Meeting the Dynamic Challenges for Quality and Patient Safety

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Today's Goal

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

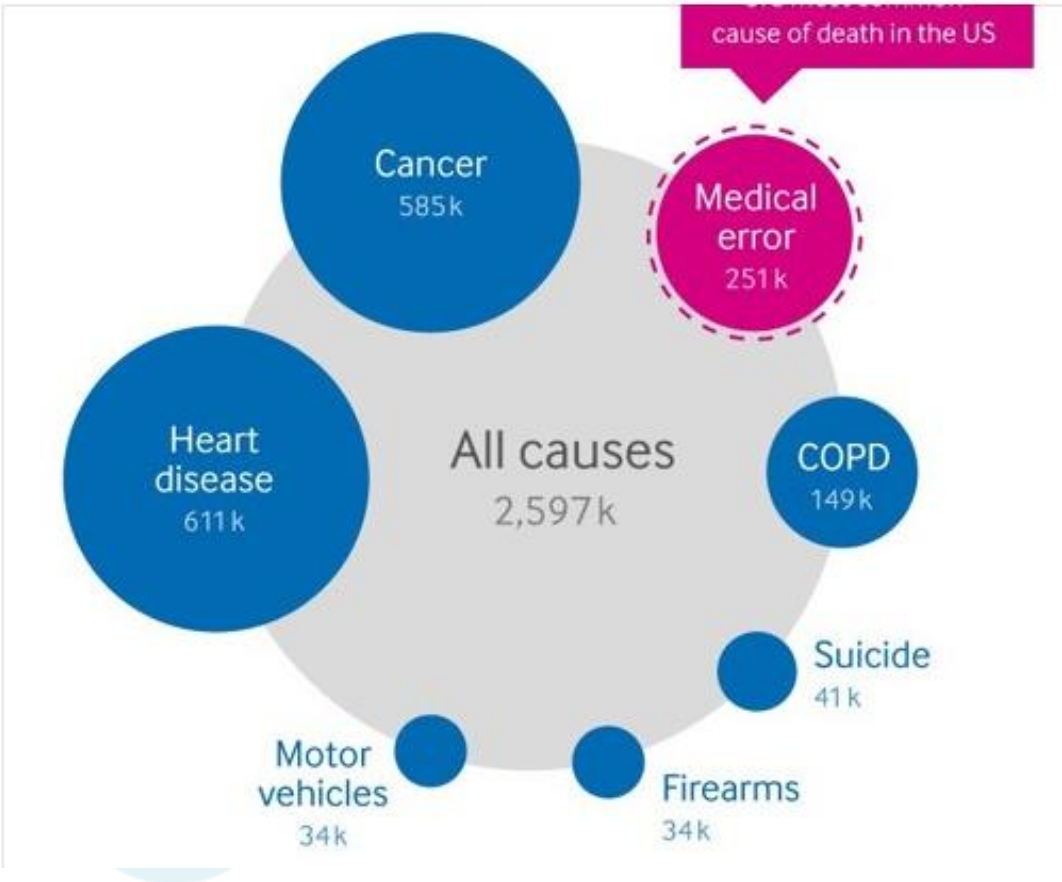
Objectives

- Discuss common ways to improve quality in the testing process
- Describe IQCP's role in error reduction
- Define CMS' new definition of QC material and the implications
- Summarize current and future POCT challenges

Goal of POCT

Quality test results for *quality* patient care

Medical Errors: Deaths from Medical Blunders and Safety Lapses*



1. Heart disease
2. Cancer
3. **Medical errors**

* - National Center for Health Statistics. May 2016, BMJ

POCT's Healthcare Role: Quality Test Results

Common quote --
60 – 70% of clinical decisions are based on laboratory/POCT results

We are part of the problem and the solution!

POCT and the Healthcare Team

Teamwork is Essential!

“Nowhere” can jeopardize the patient!

Quality Strategies:

As a “team” member -- where to start?

Quality Strategy: Buy Smart

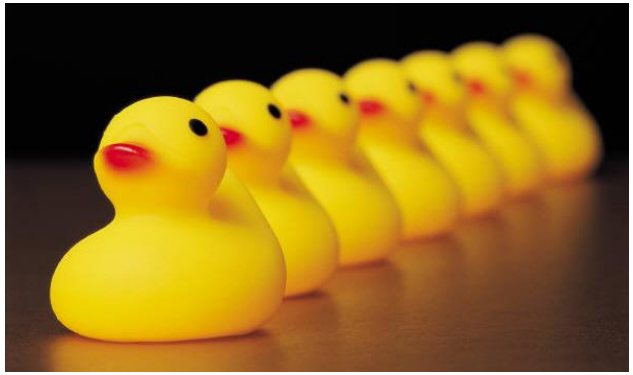
Many choices; Choose *right* for YOUR situation

- Know
  - Clinical requirements
  - Patient population
  - Methodology/technology performance specifications
    - Accuracy, precision, reportable range
  - Method limitations, interferences
  - Sample type and size; collection requirements/ease
  - QC approach and its adequacy
  - Menu
- Assess
  - Ease of use, staffing abilities, training, competency needs
  - IT capabilities; ease of connection
  - Regulatory compliance capabilities
  - Reagent needs; storage requirements
  - Costs

POCT09-A: Selection Criteria for Point-of-Care Testing Devices; Approved Guideline. 2010
http://www.clsi.org

Quality Strategy: Avoid Deficiencies

- Make sure your “&#%!@?!” is covered!!
  - First, always do the “right” thing; POCT is more than compliance with regulations, but
  - Know and avoid common/frequent deficiencies from inspecting organization
    - Testing requirements do represent good practices
  - Ensure POCT “lines up” with the requirements



CLIA: 2015 Top 10 (Cond. Level)

