Meeting Dynamic Challenges for POCT Quality and Patient Safety

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SCHOOL OF MEDICINE AND PUBLIC HEALTH
UNIVERSITY OF WISCONSIN, MADISON, WI

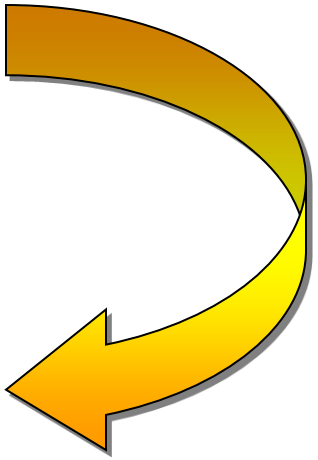
Today's Goal

Developing strategies to meet today's and tomorrow's challenges and enhance POCT's contribution to the healthcare team

Goal: Laboratory & POC Testing

Positive contribution to healthcare team for quality patient care

Healthcare Lab/POC Focus



Merging of Quality and Patient Safety

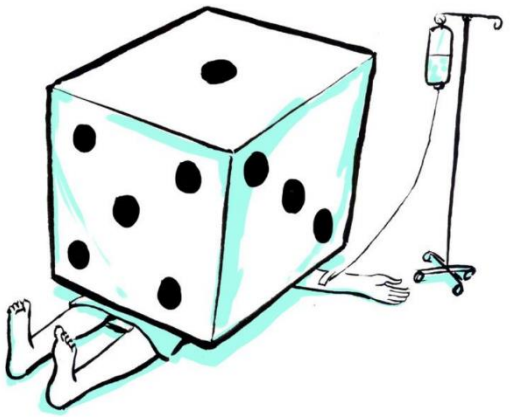
Annual Causes of U.S. Death*

Top Causes	2,597,000
Heart Disease	**611,000**
Cancer	585,000
Medical Error	251,000
COPD	149,000
Suicide	41,000
Firearms	34,000
Motor Vehicles	34,000
Other	892,000

*National Center for Health Statistics. May 2016, BMJ

Outpatients: Death by Medical Error

- In U.S., at least 5% of adults seeking outpatient care:
  - Experience a diagnostic error
  - These errors contribute to
    - Nearly 10% of deaths annually
    - Up to 17% percent of adverse hospital events



Singh H, et al. https://psnet.ahrq.gov/resources/resource/27899/the-frequency-of-diagnostic-errors-in-outpatient-care-estimations-from-three-large-observational-studies-involving-us-adult-populations
NQF. Improving Diagnostic Quality and Safety, FINAL REPORT. (2017) https://www.qualityforum.org/Publications/2017/09/Improving_Diagnostic_Quality_and_Safety_Final_Report.aspx
Carroll A. https://www.nytimes.com/2016/08/16/upshot/death-by-medical-error-adding-context-to-some-scary-numbers.html

Quality Test Results: Part of Solution

Common quote --
60 – 80% of clinical decisions are based on laboratory/POCT results

Quality Strategies:

As a healthcare “team” member -- where to start?

Strategy:

Stay in the "KNOW"

CLIA

The Joint Commission

COLA

COLLEGE of AMERICAN PATHOLOGISTS

A2LA

Don't forget to comply
with the state requirements too

Meet testing requirements

- Know and comply with CLIA/accreditation requirements
  - Established testing regulations/requirements/standards represent GLP
  - BUT…Always do the “right” thing and this may mean more (e.g., think waived testing as one example)

Strategy: Inspection Preparation (To test compliance)

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

Make sure all staff are doing what P/P state

- Pay particular attention to frequent deficiencies, e.g., training/competency, laboratory director’s responsibilities, etc.

CLIA: Top 10 (Jan. 2017) deficiencies

Regulation	Deficiency	% All Lab Cited	% POLs Cited
493.1252(b)	Criteria for reagent and specimen storage; test system operation; test result reporting	5.1%	5.1%
493.1289(a)	Policies/procedures followed to monitor, assess, and correct problems identified in 493.1251-.1283	4.9%	3.0%
493.1251(b)	Complete procedure manual	4.6%	4.5%
493.1236(c)(1)	At least 2X every year, verify accuracy of tests not enrolled in HHS approved PT	4.4%	4.7%
493.1291(c)	Test report includes all mandated items	4.3%	4.3%
493.1235	Policies/procedures followed to assess employee and, if applicable, consultant competency	3.9%	3.4%
493.1252(a)	Tests performed as specified by manufacturer and within lab's stated performance specifications	3.6%	3.1%
493.1252(d)	Reagents, solutions, etc. used, not outdated or of substandard quality	3.4%	3.3%
493.1254(a)(1)	Maintenance performed at least at manufacturer's stated frequency	3.3%	2.9%
493.1255(b)	Cal verif performed as specified by manufacturer or at least every 6 months	3.2%	2.7%

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf

CLIA: Top 10 (Jan. 2017) Conditions

(problem that has potential to or adversely affects patient test results or care)

Regulation	Deficiency	% All Lab Cited	% POLs Cited
493.1403	Director meets qualifications (493.1405) and provides management/direction (493.1407)	2.6%	2.8%
493.1441	Director meets qualifications (493.1443) and provides overall management/direction (493.1445)	1.6%	0.9%
493.801	Enrolled in HHS approved PT for each specialty and subspecialty tested and tests samples like patients	1.2%	1.1%
493.1250	Nonwaived testing meets requirements (493.1251-.1283); monitor, evaluate quality and correct problems (493.1289)	1.2%	1.1%
493.803	Nonwaived testing enrolled in HHS approved PT; lab successfully passes PT	1.0%	1.1%
493.1409	Lab has qualified technical consultant (493.1411) who provides oversight (493.1413)	0.9%	1.0%
493.1421	Lab has sufficient qualified individuals (493.1423) to perform functions (493.1425)	1.0%	0.9%
493.1415	For hematology testing, meets requirements (493.1230-.1256, 1269, 1281-.1299)	0.6%	0.4%
493.1487	High complexity labs have sufficient qualified individuals (493.1489) to perform functions (493.1495)	0.5%	0.5%
493.1447	High complexity labs have a qualified technical supervisor (493.1449) to perform functions (493.1451)	0.4%	0.2%

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf

Help in Inspection Readiness

CAP Inspected Testing Sites

Fast Focus on Compliance

12 Inspector Tools To Make Your Inspection Go More Smoothly

Purpose: provide tip sheets to inspectors to help ensure consistent inspection findings

What's good information for the inspector is good for us too!

