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IQC

Dr David Housley

Clinical lead Clinical Biochemistry / Immunology,
Bedfordshire Hospitals

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OVERVIEW

I will present:

- Very brief overview of what we do badly
- Overview of what we should be doing
- Discuss some supplementary areas

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Review Article

The Association for Clinical Biochemistry & Laboratory Medicine
Better Science, Better Testing, Better Care

Annals of Clinical Biochemistry
2016, Vol. 53(1) 32–50

DOI: 10.1177/0004563215597248
acb.sagepub.com
SAGE

Quality control review: implementing a scientifically based quality control system

James O Westgard and Sten A Westgard

Abstract

This review focuses on statistical quality control in the context of a quality management system. It describes the use of a 'Sigma-metric' for validating the performance of a new examination procedure, developing a total quality control strategy, selecting a statistical quality control procedure and monitoring ongoing quality on the sigma scale. Acceptable method performance is a prerequisite to the design and implementation of statistical quality control procedures. Statistical quality control can only *monitor* performance, and when properly designed, alert analysts to the presence of additional errors that occur because of unstable performance. A new statistical quality control planning tool, called 'Westgard Sigma Rules,' provides a simple and quick way for selecting control rules and the number of control measurements needed to detect medically important errors. The concept of a quality control plan is described, along with alternative adaptations of a total quality control plan and a risk-based individualized quality control plan. Finally, the ongoing monitoring of analytic performance and test quality are discussed, including determination of measurement uncertainty from statistical quality control data collected under intermediate precision conditions and bias determined from proficiency testing/external quality assessment surveys. A new graphical tool, called the Sigma Quality Assessment Chart, is recommended for demonstrating the quality of current examination procedures on the sigma scale.

Internal quality control: best practice

Helen Kinns,[1] Sarah Pitkin,[2] David Housley,[1] Danielle B Freedman[1]

[1]Department of Clinical Biochemistry, Luton and Dunstable University Hospital NHS Trust, Luton, UK
[2]Department of Clinical Biochemistry, Barts Health NHS Trust, London, UK

Correspondence to
Dr Helen Kinns, Department of Clinical Biochemistry, Luton and Dunstable University Hospital NHS Trust, Lewsey Road, Luton, LU4 0DZ, UK;
helen.kinns@ldh.nhs.uk/David.Housley@ldh.nhs.uk

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ABSTRACT

There is a wide variation in laboratory practice with regard to implementation and review of internal quality control (IQC). A poor approach can lead to a spectrum of scenarios from validation of incorrect patient results to over investigation of falsely rejected analytical runs. This article will provide a practical approach for the routine clinical biochemistry laboratory to introduce an efficient quality control system that will optimise error detection and reduce the rate of false rejection. Each stage of the IQC system is considered, from selection of IQC material to selection of IQC rules, and finally the appropriate action to follow when a rejection signal has been obtained. The main objective of IQC is to ensure day-to-day consistency of an analytical process and thus help to determine whether patient results are reliable enough to be released. The required quality and assay performance varies between analytes as does the definition of a clinically significant error. Unfortunately many laboratories currently decide what is clinically significant at the troubleshooting stage. Assay-specific IQC systems will reduce the number of inappropriate sample-run

samples. By definition, this is not completely
for random errors. However, the error detec
rate of an IQC system can be maximised by u
(i) appropriate IQC material analysed at (ii) ap
priate intervals and interpreted using (iii) appro
ate IQC ranges with (iv) appropriate IQC ru
Patient data algorithms (such as delta checks
absurd value recognition) should be used
adjuncts to IQC to aid detection of random erro

An audit of IQC practice conducted in 2
showed a wide variation in the laboratory appro
to implementation, review and troubleshooting
IQC across the UK.[4] This variation in prac
needs to be addressed so that IQC procedures
compatible with the progression towards pathol
harmonisation and the formation of laboratory
works. This article sets out practical guideline
promote best practice and limit variation at
stages of IQC management.

SELECTION OF IQC MATERIAL

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Tools, Technologies and Training for Healthcare Laboratories

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BASIC QC PRACTICES

2025 Great Global QC Survey Results: The whole world

In 2025, the Westgard Great Global Survey assessed the state of QC practices.

The 2025 Global QC Survey Results: Quality is getting more out-of-control

Sten Westgard, MS
August 2025

[This survey was completed with the support and partnership of Thermo Fisher MAS controls.]

