Rethinking Traditional QA/QC: Weaknesses of Current Practices; Six Sigma Metrics and Tools for Improvement

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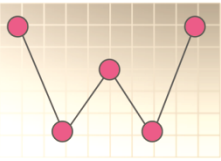
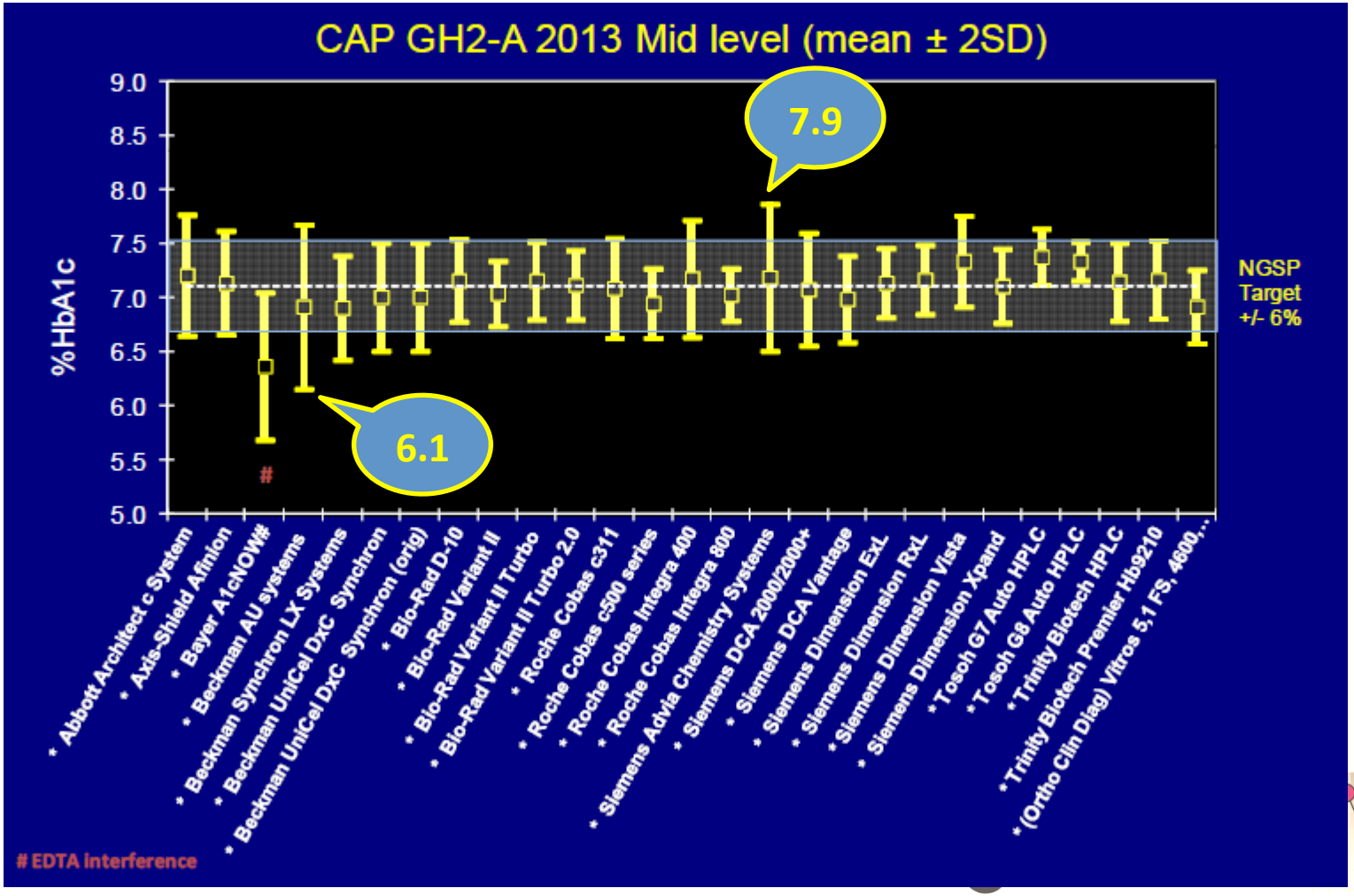


"Hospitals recognize need for uniform lab test data"

- Dark Report, Sept 9, 2013
  - ACOs have need for "populating the electronic health record with lab test data that has standardized reporting forms and standardized reference ranges… to allow physicians to track and trend patient data in a meaningful way."
  - Electronic Health Record needs to contain test results from POC, clinic, hospital, reference labs
  - BUT, what if different methods in different labs don't provide standard consistent test results?

CAP 2013 HbA1c 7.11 %Hb
26 Method subgroups



“Lack of continuity problem”

- “ACO administrators… recognize that having multiple laboratories provide test data for the same patient creates alack-of-continuity problem.”
- “It means that physicians must sort through different lab test methodologies, different names for the same test, and different reference ranges.”

But that's NOT the problem with HbA1c!

- All methods in use in US are certified by the National Hemoglobin Standardization Program (NGSP) to provide equivalent results
- Units are the same, %Hb
- Have standard diagnostic & treatment targets
  - Cut-off for diagnosis for diabetes is 6.5 %Hb
  - Normals ≤ 5.6%Hb; 5.7 to 6.4 %Hb "pre-diabetic"
  - Treatment goal is 7.0 %Hb

“A rose is a rose is a rose!”

Why isn’t a GHb a HbA1c or an NGSP A1c?

Errors in the Total Testing Process

- Which errors have the most impact on inappropriate patient care?
  - Pre-analytic
  - Analytic
  - Post-analytic

What errors have been observed in the Total Testing Process?

Ross & Boone. CDC, 1989 Conference Abstract

46% **7%** **47%**

Plebani & Carraro. Clin Chem 1997:43:1348-51

68% **13%** **19%**

Carraro & Plebani. Clin Chem 2007:53:1338-42

62% **15%** **23%**

Lab Errors and Patient Care Plebani-Carraro

- Clin Chem 2007:53:1338-42
  - 51,746 tests
  - 393 questionable results
  - 160 confirmed as laboratory errors
  - 46 caused inappropriate patient care
  - 24 of those were analytical errors
- Analytical errors are still major cause (over 50% cases) of inappropriate patient care

Plebani
Clin Chem Lab Med 2007;45:700-7

- *"… detected analytic errors are only the tip of the iceberg. Both laboratory professionals and clinicians currently acknowledge a restricted number of analytical errors for various reasons, ranging from the limited design of quality control procedures… to poor response of clinicians to possible laboratory errors…"*

Plebani
Clin Chem Lab Med 2013;51:39-46

- *"A better analytical quality should be achieved by setting and implementing evidence-based analytical quality specifications; if this is done, rules for internal quality control and external quality assessment procedures would be more appropriate… Finally, more stringent metrics, such as Six Sigma, should be largely introduced…"*

Weaknesses in Analytical Quality Management (AQA) - Plebani

- **Current QC practices are not adequate to detect medically important errors**
  - **US has reduced QC requirements**
- Proficiency testing programs show poor performance *"when examined on the sigma scale"*
- External quality assessment schemes show laboratories do not comply with existing quality specifications

Current QC Practices
What might be wrong?

