

# Meeting Dynamic Challenges for Quality and Patient Safety

**SHARON S. EHRMEYER, PH.D., MT(ASCP)**

PROFESSOR EMERITUS, DEPARTMENT OF PATHOLOGY  
AND LABORATORY MEDICINE  
SCHOOL OF MEDICINE AND PUBLIC HEALTH  
UNIVERSITY OF WISCONSIN, MADISON, WI





# Today's Goal

Developing strategies to meet today  
and tomorrow's challenges to  
enhance POC & laboratory testing's  
contribution to patient care



# Ultimate Goal:

Quality test results  
for quality  
healthcare!

# Quality



Common quote --  
60 – 80% of clinical decisions are  
based on test results

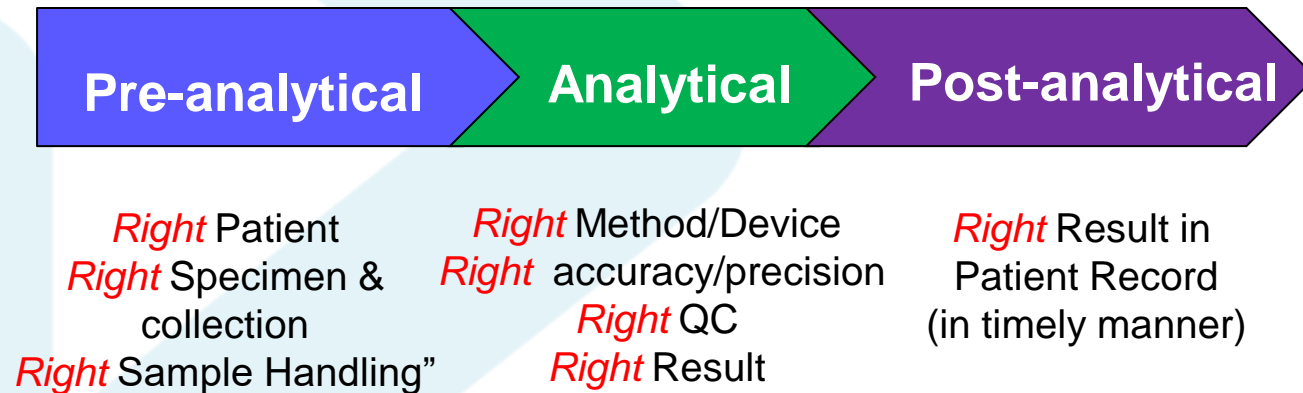
# So, What is Quality Testing?

Guarantee that total testing process (TTP) is performed correctly, so reliable patient results lead to valuable decision making and effective patient care!

This means *weaknesses* are recognized,  
and  
*corrective / preventive* actions are  
designed and implemented

Plebani M. AACC.org. September 2014. <https://www.aacc.org/science-and-research/scientific-shorts/2014/what-is-quality-in-clinical-laboratory-testing>

# POCT Quality in TTP



# Quality Requires: Error Recognition and Correction



Clinical and Laboratory Standards Institute. [www.CLSI.org](http://www.CLSI.org);  
ISO14971:2007. Medical devices -- Application of risk management to medical devices. ([www.iso.org](http://www.iso.org));  
CMS IQCP Information. [https://www.cms.gov/RegulationsandGuidance/Legislation/CLIA/Individualized\\_Quality\\_Control\\_Plan\\_IQCP](https://www.cms.gov/RegulationsandGuidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP)

