Getting it Right for the Patient:
Patient-Focussed laboratory Medicine

Dr Martin Myers

- Consultant Clinical Biochemist
- Co-Clinical Lead NHSE GIRFT, Pathology

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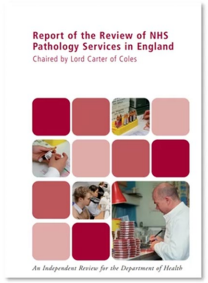
Pathology: A balance of emphasis

Organisational

Fragmented

Integrated



Clinical Quality

Regulated

Improved

- Seek out **unwarranted variation**
- Use evidence to improve quality

- Government
- NHSE/DHSC
- Regions
- Arms Length Bodies
- ICBs
- Trusts
- Primary Care Networks
- Service Networks

- **Right Test**
- **Right Place**
- **Right Time**

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"Our approach is to deliver clinically-led improvement and **put the patient in the heart of the system.** We deliver this through an approach called Getting It Right First Time (GIRFT)."

GIRFT Methodology (over 40 Clinical disciplines)

1. Collect relevant **data**
   - National, e.g.: HES, professional bodies, national audits
   - **Questionnaire**: issued to all Trusts – ***crucial for Pathology***
   - **Identify Unwarranted Variation**

2. Report (data pack) issued to each trust, prior to Visit (deep dive) with Path clinical staff, senior Trust managers
   - carry out Deep-Dives in each English Laboratory (~130)
   - highlight best practice, unwarranted variation, challenges

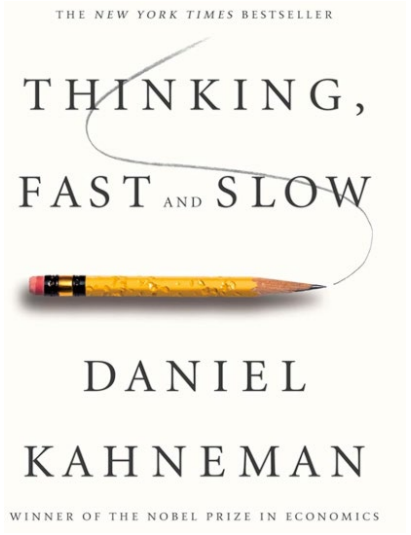
3. Agree local action & implementation plan
   - support provided by regional GIRFT teams

4. National Report
   - highlight best practices, concerns, challenges
   - 21 key recommendations

5. Legacy-making it happen
   - discussion with stakeholders and setting up Task Forces

https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2022/05/Pathology-4May22j.pdf

Human Judgement and Analytical performance: unwarranted variation



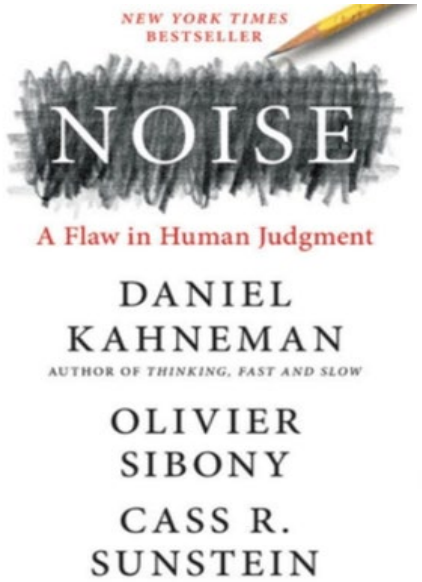
System 1 thinking:

- fast, instinctive, emotional, cognitive bias, unwarranted variation

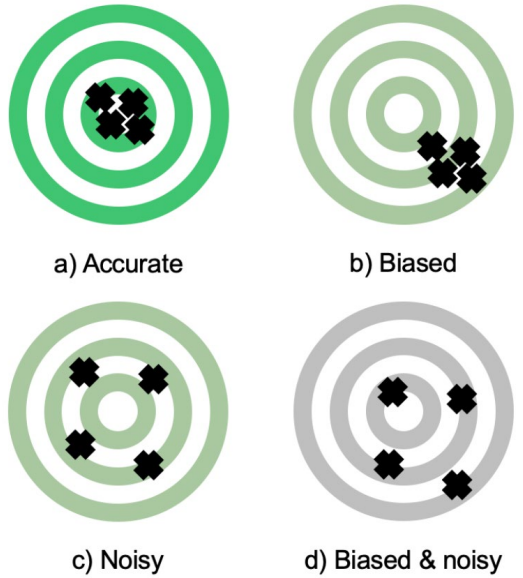
System 2 thinking:

- Data-driven, slower, more logical, insightful, rational, reflection

- GIRFT is about obtaining the evidence on unwarranted variation in service delivery



Noise: Undesirable variability in judgements of the same problem
Imprecision: Undesirable variability in the test result
Cognitive Bias: deviation from "norm"
Analytical Bias: deviation from the "true" result



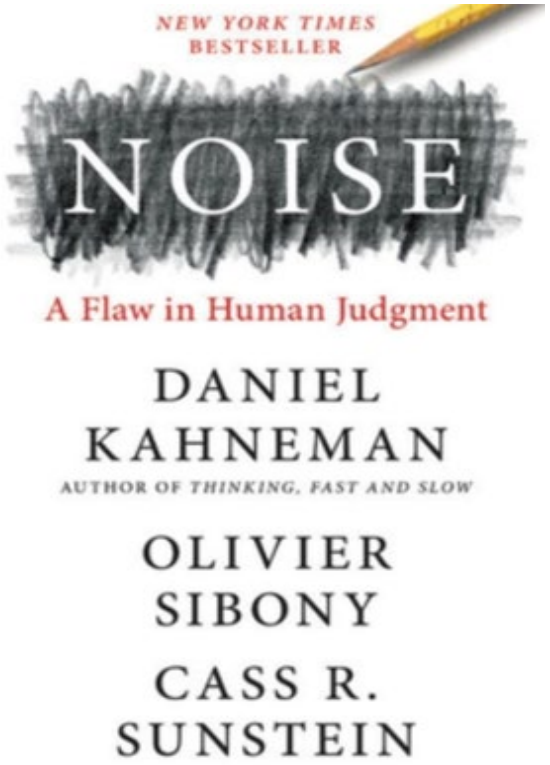
The combination will result in unwarranted variation in