Table of Contents

325 Waukegan Rd. |Northfield, IL 60093
t: 800-323-4040 | cap.org

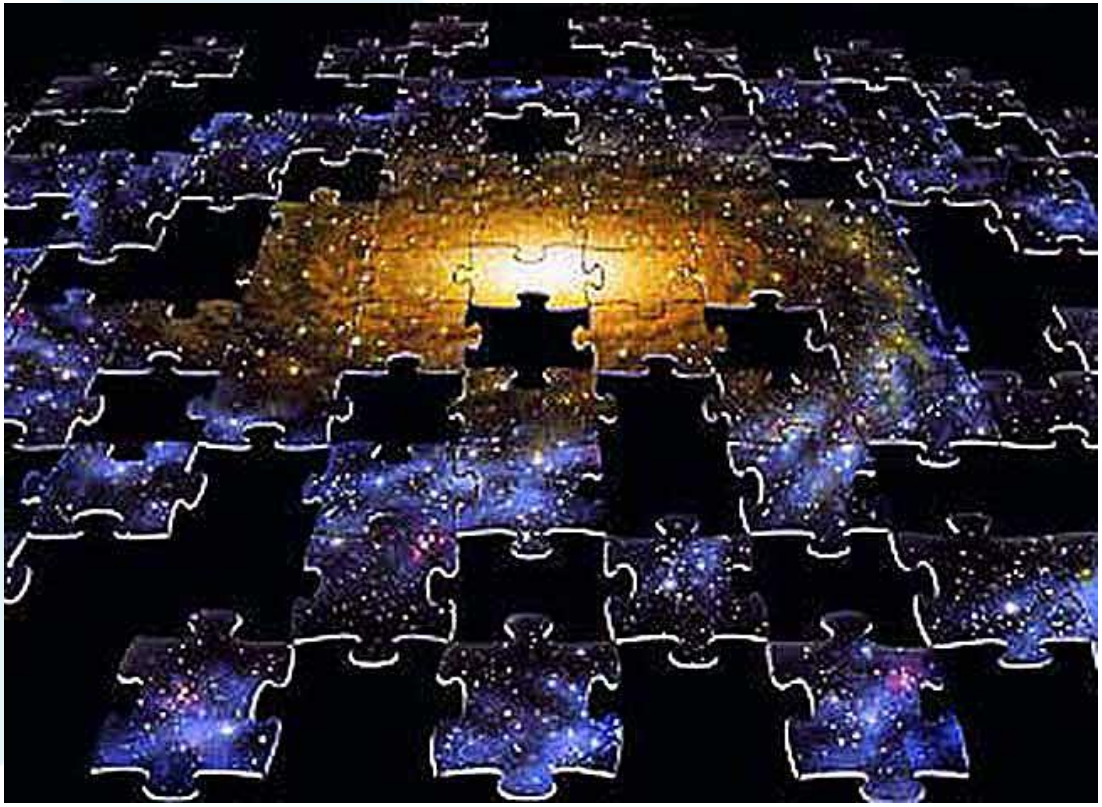
Version no.

http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/DctmContent/education/OnlineCourseContent/2016/FFoC_Resources_080116.pdf