Reg. Subpart	Reg. Cited	Deficiency	% POLs/ % Labs*
Personnel-Mod. Complex	493.1403	Director meets qualifications/responsibilities	3.5 / 3.1
Proficiency Testing	493.803	Participate in CMS approved PT for all reg. analytes tested	1.8 / 2.1
Personnel-High. Complex	493.1441	Director meets qualifications/responsibilities	0.8 / 1.5
Analytic Systems	493.1250	Meet section requirements; monitor & evaluate quality; correct problems	1.2 / 1.3
Proficiency Testing	493.801	Enroll in approved PT for all reg. analytes; treat PT samples like patients	1.4 / 1.3
Personnel-Mod. Complex	493.1409	Qualified technical consultant; provide technical oversight	0.8 / 0.9
Personnel-Mod. Complex	493.1421	Have sufficient, qualified analysts for testing volume & demands	0.2 / 0.5
Hematology Quality System	493.1415	Meet requirements in 493.1230-1256, .1269,.1281-1299	1.8 / 2.1
Personnel-High Complex	493.1487	Have sufficient, qualified analysts for high complexity tests	0.6 / 2.1
Personnel-High Complex	493.1447	Qualified technical supervisor; provide technical supervision	0.2 / 0.3

* #sites - 11,156/17,372

N. Hess. CLIA and regulatory readiness: How can your lab always be ready http://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201607/html/index.html?page=40 July 2016

CLIA: 2015 Top 10 (Std. Level)

Reg. Subpart	Reg. Cited	Deficiency	% POLs/ % Labs
Analytic Systems	493.1252(b)	Define criteria for reagent./specimen storage; accurate/reliable system operation and result reporting	5.3 / 5.3
General Lab Systems	493.1236(c)(1)	At least 2X/year verify accuracy of tests	5.2 / 4.7
Analytic Systems	493.1251(b)	Procedure manual includes specified requirements-specimen acceptability, etc.	4.4 / 4.4
Analytic Systems	493.1289(a)	Establish/follow policies/procedures to monitor, assess, and correct problems	2.8 / 4.4
Post-Analytic Systems	493.1291(c)	Test report must indicate patient identification, name/address of lab, etc.	4.3 / 4.2
Personnel Competency Assessment	493.1235	As specified in subpart M, establish/follow policies/procedures to assess staff	3.8 / 4.1
Analytic Systems	493.1252(b)	Testing follows manufacturers' instructions and meets lab's stated perform. specs	3.1 / 3.5
Analytic Systems	493.1255(b)	Perform/document calibration verification at least once every 6 months, etc.	3.1 / 3.7
Analytic Systems	493.1252(d)	Reagents, soln., media, QC/cal materials, etc., not used after expiration date, etc.	3.3 / 3.4
Personnel-Mod. Complex (cond. Level)	493.1403	Director meets qualifications/ responsibilities	3.5 / 3.1

N. Hess. CLIA and regulatory readiness: How can your lab always be ready http://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201607/html/index.html?page=40 July 2016

CAP: 2015 Top 10

Checklist Number	Deficiency	# Citations (# surveys??)
GEN.55500	Personnel competency assessment	1131
COM.01200	Complete and accurate activity menu	966
COM.01000	Complete PM available in the work area	757
COM.04250	Comparability of instrument methods	658
COM.01700	PT evaluation and corrective actions	642
COM.30600	Maintenance function checks	632
COM.00100	PM review by current lab director / designee at least every 2 years	619
COM.01400	Signatures on PT attestation forms	540
GEN.20375	Document control	530
COM.04200	Instrument/equipment record review	524

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COLA: 2015 Top 10

Requirement Number	Deficiency
PER 5	Personnel competency assessment
LDR 4	Lab director fulfilling PT responsibilities
WAV 2	Not performing and/or documenting QC on waived testing
PT 16	PT result review by director and supervisory staff
LDR 5	Lab director fulfilling QC and QA responsibilities
PER 4 C	Technical consultant or technical supervisor fulfilling responsibilities
CA 2	Performing calibration verification
PT 15	Maintaining PT attestation statements signed by lab director & testing personnel with PT records
QC 16	Review of cumulative QC data to assess continued accuracy/precision
LDR 3	Lab director fulfilling personnel management responsibilities

N. Hess. CLIA and regulatory readiness: How can your lab always be ready http://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201607/html/index.html?page=40 July 2016

The Joint Commission: 2015 Top 10*

Standard Number	Deficiency	%
QSA.01.01.01	Participation in approved PT for all regulated analytes tested	77
HR.01.06.01	Competent staff to perform responsibilities	44
QSA.01.03.01	Process for handling and testing PT samples	35
DC.02.03.01	Complete result report in patient's clinical record	32
QSA.02.08.01	Correlations to evaluate test results performed on different methodologies /instruments/sites	31
QSA.02.03.01	Calibration verification performed	29
QSA.01.02.01	Maintain records of PT participation	28
EC.02.04.03	Inspects, tests and maintains laboratory equipment	27
QSA.02.11.01	Surveilance of patient results and related records as part of QC program	19
HR.01.02.05	Verification of staff qualifications	15

* Data derived from average of 785 applicable surveys

N. Hess. CLIA and regulatory readiness: How can your lab always be ready http://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201607/html/index.html?page=40 July 2016

Common 2015 deficiencies

- Personnel qualifications and associated records
- Competency assessments
- Proficiency testing – enrollment (all regulated analytes) to review of results to corrective actions to maintaining records
- Method comparisons
- Calibration verification
- Equipment maintenance and associated documentation

N. Hess. CLIA and regulatory readiness: How can your lab always be ready http://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201607/html/index.html?page=40 July 2016

Technical Consultant (assesses competency for Moderate Complexity)

