Monitoring and Correcting for Error

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For this week, we will follow the words of Toby Keith (American Country Music Artist)

A little less talk…

and a lot more

ACTION

Monitoring and Correcting For Error

1. Quality Control
2. OFI Recording
3. Complaints recording
4. Quality Indicators
5. Proficiency Testing
6. Internal Audit
7. External Audit
8. Customer monitoring

About Organizations and Errors

- **TERRIBLE** Organizations
  Neither know nor care about errors
- **POOR** Organizations
  Know there are errors but do nothing about them
- **BETTER** Organizations
  Understand there are errors and
  Implement policies to prevent them
- **SMART** Organizations
  Understand there are errors and their consequences
  Implement procedures to detect them and correct them and
  Learn from them in order to reduce repeating them.

About Errors…

- Errors happen ALL the time
- ALL Errors have ONE thing in common
  - Directly or Indirectly **ALL** errors are caused by humans
    - Most (ALMOST ALL) are inadvertent and **INDIVIDUAL**
      - **SLIPS and MISTAKES and GAFFS**
      - **Misunderstandings**
      - **Judgement errors**
      - **Risk Miscalculations**
      - **Knowledge Gaps**

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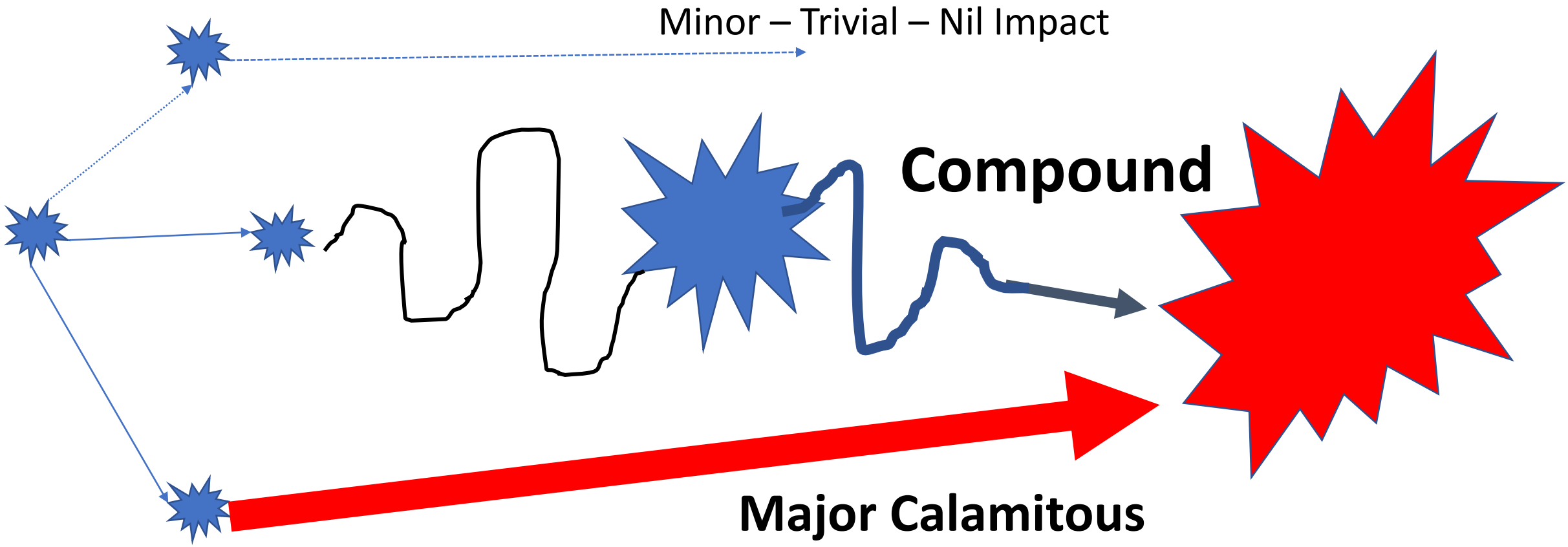
      - **Misunderstandings**
      - **Judgement errors**
      - **Risk Miscalculations**
      - **Knowledge Gaps**
  - **MANY Individual Errors are the result of Systemic (organizational) Factors**

