When Things Go Wrong: Causes, Cures and Prevention

Sally Thompson-Iritani, DVM, PhD, CPIA, CCFP, CHABP
Director, Animal Welfare and Research Support
Associate Director, Washington National Primate Research Center

Kamm Prongay, DVM, MCR, DABVP
Head, Resources & Logistics, Department of Comparative Medicine
Oregon National Primate Research Center
It's human to make mistakes and some of us are more human than others.

— Ashleigh Brilliant —
I wake up in the morning with a plan to make lots of mistakes!!
When things go wrong....

• Root Cause Analysis
• Incident Response Tracking
• Good Catch initiatives
• Supporting personnel
Normal accidents and HRO’s

A highly reliable organization (HRO) “....an organization that has succeeded in avoiding catastrophes in an environment where normal accidents can be expected due risk factors and complexity.”
Each of these layers has inherent vulnerabilities which, when aligned, may lead to undesirable outcomes.
Root Cause Analysis - The Concept

The Weed

Problem
Above the surface, obvious

Source
Below the surface, obscured

- Contributing factors
- Underlying issues
- Drill down
- Root out
- Dig into

Copyright 2018 ThinkReliability
Root Cause Analysis (RCA): a systematic retrospective process for identifying factors that contribute to adverse events or near misses.
- Knowledgeable team investigates what/why/how
- Analysis focused on systems and processes
- Identifies system weaknesses that allowed the error
- Change/modify system and process to prevent reoccurrence.

**Event, hazard, system vulnerability**

**What happened?**
- What, when, and where did the event happen?
- Who was involved?
- Isolated occurrence or pattern?
- What are the consequences of the event?

*Key Point: fact finding, through interviews and document reviews.*

**Evaluate severity & probability of occurrence**
- Use pre-established, risk-based prioritization
- High risk = invest in RCA
- Low risk = evaluate processes and refine using less formal pathways

*Key Point: not all errors need an RCA.*

**Identify all the causes**
- Brainstorm all possible causes
- Build a process map: what happened before and after? What was supposed to happen?
- Environmental factors and influences
- Categorize all possible causes

*Key Point: be patient and systematic*

**Identify the Root Cause: Ask 5 Why’s**
- Write down the starting point
- Ask “why did this occur?”
- The first answer is usually a proximal cause, a cause leading to the root cause
- Keep asking “why” until no new answer

*Key Point: don’t declare victory too soon.*

**Find solutions and implement**
- Explore options, working from weak (policy change) to medium (redundancy, software change), and stronger (facility modification)
- Review with stakeholders
- Develop an implementation plan (who, what, when)

*Key Point: implement at least 1 medium or strong solution*

**Measure and assess**
- Each solution implemented should have measurable outcomes
- Outcomes should be reported to all stakeholders
- If outcome poor, what further effort is needed?

*Key Point: refine solutions using feedback*
Root Cause Analysis-Concept and Process

Evaluate severity & probability of occurrence

- Use pre-established, risk-based prioritization
- High risk = invest in RCA
- Low risk = evaluate processes and refine using less formal pathways

Key Point: not all errors need an RCA.
The Safety Assessment Code (SAC) Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Occasional</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Uncommon</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Remote</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Root Cause Analysis-Concept and Process

What happened?
• What, when, and where did the event happen?
• Who was involved?
• Isolated occurrence or pattern?
• What are the consequences of the event?

Key Point: fact finding, through interviews and document reviews.
Collect and Evaluate Physical Evidence and Documents

Including

• IACUC Protocol
• Medical Records
• Training Records
• SOP’s
• Room Logs
• Photographs
Interviews
Root Cause Analysis-Concept and Process

Identify all the causes
• Brainstorm all possible causes
• Build a process map; what happened before and after? What was supposed to happen?
• Environmental factors and influences
• Categorize all possible causes

Key Point: be patient and systematic
Introducing the Ishikawa Fish
Identify the Root Cause: Ask 5 Why’s

- Write down the starting point
- Ask “why did this occur?”
- The first answer is usually a proximal cause, a cause leading to the root cause
- Keep asking “why” until no new answer

Key Point: don’t declare victory too soon.
Problem: Baboon on a walkabout
Root Cause Analysis-Concept and Process

Find solutions and implement
• Explore options, working from weak (policy change) to medium (redundancy, software change), and stronger (facility modification)
• Review with stakeholders
• Develop an implementation plan (who, what, when)

Key Point: implement at least 1 medium or strong solution
Root Cause Analysis-Concept and Process

Measure and assess
• Each solution implemented should have measurable outcomes
• Outcomes should be reported to all stakeholders
• If outcome poor, what further effort is needed?

