Don’t Forget the Examination Phase

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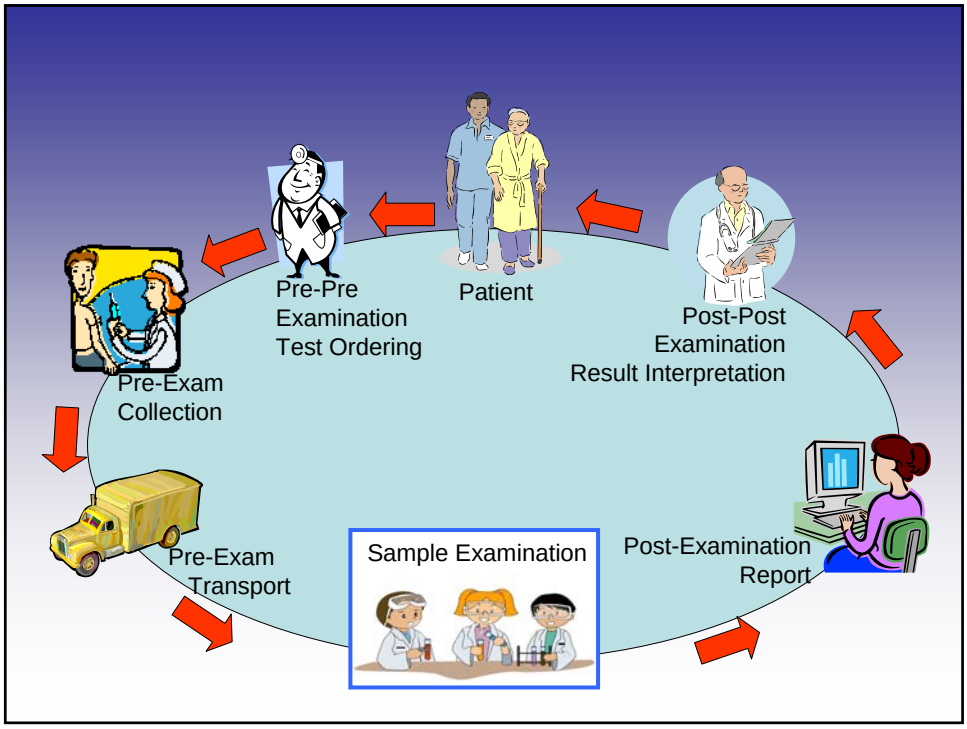
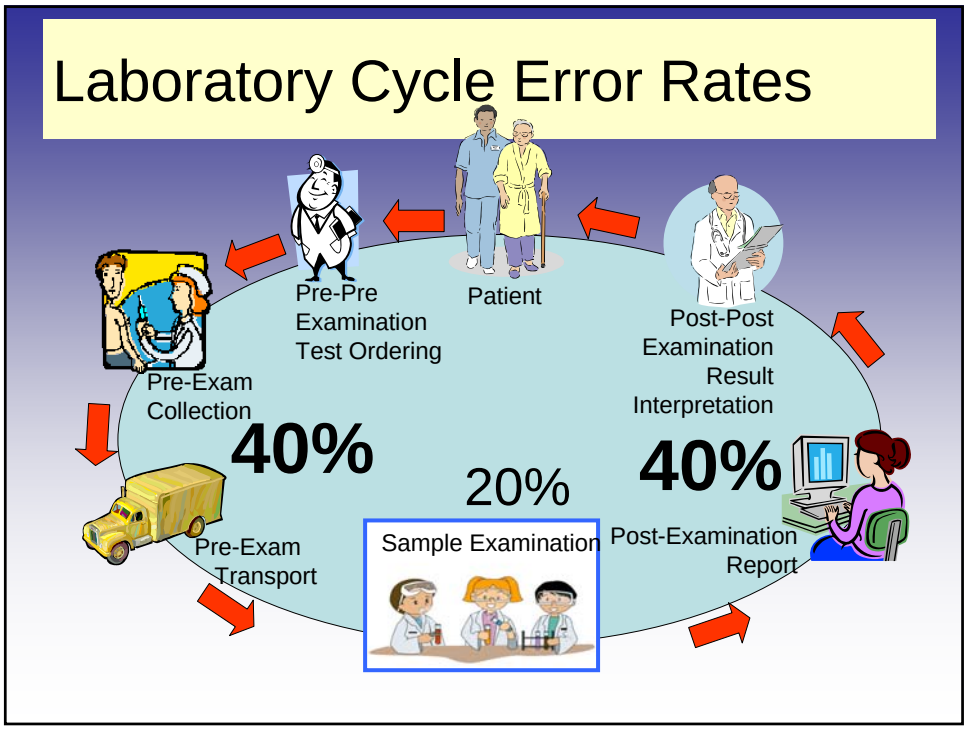
Phillip Crosby