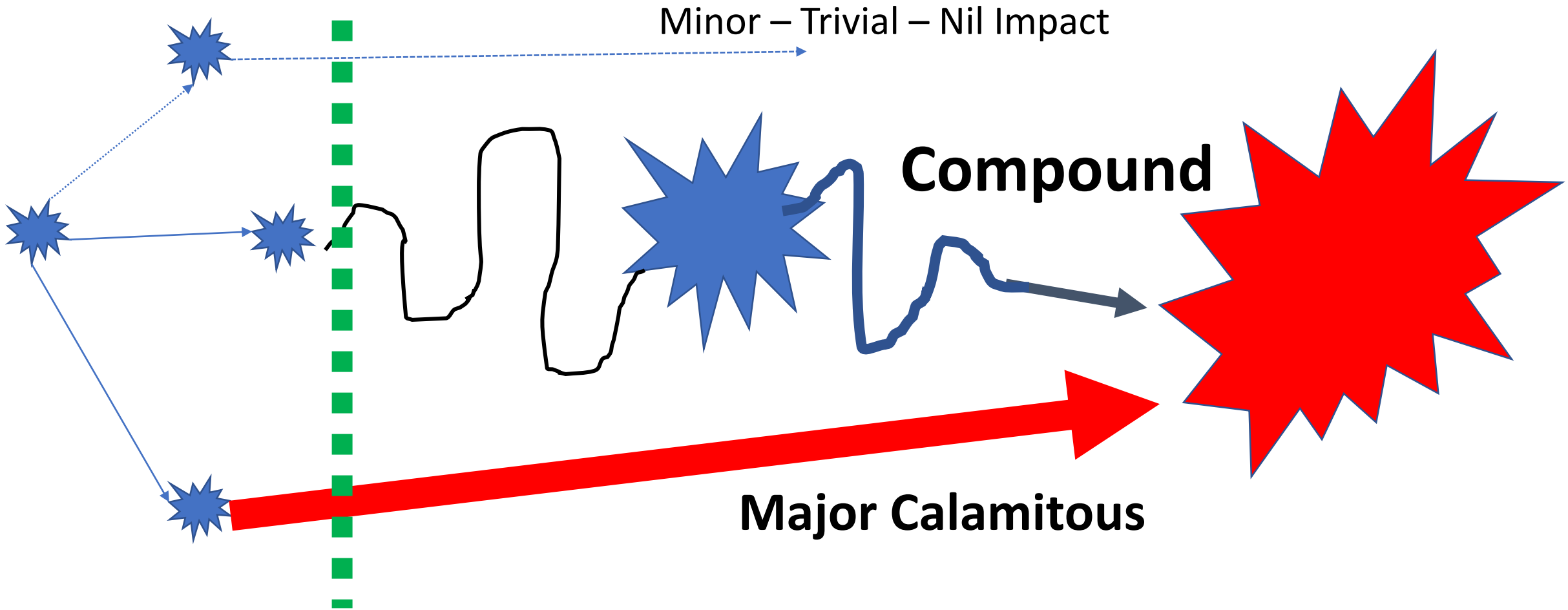
About Errors…

- Errors happen ALL the time
  - **Systemic (organizational) Factors that contribute to individual errors**
    - **Physical (Environmental) Worksites**
      - Noise, Light, Temperature, Safety, Clutter
      - Equipment inadequacies
      - Reagent and Supplies inadequacies.
    - **Education and Training**
      - Training Gaps
      - Absent Continuing Education
    - **Quality and Management**
      - Poor Work Culture
      - Work Burden Misalignment
      - Policy Gaps
      - Failures in Procedure Updates
      - ***Absent Error Correction Processes.***

Tracking Errors



Error Awareness Helps Reduce BAD OUTCOMES



Error Awareness Result in Opportunities for Improvement

Any Activity that can make your laboratory…

SAFER,
FEWER ERRORS,
BETTER SERVICE,
MORE EFFICIENT,
MORE EFFECTIVE
MORE PRODUCTIVE

is an Opportunity for Improvement.

If an activity can
improve your life and
the lives of your customers,
then it is an activity that
you should ensure
actually gets done

If an activity can
improve your life and
the lives of your customers,
then it is an activity that
you should **ensure**
actually gets done

What is the activity and why we want it completed?

Who is in charge of getting it organized and done?

When can we expect it is completed?

How will we check if it is in place and still working?

If it is important, record it and track it.

Opportunities for Improvement				
Item		**Description and Objective**	**Owner**	**Due Date Date Check**
1				
2				
3				
OFI.VersionA.Nov2018				

If it is important, record it and track it.

Opportunities for Improvement				
Item		**Description and Objective**	**Owner**	**Due Date** **Date Check**
1		• *Was this a result from a Prevention Audit **(PA),** and Internal Audit(IA), External Audit **(EA),** Error Detection **(ED),** Laboratory Project **(LP)*** • *If PA or LP classify by PRIORITY (H-M-L)* • ***More Details are incorporated in the associated Corrective Action form or Preventive Action form.***		• When setting dates be generous, but expect results
2				
3				
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What Corrective Action Forms Include:

1. Date:
2. Reporter name:
3. Event title:
4. Event Classification
5. Event Description (50 words or less)
6. Causes (Probable)
7. Corrections to be implemented
8. Event owner (person RESPONSIBLE for follow through
9. Expected Day of completion
10. Actual Day of completion
11. Follow-through Plan
12. Sign-off
13. Final Sign-off

What Corrective Action Forms Include:

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12. Sign-off
13. Final Sign-o

Every Event in the OFI Form

REQUIRES

A Corrective Action Form

That is completed and signed-off

BY THE EXPECTED DAY OF COMPLETION

.

Corrective Action Completion Record is a

KEY QUALITY INDICATOR

Advantages of Monitoring through OFI

- Understand where your challenges are coming from
- Know how well your laboratory is dealing with opportunities
- Are you being successful in meeting deadlines
- Builds encouragement
- Builds professionalism
- Builds a positive culture
- Builds documentation of successes
- Builds documentation of improvements.
- **Improves Quality**

A word of caution…

- People may have some concerns about starting down the OFI trail because they may:
- Feel that reports can be used against them and risk employment loss.
- Feel secure in their jobs but may feel they will be embarrassed or ridiculed for making mistakes

These feelings
may become
barriers too impossible
to overcome.