- Analytical performance
- Human judgement and decision making
- Service delivery

Unwarranted variation in Human Judgement and Analytical Performance

Decision and Analytical Hygiene

- Choice Architecture
- Balance of Form and Function
- Demand optimisation
- Failure Demand
- Nudge and de-biasing
  - Algorithms
  - Agreed reference points on decisions and tests – use IRSs
  - Aggregation of judgement- best practice
  - Is the service, is the test, fit for purpose? – Use case, test performance



Decision Hygiene

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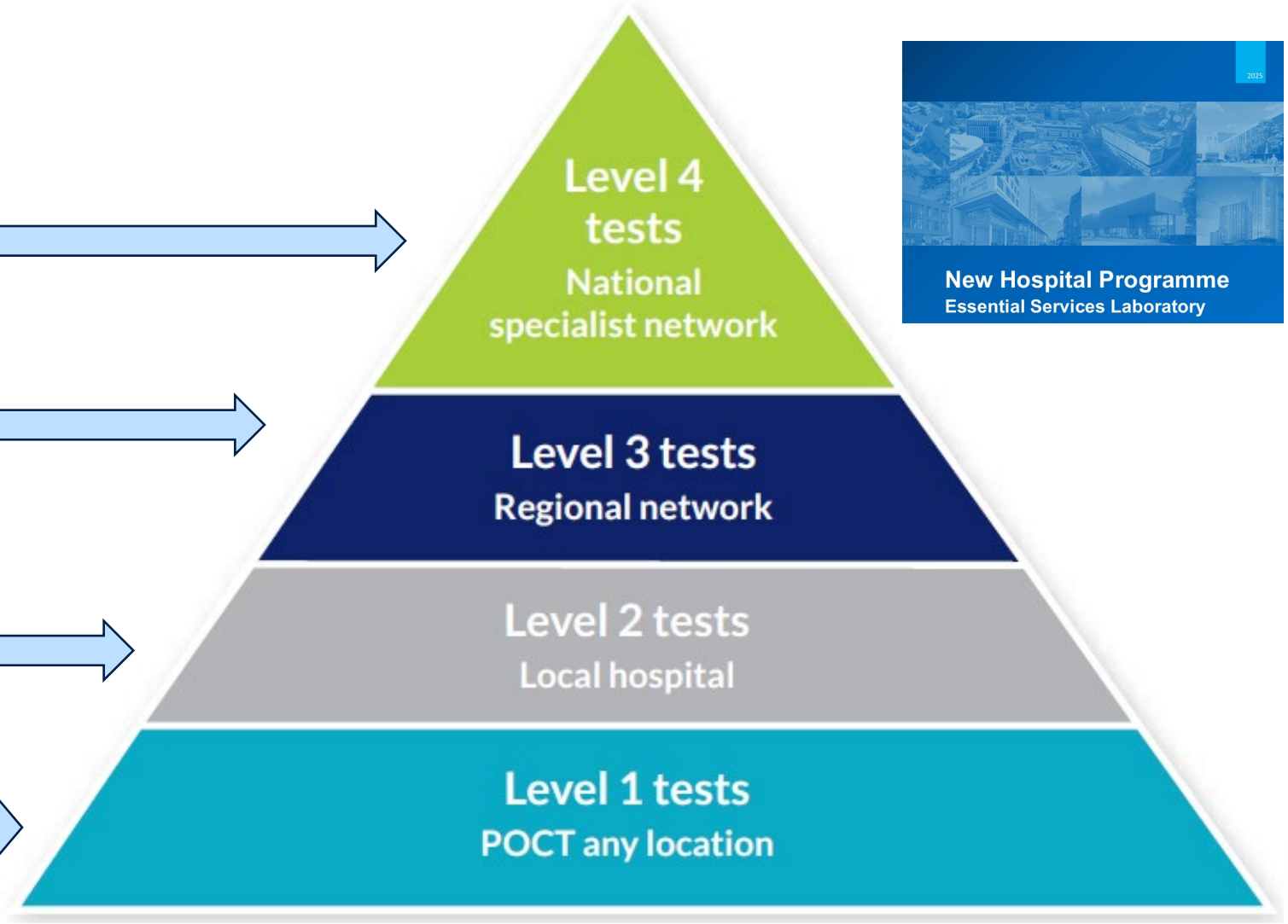
Choice Architecture *In-Vitro* Diagnostics Delivery Framework

Regional lab
Core Lab plus specialist testing to serve a regional population

Core lab
traditional laboratory scope, right size according to network and geographical needs

Essential services lab
provision of urgent, time critical tests through a mixture of point of care testing (POCT) and laboratory testing.