- Quality Compliance, not control
  - Minimum requirements now interpreted as maximums for purposes of cost control
- Influence of "Equivalent Quality Control"
  - Protocols not scientifically valid, but used anyway to qualify methods for reduced QC
  - CMS's reliance on inspectors to be able to "see" problems though little QC data to inspect

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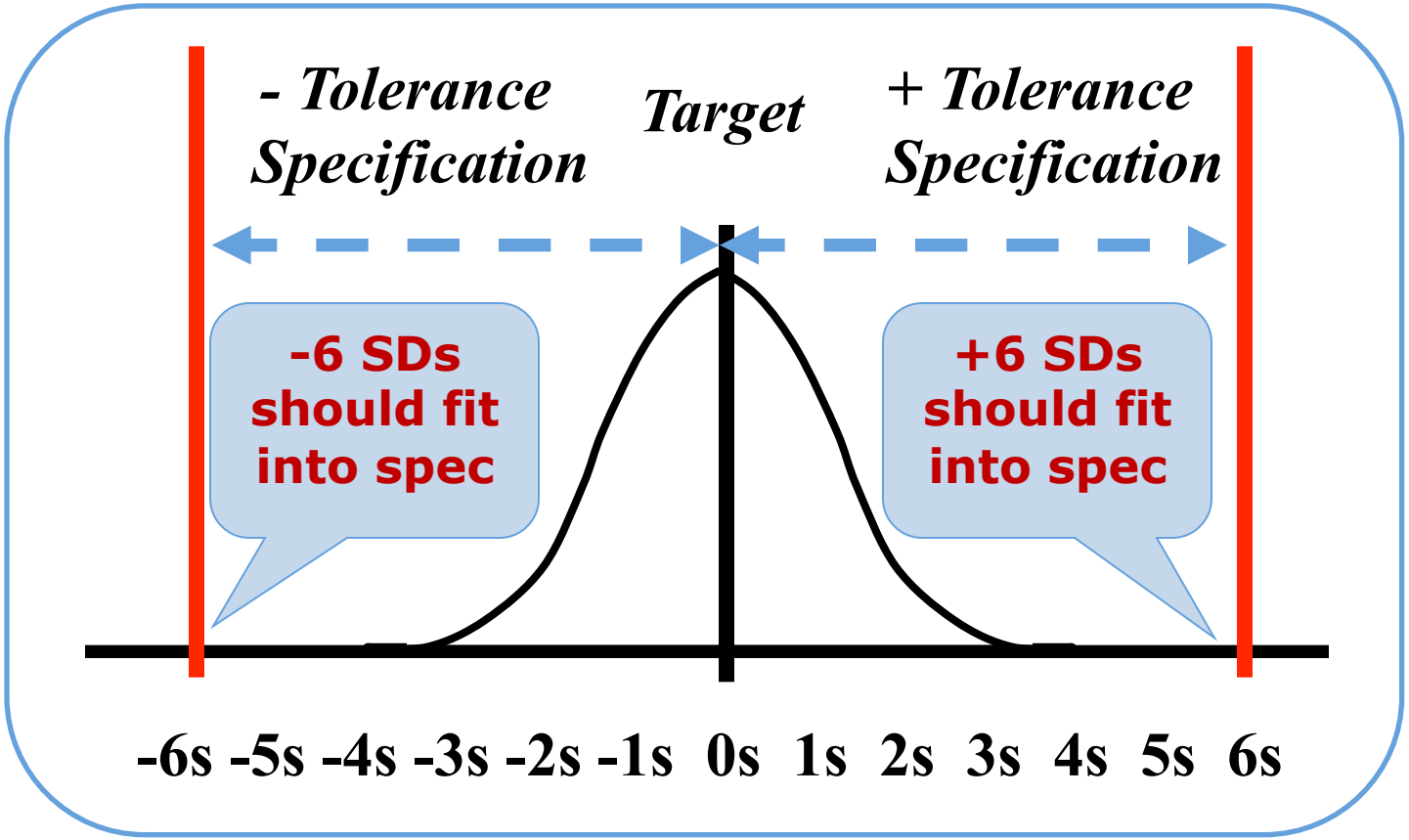
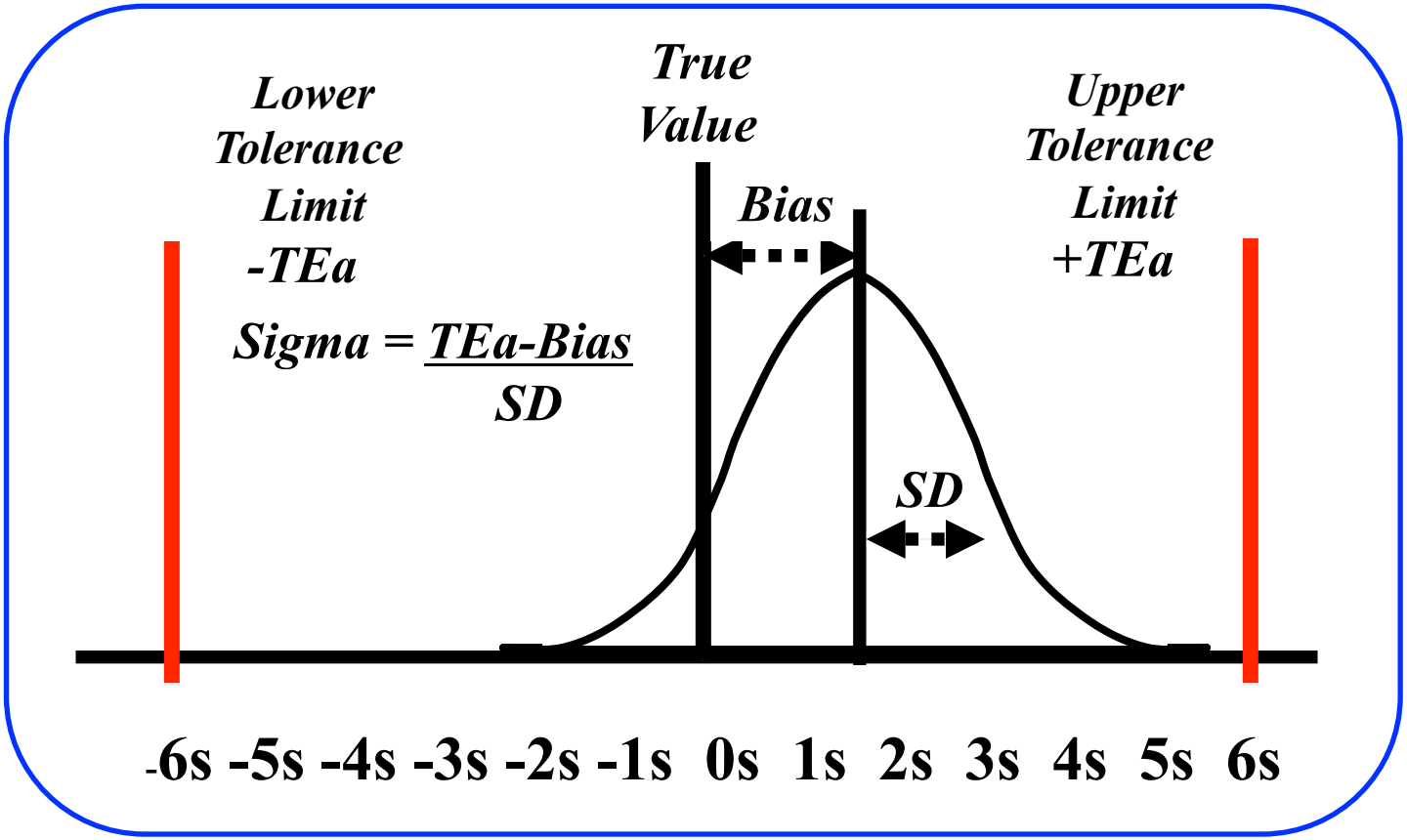
What does Six Sigma mean?