A word of caution…

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- Feel that reports can be used against them and risk employment loss.
- Feel secure in their jobs but may feel they will be embarrassed or ridiculed for making mistakes

In my laboratory
adoption of OFI was fairly easy to implement.
Once it was accepted that
we ALL make mistakes,
including (and maybe especially) me,
and that everyone's errs were recorded
it because easier to get everyone on board.

OFI records are **REQUIRED** for Management Review

Every Year
Every Accredited Laboratory
Must Submit a Management Review
Which Includes a Records Including but not limited to
OFIs
Corrective Actions
Preventive Actions
Quality Indicators
Complaints Tracking
Goals and Objectives

By checking your Management Reviews you can track
YEAR-OVER YEAR PROGESS

Today’s Assignment

- Create an OFI form that you can implement in your laboratory
- Create a plan on how you would promote the value and benefit of reporting OFIs in YOUR laboratory and describe what you can do to encourage people to start recording their errors.

An *important* thing About Errors…

- Some errors occur when you make a mistake by not following what a standard or guideline tells you what to do.
  These errors are called ***Nonconformities***.

- But most errors do NOT result from Nonconforming activities.
  - Slips, Mistakes, Gaffs, Misunderstandings, Judgement Errors, Risk Miscalculations, Knowledge gaps are not specified or discussed in any standard.
    - These are simply errors of knowledge or practice or behaviour.
    - **Do not call them or refer to them as Nonconformities.**

Complaints Recording

- Complaints arise all the time:
  - Usually they are the result of a MISUNDERSTANDING.
  - Usually they are a result of a “one-off” UNANTICIPATED EVENT
  - Sometimes they are the stem from a PAST EXPERIENCE.
  - Sometimes, rarely, they are **OUR FAULT.**

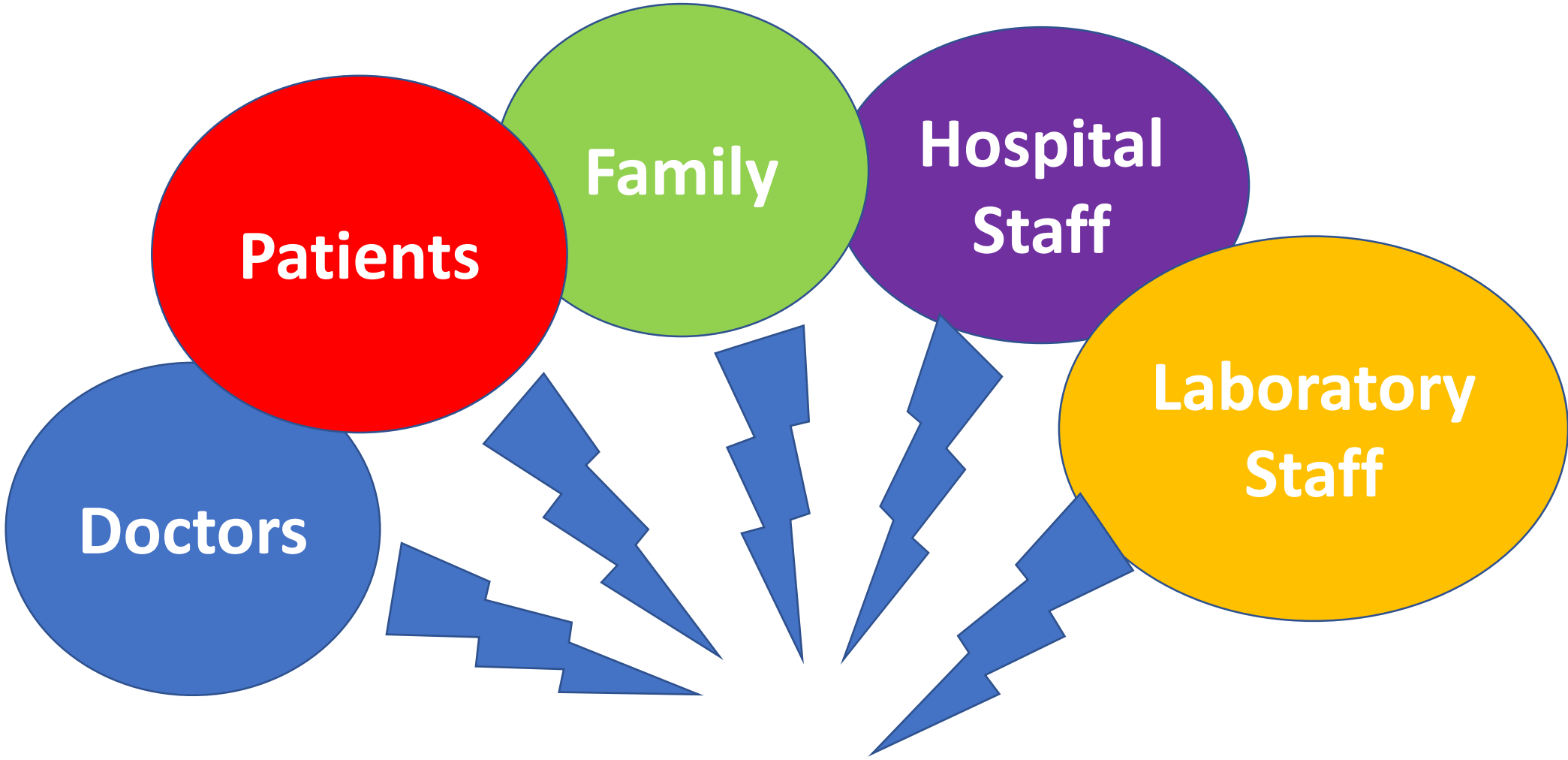
Individual Complaints

need to addressed with some attention to detail.

