Getting to the root of the problem – there must be a better way!

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What I will cover...

- Critical Thinking and Root Cause Analysis (RCA)
- Traditional approaches to RCA
- Synthesizing a new approach - DIGR®
- Bringing DIGR® together with Behavior Engineer Models
Critical Thinking and RCA

Analyzing
Stepping through a process to look for failure points

Applying Standards
What are the standard procedures / training?

Discriminating
Is it one issue or two?

Information Seeking
When did it start? Is it in this country or that?

Logical Reasoning
I can track from the root cause(s) to the issue/risk with “which leads to”

Predicting
If this is the root cause then we should see these results

Transforming Knowledge
These are typical errors that people make – could they make them in this system?

Ref: B. K. Scheffer and M.G. Rubenfeld, “Critical Thinking: What Is It and How Do We Teach It?”
“Recently, I was asked if I was going to fire an employee who made a mistake that cost the company $600,000. No, I replied, I just spent $600,000 training him. Why would I want somebody to hire his experience?”

- Thomas J Watson

How about “Re-training”?
The corrosive effect of blame

- Once you start to blame, people clam up
- Unlikely to get to true root cause(s)
- If one person made an error today…another could do the same tomorrow
  - “Nobody goes to work to do a bad job.” [W. Edwards Deming]

Practical Challenges:
- Involvement of Legal e.g. Grenfell Tower enquiry
- What if a root cause might lead to a sanction of an individual?
Let’s Understand Why - Five Whys

- Start with the issue and ask “why did that happen”
  - Note the best one or two answers
  - For the best answer(s), ask “why” again
  - Continue this five times until you get to a cause or causes that the team agree are most likely
Let’s take a scenario and use Five Whys

- Expired vaccine administered at two different sites
- Why? Because an expired batch was administered at several sites
- Why? Because the pharmacists didn’t check the expiry date. Or maybe because the expired batch wasn’t quarantined
- Why? Because sites didn’t carry out their regular check for expired vaccine
- Why? Maybe because they forgot? Or they didn’t know?

Why is a good question to ask. But what about what, where, when, how many and how?
Then prioritise the causes and focus on the top ones.
Fishbone Diagram – Example 1

- **PEOPLE**
  - CRA didn't check
  - Check not carried out

- **PROCEDURES**
  - No quarantine procedure

- **MATERIAL**
  - Date format unclear for some countries

- **EQUIPMENT**
  - CRA didn't check

- **Expired vaccine administered**

- This is a “divergent” approach and will lead to many, many possible causes. How do you prioritise?
Helpful to explore a system. But not for root cause analysis.
Root Cause Analysis

There is a better way!

- Takes into account information you know about the issue
- Gets you focused on process
- Synthesizes proven approaches from other industries
- Has a mnemonic that is easy to remember
Define the problem. What?


Go step-by-step. How?

Root cause. Why?
**DIGR® Pedigree:**

- Define is part of Six Sigma and A3 methodology.
- Is – Is Not is from Kepner and Tregoe in “The New Rational Manager”
- Go Step-by-Step is from Lean’s walking the process (“Gemba”)
- Root Cause is similar to Five Whys but without the need for Five
DIGR - Define

- Let’s make sure everyone agrees on what the problem is.
- It’s not that a nurse didn’t notice that a vial that was about to be administered was past its expiry date.
- It’s that expired vaccine has been administered to multiple patients at multiple sites.
This gives you other dimensions of the problem:
- What
- Where
- How Many
- When

These might give clues as to cause. If it happened here but not there, why?