The technical consultant must—

(1) (i) Be MD or DO licensed in State where lab is located; and

(ii) Be anatomic or clinical pathology certified or equivalent

(2) (i) Be MD, DO, or Dr. of podiatric medicine licensed in State where lab is located; and

(ii) Have at least 1 year training/experience (non-waived testing) in designated specialty/subspecialty, or

(3) (i) Hold Ph.D. or MS degree in a chem, physical, biol sci, or [degree] in clin lab sci/med tech from accredited institution; and

(ii) Have at least 1 year training/experience (non-waived testing) in designated specialty/subspecialty; or

(4) (i) Have a BS degree in a chem, physical, biol sci or med tech from an accredited institution; and

(ii) Have at least 2 years of training/experience (non-waived testing) in specialty/subspecialty areas where responsible.

http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_1141

Competency Assessment: 6 elements for moderate complexity testing

- Direct observations- routine patient test performance;
  - patient preparation (when applicable) specimen handling, processing and testing;
- Monitoring recording and reporting of test results;
- Review intermediate test results/worksheets, QC records, PT results, and preventive maintenance records;
- Direct observation- instrument maintenance/function checks;
- Assess performance- testing samples with known values;
- Assess problem solving skills.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11413

Competency Assessment: Waived testing

- **CMS (CLIA) – none**
- **CAP GEN.55500**
  - Must be performed at least annually
    - Lab may select which elements to assess for each test
- **The Joint Commission WT.03.01.01**
  - …using at least two of the following methods/person/test:
    - Performance of a test on a blind specimen
    - Periodic observation of routine work by the supervisor or qualified designee
    - Monitoring of each user's QC performance
    - Use of a written test specific to the test assessed
- **COLA WAV 6 R**
  - …assessed and documented prior to initiating testing, at 6 months during 1st yr of employment; annually thereafter

Competency Assessment & PPM

How is it going?

POCC FORUM AACC 2016

The 2016 Point of Care Forum topic at the AACC Annual Conference in Philadelphia was *'Leadership Communication for the POCC: Overcoming the Barriers of Productive Communication'*, presented by Rick Import of Whitehat Communications. Several scripted dialogs were performed by a panel of POCC's to demonstrate effective communication skills. One dialog in particular drew a lot of attention from the audience, and many in attendance requested that it be made available for reference in their own settings. Here is that dialog. We hope it helps and want to thank Marcia Zucker, PhD for providing the segment of the dialog that POCC's will find so valuable when discussing PPM competency with physicians.

Use of effective communication skills when discussing an overdue Physician Performed Microscopy competency assessment with a physician.

POCC: Dr. Green, I'm glad I caught you. I need about 3 minutes of your time.

PHYSICIAN : I have 3 patients to get back to and a tumor board meeting that I'm chairing starting in about 10 minutes, and these slides I need to check and add to my patient's record, so about 3 minutes is all I've got.

POCC: Gotcha. This shouldn't even take that long. You probably know that one of my responsibilities is to ensure that competency assessments are up to date, and I noticed that your PPM competency expired on Friday. With all you have to do, the reminder email I sent a while back probably slipped through the cracks. When will you be getting that out of the way?

PHYSICIAN (impatient): I went to medical school, Marcia. Taking an assessment on my microscope skills is ridiculous!

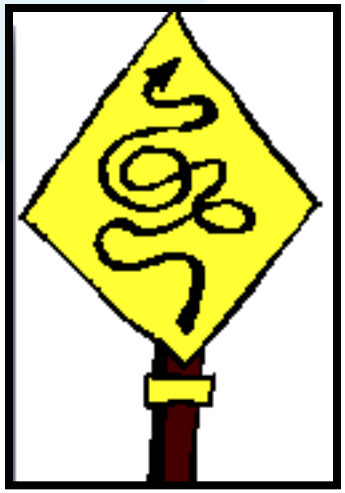
POCC: You're upset with the fact that you have to take a PPM assessment.

PHYSICIAN (insulted): Yes I am! I'm a doctor, Marcia. And I would never do anything to risk my patients' safety, you know that. I don't need to prove to anyone that I can use a microscope.

Marcia Zucker. www.pointofcare.net/CPOCT/2016_POCC_Forum_PPM_Dialog_Summary.pdf

Proficiency Testing

Know and play by the PT rules



Quality Strategy: Risk Management

Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971)*

- **Simple Definition of *risk* --** possibility that something bad will happen**

* ISO 14971: www.iso.org

**Merriam-Webster's Learner's Dictionary

Criteria for Quality Test Results
(Covers Entire Testing Process)

- Correct patient
- Correct time for specimen collection
- Correct specimen and processing