Repeat Complaints

tell us we have a major concern
that will cause us irrevocable harm

Complaints come from…



Getting Complaints is a GOOD THING!!

When People Complain, it means:

- **Your Customers are communicating with you**
- Your Customers are talking about their problems

When People Complain, it means YOU LEARN ABOUT:

- Misunderstandings about your information
- Errors that are occurring
- Service Problems that are happening

Don’t Want Complaints?

Make it as difficult as possible to register a complaint

Deal with all complaints with the view that they are NOT your fault and NOT you problem

Ignore complaints when they are made

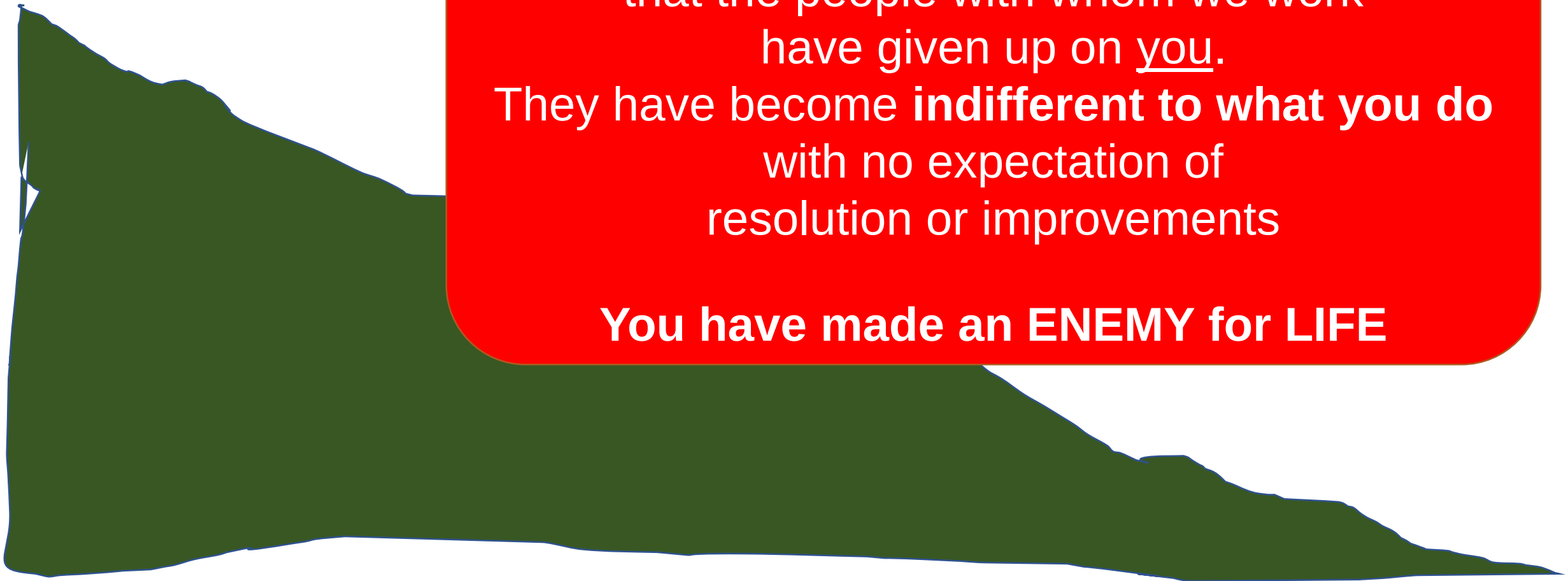
The thing about complaints, left unattended they either grow and grow and grow…

The thing about complaints, left unattended they may disappear, but **NOT** in a good way!

The thing about complaints, left unattended may disappear, but **NOT** in a good way!

When Complaints disappear it usually means
that the people with whom we work
have given up on you.
They have become **indifferent to what you do**
with no expectation of
resolution or improvements

You have made an ENEMY for LIFE



What to do when a you receive a complaint.

1. Record
2. Reply
3. Investigate
4. Respond
5. Report

What to do when a you receive a complaint.

1. Record

- Who complained
- When was the complaint received
- How was the complaint received?

  Email, Telephone, Letter, In person
- Record the problem as you understand it. Be as specific as possible

  “On March 2, 2018, a complaint was registered by Dr. ****** that the report for blood glucose sample report on patient **** (dat , number) was very received after 6 hours, even though we required it stat.”

What to do when a you receive a complaint.

