THE PEW CHARITABLE TRUSTS

A Guide for Conducting Food Safety Root Cause Analysis

AFDO

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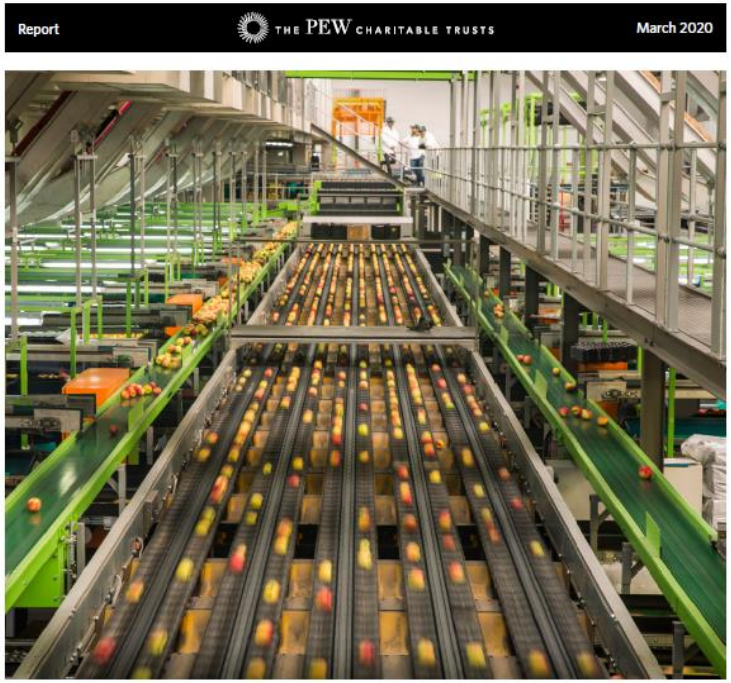

https://www.pewtrusts.org/en/research-and-analysis/reports/2020/03/a-guide-for-conducting-a-food-safety-root-cause-analysis

Presentation Outline

- Pew's Root Cause Analysis (RCA) Initiative
- Approach to RCA guide
- Guide content

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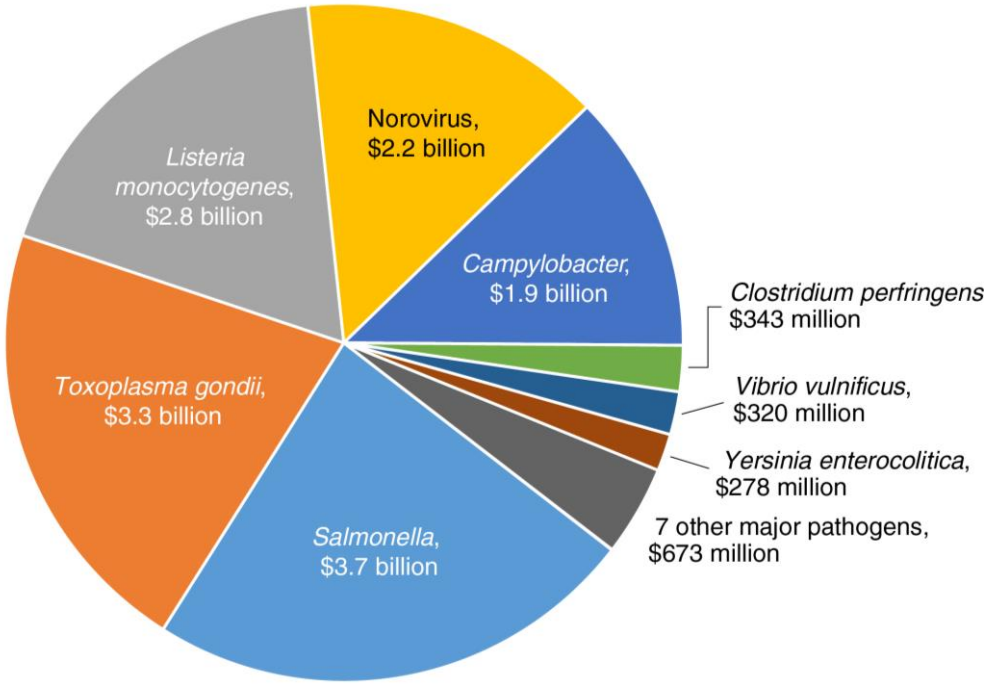
Burden of foodborne illness

Estimated yearly cost of illnesses

- 15 major foodborne pathogens cost the U.S. economy $15.5 billion per year in medical care, lost time from work, and losses due to premature death.