*“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*


Pre-Pre
Examination
Test Ordering
Patient
Post-Post
Examination
Result Interpretation
Pre-Exam
Collection
Pre-Exam
Transport
Sample Examination
Post-Examination
Report


Laboratory Cycle Error Rates
Pre-Pre
Examination
Test Ordering
Patient
Post-Post
Examination
Result
Interpretation
Pre-Exam
Collection
40%
20%
40%
Pre-Exam
Transport
Sample Examination
Post-Examination
Report

Message

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

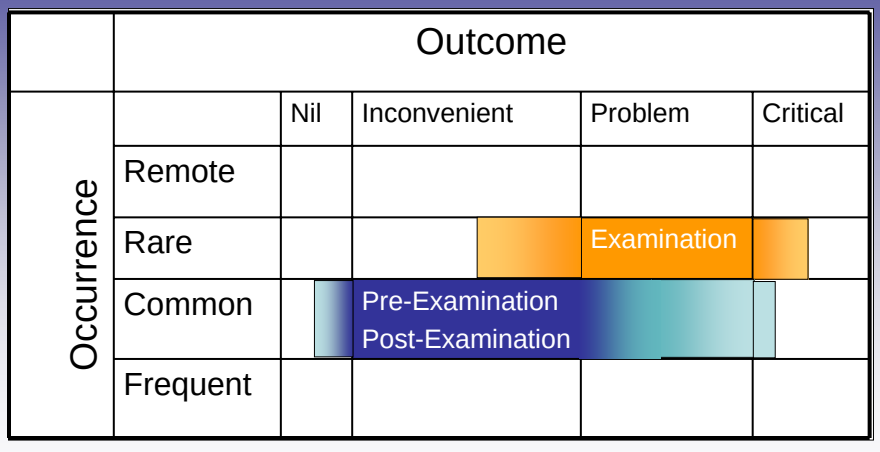
Post-Exam Errors

- 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.

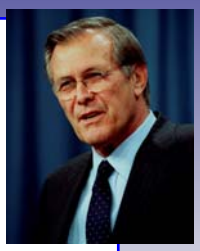
Occurrence – Outcome and Laboratory Cycle Phase Error



Examination Errors have multiple causes

- **Personnel**
  - Slips
  - Training
  - Documentation
- **Sample Error**
  - Poor mixing
  - Inhibitors and Interference
- **Mechanical**
  - Internal systems
  - Data management
- **Reagents and Supplies**
  - Contamination
  - Out-dated
  - Cross reactivity
- **Environmental**
  - Temperature, Humidity

Plus the Rumsfeld factor…



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

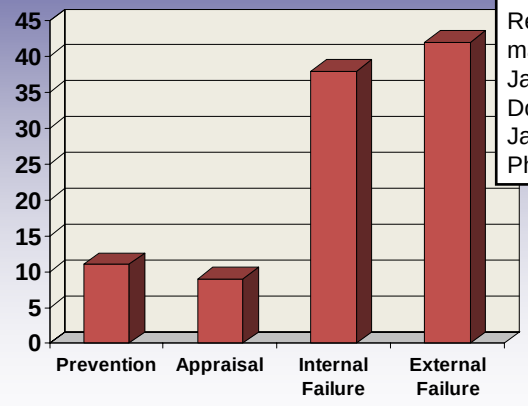
There are known unknowns; that is to say,
there are things that we now know we don't know.