Laboratory Anywhere
POCT where needed, e.g. Neighbourhoods



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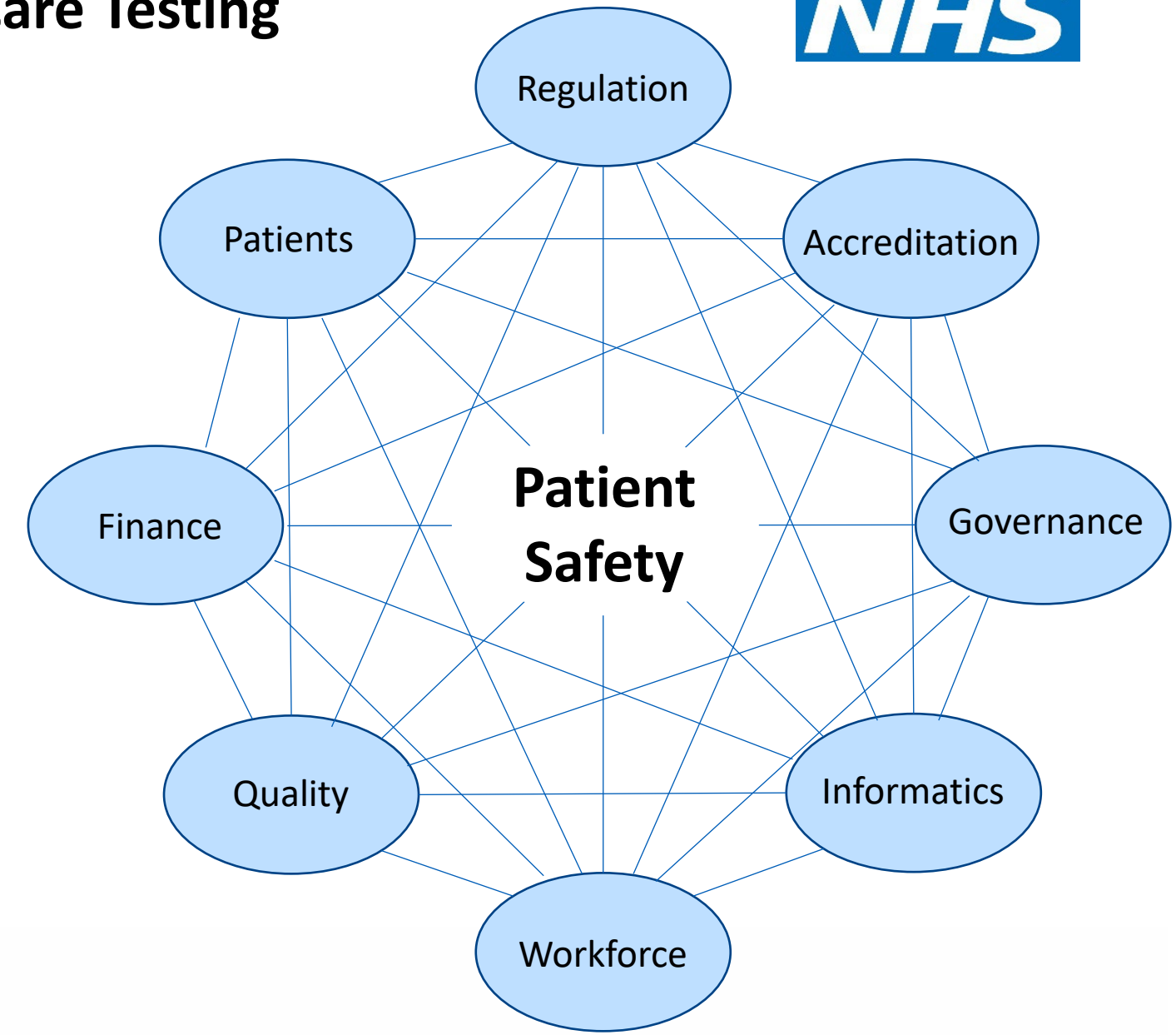
Choice Architecture for Point of Care Testing



The GIRFT POCT Quality wheel

- This forms the basis of a Quality Management System for the introduction and safe use of POCT

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Choice Architecture in pre-analytics

Significant variation in the quality of the pre-analytical phase

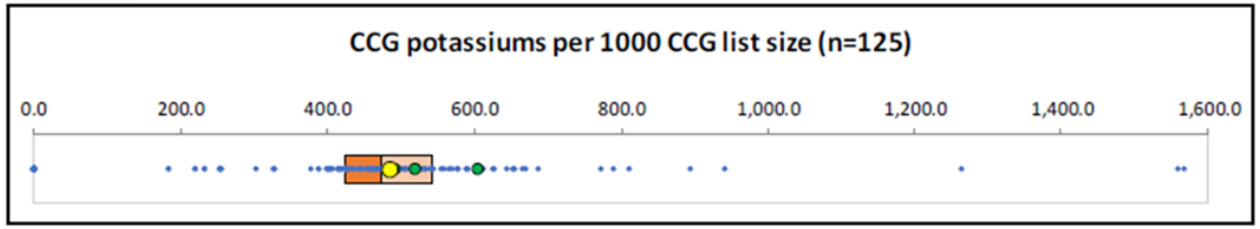
- Delays in transport- TIME
- No control of temperature of transport - TEMPERATURE
- Errors in phlebotomy

GIRFT have recommended that

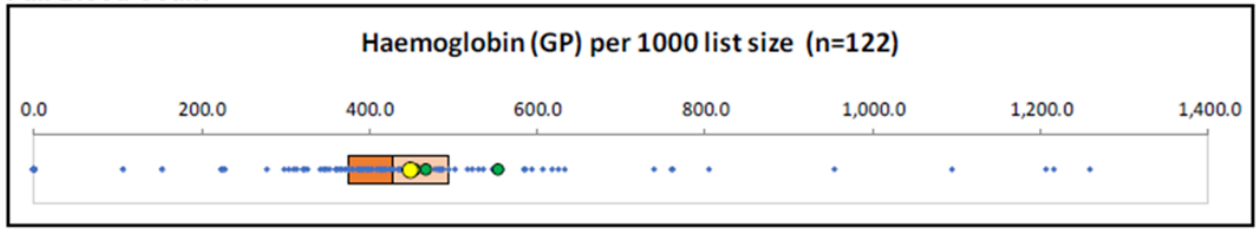
- The pre-analytical process must be better designed, monitored and controlled
- KPIs for the time from needle to centrifuge time
- KPIs for transport temperature
- Audit against the KPIs, and to mitigate if KPIs are failed
- The pre-analytical process should be accredited under ISO15189:2022, using ISO22367:2026 for Audit Design
- Discussions between GIRFT, ALM and EFLM on pre-analytical phase