Source: USDA, Economic Research Service, Cost of Estimates of Foodborne Illnesses data product. https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=88113.

Why is RCA a priority for Pew

- Foundation of a prevention-based food system
  - But it's underutilized, ineffectively shared, lost opportunities
- Improvements require collaborative approach
- Better alignment among FDA, CDC, FSIS, state & local gov, industry would lead to improved public health

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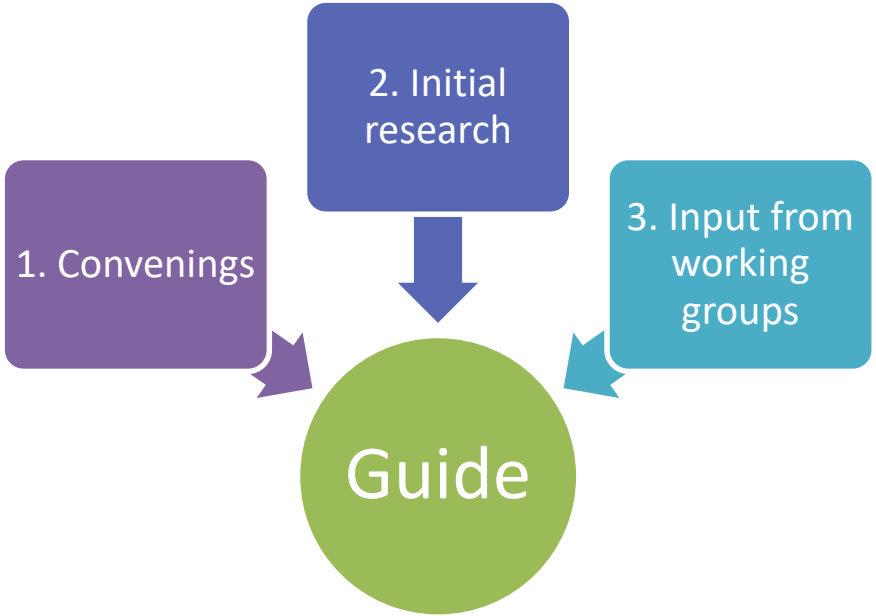
Guide information sources



Guide information sources

1. Key topics discussed in Convenings
   - What is an RCA
   - Considerations before conducting an RCA
   - How should an RCA be conducted
   - How should findings be communicated

Became structure for the guide →

Guide information sources

2. Initial research questions
   - How are other organizations conducting RCA?
     - How do they decide when to conduct a RCA?
     - How do they perform the RCA?
   - How are the key findings disseminated and used?
   - What is working & what is not?

Audience

- Food industry; federal, state, local food safety agencies; trade and professional associations; academia; consulting companies
  - Practitioners
  - Managers/leadership
- Varying backgrounds, experience, food settings

Goals

- Convince organizations to conduct RCAs
- Improve conduct of RCAs
- Improve reporting and communication of RCA findings

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Guide content

Introduction	Approaches for RCAs	Conclusions & next steps	Resources
• Examples from other sectors • Value for food safety • Challenges	• What is RCA • Prepare for RCAs • Conduct RCAs • Report findings and conclusions	• Develop plans and allocate funds for future RCAs • Reporting system	• Training, RCA courses • Guidance, manuals, toolkits from other sources

I. Introduction

- Purpose
  - Improve food safety by encouraging the use of RCA in food operations
- Suggested usage: Template & reference for developing RCA practices and procedures
  - Plan RCAs
  - Ensure process includes steps essential to finding root causes
  - Design corrective actions that will prevent recurrence