2. Reply

- Send a note to Dr. ****** that you received the complaint.
- Inform that the complaint has been recorded and registered.
- The laboratory will investigate the complaint
- The laboratory commits to reporting back by a set date.
- Thank you for letting us know of your concerns.

What to do when a you receive a complaint.

3. Investigate
   - Record the complaint as an OFI
   - Actively investigate:
     - Does the laboratory record a problem?
     - Did the laboratory identify the cause?
     - Did the laboratory correct the cause?
     - What is the laboratory doing to monitor?

What to do when a you receive a complaint.

4. Respond

- Reply in writing to Dr***** on or before the date identified in the reply form
- Report the laboratory's results of the investigation
- Report how the laboratory will follow through to reduce repeating the problem.

What to do when a you receive a complaint.

5. Report

- Complete the OFI record
- Include the report in the next Management Review.

The ONLY way to successfully survive complaints is to OFI them…

Opportunities for Improvement				
Complaints		**Description and Objective**	**Owner**	**Due Date** **Date Check**
1	**C-MD**	• MD – Doctor; PAT-Patient, WS-Ward Staff • What and When and Why is the complaint? • Investigate to verify and if necessary correct • Is it something that needs an action plan? • Is it something that needs immediate attention?		• When setting dates be generous, but expect results
2	**C-PAT**			
3	**C-WS**			
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Change complaints into opportunities to monitor and track for improvement

Complaints Tracking Summary	Complaints for 2018					
Source of Complaints	MD	PAT	WS	FAM	OTH	
Complaint concerns	1	2	3	4	5	6
Total Complaints/Complaints Resolution	Total	Complete	Partial	No		
Commentary Complaint Concerns 1- Wrong Test Performed 2- Rejected without informing 3- Suspect accuracy 4- Late reporting 5- Pain 6–Rudeness	Of the complaints received we noted that most were received after weekends and especially in summer. Recurrent concerns were displeasure with our rejection policies and late reports. We had no complaints about staff rudeness. We have adjusted our policy and process for rejection and notification. We have adjusted our testing times to have results out earlier.					

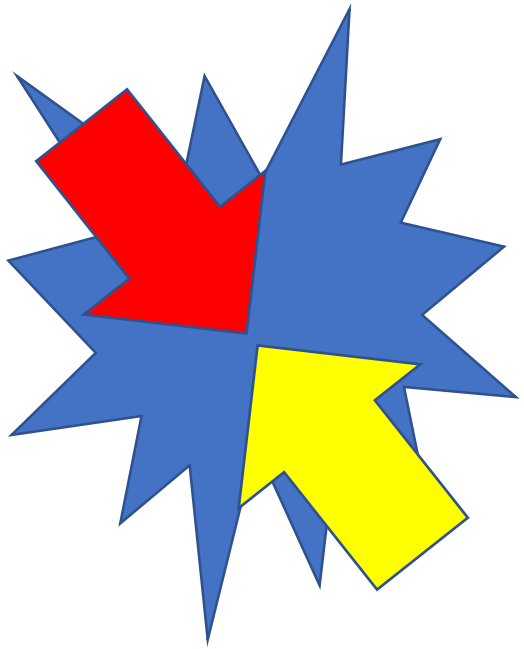
Where Complaints and Confidentiality Collide.

- *Complainants are often concerned there will be negative consequences when they complain. They may think that you may take your anger out on them, their test samples, their family.*

- Complaint details including who complained, the specifics of why they complained should be kept SEPARATE AND SECURE.

- Public records may allude to the complaint but the details should be confidential.

- If the complaint describes a situation that is egregious, the details will come out anyways, but they do not and **MUST NOT come from you.**



Today’s assignment

- Create a form that you can use to record all complaints raised by laboratory customers
  - This form can be used as the replay form for responding to every complaint received.
    - Who complained?
    - When and how was the complaint received?
    - A summary of the complaint?
    - When will an investigation be completed.

    - Note: ***Because this is a form that you will use as a response form that you may change from time to time, it should be registered in your document control system.***

Informal Internal Audits

- Internal Audits are a self-inspection tool that organizations are expected to perform if they want to reduce error and improve quality performance.

  There are two types of Internal Audits that can be performed:

Internal Audits

- Internal Audits are a self-inspection tool that organizations are expected to perform if they want to reduce error and improve quality performance.

  There are different types of Internal Audits that can be performed:

  Formal Internal Audits:

  Informal Internal Audits:

  External Internal Audits:

Internal Audits

Formal Internal Audits:

A self inspection process, usually proscribed by an oversight body requiring certain rules, requirements, and expectations.

A. Based on an formal checklist designed from:
    a) A standard (ISO 15189:2012)
    b) A specified guide (SLMTA)
B. Rules based procedure
C. May take a day or more to complete
D. Rarely done more than once (or twice) per year.

Internal Audits

External Internal Audits:

A self inspection process, usually that is performed for internal laboratory purposes but is performed by an person from outside the laboratory, such as a colleague from another laboratory.

A. May be done as either an Formal or Informal Internal Audit.
B. Regardless of format, it should be rules based.
C. May or may not require compensation for expenses or time
D. Should be documented and found deficiencies should be properly addressed.