Key Point: refine solutions using feedback
Incident Response Tracking
Incident Reports

- Formalized reporting procedure utilized after every incident/error involving NHP, includes:
  - **Document** event and immediate post event response on “WNPRC Incident Report” forms
    - Person(s) directly involved in the incident
    - Supervisor
    - Compliance Coordinator
    - AV/clinical veterinary staff
  - Sets stage for post-incident response
    - **Inform** appropriate entities (e.g., AV, PI, IACUC, OLAW, USDA)
    - **Examine** incidents thoroughly to determine cause
    - **Initiate** preventive actions
    - **Retrain** individuals/groups
    - **Compile** data on type and frequency of events and personnel committing errors
Retraining Procedure

- Retraining is provided by our training coordinator and/or supervisor of individual(s)
  - Incident is thoroughly reviewed with the staff member(s)
  - Retraining is provided with reference to relevant SOPs and suggestions are made to prevent similar incidences in the future
  - Retraining session informs management staff about:
    - **Competency** level of individuals involved in incident and level of retraining required
    - **Changes** that may be necessary in animal area
    - **Equipment** that needs repaired
    - **Improvements** needed in training program
    - **Changes** that need to be made in SOPs
Incident Prevention Committee

- Instituted in 2013
- Consists of members from Compliance, Safety, Training, PI staff, SPI, Veterinary, and HR staff
- Meets monthly to discuss recent incidents
- Makes recommendations to modify policies, procedures, equipment, and animal area to prevent recurrence of similar incidents
- Monitors progress/success of implemented solutions
- Evaluates statistics
  - Who is making errors
  - What is experience level of personnel making errors
  - What types of errors recur

<table>
<thead>
<tr>
<th>Type of Incident</th>
<th># of Incidents</th>
<th>Suggested resolutions to minimize incident reoccurrence</th>
<th>Status of suggested resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong blood tube type used or requested</td>
<td>13</td>
<td>1. Double check tube type and volume before proceeding. Recommendations for double checking are: read schedule immediately before the procedure, double check by someone else, verbal verification of what the schedule indicates (i.e., read out loud from the schedule vs. ‘yes’).</td>
<td>1. Always</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Read blood draw schedule thoroughly and in advance to ensure the proper blood tubes are in supply and available when needed.</td>
<td>2. Always</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Ask for clarification when a blood tube type is requested but not commonly used (don’t make assumptions).</td>
<td>3. Always</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Color code the procedure sheet used for PEs/tb testing so the column color matches the tube type color.</td>
<td>4. This is being done.</td>
</tr>
</tbody>
</table>

Incident Report Statistics – 2017

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th># of Procedures Performed</th>
<th># of Animals Involved in Errors</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood draws</td>
<td>24,297</td>
<td>14</td>
<td>0.06%</td>
</tr>
<tr>
<td>Food deprivens</td>
<td>2,368</td>
<td>43</td>
<td>1.82%</td>
</tr>
<tr>
<td>Treatments</td>
<td>* 273,448</td>
<td>49</td>
<td>0.02%</td>
</tr>
</tbody>
</table>

*This number includes all treatments prescribed by veterinary staff or requested by research staff including the provision of hormones, research compounds, and supplemental food. It also includes the provision of water to animals that are on water control and the placement of extra enrichment devices that were requested by Behavior Management.*
Incident Review

- Retraining session with staff involved in incident
- Incident Prevention Committee meetings
- Unit meetings
- PI lab meetings
- Animal Services Division staff meetings
- IACUC meetings
- USDA inspections
Good Catch Initiative
• Adopted/adapted as a result of meetings with UW Hospital Q/A Unit
• Inspires a proactive approach to problem solving
• Focused on prevention
• Reminds WNPRC staff that they play an important role in the Center mission and that their input is valued
SUPPORTING PERSONNEL
INTERACTION AND OVERSIGHT

Research Animal

- Numerous interactions throughout its life in a laboratory
- ~100s of people involved in direct interaction and/or oversight of the animals

Husbandry Staff
Behavior Management
Veterinary Staff
Research Staff
IACUC
Occupational Health & Safety
Infrastructure Support
Institutional Support
Government/Company
Facility Services
Vendor
Professional Transportation Services
CRITICAL ANALYSIS