How define “tolerance specification”?

- Proficiency Testing (PT) or External Quality Assessment (EQA) criteria for acceptable performance
- Format of “allowable Total Error”, TEa
  - US CLIA requirements
    - Glucose Target Value ± 10%
  - CAP requirements
    - HbA1c Target Value ± 7.0%

How do you calculate sigma?



Example calculations HbA1c CAP TEa=7.0%

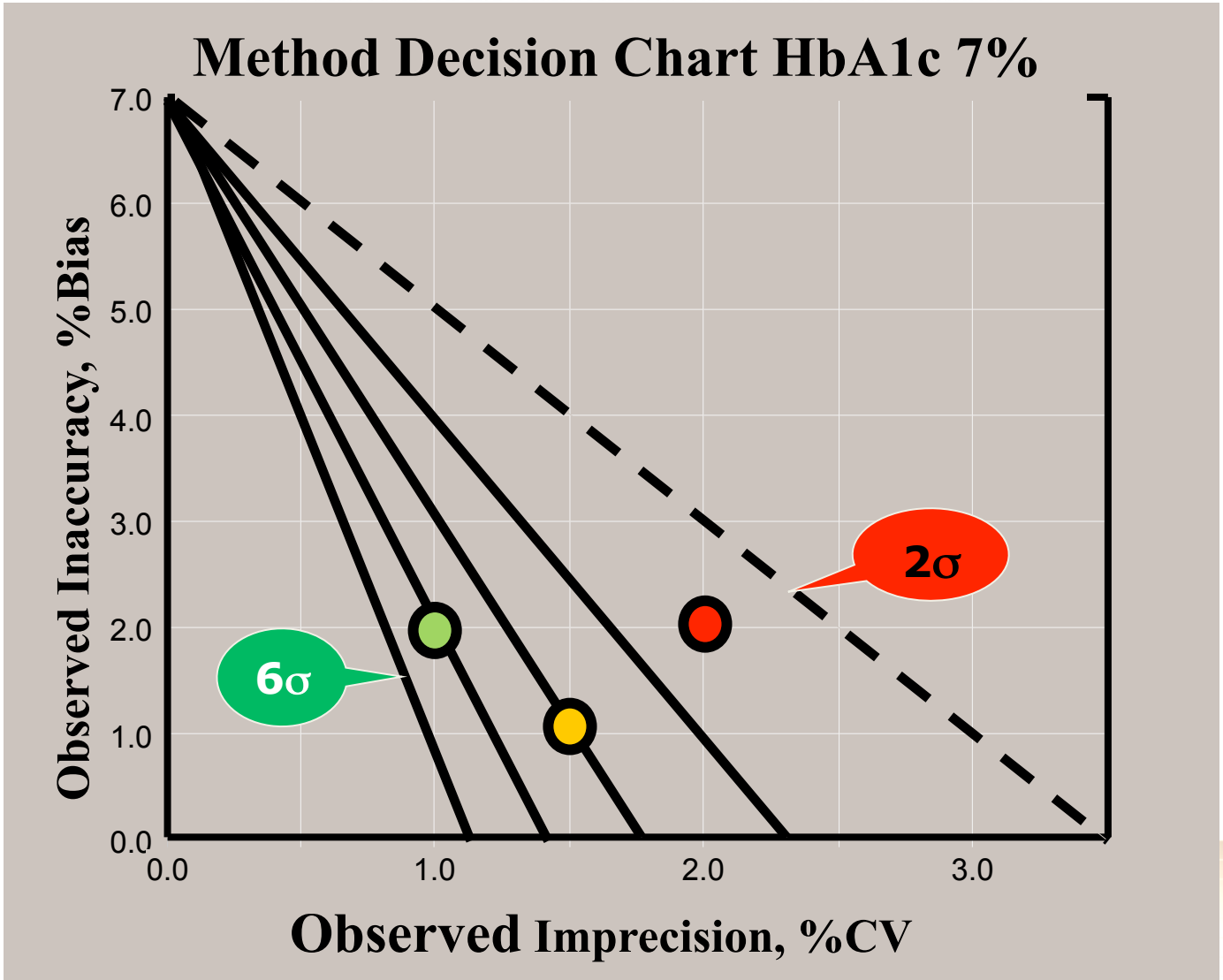
- Sigma = (%TEa - %Bias)/%CV
- TEa=7.0%, Bias=2%, CV=1%

  Sigma metric is (7-2)/1 or 5 sigma
- TEa=7.0%, Bias=1%, CV=1.5

  Sigma metric is (7-1)/1.5 or 4 sigma
- TEa = 7.0%, Bias = 2%, CV=2%

  Sigma metric is (7-2)/2 or 2.5 sigma

Graphic Display of Sigma Quality (%bias=y-coord, %CV=x-coord)



Proficiency Testing Quality on the Sigma Scale (1)

- Review of quality of cholesterol, calcium, glucose, HbA1c, PSA, PPT, INR, fibrinogen
  - Surveys by AAFP, MLE, AAB, API, CAP
  - Number of CAP labs predominate
    - Reference: Westgard JO, Westgard SA. The Quality of Laboratory Testing Today: An assessment of sigma metrics for analytical quality using performance from PT surveys and the CLIA criteria for acceptable performance. Am J Clin Pathol 2006;125:343-354.