# Common Causes for Error in TTP

Test system

Reagents

Personnel

Specimen

Environment





# Pre-analytic Errors Costs (US): \$\$\$\$

**\$208 - average cost per pre-analytical error**

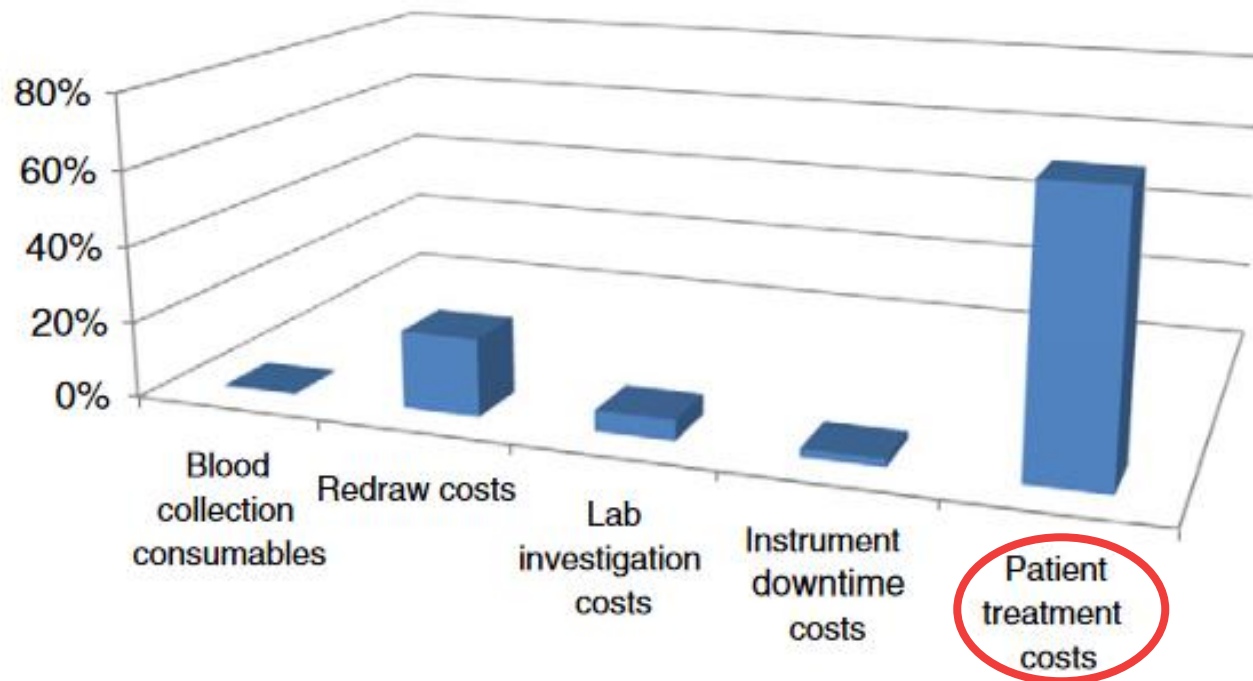
- Mislabeling, wrong samples, insufficient sample volumes, etc.
- \$180,000 / year is average cost incurred by labs

**Typical mid-sized hospital processing approximately 182,500 tubes / year, experience:**

- 0.66% of tubes have pre- or post-analytical errors
- 72% of the tubes directly contribute to additional costs

Reithel J. Minimizing laboratory errors with automation. MLO July, 2021. [https://www.mlo-online.com/continuing-education/article/21230466/minimizing-laboratory-errors-with-automation?utm\\_source=MLO+Issue+on+its+Way&utm\\_medium=email&utm\\_campaign=CPS210721066&o\\_eid=0229J2734001I2O&rdx.ident%5Bpull%5D=omeda%7C0229J2734001I2O&oly\\_enc\\_id=0229J2734001I2O](https://www.mlo-online.com/continuing-education/article/21230466/minimizing-laboratory-errors-with-automation?utm_source=MLO+Issue+on+its+Way&utm_medium=email&utm_campaign=CPS210721066&o_eid=0229J2734001I2O&rdx.ident%5Bpull%5D=omeda%7C0229J2734001I2O&oly_enc_id=0229J2734001I2O)

# Costs of Poor Specimens!



**Fig. 2.** The total cost of specimen rejection can be quantified by cost category.

Sol F. Green The cost of poor blood specimen quality and errors in preanalytical processes. Clinical Biochemistry 2013. <http://velanovascular.com/wp-content/uploads/2017/01/Elsevier-The-Cost-of-Poor-Blood-Specimen-Quality-and-Errors-1.pdf>

# Human Costs: Patient / Specimen Misidentification Errors

Test system

Reagents

Personnel

Specimen

Environment

- Est.  $\geq 160,000$  adverse patient events / year due to patient specimens ID errors
- Improper patient / specimen ID / labeling lead to catastrophic consequences:
  - Misdiagnosis
  - Incorrect treatment
  - Failure to treat existing conditions
  - Unnecessary surgery
  - Injury, disability, and death

Christopher JP. A nonconforming event program reduces misidentification errors. MLO September 2021 <https://www.mlo-online.com/management/qa-qc/article/21235139/a-nonconforming-event-program-reduces-misidentification-errors>

# Heads UP: CAP's New (2021) Emphasis



## **Accreditation checklists**

New and revised requirements in seven checklists center on specimen integrity. What's required and why.

