

TEST STANDARDIZATION: SOME PRACTICAL GUIDANCE

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Why standardization matters: a review



Impact of the testing setting
on standardization
considerations

POL and de-centralized testing
examples



Systematically managing the standardization process and
stakeholder needs and desires



Innovation in a standardized environment: cutting edge or
status quo?



Some questions to consider to guide your decisions on
standardization

LEARNING OBJECTIVES

Standardization enables trustworthy data to create better patient outcomes

- ▶ Where you test matters
- ▶ Physician Office Lab considerations
- ▶ In facility, but outside the core lab

Systematic Approach to Standardization

- ▶ Platform considerations
- ▶ Guiding principles drive the process and progress
- ▶ Stakeholder selection
- ▶ Assigning responsibility
- ▶ Managing control: “cop or colleague”

DISCUSSION TOPICS

Promoting innovation in a standardized environment

- ▶ What does the balance look like?
- ▶ When it's not obvious
- ▶ Sponsor responsibility
- ▶ Technology evaluation thoughts

Questions to guide your thinking

- ▶ Look outside your setting and yourself
- ▶ Keep the end in mind
- ▶ Questions that have helped me

DISCUSSION TOPICS

In all but the most acute settings, no single quantitative result determines the diagnosis or path to care

- ▶ Chronic care is all about trending results
 - ▶ Thinking about the **time telescope**
- ▶ Variability between platforms is the enemy
 - ▶ Direct and indirect ISE (high protein/high lipid concentrations)
 - ▶ Working to understand and standardize: Lipids: NIH/NCEP; A1C: NGSP, etc
 - ▶ Some excellent references on method comparison procedures
 - ▶ <https://acutecaretesting.org/en/authors/ana-maria-simundic>
- ▶ BUT, so are missing results or failure to screen appropriately (CRC, HIV, HCV, pre-diabetes, etc)
- ▶ Quantitative and qualitative tests have different criteria
- ▶ Bottom line: the right test at the right time for the right reason matters. Standardization is the tool to assure results over time have meaning

WHY STANDARDIZATION MATTERS: REVIEWING WHAT YOU KNOW

IMPACT OF THE CARE SETTING

Setting	Patient mix	Test Rationale	Clinician	Criteria	Comments
Physician Office Setting	Typically chronic disease and wellness management	Long term treatment plan; long time telescope	Present	Screen, Monitor Trends and Compliance	Few acute/peri-acute patient considerations
Hospital POC	Variable, mostly peri-acute	Assess treatment; mid range time telescope	Present	Monitoring progression/What do I need to know now	ER, ICU, not clinics
Hospital core lab	Test samples, not patients; service to care givers	Speed, quality, availability, interpretation; variable time telescope	Absent	Provide the most extensive, high quality service possible	Lab professional driven

Time Telescope: The time interval between results most meaningful to manage a clinical condition

CLINICAL PERSPECTIVE ON POL TESTING

The primary reason clinicians use POL testing:

To have tests available during the patient encounter that can be used to initiate or modify a patient treatment program

Speed diagnosis, OR assess progress after initiation of therapy

Provide a progress assessment to the patient

Method conforms to the “15 minute rule”

Confirm patient compliance with a treatment program

Diet, exercise, use of medication, lab tests, specialist treatment

Enable positive communication and solidify the relationship with the patient

Help the patient to understand and internalize THEIR responsibility for managing and maintaining their health