It might lead you to redefine the problem.
### DIGR – Is/Is not

<table>
<thead>
<tr>
<th></th>
<th>Is</th>
<th>Is Not</th>
</tr>
</thead>
<tbody>
<tr>
<td>What</td>
<td>One batch has currently expired</td>
<td>Any other batches</td>
</tr>
<tr>
<td>Where</td>
<td>Two regions (North America &amp; Europe)</td>
<td>All regions</td>
</tr>
<tr>
<td>How many</td>
<td>2 sites</td>
<td>40 other sites (that we know of)</td>
</tr>
<tr>
<td>When</td>
<td>3 administrations since the expiry date</td>
<td>5 administrations where the expired batch could have been administered but was not</td>
</tr>
</tbody>
</table>
If you have a written procedure or a process map, it’s a great tool
But you can talk through the process without one
“If you can't describe what you are doing as a process, you don't know what you're doing.” [W. Edwards Deming]
Does everyone agree on the process and is it followed?
DI GR – Go Step-by-step

Drug Accountability during on-site Monitoring Visit

Escalate significant issues

Confirm with site that expired vaccine is quarantined

Email informing of impending expiry

Collect and destroy expired vials

CRA

Drug Management System / Drug Depot

Signal that vials needed at Site

Ship vials

Track vial usage

Receive and log vials

Regular stock check and quality check

Quarantine expired vials

Site
DIGR – Root Cause

- Use the information you’ve pulled together
- Ask ‘why’ questions here
- Get to root cause(s) that you can act on
- In our example, we discovered we were lucky in 5 cases – the pharmacist / nurse must have noticed the expired vials
- Why did they have expired vials in the first place?
- Process failure with emails, errors in addresses
- **The process of identifying expired batches and quarantining them has not been verified**
DIGR – Root Cause

- Should flow logically to the issue
- Should be something you can act on / influence
- Not “Human Error”

- Use “because” or “leads to” statements to show it is logical
- Because the process of identifying expired batches and quarantining them has not been verified, sites have expired batches that are not quarantined...
DIGR® encourages Critical Thinking

Define the problem. *What?*


Root cause. *Why?*

- Analyzing
- Logical Reasoning
- Applying Standards
- Predicting
- Discriminating
- Transforming Knowledge

DIGR® encourages Critical Thinking
Reduce Impact Before RCA

The clock is ticking! Don’t let RCA hold you back with immediate actions e.g.

- Ensure expired batch is quarantined at all sites
- Review patient data on AEs
- Inform patients affected
- Medical review
- Note to all sites to remind them of importance of checking expiry dates and reminder of process for quarantine / destroying
Acting on the Root Cause(s)

Establishing root cause gets us to these actions:

- **Corrective (this study):**
  - Send test emails to all sites
  - Modify email text to CRAs to clarify their action on receipt
  - Train CRAs in process
  - Add verification step whenever site email address is entered

- **Preventive (future studies):**
  - Build this in from the start
Effectiveness checks

How do you know whether your actions have worked?

- Monitor whether CRAs come across any instances where sites have not quarantined as required
- Check whether emails are bounced
ICH E6 (R2) 5.0

Risk Identification: what issues have occurred previously?

Risk Evaluation: how often have they occurred? What was the cause? How can the risk be monitored? Review preventive actions

Risk Control: does evidence indicate need for additional controls?

Add to “Risk List”
## Gilbert’s Behavior Engineering Model (BEM): Factors That Support High Performance (Root Cause Categories)

<table>
<thead>
<tr>
<th>#1 INFORMATION Environment</th>
<th>#2 RESOURCES Environment</th>
<th>#3 INCENTIVES Environment</th>
</tr>
</thead>
</table>
| * Description of what is expected of performance  
  * Clear and relevant guides on how to do the job  
  * Relevant and frequent feedback on adequacy of Performance | * Tools, resources, time, and materials designed to achieve performance needs  
  * Access to leaders  
  * Sufficient personnel  
  * Organized work Processes | * Adequate financial incentives contingent upon performance  
  * Non-monetary incentives  
  * Career development opportunities  
  * Clear consequences for poor performance |
| #4 KNOWLEDGE Individual | #5 CAPACITY Individual | #6 MOTIVES Individual |
| * Systematically designed training to match requirements of exemplary performers  
  * Opportunity for Training | * Match between people and position  
  * Good selection processes  
  * Flexible scheduling to match peak capacity of workers | * Recognition of worker’s willingness to work for available incentives  
  * Assessment of worker’s motivation  
  * Recruitment of workers to match realities of work conditions |
Coming Soon...

Demo available on YouTube
Thank You!

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