Demand Optimisation

Potassium

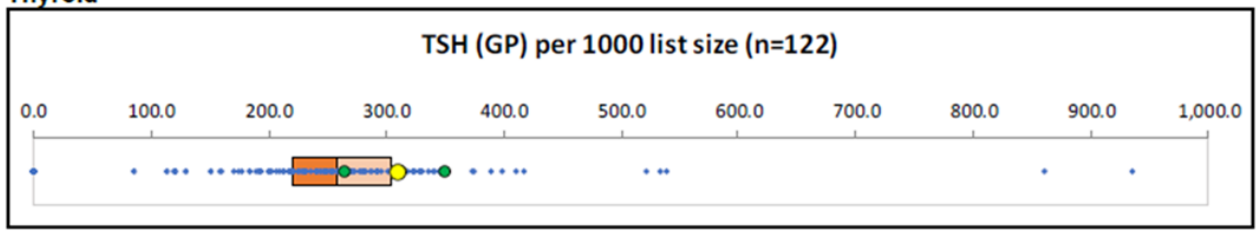


Full Blood Count



Liver

Thyroid



- For every test we found 3-5 fold variation in requesting rates
- Variable use of demand optimisation
- Excessive testing:
  - Costs money
  - May be harmful
  - Increases waste and carbon footprint
  - Up to 20% of Pathology testing may be unnecessary

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Demand Optimisation: GIRFT Toolkit

1. **Stopping unnecessary tests in Profiles**
   - Gamma GT in a Liver Function Test, Urea in GP U&E, both AST and ALT in a Liver Function Test, Free T4 in a Thyroid function Test
2. **Use of Intelligent Requesting in GP e-Ordering**
   1. *Intelligent buttons*
      - Introducing "pop-up" questions at e-ordering to ensure that the request is optimal
      - Vitamin D, Thyroid Function, Allergy requests etc
   2. *Condition Requesting Care Sets*
      1. Introducing agreed tests for a clinical condition optimises care and reduces unnecessary testing- Clinisys ICE
3. **Limiting tests that are significantly expensive**
   - Allergy testing
4. **Stopping tests of limited or no clinical value**
   - GIRFT showed significant unwarranted variation in testing rates
   - The RCPath have published a list of Tests of Limited Value in Cellular Pathology
   - Daily habitual testing, Discharge bloods
5. **Identifying unwarranted variation in GP requesting**

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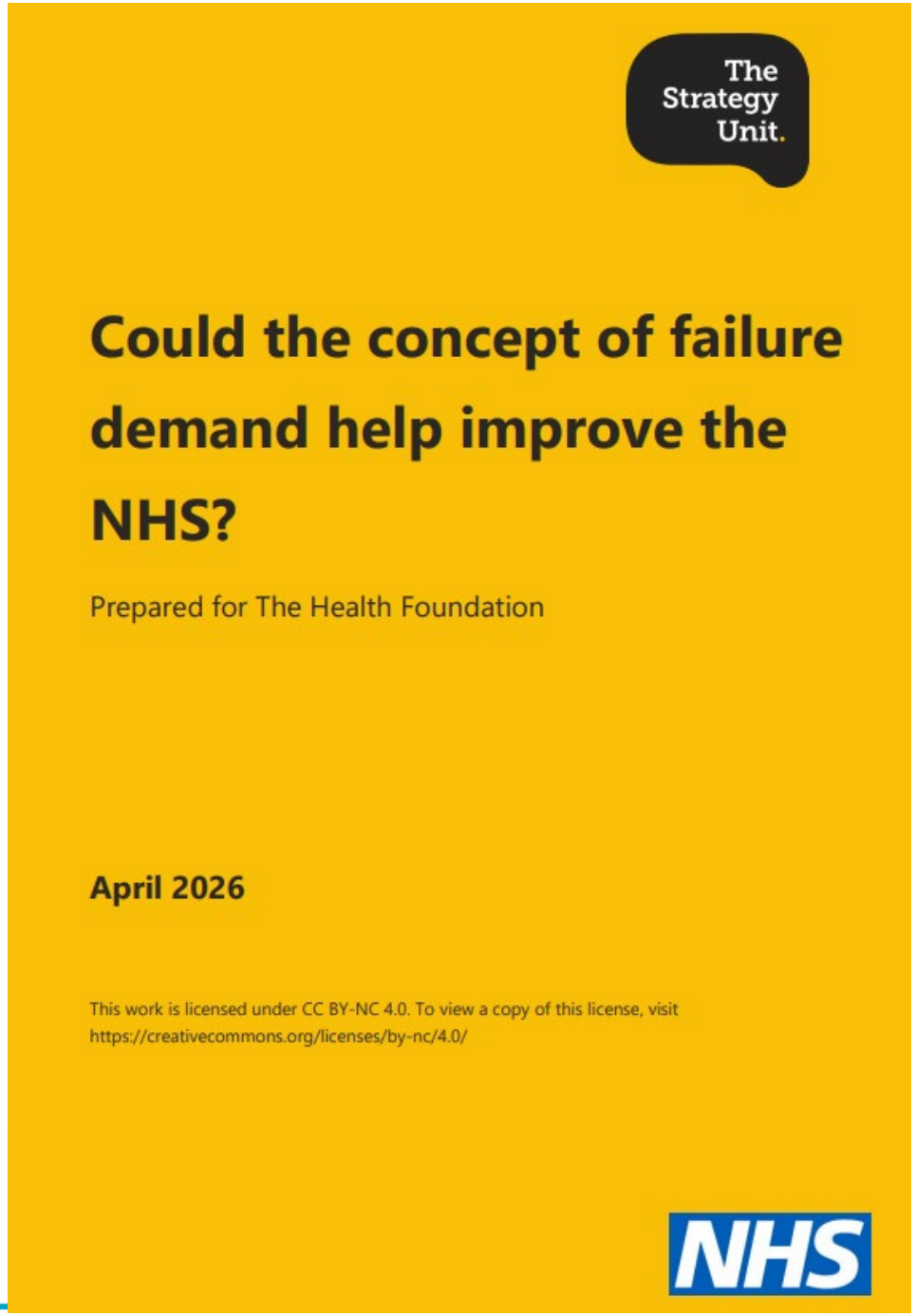
Failure Demand