PT Quality on the Sigma Scale (2)

- Cholesterol, TEa=10%
  - Sigma 2.88 to 3.67 at 211 mg/dL, 9,258 labs
- Calcium, TEa=1.0 mg/dL
  - Sigma 2.84 to 3.86 at 10.7 mg/dl, 9,786 labs
- Glucose, TEa=10%
  - Sigma 2.95 to 4.00 at 121 mg/dL, 10,722 labs
- **Remember baggage handling benchmark is about 4.0 sigma!**

PT Quality on the Sigma Scale (3)

- Prothrombin Time, TEa=15%
  - Sigma 1.77 to 5.35 at 16.8 sec, 800-900 CAP labs
- INR, TEa=20%
  - Sigma 2.39 to 3.52 at 1.57, 800-900 CAP labs
- Fibrinogen, TEa=20%
  - Sigma 1.78 to 3.24 at 260 mg/dL, 800-900 labs
- HbA1c, TEa=10%
  - Sigma 1.93 to 2.57 at 9.0 %Hb, 5,066 labs

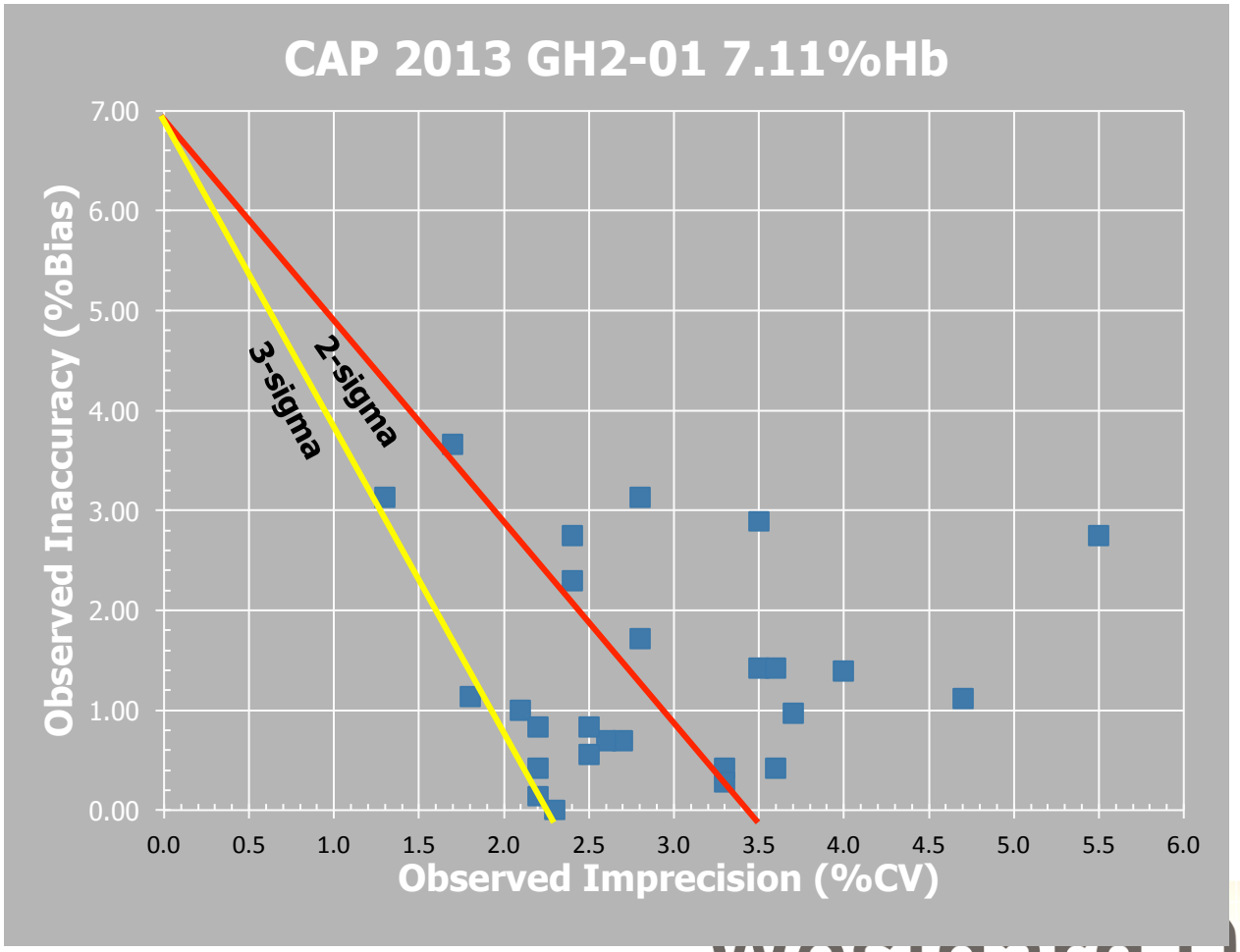
PT Quality on Sigma Scale (4)

- Prostate Specific Antigen (PSA)
  - NO CLIA defined criterion for acceptable performance
  - PT data from 2,353 CAP labs
  - "Sensitivity analysis" at 4.5 ng/ml
    - 10% TEa (±0.45 ng/ml), Sigma 1.17 to 1.76
    - 20% TEa (±0.9 ng/ml), Sigma 2.34 to 3.52
    - 30% TEa (±1.35 ng/ml), Sigma 3.51 to 5.28
    - 40% TEa (±1.8 ng/ml), Sigma 4.67 to 7.04

PSA Today!