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Audit of internal quality control practice and processes in the south-east of England and suggested regional standards

David Housley[1]*, Edward Kearney[2], Emma English[3], Natalie Smith[1], Teresa Teal[4]*, Janina Mazurkiewicz[4]* and Danielle B Freedman[1]

[1]Department of Clinical Biochemistry, Luton & Dunstable Hospital NHS Foundation Trust, Lewsey Road, Luton LU4 0DZ, UK; [2]Department of Clinical Biochemistry, Queen Elizabeth the Queen Mother Hospital, East Kent Hopsitals NHS Trust, St Peter's Road, Margate, Kent CT94AN, UK; [3]Department of Clinical Biochemistry, Addenbrooke's Hospital NHS Trust, Box 232, Hills Road, Cambridge CB2 2QQ, UK; [4]Department of Clinical Biochemistry, Eastbourne District General Hospital, Kings Drive, Eastbourne, East Sussex BN21 2UD, UK; *The authors belong to the North Thames Audit and QA Group
Corresponding author: Dr David Housley. Email: David.Housley@nhs.net

Abstract

Background: Internal quality control (IQC) has a long and well-established role in clinical biochemistry laboratories. However, despite the duration of use, and the publication of several articles detailing best practice, the implementation and use of IQC vary significantly between institutions. Consequently, the North Thames Audit and Quality Assurance Group undertook a region-wide audit of current IQC practice in 2006.
Methods: On aspects of IQC testing, interpretation and laboratory processes, 54 laboratories in the region were audited.
Results: Audit data showed significant variability in all aspects of practice, including IQC frequency, use of appropriate material, statistical processing and grades of staff involved.
Conclusions: Some of the variation in practice may affect the effectiveness of laboratory IQC, and thus the adequacy of a laboratory to monitor system performance. Consequently, a set of proposed regional standards have been developed and disseminated, prior to re-audit at a future date.

Ann Clin Biochem 2008; **45**: 135–139. DOI: 10.1258/acb.2007.007028

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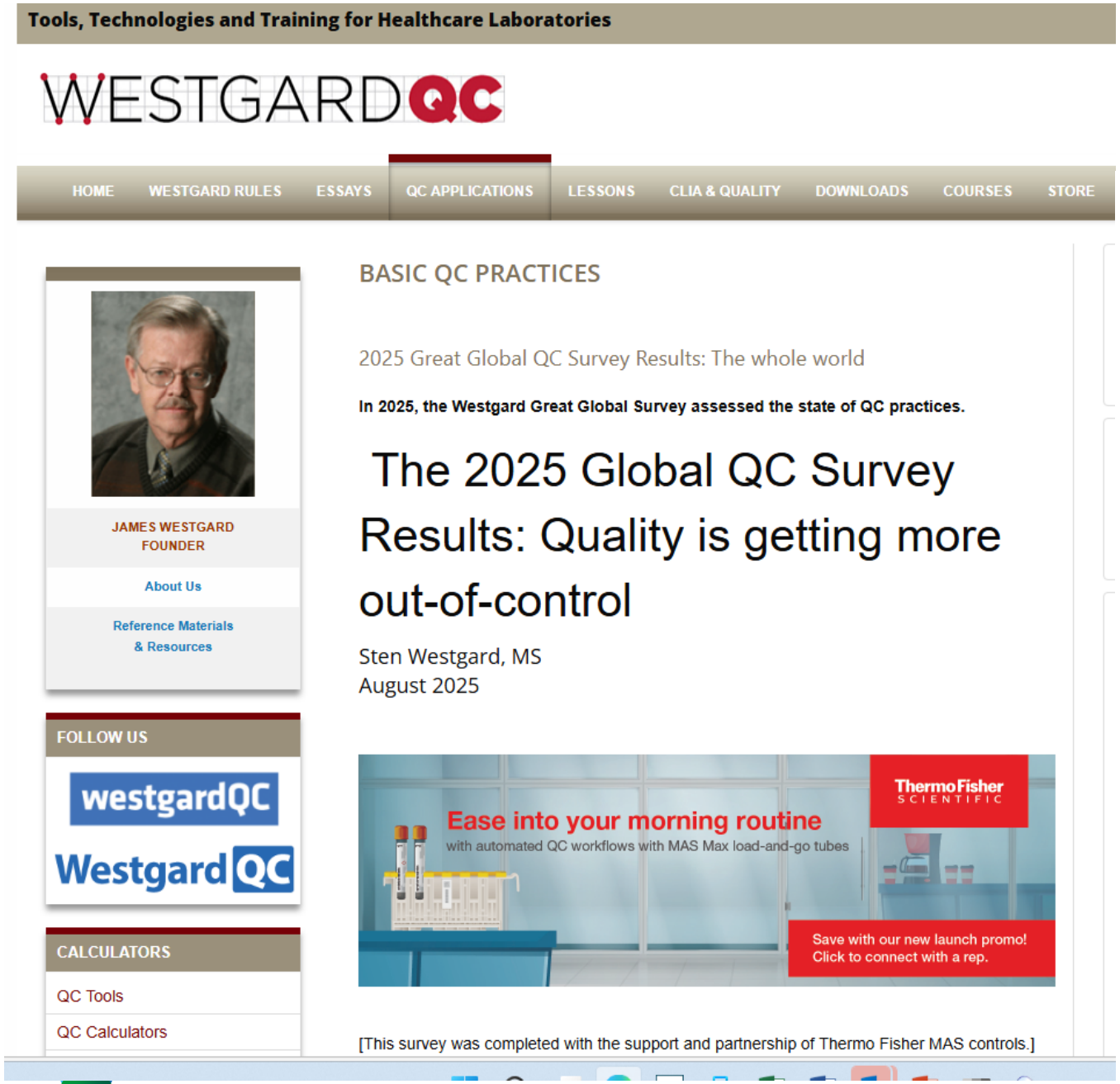