COLA Inspected Testing Sites

https://www.cola.org/insights-newsletters/2016/fall/insights-fall-2016.pdf

Strategy: Managing the BIG picture: Quality/Risk Management



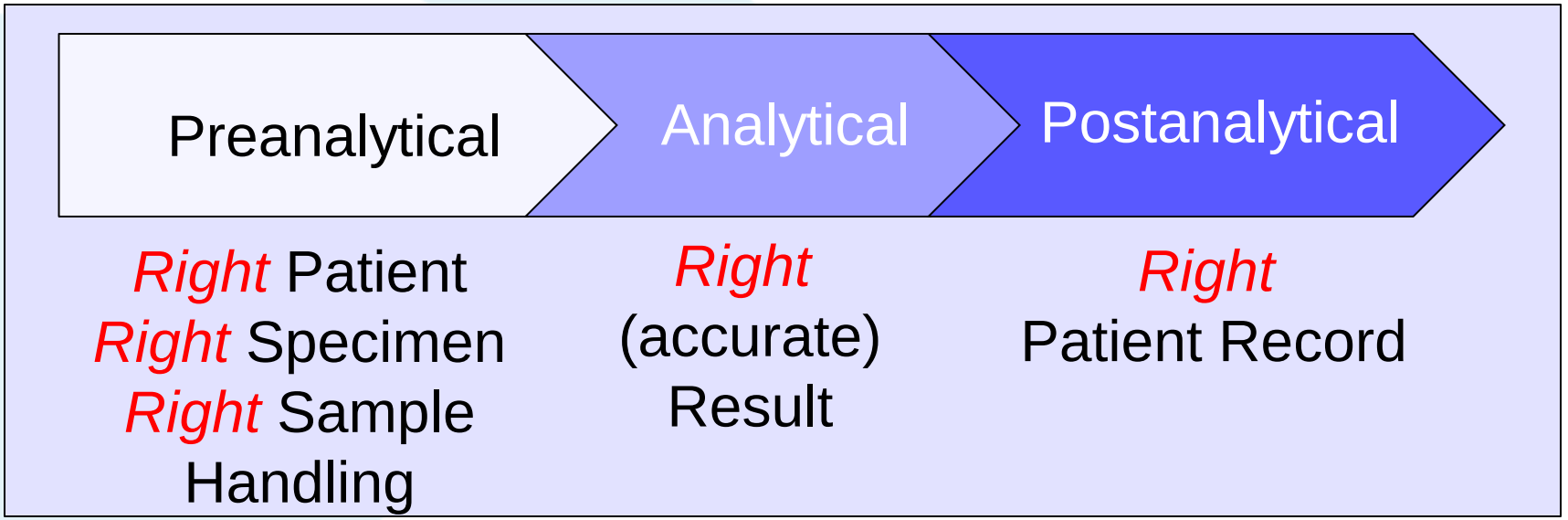
Quality/Risk Management

Pre-analytical

Analytical

Post-analytical

Quality/Risk Management: *At first glance:*



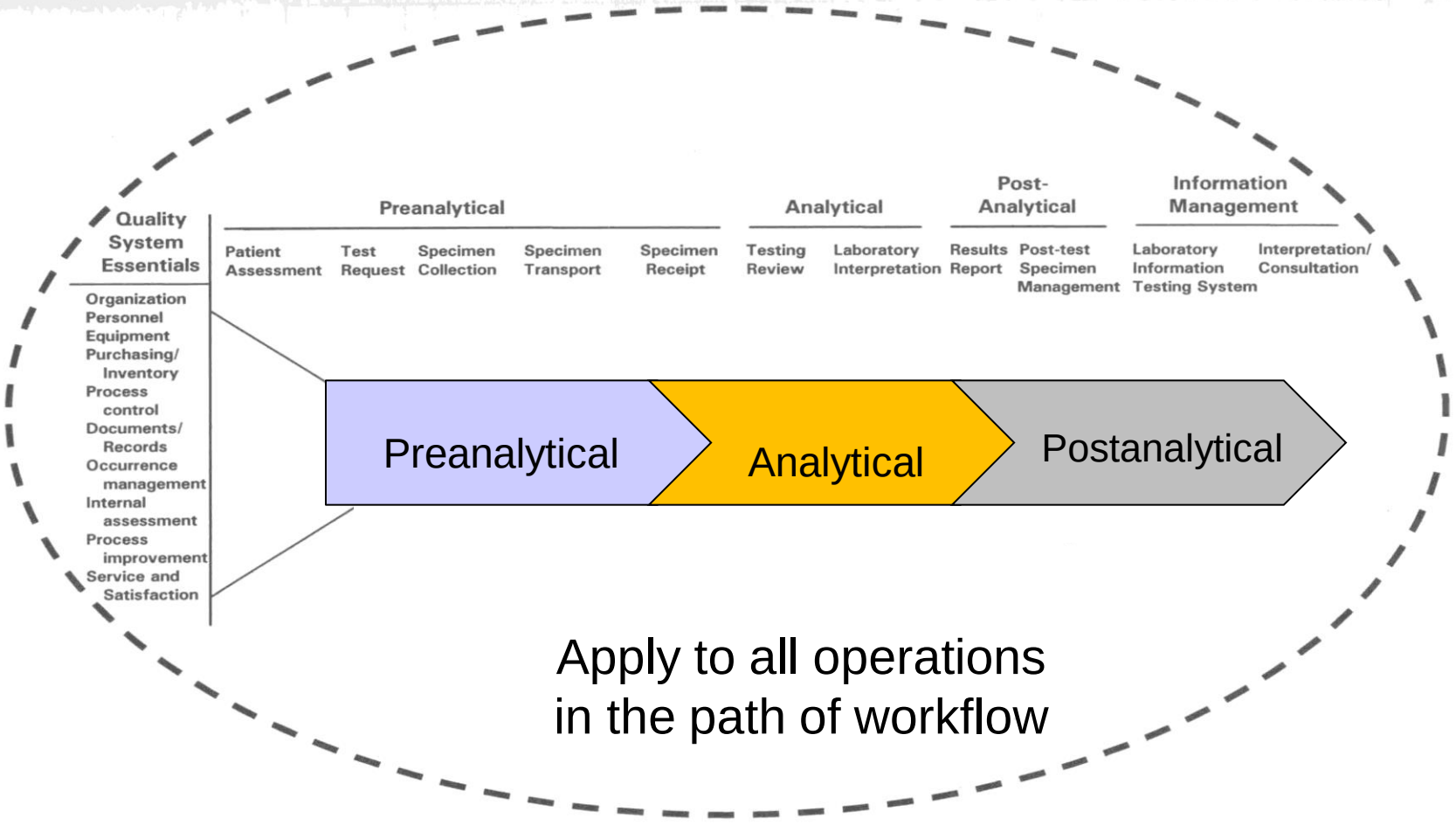
Think beyond IQCP development

QUALITY → Patient Safety

Failure to recognize lack of quality and Improve quality in the *entire testing* process can jeopardize patients' safety

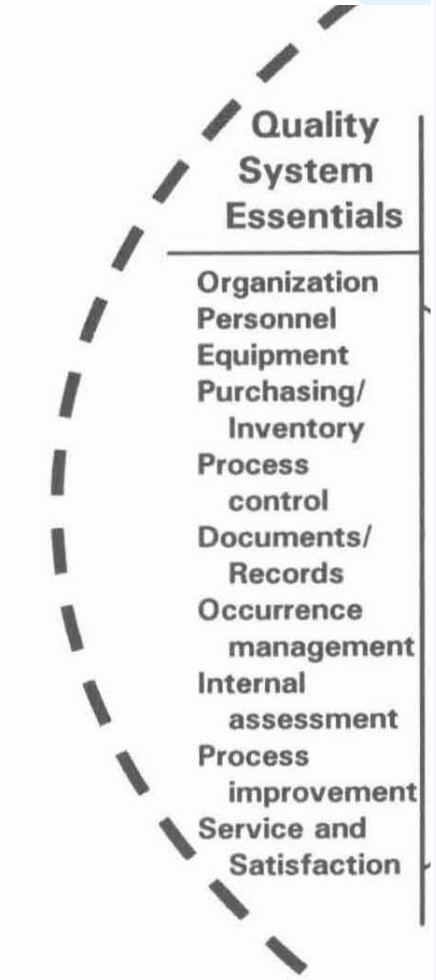
Need effective quality/risk management

Quality/Risk Management Essentials: BIG picture includes so much more!