I. Introduction

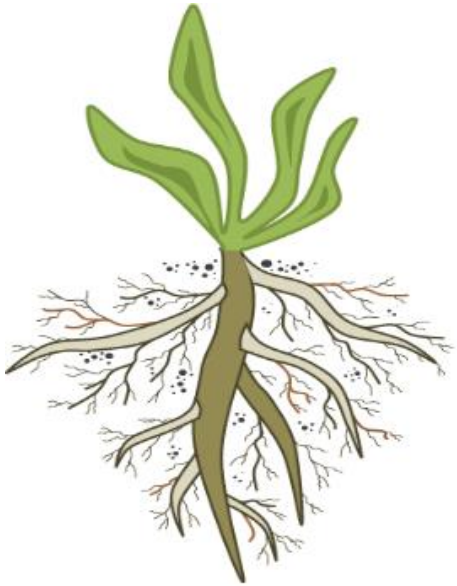
- History in other industries
  - Car industry: Taiichi Ohno credited with development in 1950s
  - Space flight
  - Civil aviation
  - Oil & gas
  - Patient safety
  - Recreational diving
- Modern food safety and associated challenges

Example: Patient Safety

- Data sharing & communication
  - U.S. Department of Veterans Affairs (VA) National Center for Patient Safety
    - Developed and mandated RCA process
    - Maintains Patient Safety Information System – database of RCAs
  - Enables analysis of RCA's impact
    - Study found postoperative complications higher at VA medical centers that performed fewer RCAs

II. What is a root cause analysis?

- Retrospective investigation used to identify why a problem occurred
  - Environmental assessment = RCA
- Contributing factor vs. Root cause
  - WHAT happened vs. WHY it happened
- When, where, who for different food settings



Example: Processed Food

→Item is re-contaminated after heat treatment and enters the market

- Contributing factors:
  - Machine corrosion from improper cleaning
  - Product not monitored post-processing
- Root causes:
  - Lack of defined maintenance SOPs
  - Unable to hire adequately trained staff

III. What should be considered before conducting an RCA?

- How should the scale be determined?
- Is sufficient capacity available?
- How long should it take?

Example: National Transportation Safety Board

- Scaling an accident investigation
  1. Accident notification
  2. “Go Team” composition based on
     - Number of injuries & fatalities
     - Location
     - Public interest
     - Magnitude of tasks
     - Previous accidents of same type

NTSB 2002

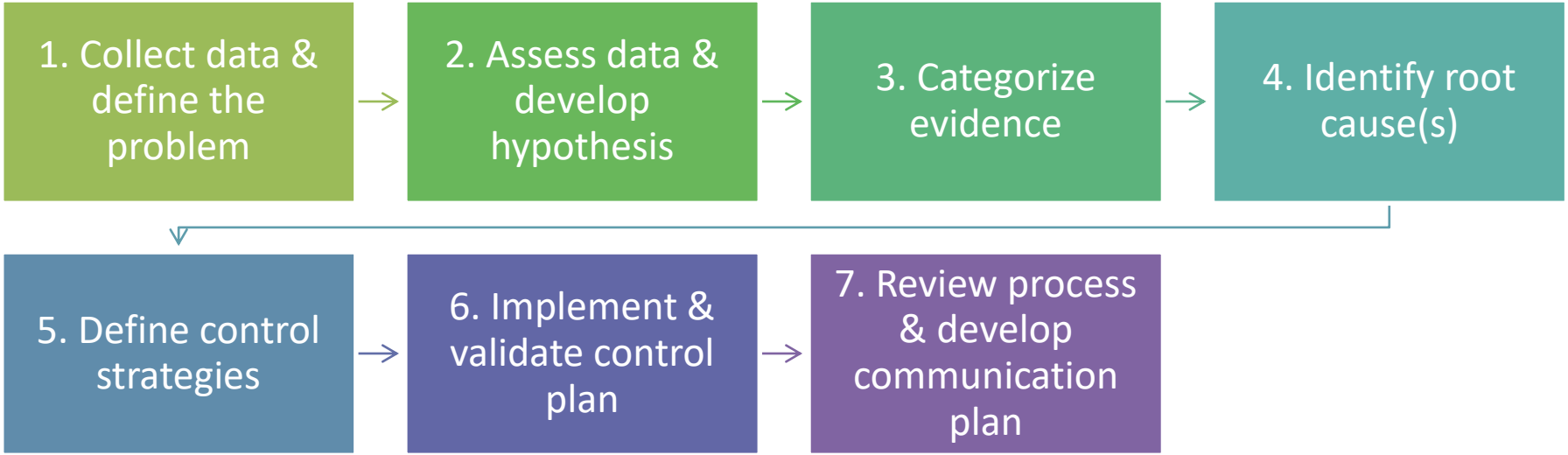
RCA capacity

- Assess current capacity to conduct RCAs and need for capacity development
  - For organization and individual investigators
- Identify core team members, technical expertise appropriate for RCA scope and tasks