“The aim...is to improve the pre-analytic quality of specimens for all types of testing”

CAP today. September 2021:

[https://digital.olivesoftware.com/Olive/ODN/CAPToday/default.aspx#\\_](https://digital.olivesoftware.com/Olive/ODN/CAPToday/default.aspx#_)

# Combating TTP Errors --

Knowledge  
is  
power!



# Testing Requirements have you Covered and in the “KNOW”

*CLIA*



COLA



Don't forget your  
state requirements too



# CLIA and Your Accrediting Agency

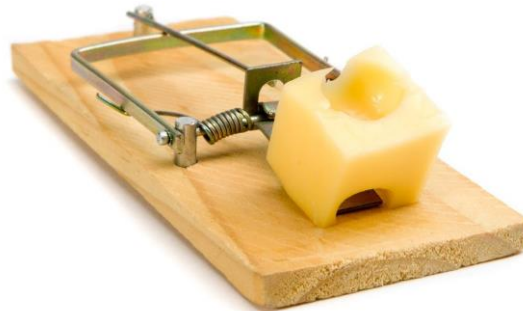
All provide useful  
information to  
prevent and correct  
errors throughout  
the TTP

All want POCT to  
Succeed!

# Regulations bring Inspections

Be prepared

*Pay attention to frequent deficiencies*  
*Don't fall into the deficiency trap*





# Regulations bring Inspections

Make sure all testing policies and procedures “line up” with requirements

Make sure all staff are doing what P/P state

**FYI - Looks like some type of BLENDED  
- virtual and in-person inspections –  
will continue**

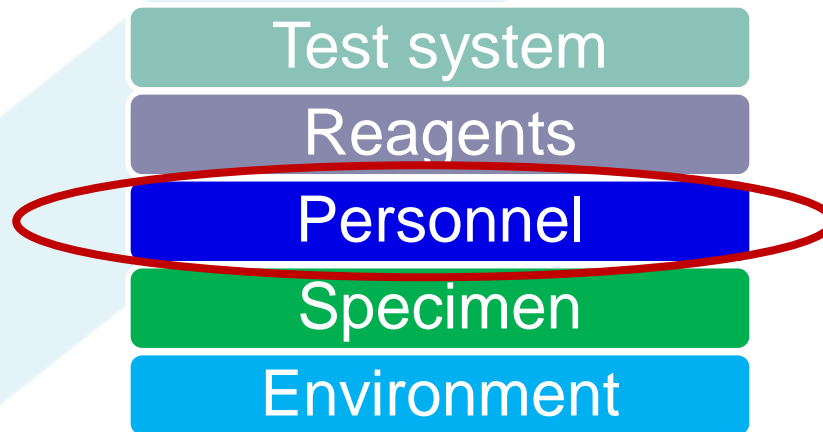
# Example: COLA's Top Deficiencies

RANK	CITATION	#	%	REASON CITED
1	PER 5	658	18%	For not performing or documenting competency assessments as required
2	LDR 4	561	16%	For the Laboratory Director not fulfilling the Proficiency Testing responsibilities of the position
3	PER 4C	472	13%	For the Technical Consultant or Technical Supervisor not fulfilling the responsibilities of the position
4	LDR 5	427	12%	For the Laboratory Director not fulfilling the Quality Control / Quality Assessment responsibilities of the position
5	PT 16	414	12%	For not documenting review of PT scores by the Laboratory Director, supervisory personnel, and testing personnel

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

# Many Deficiencies concern Personnel

Not having *right*, qualified personnel  
doing the *right*, required things!





Qualifications/Qualified...Means:

Education

Training

Competency (Assessment)

AND

Fulfillment of responsibilities

# Best Practices: Quality Testing Sites have:

- Established and well-defined quality management plan
- Laboratory/site director involvement
- Thorough training and competency assessment program
- Clear policies/procedures for all staff



# Important Mantras for “Problem” Avoidance

**Check, check, check**

**Train, train, train**

**Assess, assess, assess**

**Remind, remind, remind**

# Train, Train, Train Assess, Assess, Assess\*

Training provides essential knowledge, skills and behaviors for analysts to meet policies and procedures

- Must be done before testing and with changes
- Records must be maintained

Competency of analysts is the correct application of knowledge, skills and behaviors

Competency assessment (CA) *confirms* application of knowledge, skills and behaviors is correct

- CA must be performed at prescribed intervals
- Must maintain records

\*Waived Testing – training/competency assessment varies with accrediting agency

# COLA TIPS for Competency Assessment

- Competency assessment does not have to be done all at once.
- Keep a running file on each person and add to it as they resolve problems, perform PT, etc.
- Include copies of documentation in the file, for example a write-up of a non-conforming event where the testing personnel resolved the situation. Include copies of routine maintenance logs, documentation of critical value communication, etc.