- August 22, 2013: Thousands got faulty prostate cancer tests
  - http://abcnews.go.com/health/thousands-faulty-prostate-cancer-tests/story?id=19985602&singlePage=true
- 7,500 patients sent letters because PSA results may have been falsely elevated during Feb 2012 to May 2013 due to reagent problem
  - 20 to 23% positive bias reported by manufacturer
  - How many unnecessary biopsies? Treatment costs and consequences?

HbA1c 7.11%Hb Sigma Proficiency 2865 Labs, 26 Subgroups



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External Quality Assessment and Quality Specifications

- Can current analytical quality performance … support evidence-based guidelines for diabetes and ischaemic heart disease?
  - Jassam N, Yundt-Pacheco J, Jansen R, Thomas A, Barth JH. Clin Chem Lab Med 2013 (accessed online)
  - *"Sigma performance for the median CV% for the participant laboratories.. Was 3.3σ for HbA1c, 3.9σ for glucose, 2σ for creatinine, 5σ for cholesterol, and 3.8σ for HDL-cholesterol."*

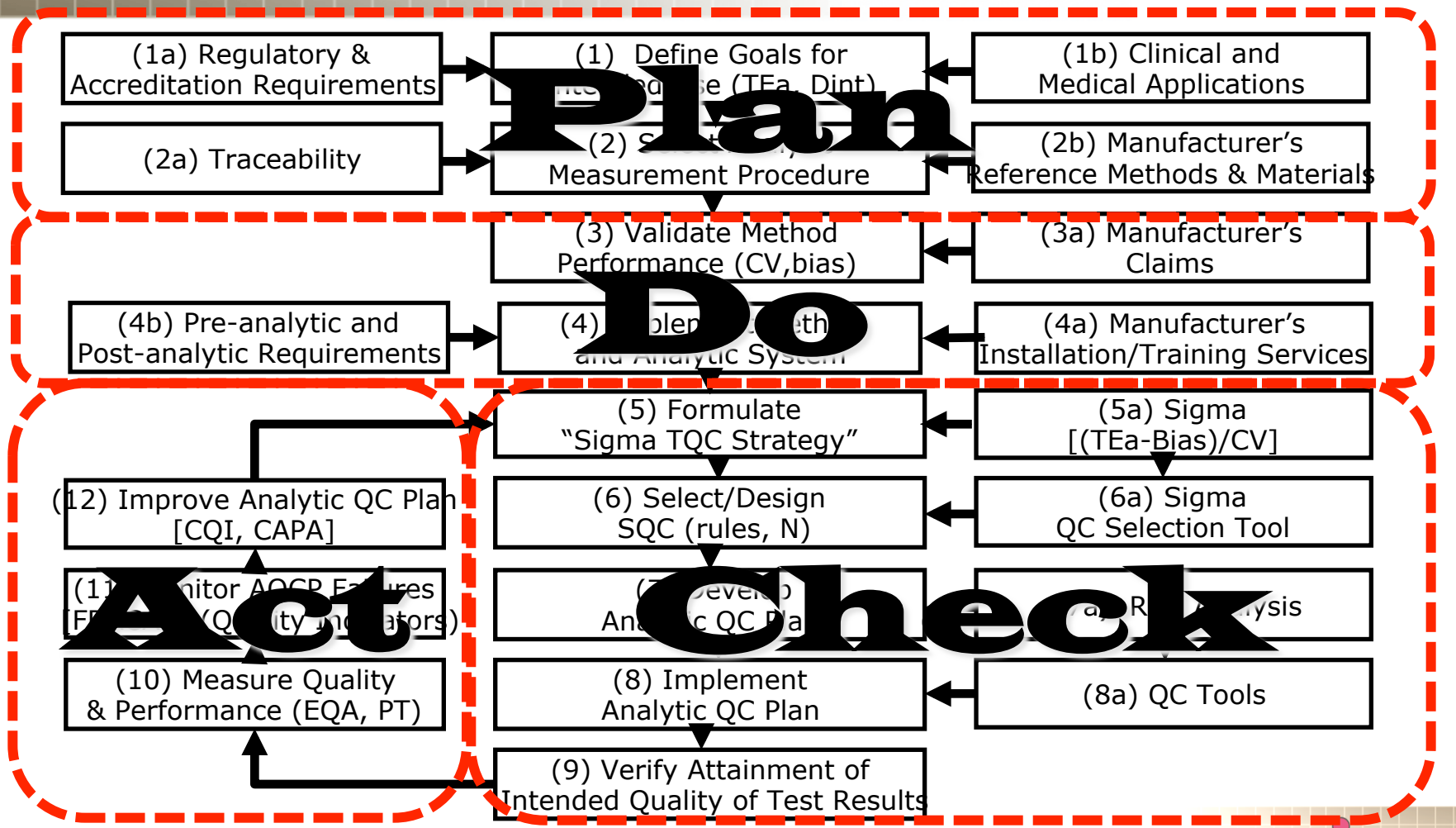
EQA and Quality Specifications
Ref: Jassam et al

- *"The implementation of national and international guidelines is beginning to standardise clinical practice… A scientifically based quality control process will be a pre-requisite to provide the level of analytical performance which will support evidence-based guidelines and movement of patients across boundaries while maintaining standardized outcomes."*