Pre-analytical

- Correct test result generated

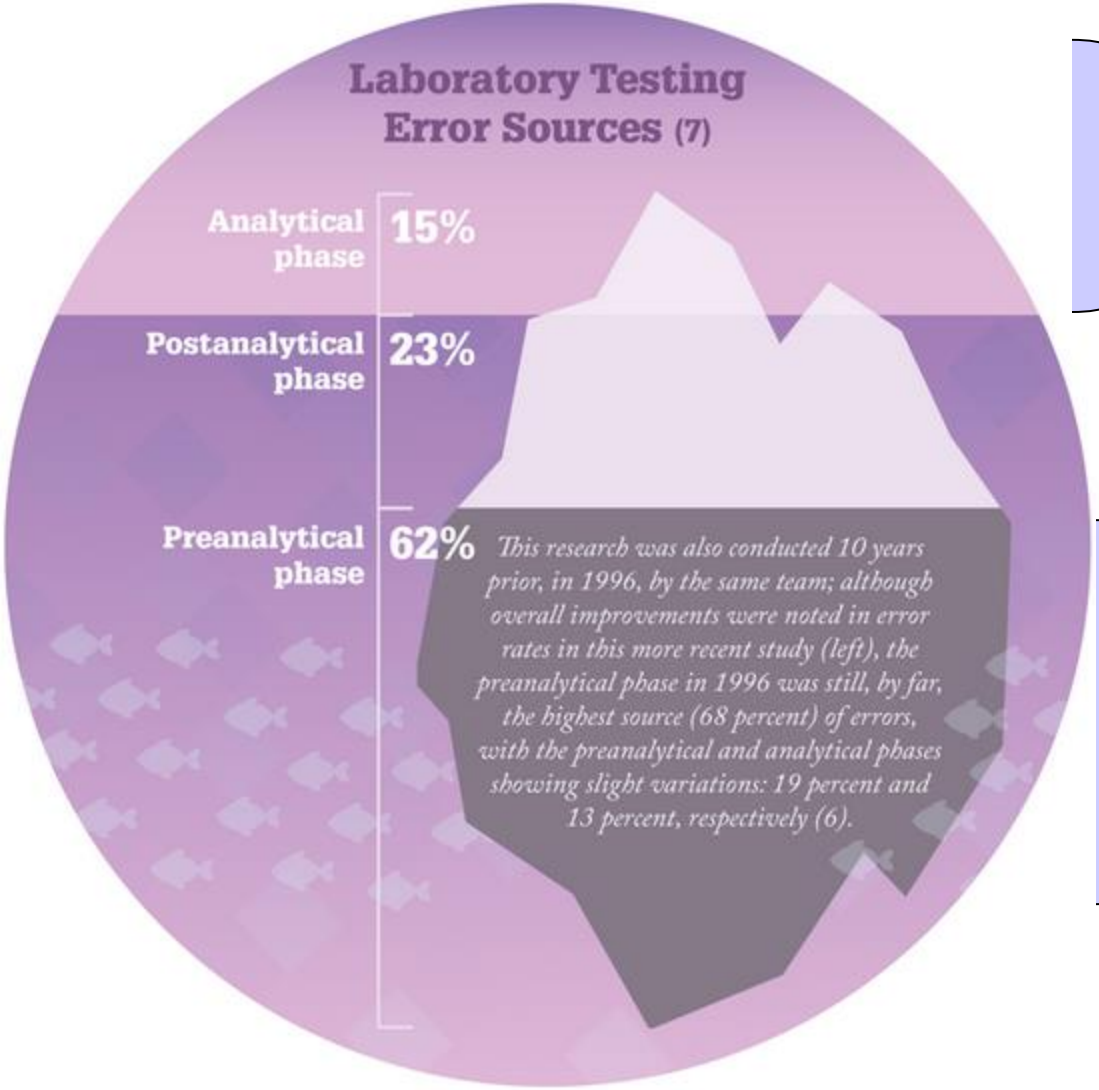
Analytical

- Correct test result reported and documented in right patient record

Post-analytical

When “wrongs” replaces “corrects” --
Quality is compromised; care can be compromised

Errors (Risks) in Testing



Analytical often the least, but so important and can't be ignored!

Preanalytical still remains the largest source of error

AM Šimundić. Avoiding Titanic Errors: The preanalytical phase is subject to more error than any other part of the testing cycle – what can we do to improve it? The Pathologist - https://thepathologist.com/issues/avoiding-titanic-errors/avoiding-titanic-errors/ (08/2016)

Risk Assessment/Management Outcome

Review of entire testing process;

Identification of potential (significant) risks;

(if present)

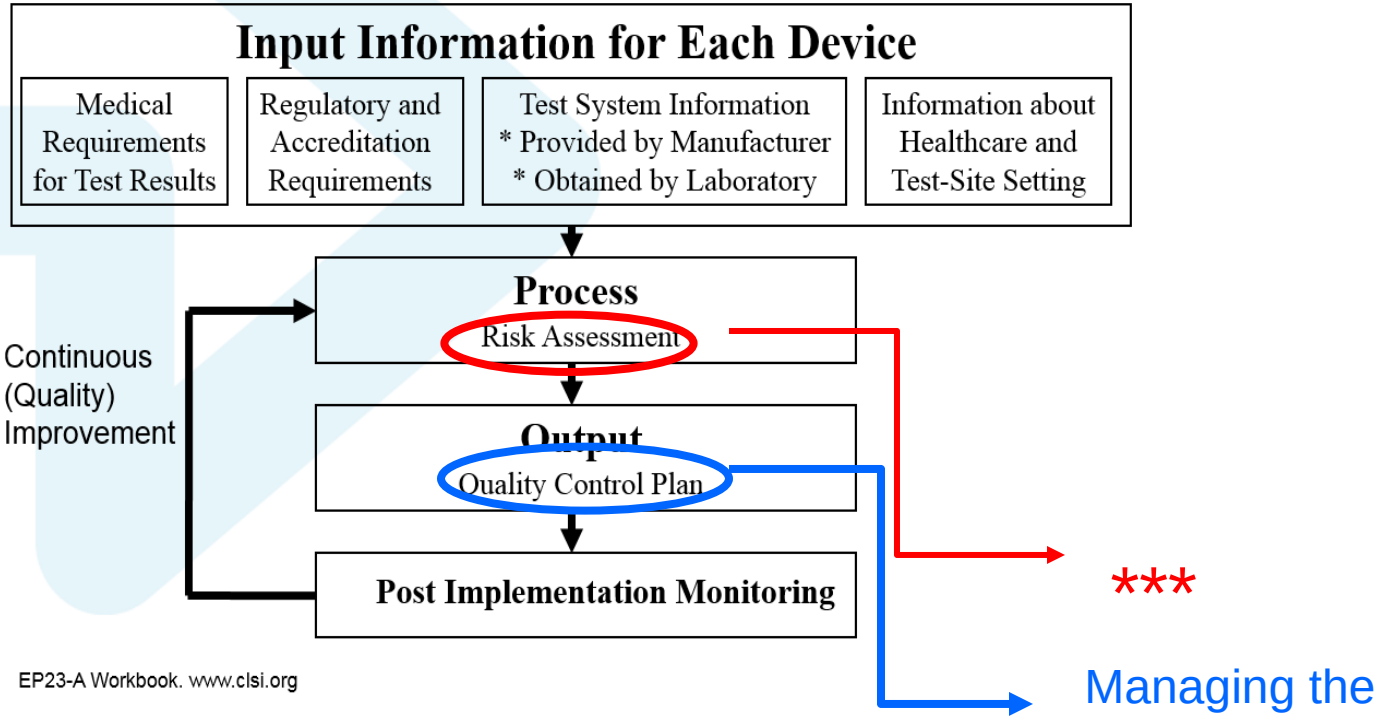
Addition of “quality activities”