Qualifications/Qualified... **Means:**

Education

Training

Competency (Assessment)

**AND**

Fulfillment of responsibilities

Everyone **MUST** be part of THE  
TEAM for *quality* patient care



*May need to  
REMIND, REMIND and REMIND  
Personnel of RESPONSIBILITIES*



QUALITY



Patient  
Safety

Failure to recognize lack of quality and  
Improve quality in the *TTP*  
can and does jeopardize patients' safety

Requires Quality Management

# Ongoing Quality Improvement Goals

Important to look and find errors throughout TTP, measure frequency, and tie to behaviors or practices so that **quality** can be **improved**

# Quality Assessment/Assurance: Monitors & Improves

- Continually and *seriously* be involved to ensure *(ongoing)* effectiveness
  - Think monitoring
  - Think problem investigation
  - Think corrective actions
  - Think quality improvement

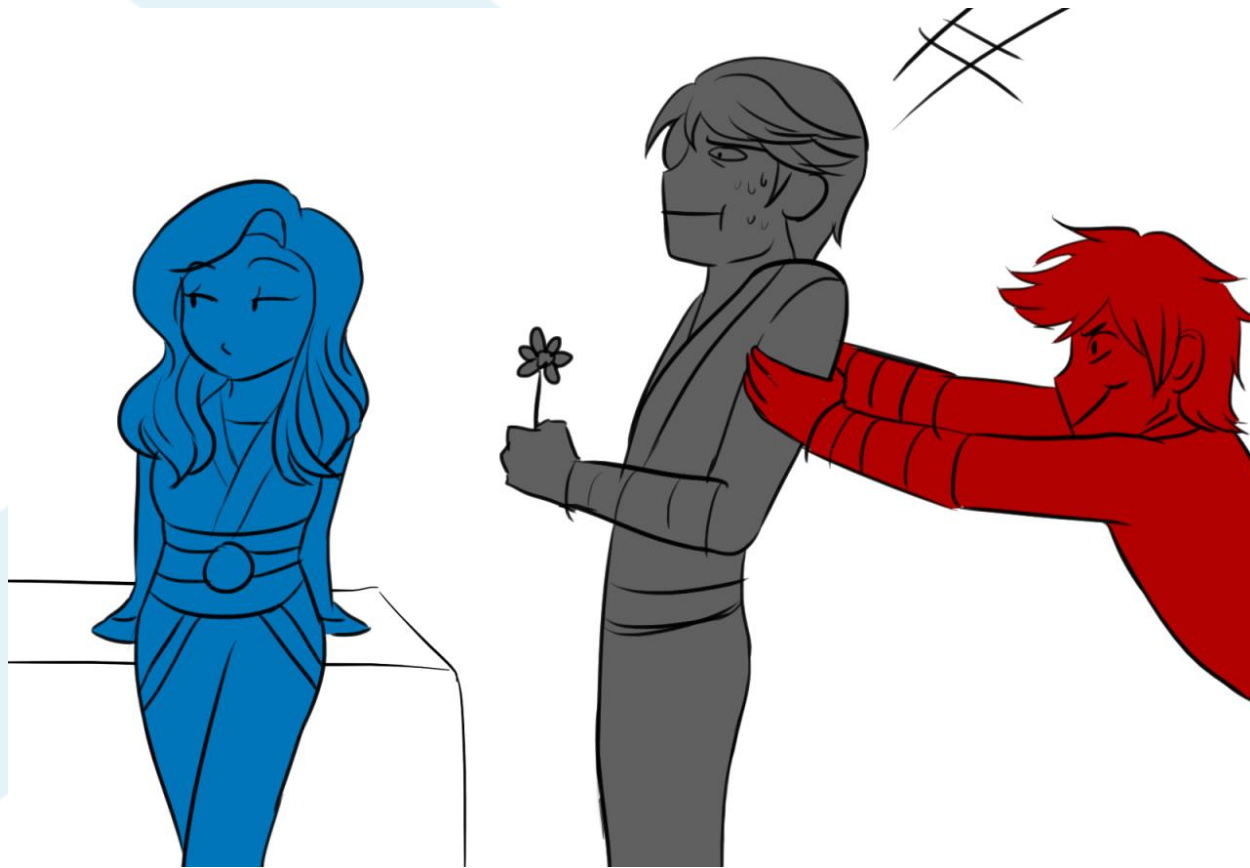


# Quality Improvement: How?



# CAP's New (2020) Approach

## A Gentle Push – to Improved Quality!



# CAP revises GEN.13806

- GEN.13806 QM Program - The laboratory has a ~~written~~ quality management (QM) program
  - CAP wants an *Active* (not just written) QM program that responds to problems