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

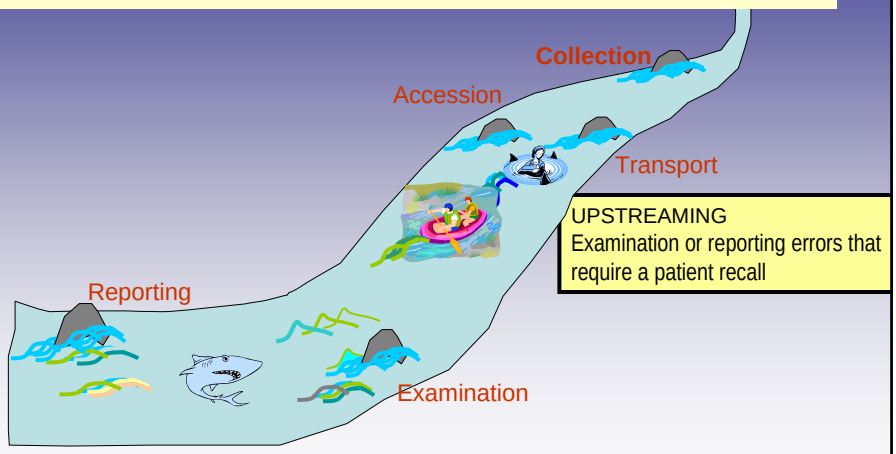


Traditional Model
First described by Josph Juran.
Reinforced or adapted by many contributors:
James Harrington
Douglas Wood
Jack Campanella
Phillip Crosby

Juran Model Categories

Prevention	Facility controls Quality system Staff training Consultants
Appraisal	Quality Control Accreditation Proficiency Testing Internal Audits
Internal Failure	Costs arising when an error is found BEFORE it is released.
External Failure	Costs arising when an error is found AFTER it is released.

Up and Down the CPQ River



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

Personnel Involved

- Accessioning contact
- Customer Information Counter
- Technologist
- Hot Line
- Information Technology
- Billing
- Quality Resources
- Supervisors
- Medical/Scientific

Activities

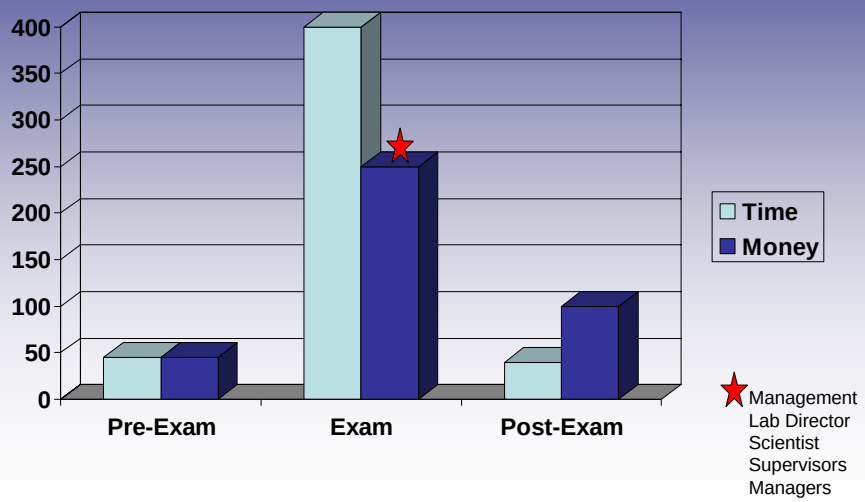
- Identify Report
- Amend Report
- Corrected Report
- Adjust Billing
- Contact Patient
- Re-accession
- Re-collection time
- Re-transport
- Re-set up
- Re-test
- Re-report
- Quality Activities

What do reported incidents Cost?