Internal Audits

Informal Internal Audits:

A self inspection process, usually proscribed by local consensus through local Quality Manager

A. Based on an in-house checklist designed from:
    a) Specified Guideline Principles
    b) Local Issues
B. Designed to be Very Local (a single bench or task area)
C. Designed to be less formal but still addresses the essential values of Internal Audits
D. Designed to take NO LONGER THAN 60-90 minutes
E. Can be repeated in multiple sites on a monthly basis
F. May incorporate a Preventive Actions audit.

Example of an Informal Internal Audit

- Only addresses a **single** laboratory area:
  - Accessioning, Haematology, Chemistry, Microbiology
  - May address single issues, such as
    - *Is the area seen as neat and tidy?*
    - *Is Quality Control being performed as required?*
    - *Are all SOPs performed in this single area up to date and consistent with current practices?*
    - *Are all Laboratory Guides that are posted to walls for rapid reference up to date and consistent with SOPs*
    - *Can staff answer questions that are drawn from current SOPs*
    - *Are there any obvious current safety risks being ignored?*
    - *Are there any out-standing complaints or concerns or corrective action forms that are not being attended to?*
  - Can be addressed by Quality Manager or a Delegate?
  - Should not take any longer than 90 minutes
  - Regardless what has been done in 90 minutes should be documented and if necessary recorded to the OFI form along with Corrective Action form.

Why do Informal Internal Audits?

- Less time consuming
- Less stressful for internal assessors
- Less stressful for staff
- Provides a lot of information.
  - *If IIAs are done monthly and each covers 9 points in 90 minutes, at the end of a year your laboratory has amassed over 100 data points that can be used as evidence of internal audit performance, but never took more than 90 minutes a month*
  - Documentation and follow through can be completed in a timely fashion because the monthly amount is less intimidating.
  - **Some areas may be audited twice or three times in the same month.**

You will still have to do a formal Internal Audit to meet oversight requirements, but…

- Many of the questions will have already been asked.
- Most of the document checking will have already been performed.
- The likelihood of finding errors will be reduced because most areas will have already gone through one-or-two audits and many of the problems will have been addressed.

Today's Assignment

- Draw up an Informal Internal Audit checklist and schedule that will allow you to complete an audit a month taking no longer than 90 minutes an audit.
  - Identify
    - Who will do the audits
    - Which bench, section is going to be audited
    - What questions you will ask
  - Create a form that you use to record each (and all) of your monthly informal internal audits.

What are Quality Indicators

Measures designed to monitor performance in Quality Management System

The Intent of Quality Indicators

The intent of indicators is to
Measure and monitor
Continual Quality
Performance and Improvement

What is useful Performance for the Organization to Monitor?

Information Arising From…

- ✓Opportunities for Improvement
- ✓Complaints and Compliments
- ✓Internal Audits Results

The Actions of Quality Indicators

Select the data for Analysis

Analyse and evaluate data and information using suitable methods

Ensure that data and information are sufficiently accurate, reliable and secure;

Ensure people are competent to analyse and evaluate data as needed;

Make decisions and take actions based on evidence, balanced with experience and intuition.

Make all data needed available to the relevant people;

Quality Indicator Procedure Steps	
Select the data for Analysis	Using the Principles of Prioritization learned through FMEA, start with the problem with the greatest risk of serious or repeated negative effects on Quality Improvement
Ensure that data and information are sufficiently accurate, reliable and secure;	
Analyse and evaluate data and information using suitable methods	
Ensure people are competent to analyse and evaluate data as needed;	
Make decisions and take actions based on evidence balanced with experience and intuition.	
Make all data needed available to the relevant people;	

Quality Indicator Procedure Steps	
Select the data for Analysis	Set up a Plan that will allow you to gather accurate information that is achievable using the resources and time available. Ensure the information is clear, specific, and related directly to the intended goal.
Ensure that data and information are sufficiently accurate, reliable and secure;	
Analyse and evaluate data and information using suitable methods	
Ensure people are competent to analyse and evaluate data as needed;	
Make decisions and take actions based on evidence balanced with experience and intuition.	
Make all data needed available to the relevant people;	

Quality Indicator Procedure Steps	
Select the data for Analysis	Commit to measure the information on a regular basis (monthly or quarterly). Keep the analysis as simple as possible make the information graphical so that it can be visually monitored.
Ensure that data and information are sufficiently accurate, reliable and secure;	
Analyse and evaluate data and information using suitable methods	
Ensure people are competent to analyse and evaluate data as needed;	
Make decisions and take actions based on evidence balanced with experience and intuition.	
Make all data needed available to the relevant people;	

Quality Indicator Procedure Steps	
Select the data for Analysis	Is statistics and analysis included on your organization's continuing education list?
Ensure that data and information are sufficiently accurate, reliable and secure;	
Analyse and evaluate data and information using suitable methods	
Ensure people are competent to analyse and evaluate data as needed;	
Make decisions and take actions based on evidence balanced with experience and intuition.	
Make all data needed available to the relevant people;	

Quality Indicator Procedure Steps	
Select the data for Analysis	The point of measuring and monitoring is the result in actions that will improve quality performance. Have the improvements you were seeking occurred and been sustained?
Ensure that data and information are sufficiently accurate, reliable and secure;	
Analyse and evaluate data and information using suitable methods	
Ensure people are competent to analyse and evaluate data as needed;	
Make decisions and take actions based on evidence balanced with experience and intuition.	
Make all data needed available to the relevant people;	

Quality Indicator Procedure Steps	
Select the data for Analysis	Quality improvement information should be transparent, even when it is not as successful as you would like. Transparency can provide the opportunity for assistance and resources, not otherwise available.
Ensure that data and information are sufficiently accurate, reliable and secure;	
Analyse and evaluate data and information using suitable methods	
Ensure people are competent to analyse and evaluate data as needed;	
Make decisions and take actions based on evidence balanced with experience and intuition.	
Make all data needed available to the relevant people;	

What do you do then?