    - Actions identify, correct, and prevent testing problems including when quality indicators DO NOT meet targets
    - Evaluates EFFECTIVENESS of these actions
    - Records ACTIONS and EFFECTIVENESS

CAP, *“No point in taking actions that do not accomplish anything”*

32



# CAP: Investigating non-conforming Events

CAP's revised (2020)  
GEN.20208 QM Patient  
Care/Client Services

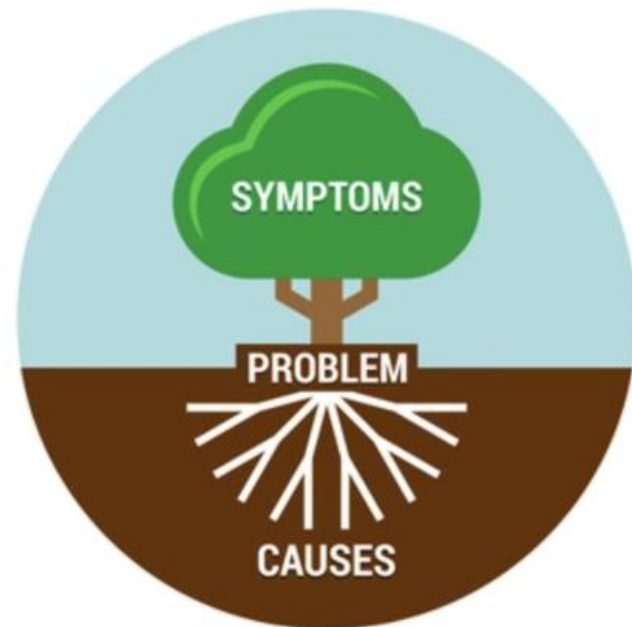
The QM program includes a process to identify and evaluate non-conforming events -- errors and incidents that may interfere with patient care/client services

CAP's new (2020) GEN.20310  
QM Investigation of Non-  
conforming Events

Requires **RCA** when non-conforming event occurs resulting in death, permanent or severe (temporary) harm, e.g., sentinel event. Nonconformances causing near misses, not sentinel events, QM program must define scope and extent of investigation required.

# Root Cause Analysis Approach

- **Root cause analysis:** A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.
- **In more general terms:**
  - Looking deeply into problems to find out why they are happening.
  - Uncovering causes that are not obvious.