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- 1. IQC policies should cover 24/7 working
- 2. IQC targets should be assigned locally
- 3. Use 3rd party IQC
- 4. Use EP5A2 or equivalent to establish ranges
- 5. Use method specific rules
- 6. Do not use inappropriate single rules
- 7. Review grades of staff accepting and rejecting IQC
- 8. Failed IQC should not be accepted
- 9. Assess each module of an analyser separately

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CLINICAL IMPACT:

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FOR HEALTHCARE LEADERS HSJ

HSJ Podcast: The NHS staff who can't be civil servants

ASK HSJ | SECTORS | TOPICS | LOCAL | COMMENT | INTERACTIVE | EVENTS | JOBS

PATIENT SAFETY

Lab fault sees hundreds fast-tracked for unnecessary cancer tests

By Ella Devereux | 2 June 2026

5 Comments

- Processing error at shared pathology service produced 4,223 incorrect test results
- Up to 1,326 patients may have been wrongly fast-tracked for urgent cancer investigation
- Harm review underway across 17 organisations

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Error leaves 55,000 diabetes patients needing new tests

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'I've lost faith in the NHS after testing error'

Robby West

A hospital has apologised after more than 80 patients were misdiagnosed with pancreatic problems and some were prescribed drugs they did not need.

[redacted] said mistakes were made between July and December of 2024, after it switched to automated faecal elastase (stool) testing for pancreatic problems.

It has now gone back to manual testing after discovering errors had occurred with 84 patients.

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HbA1c LESSONS LEARNED – CATEGORIES:

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- Incident management
- Oversight of quality
- Post-market surveillance / reporting
- What are clinically significant events
- IQC
- EQA
- Statistics and data interpretation
- Access to data
- Output based quality metrics
- What does a good investigation look like

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LESSONS LEARNED - IQC:

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- IQC STRATEGY:
- IQC ranged from twice per day (800 – 900 samples) to every 30 samples – no evidence of risk based or if it was serving a useful purpose.
  - MORE QC IS NOT BETTER QC – LABS WITH GREATEST QC FREQUENCY OFTEN WORST AFFECTED

- Supplier in responses suggested IQC ranges – equivalent to 4SD

- Several labs not using third party QC – IQC not all behaving the same

- Trouble-shooting – rerun and recal

- Patient based IQC – high variability in interpretation

- Using subjective assessments of clinical significance to accept failed IQC

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IQC - CLINICALLY SIGNIFICANT CHANGES:

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- Clinical requirement was considered post-analytically after the IQC had failed – as a form of acceptance

- Highly variable approach to defining clinically significant change in results – what data / what statistics / what thresholds. Significant amount of subjective decision making.