CLSI. K2Q Key to Quality. https://clsi.org/standards/products/quality-management-systems/companion/k2q/

QSE & ISO 15189 Quality Requirements



4. Management requirements

4.1 Organization and management responsibility
4.2 Quality management system
4.3 Document control
4.4 Service agreements
4.5 Examination by referral labs
4.6 External services and supplies
4.7 Advisory services
4.8 Resolution of complaints
4.9 Identification and control of non-conformities
4.10 Corrective action
4.11 Preventive action
4.12 Continual improvement
4.13 Control of records
4.14 Evaluation and internal audits
4.15 Management review

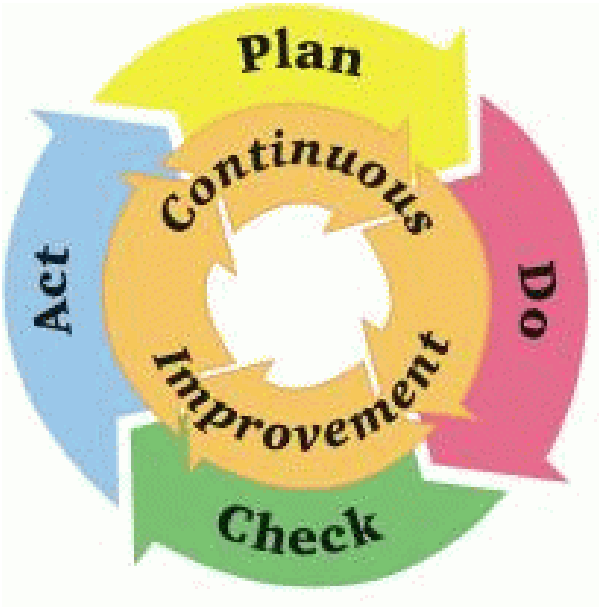
5. Technical requirements

5.1 Personnel
5.2 Accommodation and environmental conditions
5.3 Laboratory equipment, reagents and consumables
5.4 Pre-examination processes
5.5 Examination processes
5.6 Ensuring quality of examination results
5.7 Post examination processes
5.8 Reporting results
5.9 Information systems*
5.10 Laboratory Information management*

www.iso.org

Strategy: Monitor, Monitor, Improve, Improve

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



Getting Started…

CLIA's Condition Level Deficiencies-*Jeopardy*?

(Have potential to or adversely affects patient test results or care)

Missing Focus for Patient Safety	Cited Deficiency
Quality leadership for management	Director meets qualifications; provides management/direction
Quality test result assessment	Enrolled in HHS approved PT for each specialty and subspecialty tested and tests samples like patients
Quality plans that ensure quality practices	Nonwaived testing meets requirements; monitor, evaluate quality and correct problems
Quality leadership for oversight	Lab has qualified technical consultant who provides oversight
Adequate qualified staffing	Lab has sufficient qualified individuals to perform functions
Adequate qualified staffing	High complexity labs have sufficient qualified individuals to perform functions
Quality leadership for oversight	High complexity labs have a qualified technical supervisor to perform functions

Why deficiencies? Lack of quality by not having the right personnel doing the right things!

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf

§ 493.1812: Action when (condition) deficiencies pose immediate jeopardy

- CMS requires immediate action to remove jeopardy
  - May impose 1 or more sanctions to help bring lab into compliance
- On revisit, if lab has not eliminated jeopardy, CMS will suspend/limit lab's CLIA certificate
  - May later revoke certificate
- When CMS thinks continuation of any activity constitutes a significant hazard to public health
  - May bring suit/seek temporary injunction/restraining order against activity continuation
    - Regardless of CLIA certificate and State-exemption

e-CFR data is current as of October 2, 2017. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

CLN OCTOBER 2017

How to Choose a Quality Improvement Project

Q&A with Michael Astion, MD, PhD, Editor-in-Chief, *CLN* Patient Safety Focus

✓ The project has no dependence on the hospital information technology department.
✓ The project requires no financial request beyond the current budget.
✓ The problem can be solved with existing lab resources and without the help of outside consultants.
✓ The problem can be solved by the team you supervise or involves working with an outside department with a strong history of collaboration.
✓ The project is likely to produce an outcome that is financially neutral or beneficial.
✓ The project improves patient safety directly or through a related outcome that is easily understood (e.g., fewer lost specimens, fewer mislabeled specimens, fewer incorrect test orders, more precise test results, fewer corrected reports).
✓ Chosen metrics (e.g., turnaround time outliers) can be measured accurately and without significant delays.
✓ The problem annoys the lab workers responsible for the project so that a solution to the problem will please them.
✓ The problem annoys the care providers that your team services most frequently.
✓ The project can be completed with existing staffing.