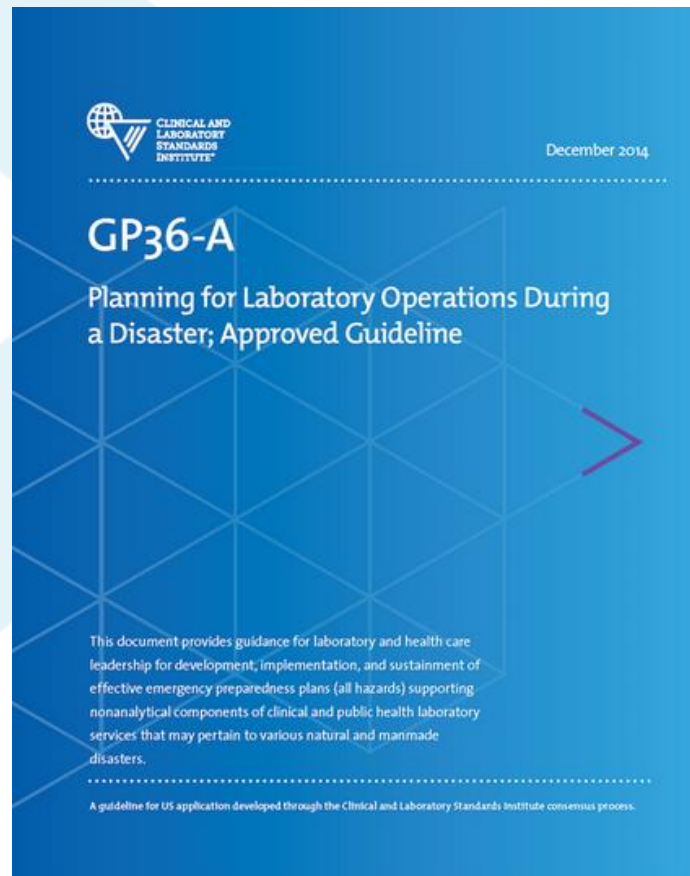


RCA's in-depth look often requires a cultural change

# **“Next Crisis?”** New Demands for POC/Critical Care Testing



# Guidance from CLSI GP36-A



# COVID-19: Essential Considerations for Cartridge-Based Systems Selection

CLSI GP36	Description	Requirements
6.6 Lab Supplies and Inventory	Sudden testing increase could deplete inventory. Continued availability of supplies is essential...acquire shelf stable, room temperature, nonperishable...POCT reagents [supplies] to enable essential testing...	Uninterrupted supply of testing cartridges.  Simplified storage of testing consumables.
6.7, 6.7.1 Lab Tests and Instrumentation	Test menu may need to be adjusted...to adapt to practicalities and priorities...	Flexible testing systems to address sudden changes in emergency situations.
6.8 Reporting of Results	...plan is accomplishing timely delivery of correctly identified, accurate test results ...	Quality results to ensure patient safety.
6.10 POCT	...exporting POCT off site...due to...testing in the community...with expansion of care...  Noted...All POCT users must be familiar with POCT device...requiring trainer capable of training, certifying, and documenting new users on [all phases of testing]...	Availability of additional POCT systems to address sudden increases in testing volume Easy to use machine with minimal lab intervention and e-learning platform

# Lessons learned at POC due to COVID

Essential requirements for critical analyses at 900-bed acute care hospital:

- 1) Timely **manufacturer support** to meet increased testing demands and ensure preparedness
  - Vendors must be available
  - Vendors must preserve the supply chain for uninterrupted clinical service to healthcare providers
- 2) Right **analyzer platforms** to support quality patient care and healthcare-provider safety

# Essential cartridge-based systems

## features:

(For operators under time constraints and wearing full PPE in areas of restricted access)

- Ease of use, minimal user intervention, minimal training
- High performance, high throughput
- Broad, flexible testing panel
- No maintenance
- Limited consumables; infection control
- Room-temperature cartridge storage
- Ensured accuracy and precision of critical results
- Integrated QMS to ensure results and minimize retesting
- Remote oversight
- Comprehensive data management system
  - View number of tests performed, operators, informatics, and quality assurance data.



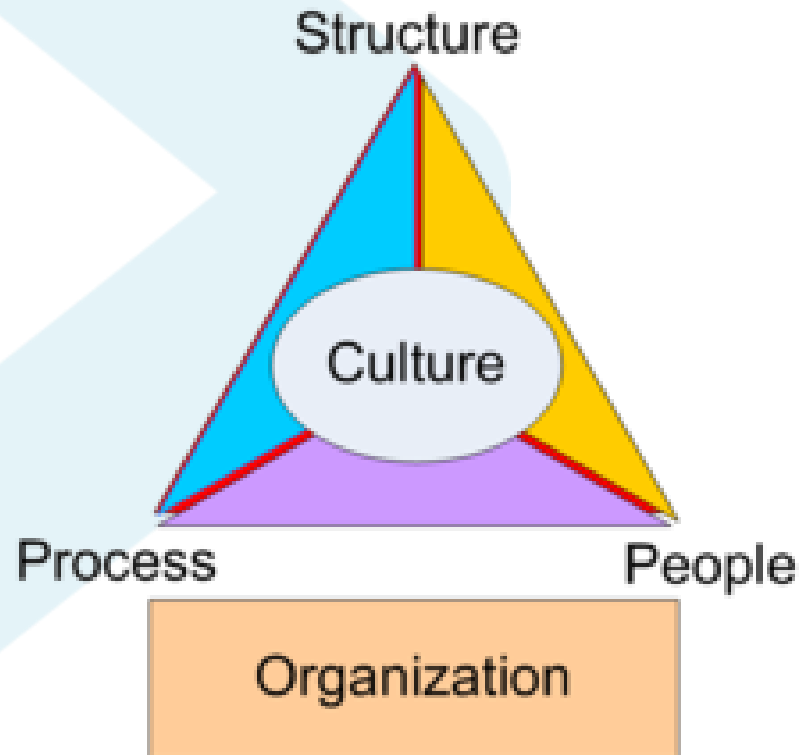
# No Surprise: These are Difficult, Stressful Times