"Failure Demand - the additional work created when services fail to meet peoples needs effectively the first time"

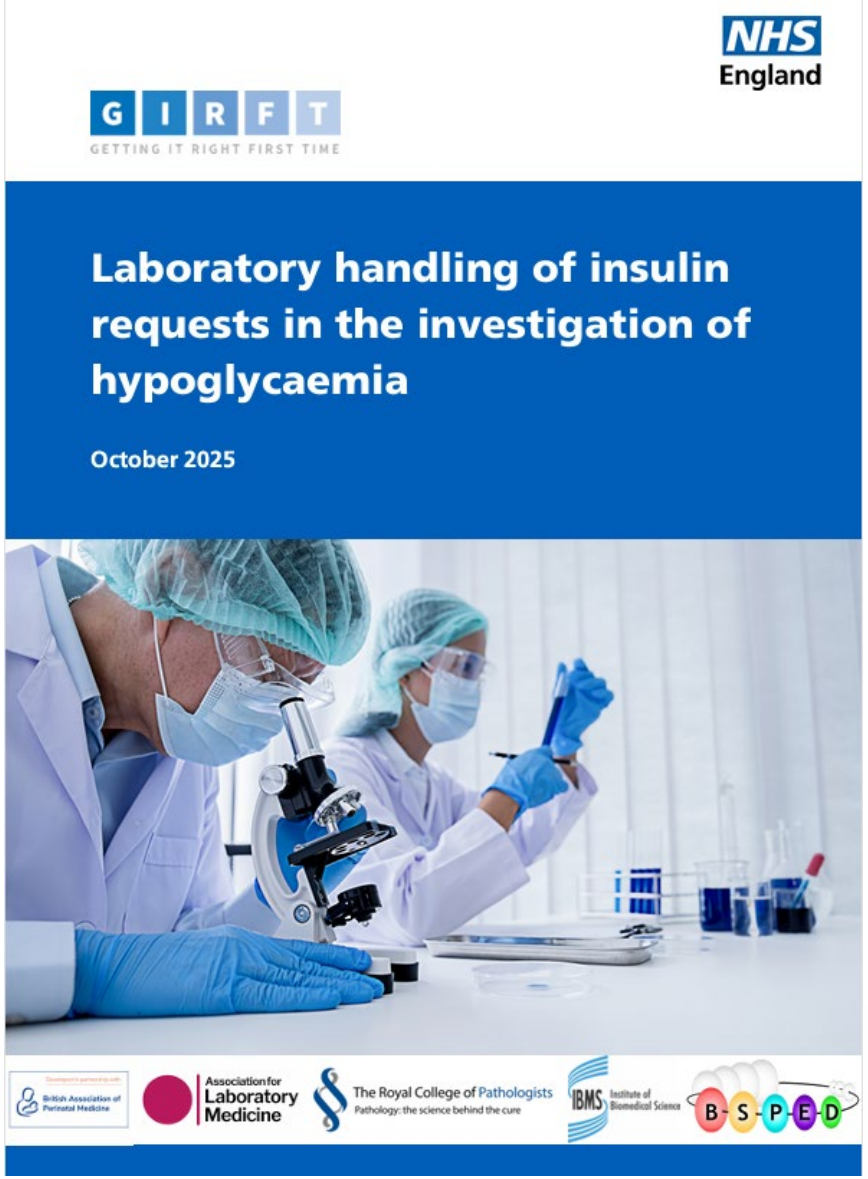
- An unnecessary test or a test with Clinically unacceptable performance could lead to a series of expensive consultations, further expensive tests (including invasive tests) and unnecessary stress to the patient (even if the initial test was the cheapest in the land)

- Getting it right for the patient starts with ensuring that the test is required and performing within clinically acceptable specifications



Best Practice: National Insulin Recommendations

- We found significant unwarranted variation in the way Hospitals/Laboratories handled insulin requests for the investigation of hypoglycaemia
- 18 Recommendations



https://gettingitrightfirsttime.co.uk/wp-content/uploads/2025/11/Laboratory-handling-of-insulin-requests-in-the-investigation-of-hypoglycaemia-guidelines-FINAL-November-2025.pdf

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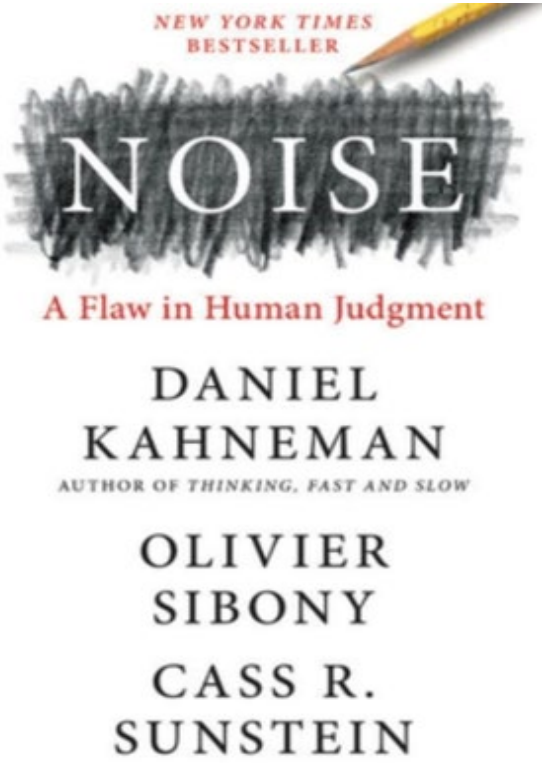