CLINICAL REQUIREMENT OF THE TEST NEEDS TO BE BUILT INTO IQC DESIGN NOT SUBJECTIVELY CONSIDERED AFTERWARDS

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BUILDING THE CLINICAL REQUIREMENT INTO IQC

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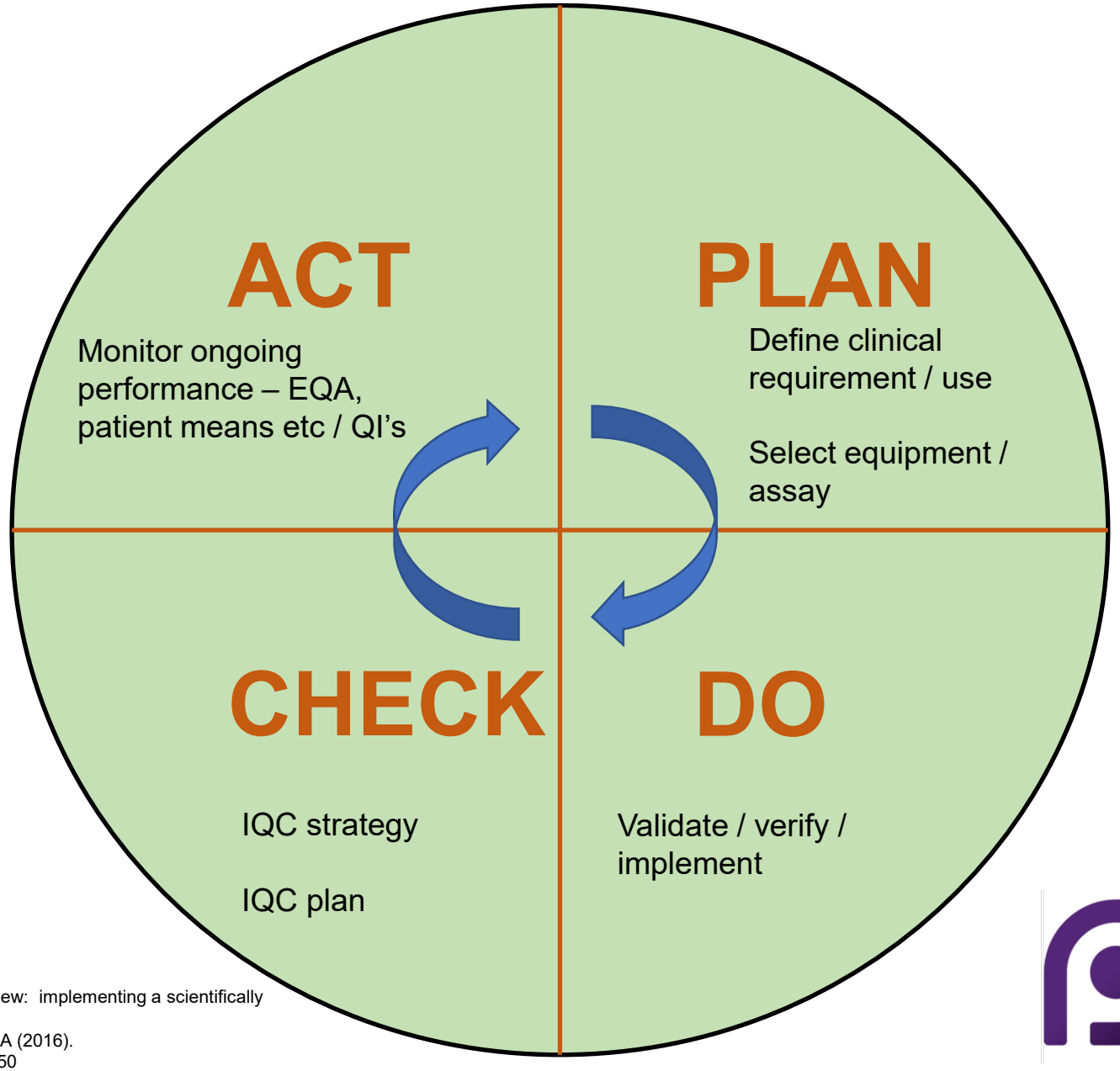

FOUR STEPS:

(P) – Define clinical requirement

(D) – Assess performance of device / test in relation to clinical requirement

(C) – Define your IQC strategy

(A) – Implement into use

Based on: Quality control review: implementing a scientifically based quality control system.
Westgard JO and Westgard SA (2016).
Ann Clin Biochem 53(1); 32 - 50

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DEFINE THE CLINICAL REQUIREMENT (PLAN)

DEFINING CLINICAL REQUIREMENT / INTENDED USE:

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- **ANALYTICAL PERFORMANCE SPECIFICATIONS**:

- MILAN CRITERIA:
- Clinical outcomes (direct or indirect)
- Biological variation
- State of the art
  - Maintenance to avoid deterioration
  - Tail end improvement – levelling up
  - Aspirational – Analytical performance goal rather than requirement

Ceriotti F, Fernandez-Calle P, Klee GG, et al. Criteria for assigning laboratory measurands to models for analytical performance specifications defined in the 1st EFLM strategic conference
. *Clin Chem Lab Med* 2017; 55:189–94

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Search Results

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Troponin I cardiac - high-sensitive (biweekly-monthly sampling)

Troponin I cardiac - high-sensitive (biweekly-monthly sampling) - Meta Analysis

Matrix	BV Estimate	Median CV	Lower CI	Higher CI	Comments	Updated
Serum/plasma	Within Subject	11.1	2.6	117.0		3/9/2025
Serum/plasma	Between Subject	34.4	25.8	63.0		3/9/2025

Analysis Tools: Analytical Performance Specification | RCV Calculation

Show BV Data Details
Datasets included and excluded from Meta Analysis

Analytical Performance Specification Calculation

Troponin I cardiac - high-sensitive (biweekly-monthly sampling)

Enter Values

% Within-subject (CVI) estimate: 11.1

% Between-subject (CVG) estimate: 34.4

Results

Specification	CVa	Bias	MAU	TEa
Minimum	8.3	13.6	16.7	27.3
Desirable	5.6	9	11.1	18.2
Optimal	2.8	4.5	5.6	9.1

There are currently three main models for calculating analytical performance specifications (APS)

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Taken from EFLM Biological variation database

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ASSESS YOUR DEVICE AGAINST THE CLINICAL REQUIREMENT (DO)

LOCAL VERIFICATION – APPLYING IT TO YOUR IQC PRACTICE

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- **SIGMA METRIC**:
- Sigma metric = (TEa – Bias) / SD
- Number between 1 – 6.