Is a Toxic Environment adding to your Stress



# The Right Culture



# Is it time to change the Culture?

## 6 Elements to Improve Culture

### The Lippitt-Knostr Model for Managing Complex Change

Vision	Consensus	Skills	Incentives	Resources	Action plan	=	Success
<del>Vision</del>	Consensus	Skills	Incentives	Resources	Action plan	=	Confusion
Vision	<del>Consensus</del>	Skills	Incentives	Resources	Action plan	=	Sabotage
Vision	Consensus	<del>Skills</del>	Incentives	Resources	Action plan	=	Anxiety
Vision	Consensus	Skills	<del>Incentives</del>	Resources	Action plan	=	Resistance
Vision	Consensus	Skills	Incentives	<del>Resources</del>	Action plan	=	Frustration
Vision	Consensus	Skills	Incentives	Resources	<del>Action plan</del>	=	Treadmill

# Its also Time to Remember Your Personal Safety

- Covid Safety\*

- Hazards faced in the workplace everyday
- PPE should not be taken for granted
- Unsafe acts of others can affect you and the team

- Your Burnout is Real\*\*

- POCT/lab personnel tend to fly under the radar

\*Scungio D. Looking Back and Moving Forward with COVID-19 Lab Safety. ML0. October 2021. <https://www.mlo-online.com/management/lab-safety/article/21238797/looking-back-and-moving-forward-with-covid19-lab-safety>

\*\*Miller J. Your Burnout is Real. CLN. October 2021.

<https://www.aacc.org/cln/articles/2021/october/your-burnout-is-real>

# What about Tomorrow for POCT?



## Next Crisis -Who knows?

- Keep current, keep “ear to ground”, be in the know
- Be flexible
- Be ready for “whatever”

More analytes; more approaches to testing

More intelligent automation to better ensure quality and patient safety

[illegible]

Westgard SA, Goldschmidt HMJ, Ehrmeyer SS. POCT Analysts' Perspective: Practices and Wants for Improvement. *J Appl Lab Med*. 2020 May 1;5(3):480-493

# Future (now?) Intelligent Automation: More Manufacturer Control of POCT?

Because (ponder these potential benefits) they can:

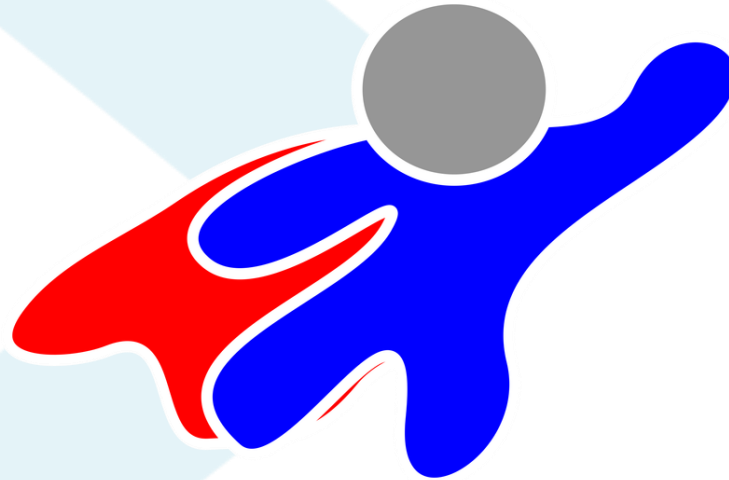
- Reduce costs
- Competition will demand it
- Address shortage of personnel
- Expand POCT and test menu
- Easily expand diagnostic acumen by addressing medical and patient needs
- Assure quality, negating need for most regulations?

# My last Word on Quality and Safety --

## Continue to:



# So Much Stuff; So Little Time



Thanks to all of you -- POCT Heroes!