Revision Required	Time (minutes)
Change of identifier information	25-35
Change of reported information	40-975
Patient Recall (laboratory time)	40-80
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

TEEM COSTS



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

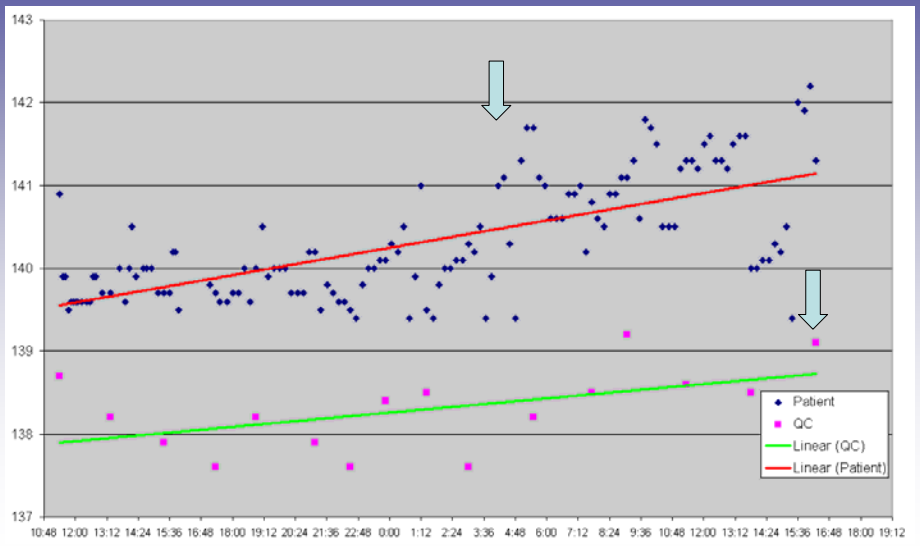
to prevent examination error

- 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.

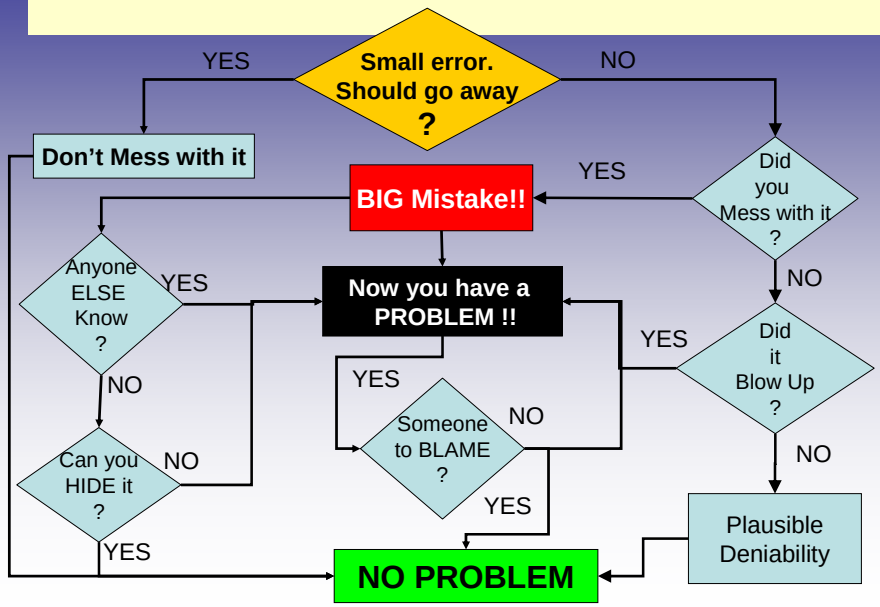
Change Turnaround Time Expectations

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

Clinton Strategy Flow Chart



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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