Sigma score	Performance
>6σ / >5.5	Excellent
4σ–6σ / 3.6 - 5.4	Suited to purpose
3σ–4σ / < 3.5	Poor performers
<3σ	Problematic

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WHAT DOES IT REVEAL ?

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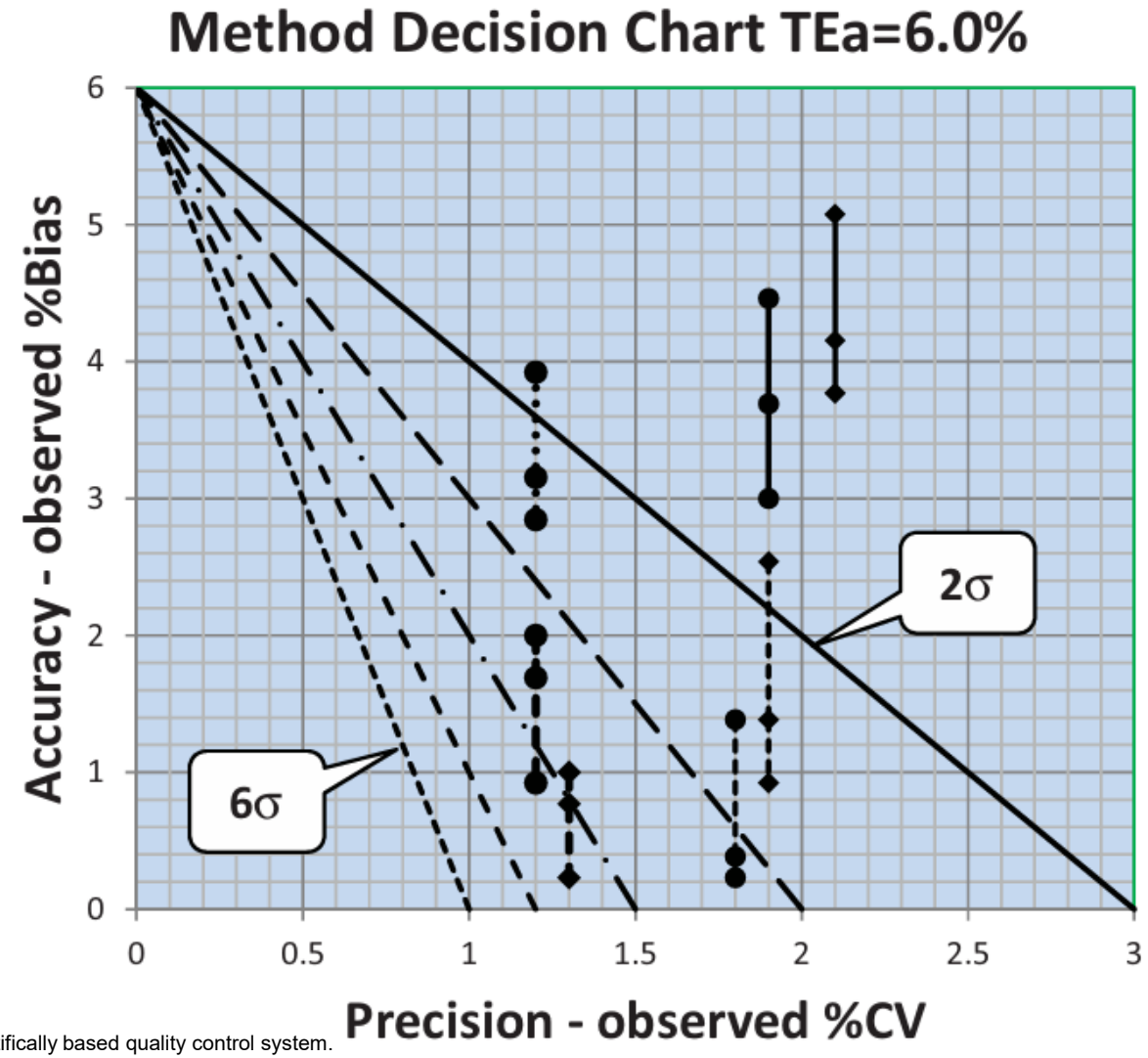
Gives real world assessment of the device:

HbA1c with TEa of 6%:

DEVICE 1:
Bias 1% and CV 1% = sigma metric 5

DEVICE 2:
Bias 0% and CV 1.5% = sigma metric 4

DEVICE 3:
Bias 1.5% and CV 1.5% = sigma metric 3



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DEFINE YOUR IQC STRATEGY (CHECK)

WHAT DO I DO WITH MY SIGMA SCORE ?