Analytical Hygiene

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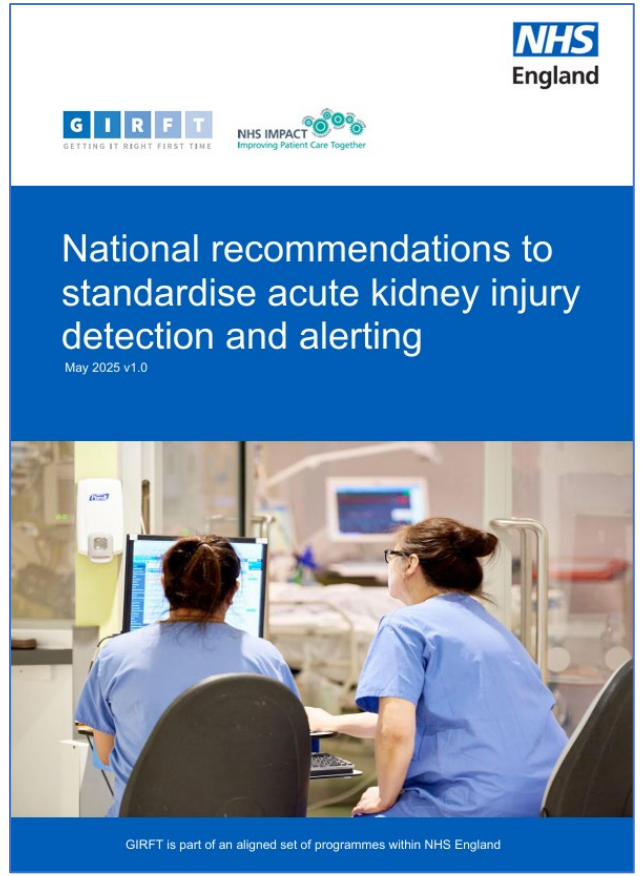
Best Practice: National AKI Recommendations

1. All Laboratories should use enzymatic creatinine assay
2. All Laboratories should participate in EQA for AKI (*first in the world*)
3. All Laboratories must use the NHSE AKI Algorithm
4. All LIMS providers in the UK must install the NHSE AKI Algorithm
5. All LIMS providers must make the NHSE AKI Algorithm un-editable locally
6. The NHSE Algorithm must be used for primary and secondary care
7. AKI reporting should be applied to everyone over the age of 28 days
8. AKI2 and AKI3 must be reported within 6 hours
9. All of the NHSE Algorithm must be used, including the “?AKI/?CKD” arm
10. Paediatric reference intervals need to be harmonised



https://gettingitrightfirsttime.co.uk/wp-content/uploads/2025/07/AKI-detection-and-alerting-recommendations-FINAL-May-2025.pdf

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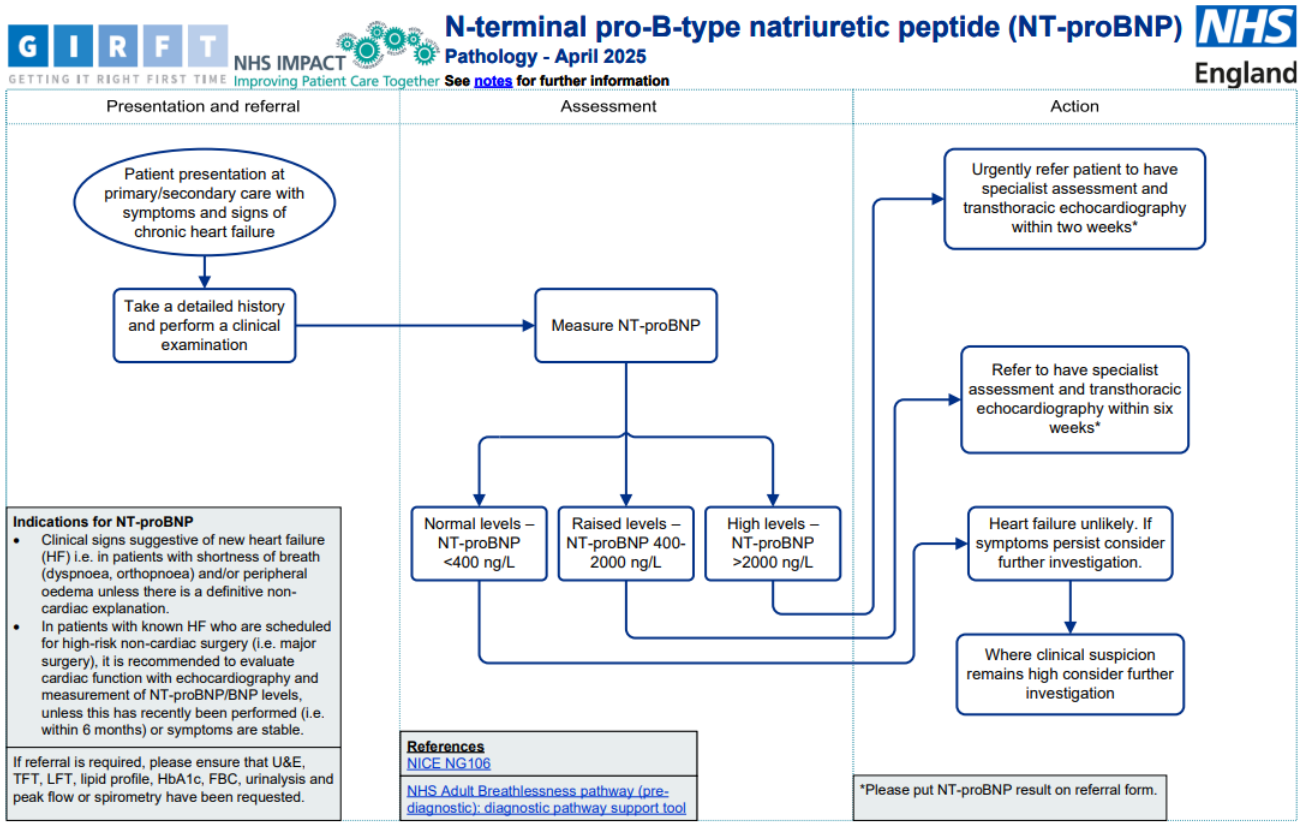
Best Practice : NTproBNP