See Something, Say Something....
AREAS FOR IMPROVEMENT

Self-Identified by individuals or groups
Identified by the IACUC or liaison
Identified by Regulatory Agencies
• USDA
• OLAW
• DOD
Identified by Accrediting body - AAALAC
Funding Source - Sponsor
INCIDENCE/ ADVERSE EVENT

Minor
Major
Study Related
Clinically Related
Protocol Non-compliance
Variation of Normal
Husbandry
Mechanical
Notification
Immediate follow-up
Supervisors, Veterinarians and Research Groups

Investigation
Team approach
Interview relevant parties – once

Reporting
Internally – IACUC, Leadership
Externally – Regulatory & Accrediting Agencies
Press Release

Prevention
Develop a plan to prevent future occurrences
Avoid putting in place a process that increases burden without solving the problem.

Check-in
Check-in to see if prevention plan solved the problem
Correct as necessary
Decision Tree for Determining Noncompliance and Reporting

Preliminary Level
- Noncompliance?
  - Fact Finding
    - Yes
    - No
    - Analyze Facts
      - Yes
      - No
      - Triage Noncompliance
        - Yes
        - No
        - Triage Noncompliance
          - Yes
          - No
          - Report to IO
    - No
    - Triage Noncompliance
      - Yes
      - No
      - Report to IO

IACUC Level
- Validate:
  - What do you know?
  - What do you not know?
  - What must you know?
- Analyze:
  - Protocol(s)
  - Process(es)
  - Facilities
  - Personnel (program)
  - Personnel (non-program)
- Categorize:
  - How quickly to respond
  - Severity of issue
- Determine:
  - Whether to report
  - If so, to whom?

Institutional Level
- Report to Appropriate Entity
- Feedback
- Preliminary Inquiry

Animal Care Unit
Hask Assessors
EHS
CEOs
General Counsel
Compliance Office
Facilities

Collaborators
Regulators
Accreditors
Funders
Sponsors

Inside Entities
Outside Entities

RCKjan 2016
SUPPORTING THE STAFF

- Personnel that provide for research animals care deeply for the animals.
- Adverse events can have devastating effects if we don't provide support.
- Avoid placing blame if at all possible.
- Give people an opportunity to talk.
TRAINING

Bites, scratches, kicks, physical trauma
Ergonomics, noise
Zoonoses, allergens, blood-borne pathogens
Caustic, infectious, radioactive, toxic agents
Sharps, hot surfaces, physical hazards
Public safety, facility and computer security
Disaster plans, fire, flood, bomb threat
Harassment, discrimination, whistle blower

Emotional Involvement?
When emotional traumas inevitably happen they must be debriefed quickly:

- Preferably within 24-72 hours.
- Talk with a trusted colleague or friend.
- Debrief with someone who understands, someone with a similar base of experience.
- Talking about it can and will ease the painful memory.
- Long accumulated or particularly painful emotional traumas may need additional help in the form of therapy.
COMPASSION IN SCIENCE PROGRAM

Needs Assessment
- Committee Formed
- Personnel wanted study endpoint notifications
- Better atmosphere to take breaks
- Developed program for daily support.
- Seminar Series, Reflections
- Endpoint Notification
- Window Project, Box Project

• Someone to talk to
Nothing changes the devastation and sorrow that can be felt with an adverse event.

**Adverse event:**

D2C committee contacted individuals directly.

D2C members designated a place to be available for anyone to come and talk and leave notes in the Box.

Having a supportive environment is essential to helping our caregivers cope.
Thank you –

D2C - https://sites.uw.edu/d2c

Photo Credits throughout:
Randy Kyes, Global Programs
Dennis Raines, CPRO
Jinhee Thom, BMS
Brian Iritani, DCM
It is better to have a Compassion Fatigue Program and not need it –

.......than to need a Compassion Fatigue Program and not have it.

~ Anthony Gray, 2017
Acknowledgements

• NIH Office of Research Infrastructure Programs grant P51 OD010425 for supporting WaNPRC
• NIH Office of Research Infrastructure Program grant P51Od011092 for supporting ONPRC
• The amazing group of staff and veterinarians who care for the animals at WaNPRC and ONPRC
“I could never do your job. I love animals too much.”

I think you meant to say:
~Thank you for your service~

~ Keeping me and my loved ones healthy. ~
~ Ensuring that Laboratory Animals are well cared for. ~
~ Supporting development of new discoveries. ~