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ALLOWS YOU DEFINE:

1. Overall quality (QMS) approach to the device / test

2. Statistical QC plan

Recommended QC tool	Sigma ⩾ 5.5	Sigma 5.4–3.6	Sigma ⩽ 3.5
Analyst/operator controls	Essential	Essential	Essential
Stand. Op. procedure	High	High	High
Operator training	High	High	High
System maintenance	High	High	High
Operator competency	High	High	High
Built-in analyser controls			
Electronic checks	Low	Moderate	High
Function tests	Low	Moderate	High
Process tests	Low	Moderate	High
Calibration checks	Low	Moderate	High
Integrated controls	Low	Moderate	High
Stable control materials			
Statistical QC	Essential	Essential+	Essential++
Frequency of QC	Low	Moderate	High
SQC with peer comparison	Low	Low	Low
Periodic EQA, PT	Regulatory	Regulatory	Regulatory
Trueness controls	Low	Low	Low
Patient data analysis			
Implausible values	High	High	High
Delta checks	Low	Moderate	High
Correlation algorithms	Low	Moderate	High
Repeat patient testing	Low	Moderate	High
Population statistics	Low	Moderate	High

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BEFORE THE STATISTICS:

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- Select your IQC material
  - Commutability
  - Supplier versus third party
  - Assayed versus unassayed
  - Target concentrations
  - Stability and lot to lot variation
  - Does the IQC testing process cover everything in the patient testing process ?

CONSIDER combining with Sigma metric to make risk assessment

  - What is your risk appetite – eg number of samples between assessments

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STATISTICAL IQC:

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How many levels

What statistical rules

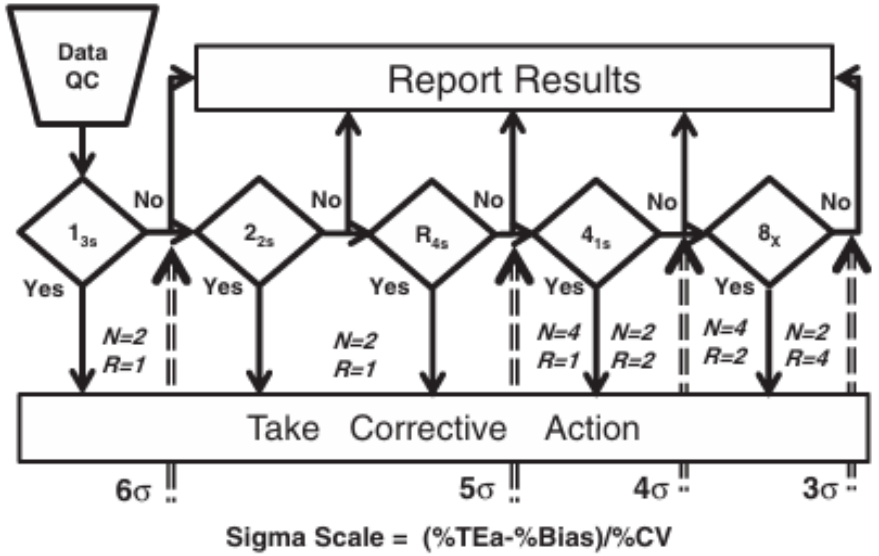
How frequently

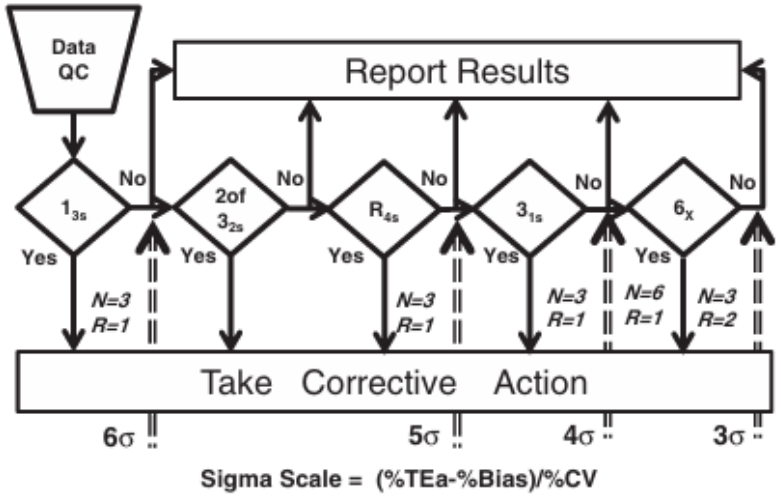
APPROACH:

DEVICE 1:
Bias 1% and CV 1% = sigma metric 5 → 2 levels with 1_{3s}, 2_{2s}, R_{4s}

DEVICE 2:
Bias 0% and CV 1.5% = sigma metric 4 → 4 x 1 or 2 x 2 levels with 1_{3s}, 2_{2s}, R_{4s}, 4_{1s}

DEVICE 3:
Bias 1.5% and CV 1.5% = sigma metric 3 → 4 x 2 with 1_{3s}, 2_{2s}, R_{4s}, 4_{1s}, 8_x





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HOW FREQUENTLY:

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RISK ASSESSMENT:

Clinical consequence

Number of samples per day

Cost complexity of failure

Start up and Monitoring rules

Sigma score	Performance	IQC design[16]
>6σ	Excellent	Once per day One level per day (alternating levels) $1_{3.5s}$ rule
4σ–6σ	Suited to purpose	Once per day Two levels per day Single IQC rule
3σ–4σ	Poor performers	Twice per day Two levels of IQC per day Multirule system
<3σ	Problematic	Three times a day Three levels Consider testing in duplicate Maximum IQC rules

Extra IQC with extra rules does not suddenly change the method performance. A poorly performing assay is still a poorly performing assay.

