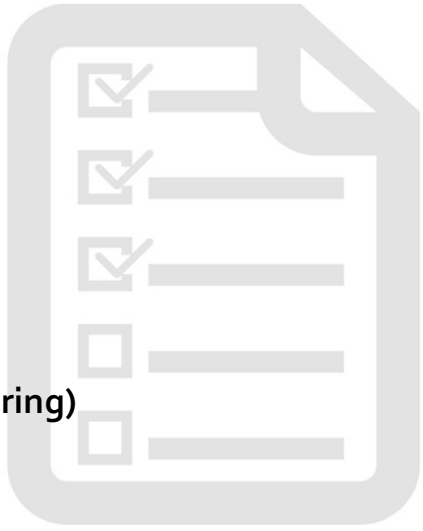
SUMMARY

- **Selective in events for RCA**
- **Base team vs. RCA team**
- **Timeline of event**
- **Root causes**
- **Corrective actions**
- **Measuring success (auditing/monitoring)**
- **Why, Why, Why, Why, Why, etc.**



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QUESTIONS
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