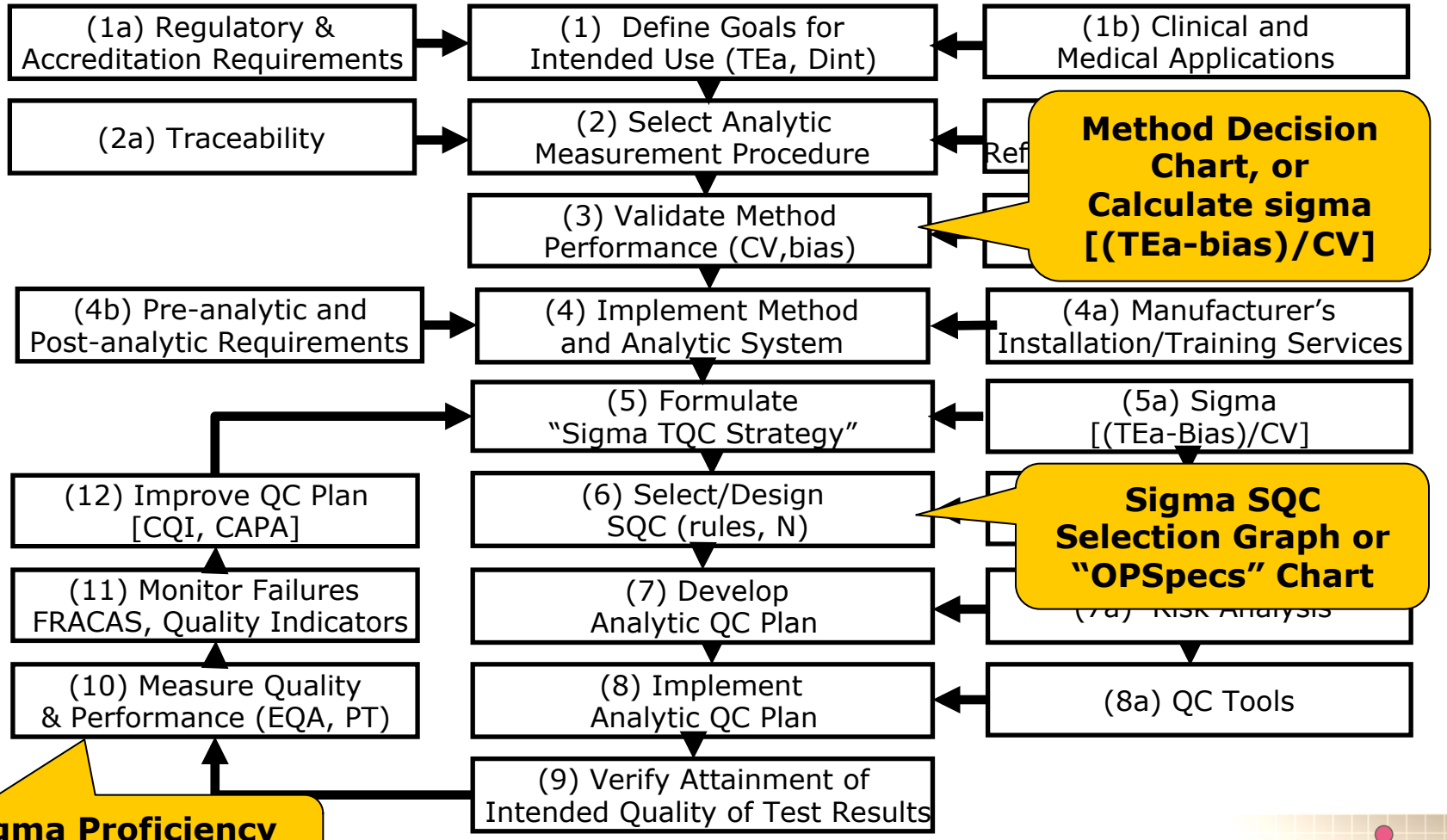
A Scientifically Based Six Sigma Quality System

- Must be driven by quality required for "intended clinical use" of laboratory tests
- Must validate method performance satisfies "intended clinical use"
- Must design QC to *verify the attainment of intended quality of test results*
- Must monitor performance over time on the sigma-scale