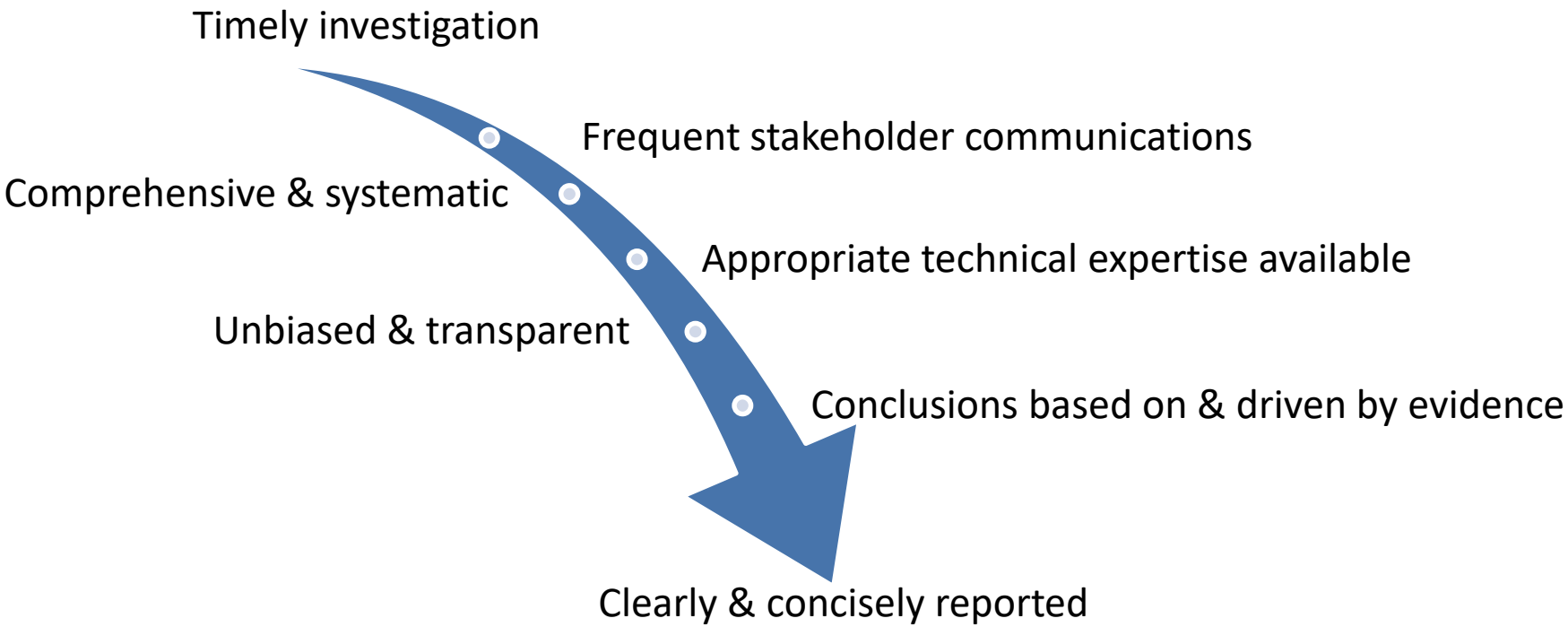
IV. How is an RCA conducted?

- What happens before the investigation begins?
- Steps for conducting RCA
- How do you know you've found a root cause?
- How can changes be maintained?
- What if you can't find a root cause?