to eliminate/minimize these potential risks

Good policies, procedures, practices

IQCP Development Intent: Identify risks/mitigate risks in entire testing process

- For devices with "built-in" QC (January 2016)
  - Perform default (external) QC, **or**
  - Develop and follow an IQCP



EP23-A Workbook. www.clsi.org

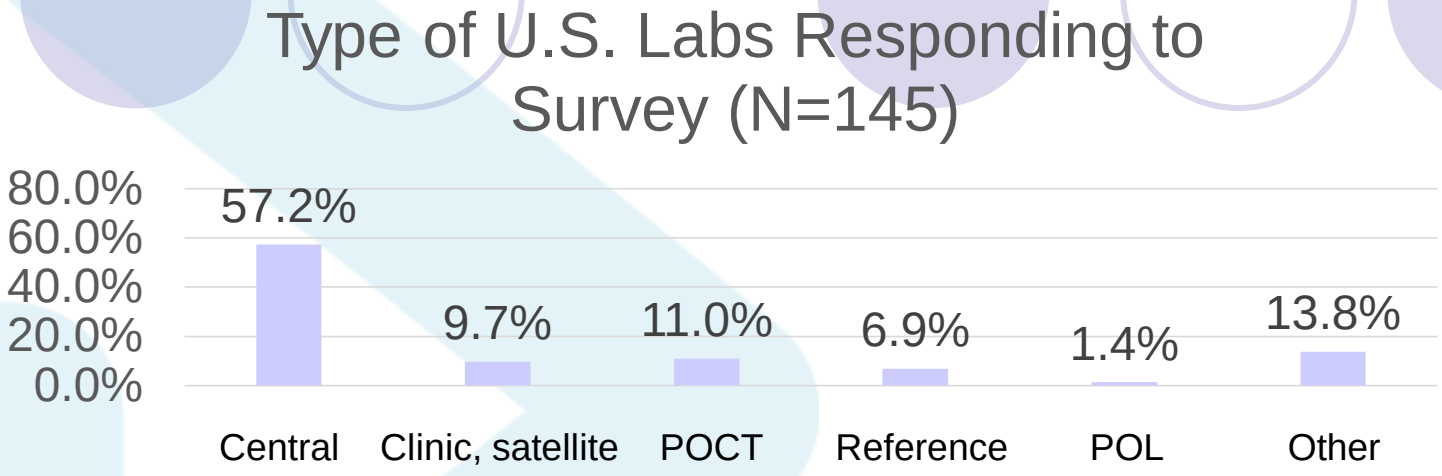
Value of Risk Management at POCT*

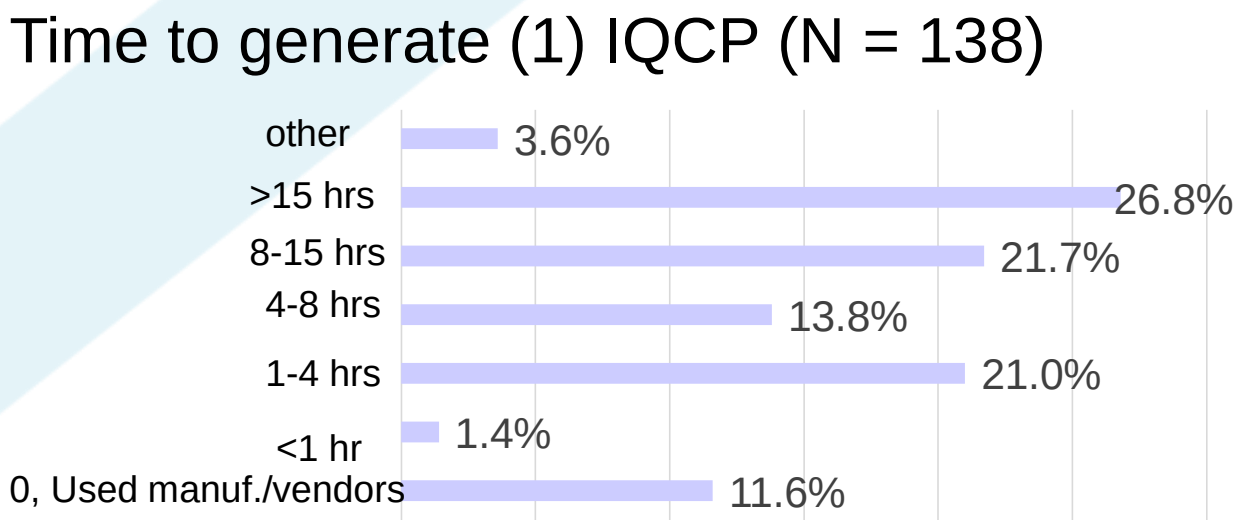
More in-depth understanding/appreciation of testing processes to:

- Identify weaknesses and discrepancies
  - e.g., harmonized sample labeling in all testing locations
- Improve efficiencies – ordering, documenting, tracking supplies, validating reagents, reducing waste, justifying required resources
- Support of quality activities, e.g., frequency of external QC
- Enhance interaction/partnership with healthcare team members -- gives POCT a “face”
- Provide opportunities for continuous improvement/optimization of practices for quality patient care

J. Nichols. Benefits of Developing an Individualized Quality Control Plan. JALM (7/16) http://www.jalm.org/content/1/1/5

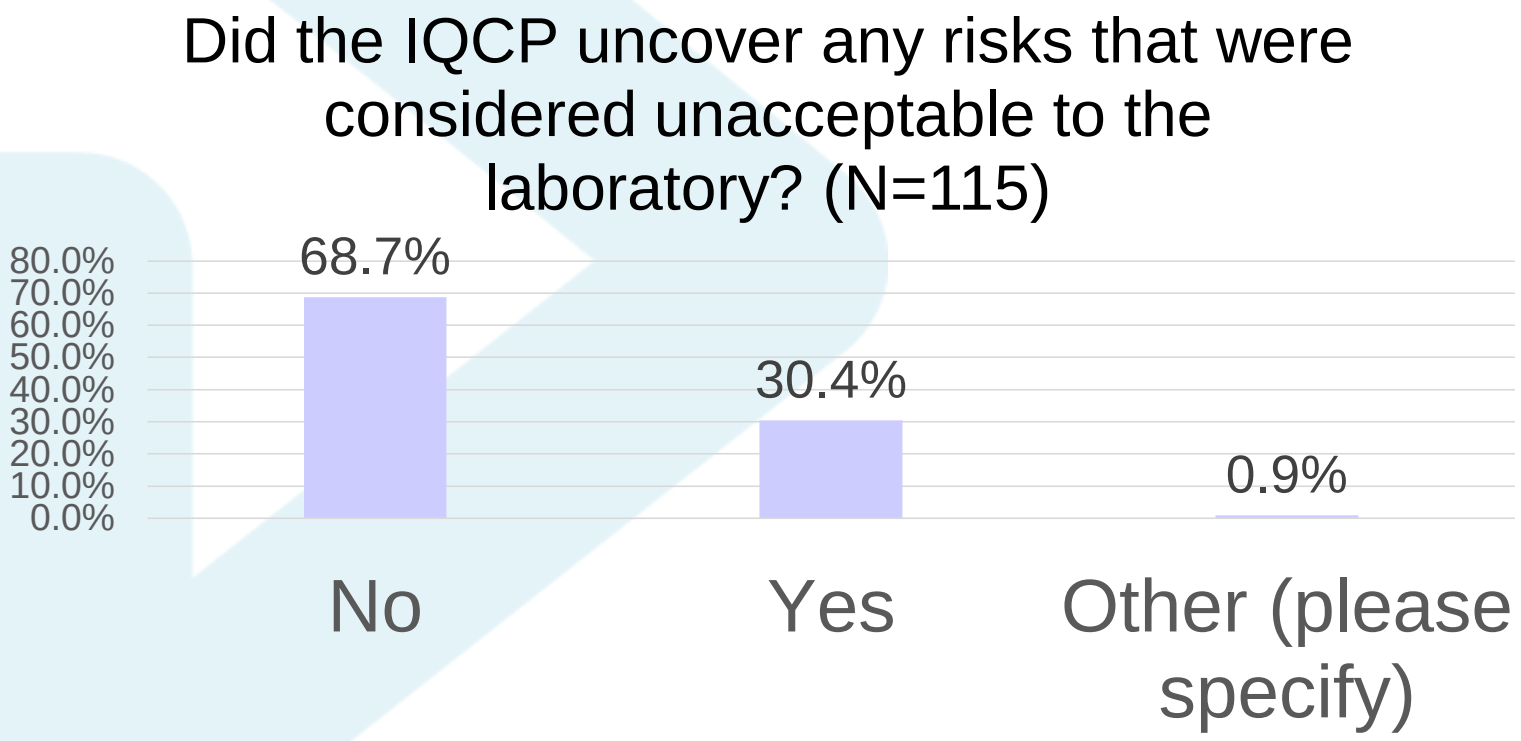
2016 IQCP User Survey





http://www.westgard.com/iqcp-user-survey.htm

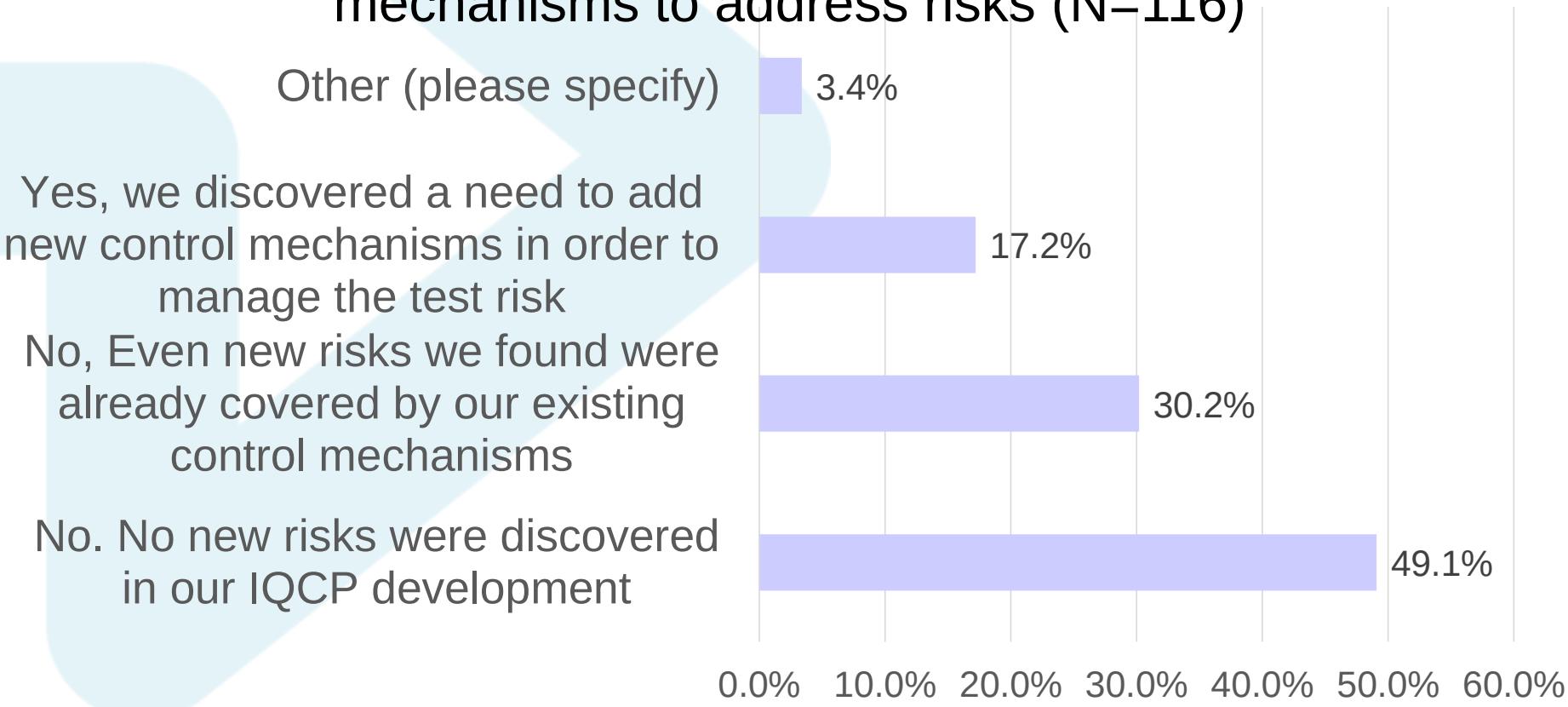
2016 IQCP User Survey



http://www.westgard.com/iqcp-user-survey.htm

2016 IQCP User Survey

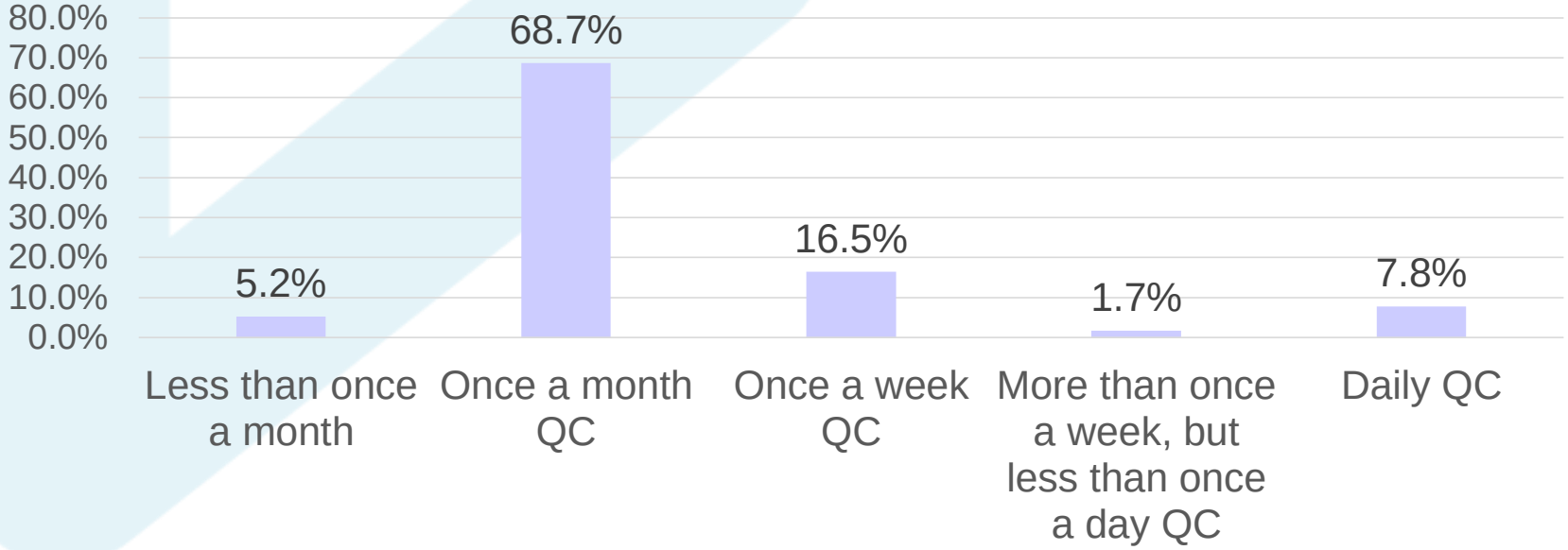
Did the IQCP process require adding new control mechanisms to address risks (N=116)



http://www.westgard.com/iqcp-user-survey.htm

2016 IQCP User Survey

For the tests where an IQCP was developed, how often is QC being run? (N=115)



http://www.westgard.com/iqcp-user-survey.htm

2016 IQCP User Survey

Inspection outcomes:

- ~ 2/3 of labs inspected had adequate IQCPs
- ~1/3 inspected without having their IQCPs inspected
- Small minority had trouble with the inspections. Problems found:
  - "Needed to add components to IQCP"
  - "…cited for failure to have an IQCP for the Affirm VPIII test. COLA subsequently accepted our IQCP response [thereafter]."
  - "TJC surveyor made recommendations related to improving the format of the IQCP's, but felt the content was adequate."
  - "We were cited for not having a count of the actual internal and external QC and failures documented for a particular time"

http://www.westgard.com/iqcp-user-survey.htm

Risk Assessment/Management for *ALL* POCT/*ALL* Testing??