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Kinns H, Pitkin S, Housley D, Freedman DB (2013). Internal Quality Control: Best Practice. J Clin Path 66(12) 1027 – 32.

CONSIDER WHAT ELSE MAY BE USEFUL

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- What if:
  - Your assay is <3.5 σ ?
  - IQC material is not commutable / does not cover all steps ?
  - How do I monitor all my assays ?

- Output based metrics
  - Patient means
  - Number of results outside RR / thresholds etc
- QC FEWL

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BE OBJECTIVE IN ALL AREAS OF IQC PRACTICE

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WHEN IQC FAILS

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If you have established your IQC approach correctly:

Probability of detecting an error is >90%

Likelihood of false rejection < 1%

IT IS A TRUE FAILURE

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WHAT DO I RETEST ?

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- In theory everything going back to the last good IQC assessment.

- BEDFORDHIRE EXAMPLE:
- IQC for Na grossly out. Approx 700 samples since last IQC.
- Run 10 samples at multiple time points – narrow window. Be objective, use MU to define poor repeats. Repeat all – n = 95.
- BMS issue amended report on anything > MU
- Escalation for clinical review / action if:
    - Result changed from critical to non-critical
    - Changed from below LLN to normal
    - Changed by more than 3 mmol/L

N = 17

MU = 2 mmol/L
APS = 3 mmol/L
RCV = 4 mmol/L

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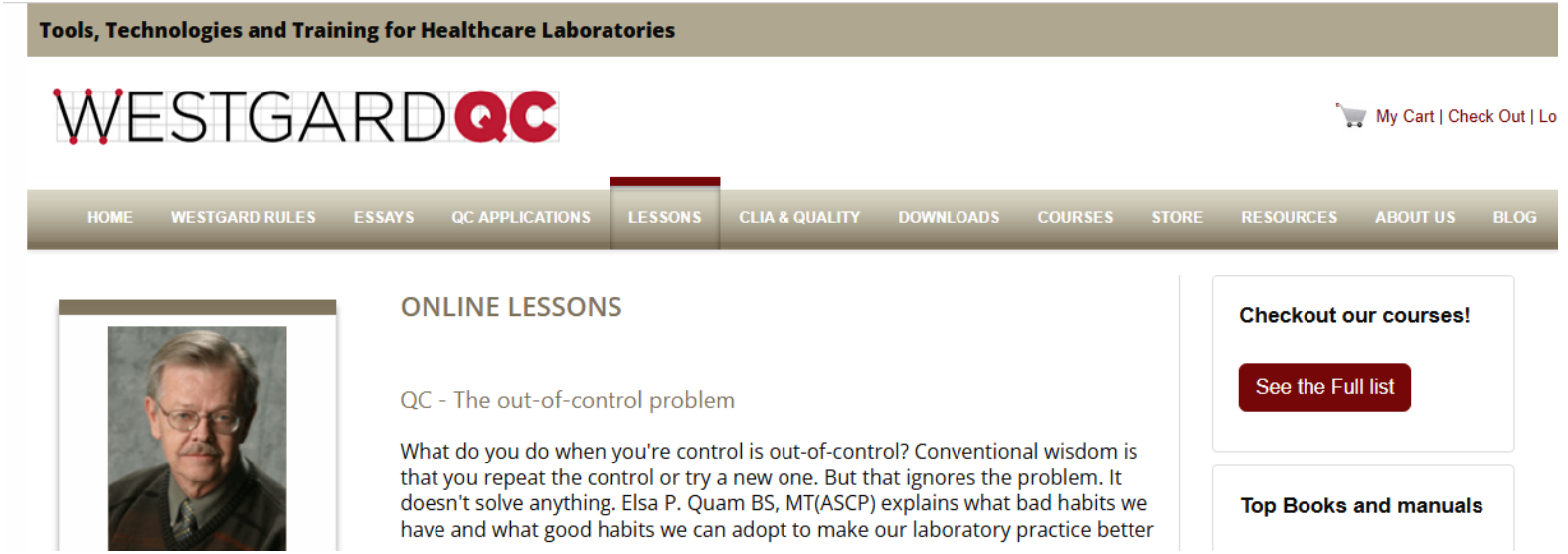
REALITY OF IQC TROUBLE-SHOOTING:

- Assumption of false signal:
  - Repeat IQC ± new bottle
- Blindly recalibrate
- Load fresh reagent