Clinicians and laboratorians see the world through a different lens

RECOMMENDED CORE POC TESTS

What's the test?	Why?	CLIA Category	Thoughts/comments
Hemoglobin	Quick check for anemia	Waived	Fast, easy, accurate
hCG	Pregnancy can strike at any time	Waived	Important for nutritional needs, pre-natal care and before imaging studies
Urinalysis	Fast, easy, noninvasive health screen	Waived	Should be part of every annual physical
Glucose	Diabetes, especially type 2, is on the rise worldwide	Waived	Treatment can't begin without a good diagnosis; use an accurate quantitative test
CBC	Infection, anemia, general health	Waived/Moderate	Next to glucose, UA and hCG, the best tool in the general use lab tool belt
CMP	General metabolic assessment	Waived/Moderate	Tells the story of overall patient status in health AND disease
BMP	Limited general health assessment	Waived/Moderate	Less data; typically no liver function tests
Lipid profile	Lipid disorders lead to serious complications and are often related to diabetes	Waived/Moderate	Use of statins has made lipid tests fundamental in adult medicine
A1C	Knowing average glucose level over time	Waived/Moderate	Are Ward and June sticking to their diet? How well controlled is their diabetes? Pre-diabetes Dx
Flu	Know what you are treating	Waived/Moderate	Only about 30% of all flu tests are positive; ever wonder what the other causes are?
Strep	Prevent very dangerous complications	Waived/Moderate	Before antibiotics, strep was a serious cause of illness and death
RSV?	Some practices love it; others want it done in a more sophisticated lab	Waived/Moderate	This test has arguments for and against in house testing; new, molecular tests make it a better in office test choice than ever
FIT/FOBT	Colorectal cancer is highly curable if detected early	Waived	Colonoscopy has left these tests "behind" to a large extent; they are still important

WHEN THE RIGHT TREATMENT SETTING AND EXPERTISE ARE CRITICAL

Test name	Why Test?	Why Not?	Optimal setting?
Troponin I	Speed AMI Dx	Treatment options?	Core Lab
Electrolytes	Metabolic imbalance/cardiac issues	Treatment options?	Depends on testing rationale
Blood gases	Metabolic imbalance	Invasive; skill/practice required	ER or Core Lab
Toxicology	Patient counseling	Equipment and staff requirements	Core lab
RSV	Knowing ASAP is important	Technology limitations*	Depends on who you ask

*new molecular tests dramatically improve NVP in particular

When it's NOT the method's fault

<https://acutecaretesting.org/en/articles/preanalytical-errors-in-point-of-care-testing>

- ▶ How will this result be used?
 - ▶ Immediate intervention
 - ▶ Treatment monitoring
- ▶ What are my options in avoiding false negative results for qualitative screening tests?
 - ▶ General screening or risk-based screening?
 - ▶ Infectious disease false negatives can increase morbidity and extend time to treatment AND lead to the spread of infections
 - ▶ CDC discussion of screening results v disease prevalence for influenza
 - ▶ <https://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm>
- ▶ Time and skill required v time to result needed
 - ▶ What is my **time telescope**?
- ▶ Do ALL my test settings have comparable results at medical decision levels?

THOUGHTS ON WHAT IS THE RIGHT SETTING

SYSTEMATIC MANAGEMENT OF TEST STANDARDIZATION

Things that work	Why (sometimes it pays to be “crafty”)
Active involvement of all stakeholders	Engagement leads to buy in and better decisions
Guiding principles v large sets of rules	Create broad decision criteria AND flexibility
Set and stick to a routine (time, agenda, platform)	Reduces entropy; increases confidence
Define how standardization will be managed <ul style="list-style-type: none">• Test/site selection• CLIA license management• Training• Proficiency testing• Quality control• Procedure manuals• Method evaluation criteria• Acceptable method performance	Boundaries and accountability improve process compliance

“You either have to be part of the solution, or you’re going to be part of the problem” E. Cleaver
“If you are not part of the solution, you are part of the precipitate” Scott Trahan

STANDARDIZATION AS A TOOL

“Perfection is approached by achieving balance” J. Poggi

Understand the role of standardization in the big picture

- ▶ The goal is optimizing result quality and timing to improve patient care
 - ▶ Standardization is a means to the end, NOT the end result

Maintain flexibility in guiding principles and change management

- ▶ Improved technology changes test selection and deployment dynamics
 - ▶ Molecular infectious disease tests v plated media and/or lateral flow
- ▶ CRC, PSA and PAP smears
 - ▶ What do they all have in common?

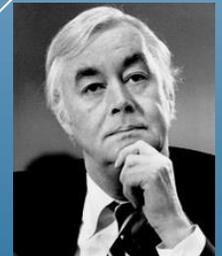
“one judges by the results”: Niccolò Machiavelli

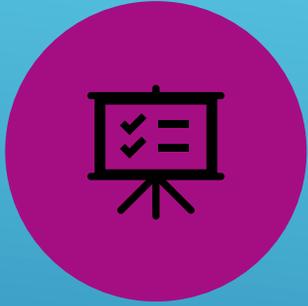
PROMOTING INNOVATION IN A STANDARDIZED ENVIRONMENT