T2 Do's and Don'ts for Performing a Basic QI Project

Do keep it simple. QI is not as difficult as other lab pursuits.
Don't spend too much time learning hip new tools. Use tools (e.g., process map, timing studies) with which you are familiar and only add those that are necessary and easy to understand.
Do choose one or two metrics that can be measured accurately.
Do choose a specific, challenging, yet achievable goal. For early wins, choose smaller increments.
Do choose interventions that rely only on existing budget and staff resources.
Avoid using outside consultants who have no skin in the game and little relevant or recent experience with managing operations.

https://www.aacc.org/publications/cln/articles/2017/october/how-to-choose-a-quality-improvement-project

CAP's (2017) Patient Safety Focus: QM Stds. critical to patient outcome

- **GEN.20316 QM Indicators of Quality**…monitoring key indicators of quality in pre-analytic, analytic, and post-analytic phases
- **GEN.20325 Employee and Patient Quality Communication**…procedure for employees/patients to communicate quality/safety concerns
- **GEN.20330 CAP Sign**…posts the official CAP sign regarding the reporting of quality concerns to CAP
- **GEN.20335 Customer Satisfaction**…[data on] satisfaction of healthcare providers or patients with lab services within past 2 years
- **GEN.20340 Notifications From Vendors**…manages notifications…of defects/issues with supplies/software that may affect patient care
- **GEN.20351 Adverse Patient Event Reporting**…procedure for reporting device-related adverse patient events, as required by the FDA
- **COM.04050 Error Detection and Correction**…written procedure for detection/correction of significant clerical/analytical errors, and unusual lab results

Quality Emphasis: Patient Safety Goals

2017 Laboratory National Patient Safety Goals

The purpose of the National Patient Safety Goals is to improve patient safety. The goals focus on problems in health care safety and how to solve them.

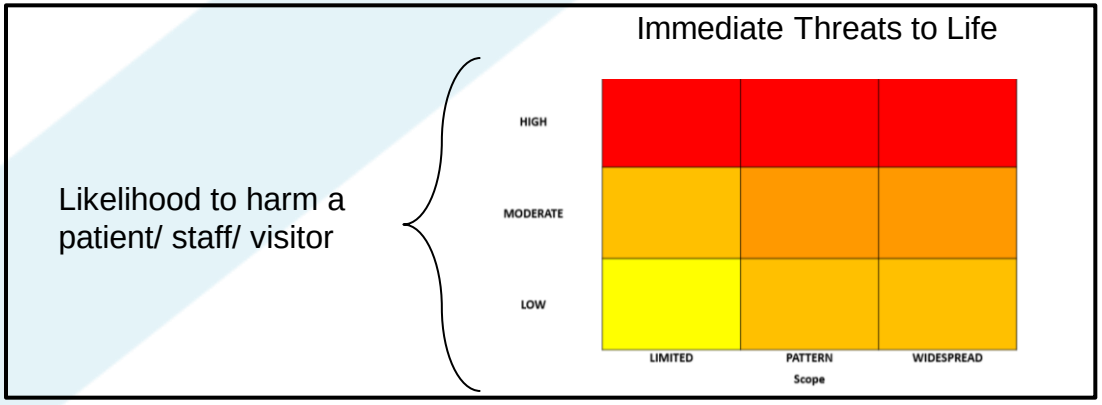
Identify patients correctly	
NPSG.01.01.01	Use at least two ways to identify patients. For example, use the patient's name *and* date of birth. This is done to make sure that each patient gets the correct medicine and treatment.
Improve staff communication	
NPSG.02.03.01	Get important test results to the right staff person on time.
Prevent infection	
NPSG.07.01.01	Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning. Use the goals to improve hand cleaning.

Effective January 1, 2018 -- several revisions to NPSG 7 requirements for hospitals, critical access hospitals, and nursing care centers were made.

https://www.jointcommission.org/assets/1/6/2017_NPSG_LAB_ER.pdf
https://www.jointcommission.org/assets/1/6/Changes_NPSG_7_hai.pdf

The Joint Commission's SAFER (Survey Analysis for Evaluating Risk) Matrix

- To better identify and communicate risk levels associated with deficiencies
- To help organizations prioritize and focus on corrective actions



https://www.jointcommission.org/assets/1/6/SAFER_Matrix_New_Scoring_Methodology.pdf

Priority for corrective action

SAFER Matrix™ Placement	Required Follow-Up Activity
HIGH/LIMITED, HIGH/PATTERN, HIGH/WIDESPREAD	• 60 day Evidence of Standards Compliance (ESC) - ESC will include Who, What, When, and How sections • ESC will also include two additional areas surrounding Leadership Involvement and Preventive Analysis • Finding will be highlighted for potential review by surveyors on subsequent onsite surveys up to and including the next full survey
MODERATE / PATTERN, MODERATE/WIDESPREAD	• 60 day Evidence of Standards Compliance (ESC) - ESC will include Who, What, When, and How sections • ESC will also include two additional areas surrounding Leadership Involvement and Preventive Analysis • Finding will be highlighted for potential review by surveyors on subsequent onsite surveys up to and including the next full survey
MODERATE / LIMITED, LOW / PATTERN, LOW / WIDESPREAD	• 60 day Evidence of Standards Compliance (ESC) - ESC will include Who, What, When, and How sections
LOW/LIMITED	• 60 day Evidence of Standards Compliance (ESC) - ESC will include Who, What, When, and How sections

The Joint Commission

https://www.jointcommission.org/assets/1/6/SAFER_Webinar_11-15-16.pdf

*Leadership** is required for lab safety (and patient safety)

- Building a culture of safety
- Encouraging openness and transparency
- Ensuring safety competency
- The incident management plan
- Process for incident investigation

*Irwin Rothenberg. Technical writer/quality advisor: COLA Resources, Inc.