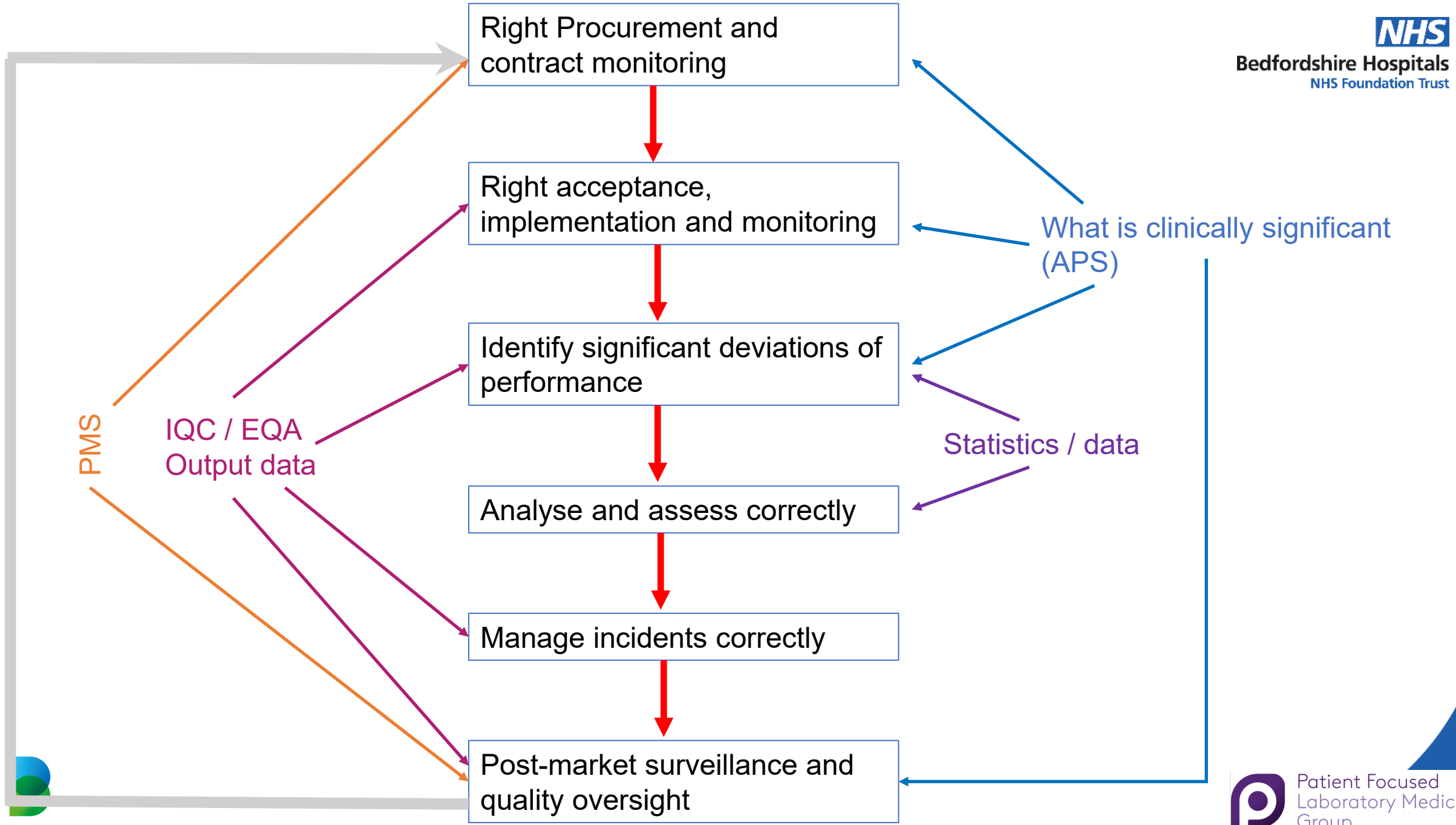
  In the UK IQC audit:

  Only 10% consistently rejected
  25% subjective if clinically significant



- No robust linking of corrective actions to an established root cause

P:\Guidelines\IQC Flowchart V2.pptx


Right Procurement and contract monitoring
Right acceptance, implementation and monitoring
Identify significant deviations of performance
Analyse and assess correctly
Manage incidents correctly
Post-market surveillance and quality oversight
PMS
IQC / EQA Output data
What is clinically significant (APS)
Statistics / data

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CONCLUSION:

There is significant literature / evidence to describe how to do IQC in a way that:

- Is clinically effective
- Cost effective

We are applying clinical assessments during the wrong part of the process

We can eliminate subjective assessments

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REFERENCES:

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Criteria for assigning laboratory measurands to models for analytical performance specifications defined in the 1st EFLM strategic conference. Clin Chem Lab Med 2017;55:189–94.

An Overview of allowable total error in the clinical laboratory
March 2026 | 11:02 | 357–367 | JALM