General steps for conducting RCAs

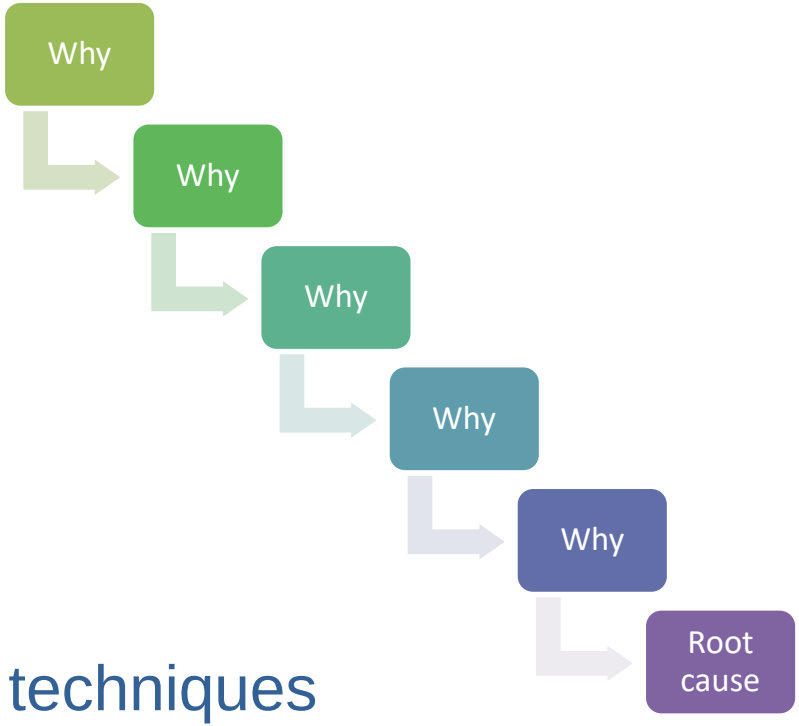


Characteristics of effective RCAs



Tools

- Cause & effect diagrams
  - Fishbone/Ishikawa
  - Fault tree
- KNOT chart
  - Classify evidence
- 5 whys
  - Very simple, use with other techniques