MLO. Achieving a culture of safety with competency and commitment. (Oct 2017) https://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201710/html/index.html?page=24&origin=reader

COLA: It's about so much more than compliance

Within the total healthcare system…we see growing awareness of the importance of accurate laboratory information to improve patient outcomes

…we know that accuracy emerges through relevant, practical, quality and safety-centered processes combined with a continuous "quality-on-the-mind" focus during daily actions of caring for patients…

Douglas A. Beigel, COLA's Chief Executive Officer, COLA 2017 Laboratory Accreditation Manual

Quality Strategy: “Right” Culture

“Quality and Patient Safety *NOT* associated with mismanagement, hostilities, “in-fighting,” incompetence, disorganization”

Anne Belanger, former inspector and Laboratory Accreditation director, The Joint Commission

Effective Quality/Patient Safety Culture

Starts at the top - leadership promotes…makes commitment evident

Vision driven clinical metrics to evaluate performance (compliance with recognized standards) and metrics to evaluate the patient experience

Involves everyone at every level - close gap of where organization is to where it should be

Evolves - Not a one-time fix; culture development is a journey

Is consistent - committed leadership; responsive to adverse events; accountability by all; realize most mistakes due to faulty processes

Transcends leadership – positive, successful culture continues when leadership changes

http://www.beckershospitalreview.com/quality/6-elements-of-a-true-patient-safety-culture.html

“Effective” Thinking for Evolving (effective) Cultures

“Right” Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Who did it?	What happened? Why?
Punitive	Fair and just
Bad people	Bad systems
Penalize the reporter	Thank the reporter
Confidential	Transparent learning
Investigation	Root cause analysis
Independent silos; no/little communication	Inclusive and interdisciplinary team; lots of communication

http://www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

“Right” Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Thinking errors are rare	Realizing errors are everywhere
Great care	Great care in a high-risk environment
Lack of direction; staff make it up as they go along	Principles of fair and just culture, guidelines algorithms, flow charts
Risk of disclosure/confidentiality	Moral duty, risk of non-disclosure
Great staff; poor systems	Great staff; great systems
Deliver care to patients	Partner with team, patients and families

http://www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

Thinking: Is another *twist* needed to improve patient safety?

Can we expand our thinking about patient safety by moving from creating environments in which as few things as possible go wrong, to creating ones in which as many things as possible go right?*

Focus on patient safety is mainly on the things that go wrong, instead of the things that do go right.

Fixation on errors is reactive and may encourage “a find and fix” approach, without changing the mindset and culture…

*Thank you goes to Ramona Lanzo, POC Specialist/Safety & Education, Columbia University, New York, NY

Hollnagel E. From Safety-I to Safety-II.University of Southern Denmark, Institute for Regional Health Research (IRS), Denmark.
www.http://resilienthealthcare.net/onewebmedia/WhitePaperFinal.pdf

Strategy: Buy smart

Many choices available
Choose *right* for YOUR testing situation

Let testing's evolving technologies (and computer capabilities) help meet many testing challenges!

Strategy: Be Alert and ready for change

Change, Never Doubt!

PREDICT

- Make a Guess
- What Will Happen Next?

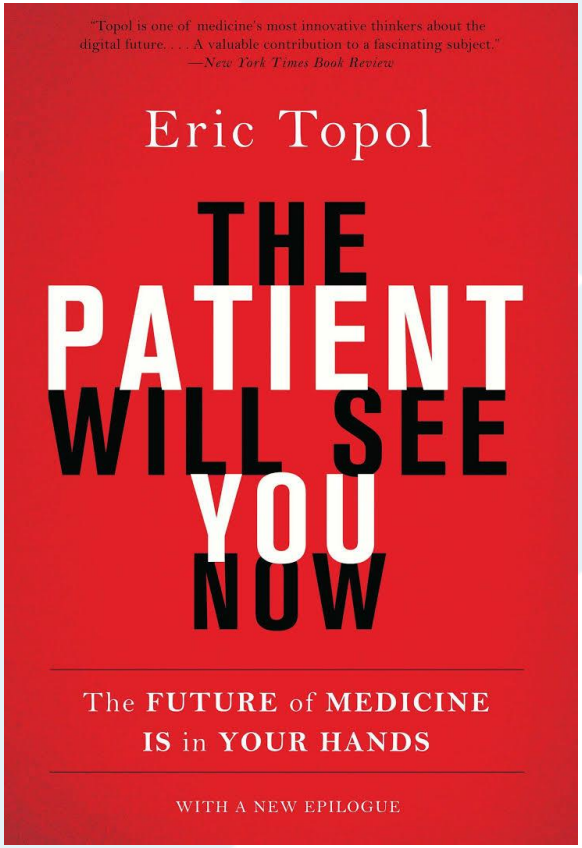
Alert: Examples that may require change

- Reimbursement
- Glucose monitoring
- Laboratory developed tests
- New technologies
- Improved technologies
- Proficiency Testing
- Expanding POCT menu
- Emerging infections/diseases
- Changing/revised test requirements
- Cancer moonshot
- Altered treatment patterns
- Precision medicine
- Cyber threats
- New pre-analytical variables
- Medical breakthroughs
- More waived tests
- New drug treatments
- New interferences
- Managed care

Alert to a different view of “*C*”

Now “*C*” = Care; Future “C” = ?

POCT = Customer



Dr. Eric Topol, cardiologist and director, Scripps Translational Science Institute, La Jolla, CA USA

Considered to be one of medicine's most innovative thinkers

Technology developments and genomics will continue to change the face of healthcare delivery

Eric Topol. Basic Books, NY, New York, 2015

Topol's "The Patient Will See you Now"

"…health care…stymied by … restrictions on patient involvement…"

"…[patient is] single most unused person in health care..."