To reduce unwarranted variation in the laboratory support to diagnose Chronic Heart failure

1. Harmonising to NT-proBNP
2. Harmonise the testing Pathway and decision limits
3. Harmonise on units of measurement
4. Harmonising the turnaround time

Date published: 18 December, 2023
Date last updated: 11 January, 2024

Enhancing GP direct access to diagnostic tests for patients with suspected chronic obstructive pulmonary disease, asthma, or heart failure



https://gettingitrightfirsttime.co.uk/wp-content/uploads/2025/04/NTProBNP-pathway-April-2025-FINAL.pdf

HbA1c and G6PD Deficiency

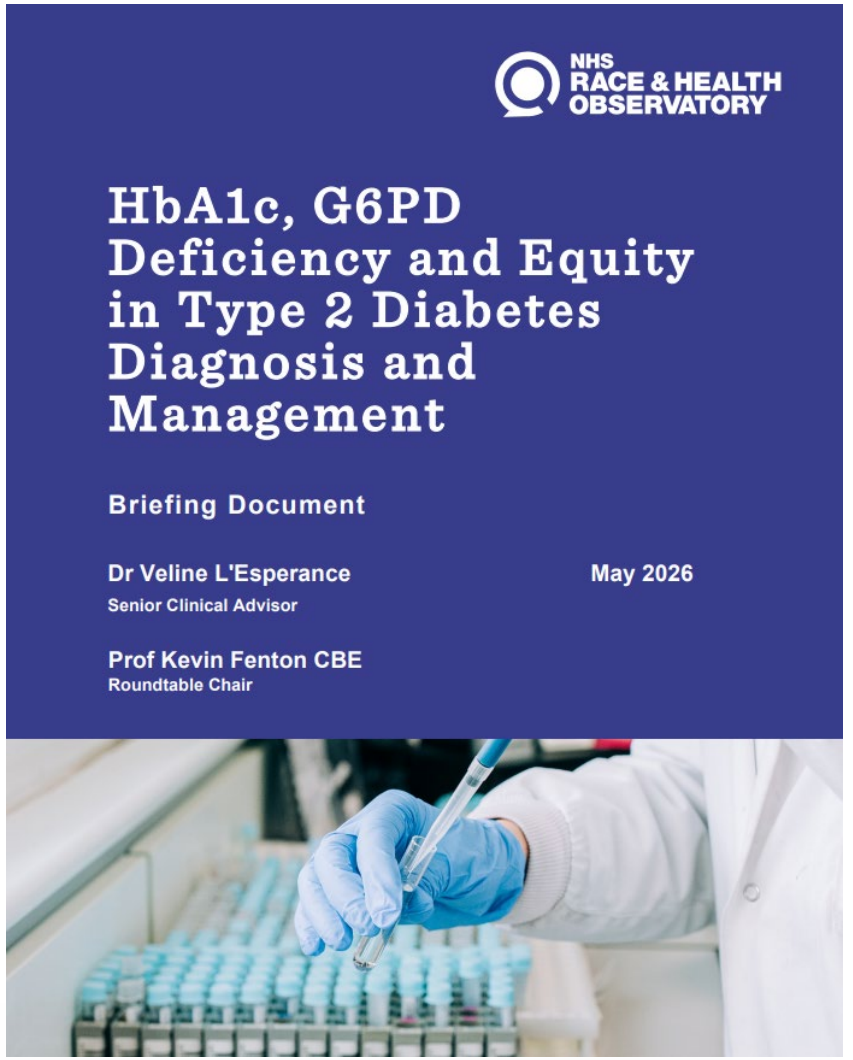
G6PD Deficiency results in

- lower HbA1c, by about 10mmol/mol
- later diagnosis of T2DM, by about 4 years
- increased risk of retinopathy, nephropathy and CVD by 40%

1 in 7 Black men, 1 in 43 Black women and 1 in 63 South Asian men in the UK have G6PD Deficiency (1 in 10,000 White men)

GIRFT and the NHS R&HO

- Looking at algorithms to assess risk
- Looking at diagnostic pathways to mitigate risk (FPG)
- Looking at the benefit of providing G6PD enzymatic assay