Once you are satisfied, that you
saw a problem,
investigated the problem,
“fixed” the problem and
monitored the outcome, and
are satisfied that it has been improved…

Move on

to the next important task

Life is too short and
Quality Improvement is too busy…

To WASTE time
following indicators with
a predictable outcome.

COMMIT TO
ADD ONE - DROP ONE

Todays Assignment…

Either use the following scenario
OR SELECT ONE FROM YOUR LABORATORY
To develop into a Quality Indicator project.
Include the following:

Define the Problem
Present the Solution
Describe how you will monitor the effectiveness of the solution

What will you measure AND ***How*** will you Measure
What statistic will you use for
ANALYSIS AND PRESENTATION

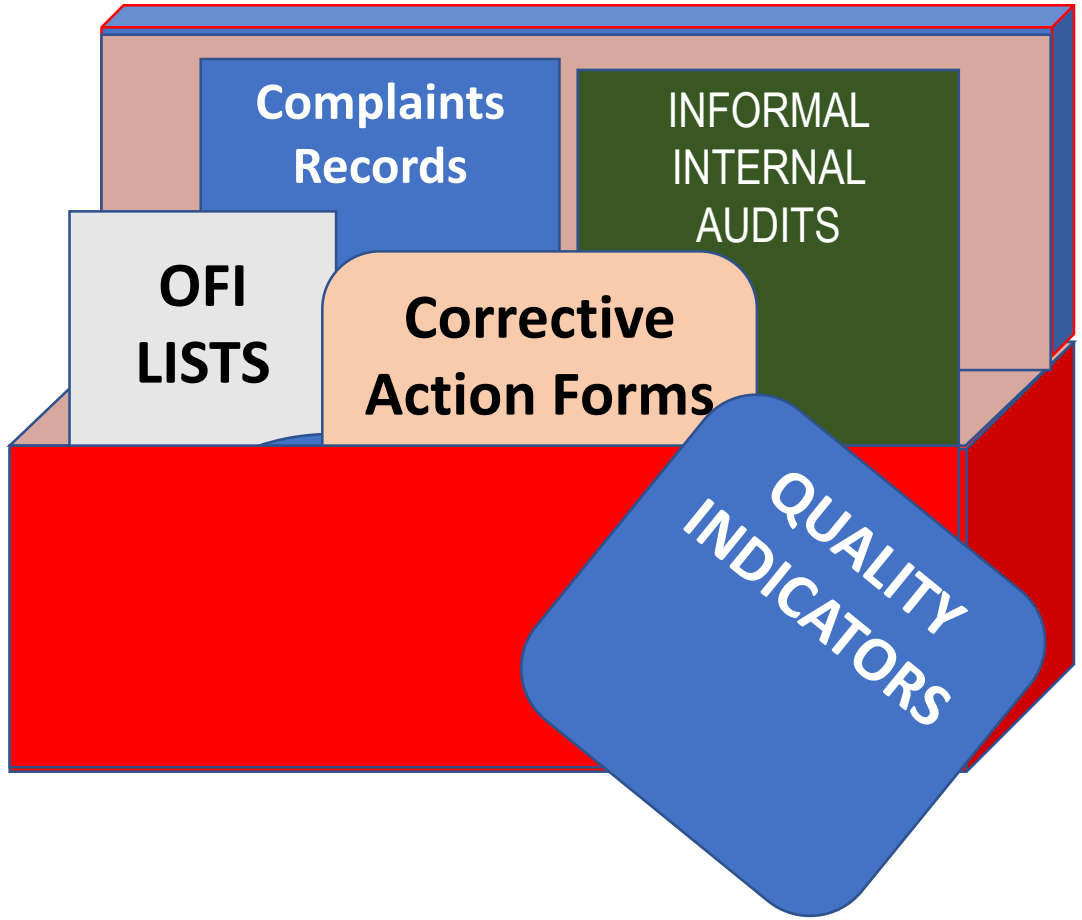
What will you define as your END POINT?

Quality Indicator for Assignment

- Your Laboratory has a Sample Rejection Rule that Urine Cultures must be rejected if the sample has not been received in the laboratory in the laboratory within 4 hours of collection, unless it has been refrigerated.
- Rather than reject samples directly your plan is to test the samples but include a large **RED** advisory on the report stating the result is unreliable because of late receipt.
- The incorporation of the advisory results in a daily decrease in late samples of 44 percent.
- You want to monitor the impact of continued use of the advisory as a way to reduce late samples.