"… [smartphone] empowered patients will take charge of their own health care…access…own medical records and generate…own medical data…"

"…smartphones will…perform blood tests, medical scans, and even parts of the physical examination…"

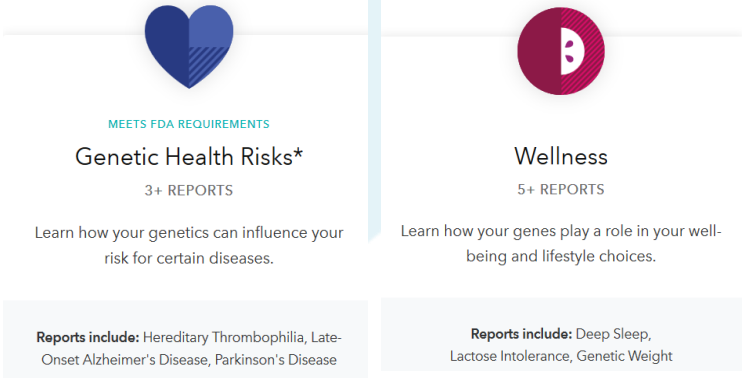
"…someday…all blood tests … normally done in a hospital or clinic laboratory will also be obtainable by smartphone…"

POCT = *Directly* Available to Customer (Customer is in Charge)

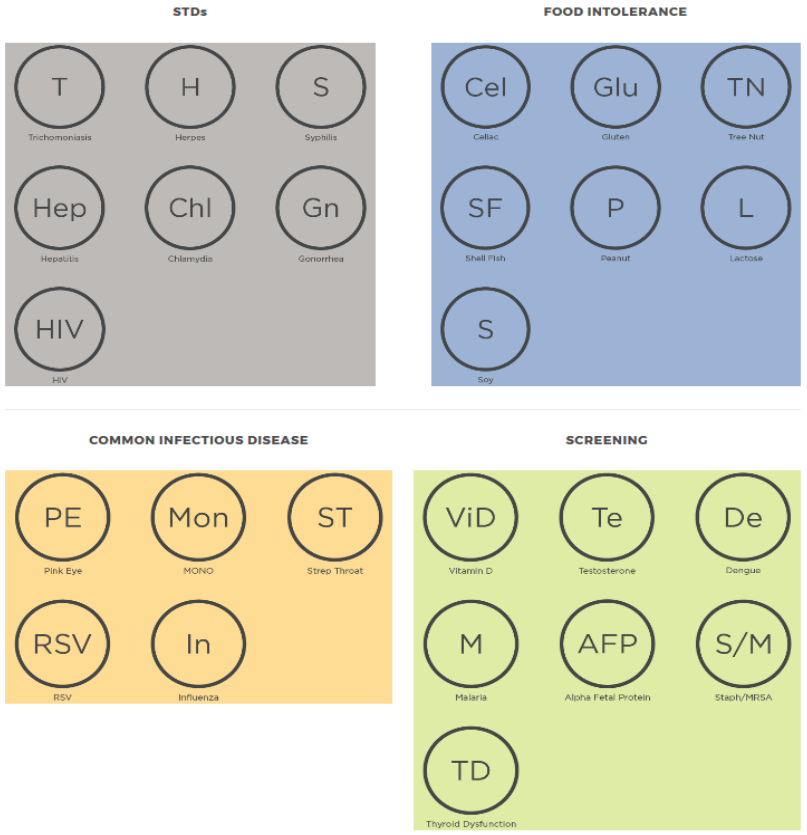
Wearable Devices

ECG t-shirt

Genomics for Health and Wellness



Future OTC

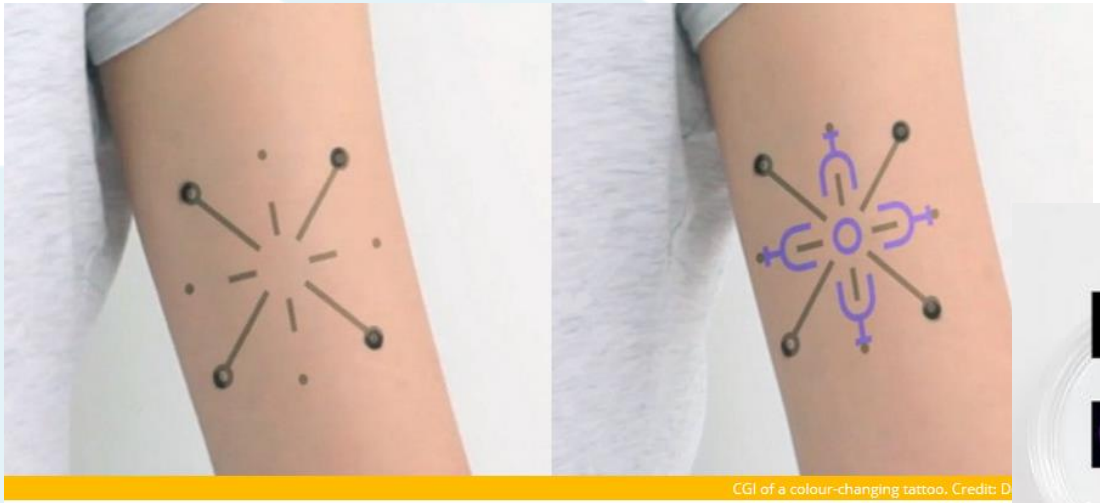


NOWDiagnostics: Medical Diagnostics Tests Reinvented. http://www/nowdx.com/

T-Shirt Sends ECG Signals To Your Smartphone – HealthWatch. http://www.personal-healthwatch. com/t-shirt-sends-ecg-signals-to-your-smartphone