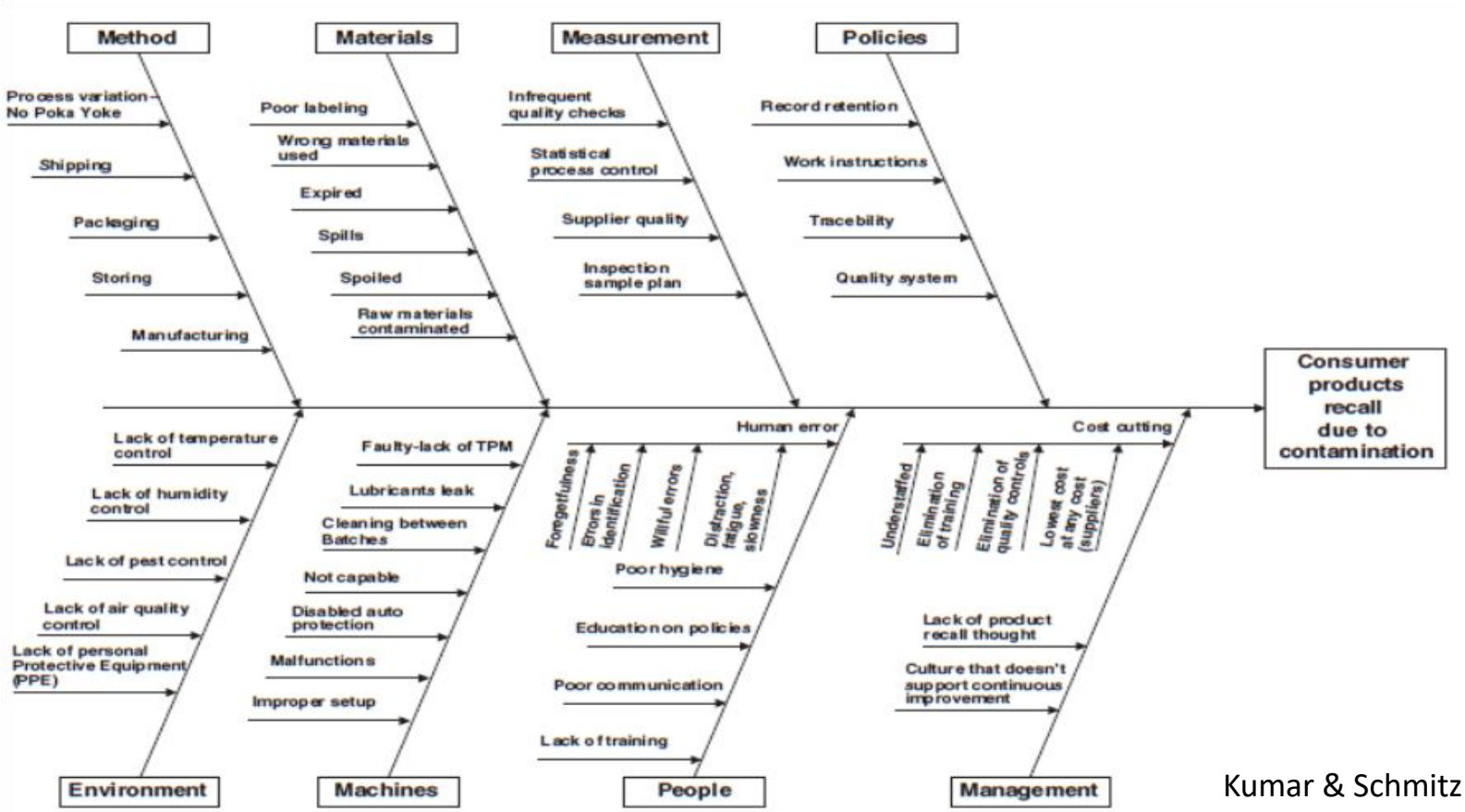


Tools: Drive investigation decision-making

	Specific Data Item	Know	Need to know	Opinion	Think we know	Action
D1	80% Humidity and Temperature of 84 degrees F at 2:00 PM	X				
D2	Belt Speed on the machine *appeared* to be slower than usual			X		Locate and interview other witnesses
D3	Operator said she was having a difficult time cleaning the contacts			X		Locate and interview other witnesses
D4	Press Head speed was set at 4500 rpm				X	Verify by review of Press Head logs
D5	Oily Substance on the floor?		X			Interview Cleaning Crew
D6						

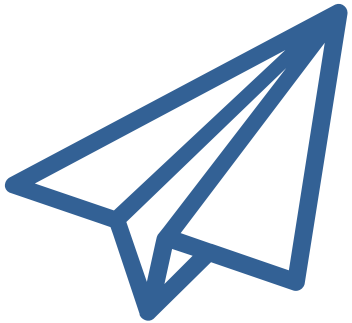
Duphily 2014

Tools: Ensure basic categories of causes are considered



Kumar & Schmitz 2011

V. How should findings from an RCA be communicated?



- Report sharing
  - Academic institutions
  - Industry associations
  - Government networks
- Education and training
- Policy action

VI. Conclusions & next steps

- Need mechanisms and platforms to share relevant lessons learned
  - E.g., confidential, nonpunitive reporting systems
  - Aviation Safety Reporting System, VA Patient Safety Information System
- RCA fosters food safety culture

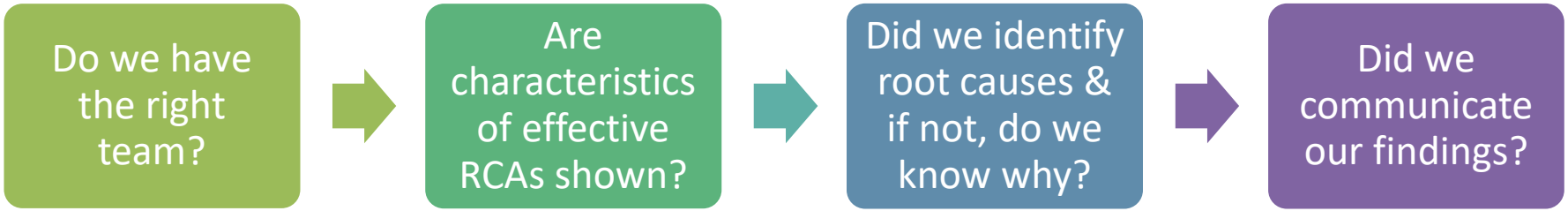
Challenges for Food Safety RCAs

Finding root causes more difficult as time passes	Product factors, closed facilities vs. open facilities	Consumer behavior & individual susceptibilities	Cross-contamination

- Corrective actions can still be designed with incomplete information
  - May be broad in scope & more expensive, but necessary for prevention
  - Every investigation is a learning opportunity, still have actionable findings

Final thoughts

- Need to improve weaknesses in food safety systems
  - RCA makes good business sense
- Provide guidance, gauge progress



- Highlight existing resources & provide value without duplicating efforts

Thank You!

Questions?

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Resources

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