Balancing the “bright shiny object v harmony by committee”

- ▶ Guiding principles are your most powerful tool
 - ▶ Create an environment where ideas can be shared safely BUT productively
 - ▶ Chairperson needs to be fair, decisive and empowering
 - ▶ Define responsibilities of the presenter
 - ▶ Have standardized product evaluation criteria
 - ▶ Have objective decision-making criteria and procedures
 - ▶ Render decisions on a timely basis and publish/enforce decisions

“Everyone is entitled to his own opinion but not his own facts”
Daniel Patrick Moynihan





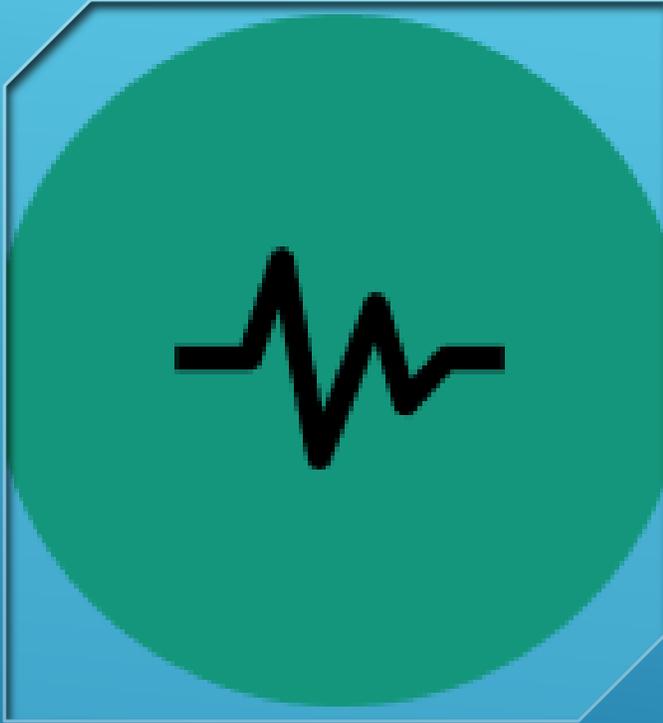
WHETHER YOU ARE CONSIDERING
ADDING A TEST, CHANGING A
METHOD OR EVEN DISCONTINUING
A TEST, CERTAIN BASIC CRITERIA
SHOULD BE MET:

CLINICAL EXCELLENCE

ECONOMIC IMPROVEMENT

PROCEDURAL EFFICIENCY

SOME FUNDAMENTAL CRITERIA



- ▶ Does the test under consideration improve the diagnostic process?
 - ▶ Clear linkage of the test result to a specific diagnosis
 - ▶ H. pylori antigen test; HCV
 - ▶ Increased sensitivity or specificity
 - ▶ Molecular RSV v lateral flow
 - ▶ Reduced false negatives/improved NPV
 - ▶ Whole blood hCG
 - ▶ FIT v FOBT
 - ▶ Greater likelihood of guiding therapeutic decisions
 - ▶ cfDNA

CLINICAL EXCELLENCE



It's not always about "cost per test or per reportable result"



It is a better use of labor
(ABG as an example)

Time required
Skill required



Reduces reflex testing;
improve speed to
diagnosis

Linked to diagnostic
excellence



Can it be scaled effectively across the network
care settings

ECONOMIC IMPROVEMENT



Does the method improve time to result and/or reduce pre-analytical and post analytical steps and labor?



Does the method conform to the needs and requirements of the care setting?



Time to result/time in setting



Whole blood methods/direct tube sampling



Process automation



Simple result interpretation



Direct connection to EMR

PROCEDURAL EFFICIENCY

How does my institution define where a test needs to be performed?

How current is our definition?

Is it consistent with the vision and mission of our institution?

Is our definition consistent with known best practices?

Is it consistent with institutions like ours?

Are our guiding principles flexible and actionable?

Are we prepared to change as our needs, technology and patient input guides us?

Do our decisions positively impact patient care and satisfaction?

Have we set up "sentinels" to gain patient and clinician feedback?

ASKING THE RIGHT QUESTIONS

HEMOGLOBIN A1C EXAMPLE OF CLINICAL AND ECONOMIC BENEFITS

- ▶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5505423/>

THOUGHTS,
QUESTIONS,
COMMENTS...