Good idea?

Note: CMS changed QC Material Definition (prior to April 2016)

External QC material

- External –liquid; mimics patient samples; analyzed like patient samples
- Used to meet default QC (2 – 3 QC levels/analyte/day)

Internal QC material – something that manufacturer includes on-board testing device; device automatically runs

- Can use to meet daily QC requirements PROVIDED POCT develops and follows an IQCP

Note: CMS *NEW* QC Material Definition (April 2016)

Acceptable control materials now include [those] on-board, i.e., ampules/cartridges… [if] have a matrix similar to…patient specimens… go through all elements of the analytic process

Instrument/electronic function checks/procedural controls do not fulfill regulatory requirement for control materials

Lab Director is responsible for determining what control materials to use in his/her lab… (depending on decision, IQCP may not be necessary)

- Labs intending to perform less QC than the regulatory requirements must develop and implement an IQCP that supports their QC plan

CLIA Surveyors will ensure lab is following its own established policies, specifically its own QC procedures

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-20.pdf

Quality Strategy: “Right” POCT 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

Quality Strategy: “Right” POCT Culture

Cultures are Developed

and

Require “Effective” Thinking

“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 that errors are rare	Realizing that 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

Quality Strategy: Stay in "the know"

Change is a Given!

- Alertness – keep your "ear to the ground"
  - Listservs, journals, webinars
  - Professional organizations, POCT and user groups, other sites/organizations, CE activities, etc.
  - Manufacturers' materials and representatives
  - Government websites
- Preparedness – it seems like few things last, so when "true" change happens -- deal with it!

Let’s Change Gears: A Look at some Future Wishes for POCT

Wishes for POCT

June 2016 - Volume 15 - Issue 2

Kent Lewandrowski, MD, editor-in-chief, asked practitioners for their 3 wishes to improve POCT

http://journals.lww.com/poctjournal/Pages/currenttoc.aspx

2016 Wishes: What are yours?

Simplified, reasonable, cost effective, relevant, evidence-based regulatory requirements

- Inconsistencies -- competency assessments, testing complexity levels, timing
- Inconsistencies with tests on PPM/PTT list – CAP has more

More testing capabilities

- CBC (waived)
- Communicable and non-communicable (emerging nations) diseases
- Different technologies

Easier sample collection for better sample

IT standardization for better technical support

Design of “small” instruments with easy data entry and network connection (think smart phones)

More manufacturer support with new installations/upgrades

Evidence-based regulatory decisions for glucose (meter) testing

2016 Wishes to Reality??

Shout out to Dr. Lewandrowski!

Make sure to let yours wishes be known too!

Quality Strategy Summary to meet (at least some) of the many POCT challenges

Buy Smart –too many things to do; too few resources to fulfill all the duties; “help” is good

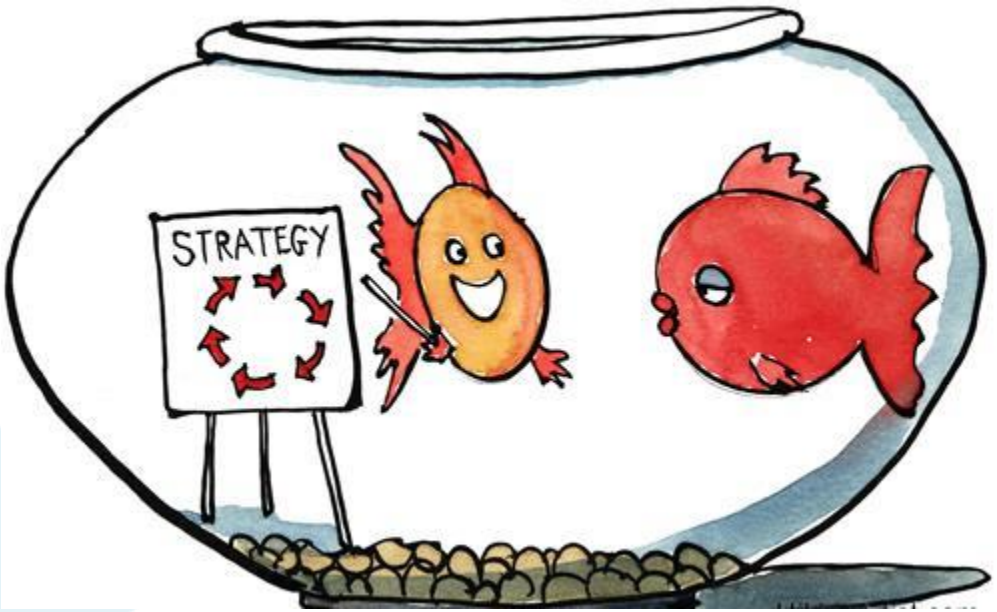
Avoid Deficiencies –corrections are time consuming; *can* diminish all our good work

Risk assessment/management to improve POCT (IQCP/no IQCP/waived/nonwaived??)

Right culture for quality and patient safety; use effective thinking

Stay in the “know”

Fish Bowl Strategy – What's Yours?



Quality and Patient Safety at POCT are Never An Accident; ...*always the result of intelligent effort*...

POCT results are connected to patients; Quality results are essential for quality patient care!

But, you are the *best*!

Thanks