Review

This week we have looked at five Quality Tools that should be in the Toolbox of every person interested in Quality and Management and Improvement



- **OFI FORMS**

  Allow you to list ALL of your incidents, errors, events, and observations. What you don't LIST you LOSE, and what you LOSE you cannot IMPROVE.

- **COMPLAINTS**

  Ignoring or hiding complaints ensures you lose support, and generate indifference and miss opportunities to make your service better.

- **INFORMAL INTERNAL AUDITS**

  IIAs are your opportunity to monitor you activities in a time effective approach. **Learn early**, **correct early**, **document early** and continually ensure improvement**.**

- **QUALITY INDICATORS**

  An essential MEASURE to ensure that you actions are on-track and working. Time efficient and Time effective when you monitor for SUCCESS.

- **CORRECTIVE ACTION FORMS**

  Your best action QUALITY tool that complements your OFI list and your COMPLAINTS and your INTERNAL AUDITS and your QUALITY INDICATORS.

  Work organized, Document consistently and Move to SUCCESS

Quiz for Quality Management Week February 2019

- Question 1
- An Opportunity for Improvement Form is useful when…
  - A: It includes a record of EVERY error, accident, and complaint that occurs in the laboratory
  - B: It is used as a quality improvement measure so that the laboratory knows how many OFIs occur in a set period
  - C: It is used as part of the laboratory annual management review
  - D: It is recorded in the laboratory quality management system so that changes to the form can be monitored
  - E: All the above are correct.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 2
- An Opportunity for Improvement Form should include space for …
  - A: recording the date the event occurred.
  - B: who caused the error and how many errors they have caused in the last 6 months
  - C: who is responsible for investing the OFI and completing a corrective or preventive action report.
  - D: by what date the investigation should be completed
  - E: All the above are correct.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 3
- Which of the following is an important aspect of Complaints
  - A: Laboratories must record all received complaints as the first step towards replying to the complainer and investigating
  - B: If a preliminary investigation can not confirm the complaint it is unnecessary to record, reply or respond to the complainer
  - C: Complaints should be made public including the names of complainers
  - D: Complaints monitoring should be kept private and NOT be used of the Management Review Report.
  - E: All the above are correct.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 4
- Which of the following is an important aspect of Complaints
  - A: Laboratories must record complaints in the laboratory OFI record and approach them similar to all other OFIs
  - B: When people stop registering complaints it is solid evidence that the laboratory is doing everything correctly.
  - C: Complaints can come to the laboratory in many ways. Regardless of how they come to the laboratory they should be recorded and investigated.
  - D: All the above are CORRECT.
  - E: All the above are NOT CORRECT.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 5
- Which of the following is an important aspect of Internal Audits
  - A: All Internal Audits must be done using an established prescribed procedure
  - B: Internal Audits should only be performed by in-laboratory personnel.
  - C: Internal Audits need to be performed once a laboratory is accredited or is preparing for accreditation.
  - D: All the above are CORRECT.
  - E: All the above are NOT CORRECT.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 6
- Which of the following is an important aspect of Internal Audits
  - A: Internal Audits can be either performed formally or informally and still find useful information for quality improvement.
  - B: Informal Internal Audits can be completed in a defined time period and still find valuable evidence useful of quality improvement.
  - C: Errors or deviations found during an informal internal audit should be recorded in the laboratory OFI form and be appropriately corrected.
  - D: All the above are CORRECT.
  - E: All the above are NOT CORRECT.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 7
- Which of the following is an important aspect of Quality Indicators
  - A: Quality Indicators must be designed as MEASURES. If the result cannot be counted, or weighed, or timed, it is not an Quality Indicator.
  - B: Quality Indicators can and should be used as follow-up to corrective actions to determine if the actions have result in error prevention.
  - C: Quality Indicators that have predictable results lose their value as Quality Indicators, and can be halted.
  - D: All the above are CORRECT.
  - E: All the above are NOT CORRECT.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 8
- Which of the following is an important aspect of Quality Indicators
  - A: Quality Indicators should be evaluated on a regular basis to determine if targets are being met.
  - B: Quality Indicators can and should be implemented even if the laboratory does not have the personnel or resources to follow them completely
  - C: Quality Indicators and their outcome measures should be included in the laboratory Management Review.
  - D: All the above are CORRECT.
  - E: All the above are NOT CORRECT.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 9
- Which of the following is an component of a Corrective Action
  - A: The Date the Event was reported
  - B: The Classification of the type of problem
  - C: Who is responsible (owner) to ensure the corrective action is investigated and completed.
  - D: The most probable cause of the problem
  - E: All the above are CORRECT.
  - F: More than one of the above are correct, but one or more is NOT CORRECT

Quiz for Quality Management Week February 2019

- Question 10
- Your laboratory organizes an informal internal audit on workbench tidiness, Document Control completeness, and Staff safety practices. The Audit has 12 questions and creates at minimum 40 responses per audit. It is performed by a different person every month for 12 months creating opportunities for month over month trending graphs. The informal internal audit takes 1 hour to complete each month.
- How many data points are collected for analysis over the year.
  - A: 12
  - B: 24
  - C: 400
  - D: 480
  - E: 480 (at minimum)