Don’t Forget the Examination Phase

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Phillip Crosby

“Take everything that would not have to be done if everything were done right the first time and count that as the price of nonconformance.”

• Quality Without Tears: The Art of Hassle-free Management
• 1984
Laboratory Cycle Error Rates

40% 40% 20% 40%
Focus your TEEM* on Pre- and Post- examination problems.

*TEEM: Time-Effort-Energy-Money

But…

Pre- and Post Examination Errors

**Pre-Exam Errors**
- High volume
- Time costly
- Mostly one-to-one
- Many outside direct laboratory control
- Many cause inconvenience
- Some cause privacy breach

**Post-Exam Errors**
- High Volume
- Time costly
- Mostly one-to-one
- Many outside direct laboratory control
- Many cause inconvenience
- Some cause privacy breach
Examination errors

- Low volume
- More TEEM costly per error.
- Many one-to-many
- Most inside direct laboratory control
- Many cause inconvenience
- Many cause diagnosis and treatment complications
- Some cause social disruption.

Occurrence – Outcome and Laboratory Cycle Phase Error

<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Remote</th>
<th>Rare</th>
<th>Common</th>
<th>Frequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>Nil</td>
<td>Inconvenient</td>
<td>Problem</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Examination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Examination</td>
<td></td>
<td>Post-Examination</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Examination Errors have multiple causes

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Mechanical</th>
<th>Reagents and Supplies</th>
<th>Environmental</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Slips</td>
<td>– Internal systems</td>
<td>– Contamination</td>
<td>– Temperature, Humidity</td>
</tr>
<tr>
<td>– Training</td>
<td>– Data management</td>
<td>– Out-dated</td>
<td></td>
</tr>
<tr>
<td>– Documentation</td>
<td></td>
<td>– Cross reactivity</td>
<td></td>
</tr>
<tr>
<td>Sample Error</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Poor mixing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Inhibitors and Interference</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Plus the Rumsfeld factor...

There are known knowns; there are things we know that we know.

There are known unknowns; that is to say, there are things that we now know we don’t know.

But there are also unknown unknowns; there are things we do not know we don't know.
Characteristics of Examination Error

- Most occur silently.
- Many occur quickly.
- Most occur on a “discontinuous” basis.
- Very difficult to prevent.
- Very difficult to predict.
- Relatively easy to detect

Costing Examination Error

- Traditional Model
  - First described by Joseph Juran.
  - Reinforced or adapted by many contributors:
    - James Harrington
    - Douglas Wood
    - Jack Campanella
    - Phillip Crosby
Juran Model Categories

<table>
<thead>
<tr>
<th>Prevention</th>
<th>Facility controls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality system</td>
</tr>
<tr>
<td></td>
<td>Staff training</td>
</tr>
<tr>
<td></td>
<td>Consultants</td>
</tr>
<tr>
<td>Appraisal</td>
<td>Quality Control</td>
</tr>
<tr>
<td></td>
<td>Accreditation</td>
</tr>
<tr>
<td></td>
<td>Proficiency Testing</td>
</tr>
<tr>
<td></td>
<td>Internal Audits</td>
</tr>
<tr>
<td>Internal Failure</td>
<td>Costs arising when an error is found BEFORE it is released.</td>
</tr>
<tr>
<td>External Failure</td>
<td>Costs arising when an error is found AFTER it is released.</td>
</tr>
</tbody>
</table>

Up and Down the CPQ River

- **Collection**
- **Accession**
- **Transport**
- **Reporting**
- **Examination**

**Upstreaming**
Examination or reporting errors that require a patient recall

**Downstreaming CPQ**
Errors that occur early, but are not detected until much later.
Downstreaming results in increasing complexity, impact, and cost.
Steps that Juran did not include, but Crosby did

- Stop the system
- Find the error sample(s)
- Retrieve the original sample(s) (if possible)
- Purge the wrong result(s)
- Start-up the system
- Re-test the original sample (if possible)
- Notify everyone who might have received the wrong result
- Retrieve the original report
- Amend the report
- Create internal incident form
- Internal incident form – action plan
- Create an external incident form
- External incident form – action plan