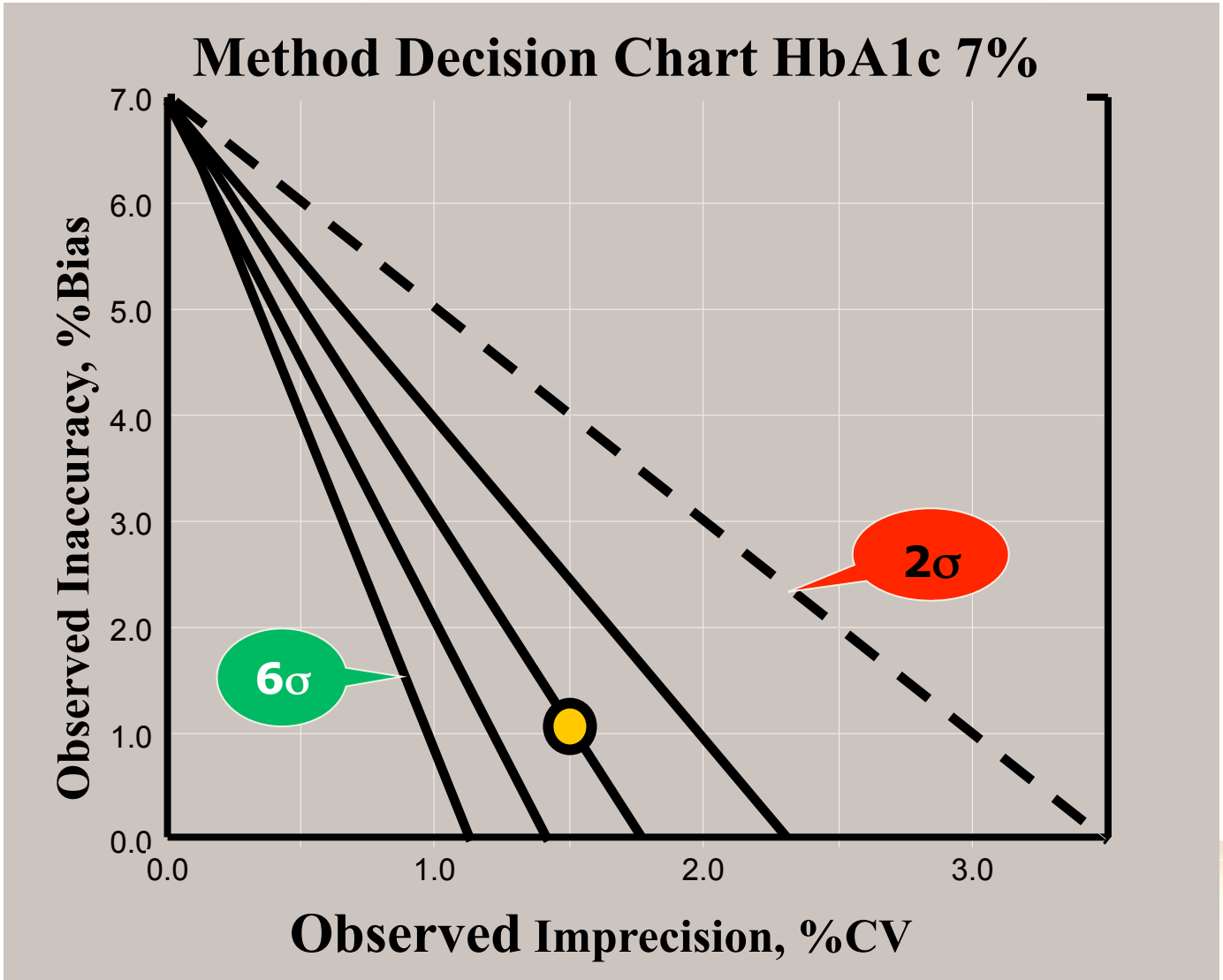
Six System Quality System



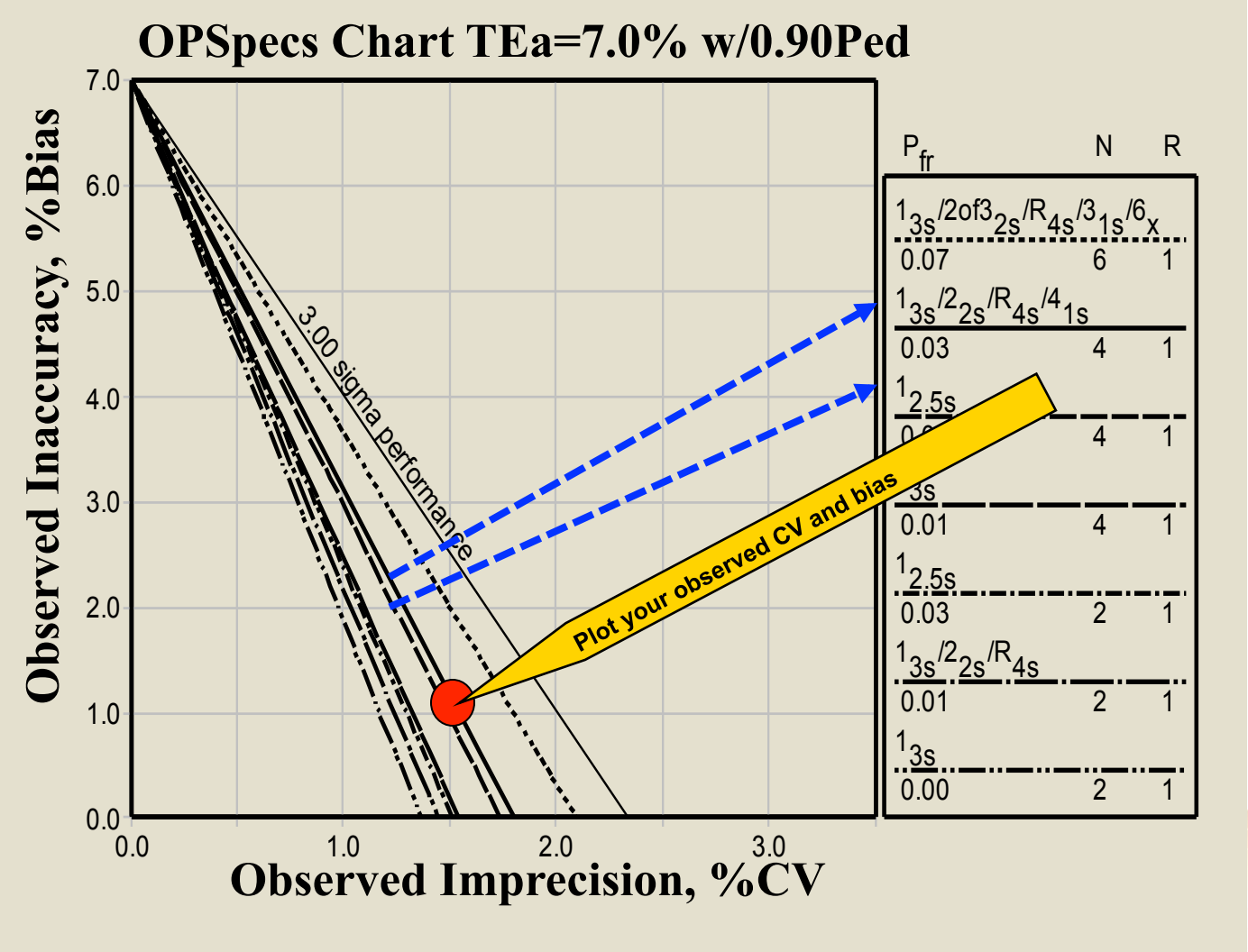
Sigma Tools
Six Sigma Quality System



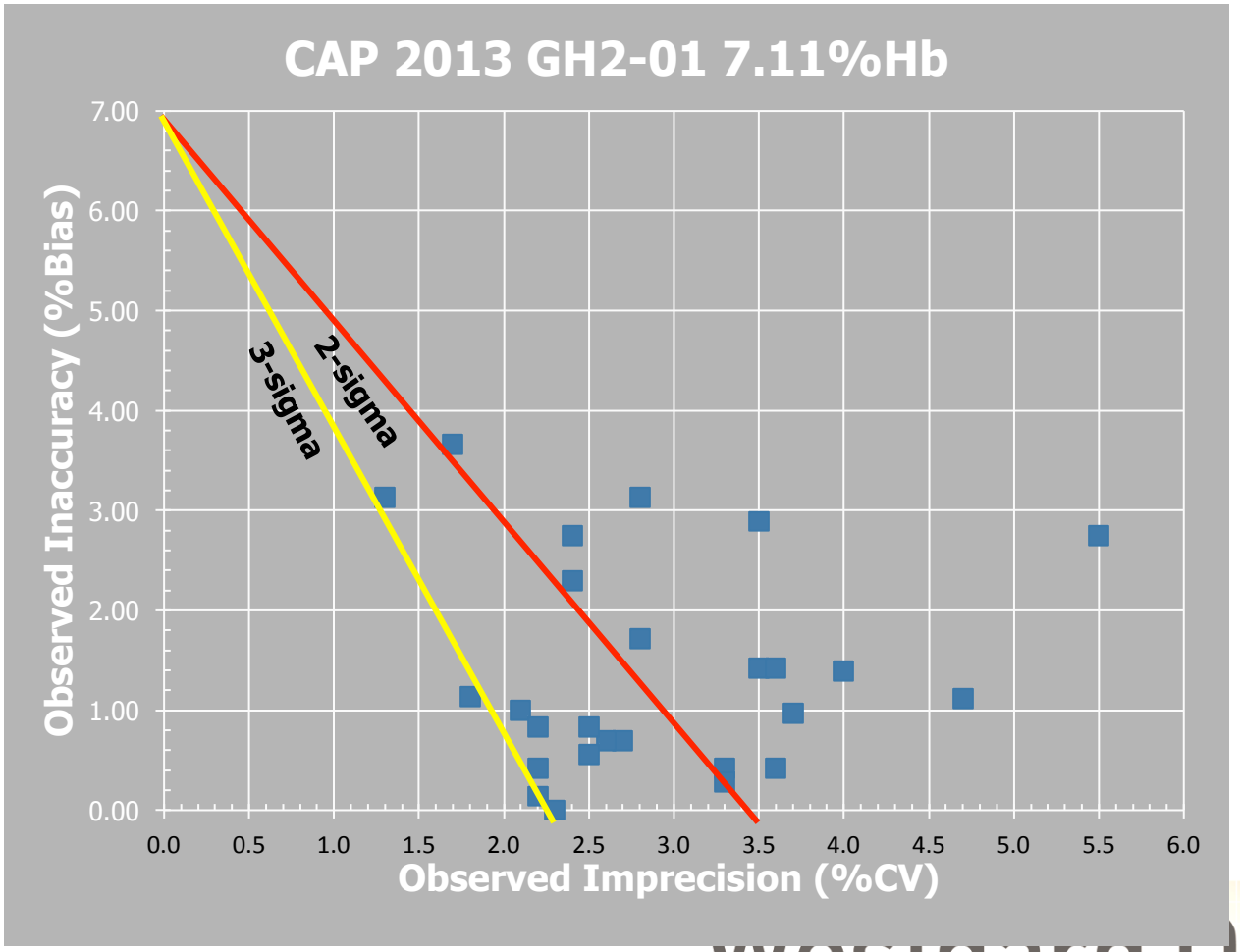
(1) Sigma Method Validation Tool HbA1c (Bias=1.0%, CV=1.5%)