DNA Testing at 23andMe. 23andme.com

Concept (now): Tracking bodily changes with “cool” biosensor tattoo



CGI of a colour-changing tattoo. Credit: D

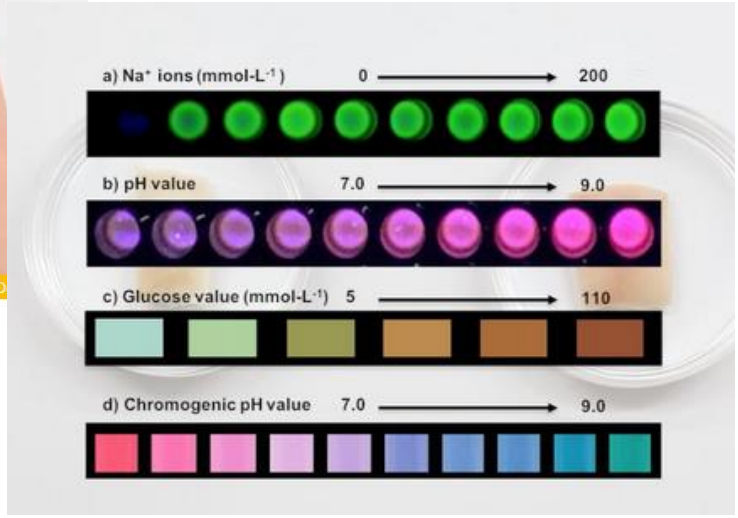
MIT Has Developed Colour-Changing Tattoo Ink That Monitors Your Health in Real Time

Perfect for diabetics.

SIGNE DEAN 13 JUN 2017

Researchers have developed a new colour-changing tattoo ink that responds to changes in the body, such as blood sugar and sodium levels.

Using a liquid with biosensors instead of traditional ink, scientists want to turn the surface of the human skin into an "interactive display" - an idea that makes this proof-of-concept an exciting one to watch. Technology like this could become a revolutionary new way to monitor health.



Proof of concept stage

https://www.sciencealert.com/mit-is-working-on-colour-changing-tattoo-ink-that-can-monitor-your-health-in-real-time

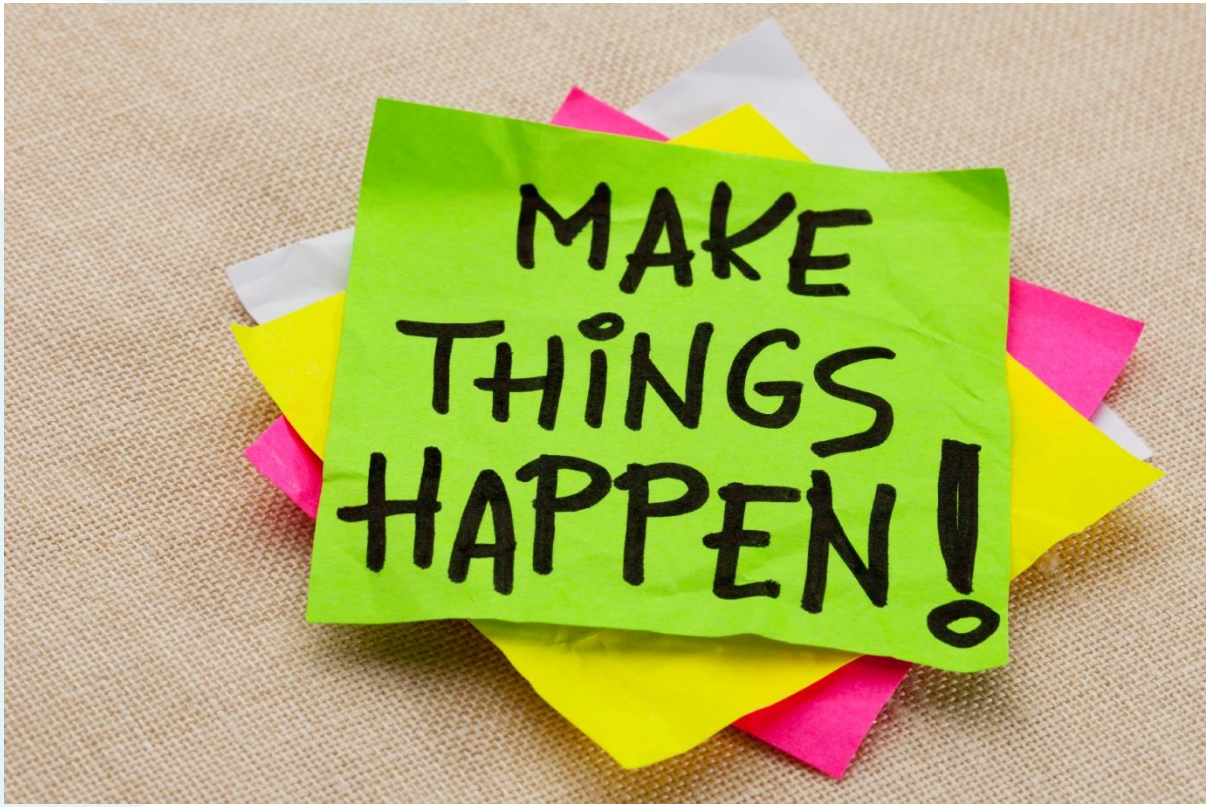
Be Alert

- Alertness – “ear to the ground,” know what is happening “outside” our testing enviroment
  - Listservs, journals, webinars
  - Professional organizations, POCT and user groups, other sites/organizations, CE activities, etc.
  - Manufacturers’ materials and representatives
  - Government websites
  - National and international news
- Preparedness – nothing lasts, so when “true” change happens – Be ready to deal with it!

Strategy Summary: To Meet (at least some) of many POCT challenges

- Meet testing requirements and more - Do the right things
- Manage Quality / Manage (the BIG picture) Risks
- Quality/Risk Management for Patient Safety
- Patient jeopardy – lack of leadership and qualified staff
- Monitor, Monitor, Improve, Improve
- Develop a Patient Safety Culture
- Different view -- Focus on what is going right?
- Buy Smart-- Let technology help with challenges
- Be Alert to change; handle change

One last Quality Strategy



Thanks