Monitorable Steps in Calculating Costs

<table>
<thead>
<tr>
<th>Personnel Involved</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessioning contact</td>
<td>Identify Report</td>
</tr>
<tr>
<td>Customer Information Counter</td>
<td>Amend Report</td>
</tr>
<tr>
<td>Technologist</td>
<td>Corrected Report</td>
</tr>
<tr>
<td>Hot Line</td>
<td>Adjust Billing</td>
</tr>
<tr>
<td>Information Technology</td>
<td>Contact Patient</td>
</tr>
<tr>
<td>Billing</td>
<td>Re-accession</td>
</tr>
<tr>
<td>Quality Resources</td>
<td>Re-collection time</td>
</tr>
<tr>
<td>Supervisors</td>
<td>Re-transport</td>
</tr>
<tr>
<td>Medical/Scientific</td>
<td>Re-set up</td>
</tr>
<tr>
<td></td>
<td>Re-test</td>
</tr>
<tr>
<td></td>
<td>Re-report</td>
</tr>
<tr>
<td></td>
<td>Quality Activities</td>
</tr>
</tbody>
</table>
What do reported incidents Cost?

<table>
<thead>
<tr>
<th>Revision Required</th>
<th>Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change of identifier information</td>
<td>25-35</td>
</tr>
<tr>
<td>Change of reported information</td>
<td>40-975</td>
</tr>
<tr>
<td>Patient Recall (laboratory time)</td>
<td>40-80</td>
</tr>
</tbody>
</table>

Mean time to amend reported incidents **140**

*Note: our calculations underestimate time consumption, and do not include attention breaks, refocus time, return to normal activity time*

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TEEM COSTS

![Bar chart showing time and money costs for Pre-Exam, Exam, and Post-Exam stages with Management, Lab Director, Scientist, Supervisor, and Managers represented.](chart.png)
What is not included…

- Patient time on telephone
- Patient return-to-laboratory time
- Patient re-accession and wait time
- Patient collection time
- Patient return to home time
- **Average Patient Time for Recall is 180 minutes**

- Physician Office notification time
- Physician Office recall and revise chart time
- Physician Office re-contact patient
- Physician Office patient consultation.
- **Average Physician Office Time for Recall is 20 minutes**

Examination Errors
Are a challenge to prevent in Microbiology

1. Pre-examination – Examination disconnect
2. Methodology slips often not appreciated.
3. Contamination usually introduced silently.
4. Contamination often intermittent.
5. Difficult to challenge or confirm automated analyzer results.
6. Absence of Absolutes.
7. Long wait to results times
8. Cross reactivity of reagents.
9. Monitoring Quality Control takes time.
Examination Errors
Are a challenge to prevent in Chemistry

Chemistry
1. Carry-over contamination
2. Undetected inhibitors or competitor agents
3. Analyzer design valves, diluters, tubes, mixers
4. Introduction of line bubbles
5. Intermittency of error
6. Introduction of software interface errors
7. Monitoring challenges (interpretation delay)
8. Rapid release of information before

The Sad Reality Is…

- Examination Error is inevitable because
  - Testing volumes far exceed manual testing
  - Complex analyzers have too many moving parts
  - Trained analyzer operators are far too limited.
  - Too many unknowns factors in patient samples.
What We **CAN NOT** Do

to prevent examination error

- Reduce dependency on automation.
- Increase preventive maintenance.
- More intensive training of personnel.
- More personnel.
- Assume that maintaining Accreditation or Certification will make the problems go away.
- Assume that maintaining Quality Management System will make the problems go away.

If you can’t stop examination errors, you might be able to detect them sooner or reduce their impact.
Rolling Means of 10 Patient Values
progressive Na electrode failure

Better Middleware

Software to:
- Capture patient data
- Capture QC data
- Examine for duplicate sample testing
- Examine for rolling means
- Alarm potential breaches.
Change Turnaround Time Expectations

If results could be held back until they can be viewed and analyzed, many examination errors could be caught before being released.

The Clinton Strategy for Addressing Laboratory Error

Don’t Ask. Don’t Tell
So…
Can we reduce Examination Error?

1. Increase and diversify Quality Control Monitoring.
   Activity specific monitoring

2. Increase Proficiency Testing or equivalent testing.
   Higher volumes to better detect system error

3. Different approaches to Real Time QC.
   Look more closely at “stable” patient results as a prediction model
   Repeat testing

4. Delay release of automated reports
   Do we have REALISTIC turnaround time expectations.
For further discussion visit

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