(2) Sigma QC Selection/Design Tool Chart of Operating Specifications



(3) Sigma Proficiency Assessment Tool HbA1c, 2865 Labs, 26 Subgroups



Sigma quality vs necessary SQC

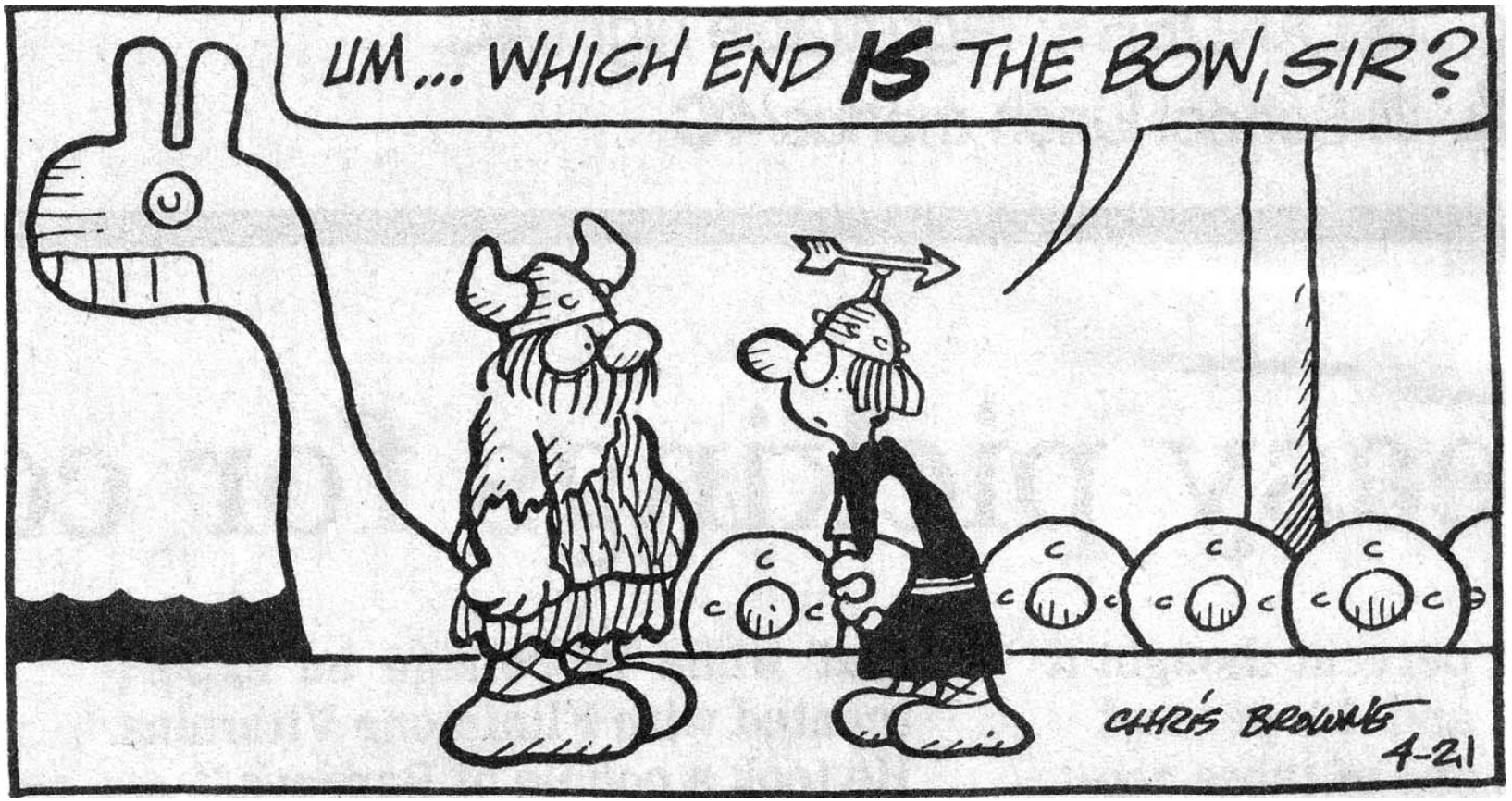
- **6 sigma process** - single rule QC with 3.0s limits and N of 2
- **5 sigma process** - single rule QC with 2.5s limits or multirule QC with Ns of 2-3
- **4-sigma process** – single rule QC with 2.5s limits or multirule QC with Ns of 4-6
- **3-sigma process** – need Ns of 6-8 or even higher, not practical for most laboratories
  - Can't afford to run enough controls to detect medically important errors!

Future QC Practices
What might go wrong?

- New age of Risk-based QC Plans
  - CLSI EP23A methodology qualitative, subjective
  - CMS appears to further simplify methodology
    - Laboratories will not need to utilize tools such as process maps, fishbone diagrams , formal risk assessment charts and protocols in their development of an IQCP
  - Laboratories face a steep learning curve to understand and correctly apply Risk QCPs

The Right Guidance!

ISO or CLSI or CLIA or YOU?



Thank you for your kind attention!