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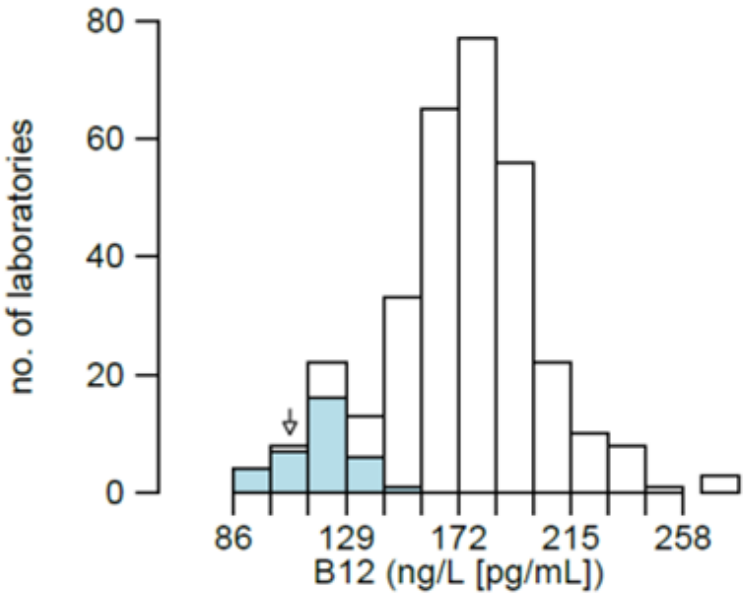
Vitamin B12:



Finlay MacKenzie[1] and Vinod Devalia[2] Birmingham Quality [UK NEQAS],

- GIRFT undertook an Audit of B12 Service
- Unwarranted variation between laboratories
- Unwarranted variation between methods
- Unwarranted variation in decision levels
- And not always the right test
- Reported findings to NICE

- Outcome
  - New NICE Guidance
  - Agreed cut-offs
    - <180 ng/L Deficiency
    - >350 ng/L Deficiency unlikely
    - 180-350 Indeterminate – measure Methylmalonic Acid
    - Holotranscobamalin in pregnancy

Vitamin B12 deficiency in over 16s: diagnosis and management

NICE guideline
Published: 6 March 2024

www.nice.org.uk/guidance/ng239

NICE National Institute for Health and Care Excellence

NICE guideline

The consequences of a positive bias in HbA1c:

- An IVD device was being used to measure HbA1c to diagnose Diabetes and NDH
- The method developed a positive bias leading to overdiagnosis in patients
- **Actions**
  - GIRFT undertook a formal review and presented the data to NHSE
  - A T&FG was set up to investigate further, understand the issue, correct it
  - All Trusts affected have had several GIRFT Audits
  - It is estimated that over 50,000 patients Nationally have been recalled
  - Luton have the results of their Patient recall.
    - 21% of patients diagnosed as Diabetic were re-classified as NDH
    - 20% of patients diagnosed as NDH were re-classified as “normal”.
  - Birmingham UKNEQAS, and WEQAS have introduced an Analytical Performance Specification for HbA1c
  - Final Report to NHSE end of June
  - IVD now withdrawn from the UK market

Patient Focused Laboratory Medicine

- What GIRFT found for the HbA1c issue has implications for many other tests in use today
- GIRFT Set up an Expert Advisory Group called:

  Patient Focused Laboratory Medicine Group (PFLM)

- We held free Webinars in Nov'25, May'26
  - posted the Meeting Report with 10 recommendations
- [over 1,000 people registered for the Webinars]

Patient Focused Laboratory Medicine Group

https://pflm.org.uk/assets/doc/downloads/getting-it-right-for-the-patient-report.pdf

February 2026

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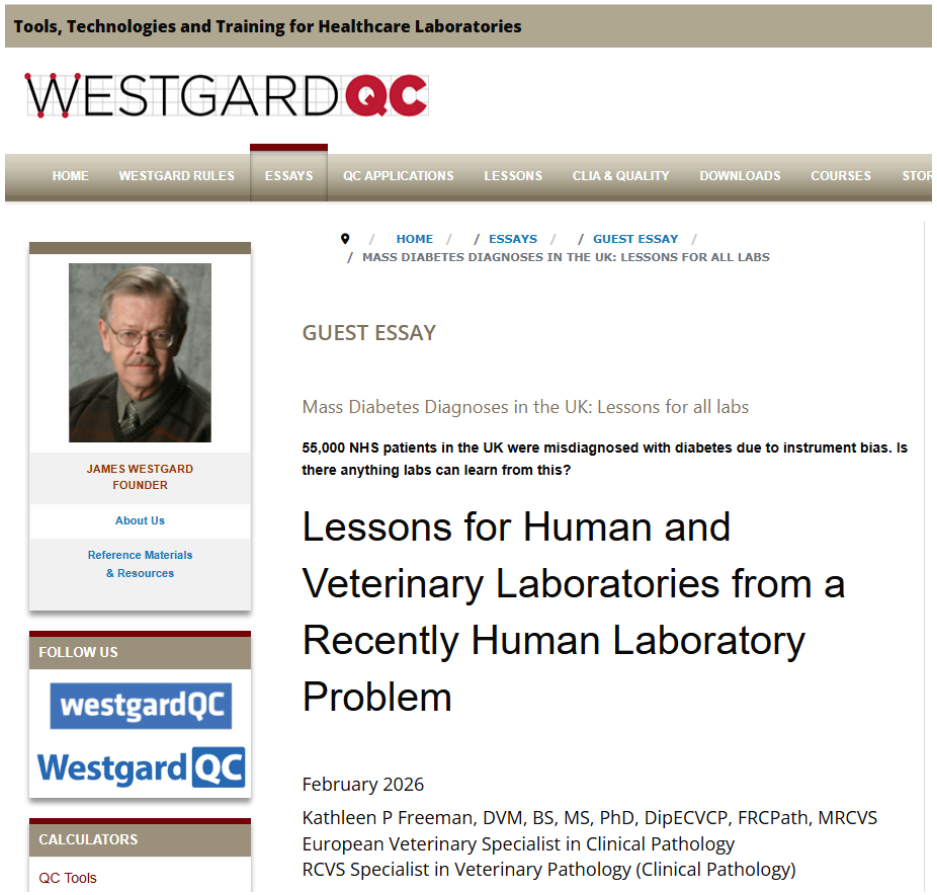
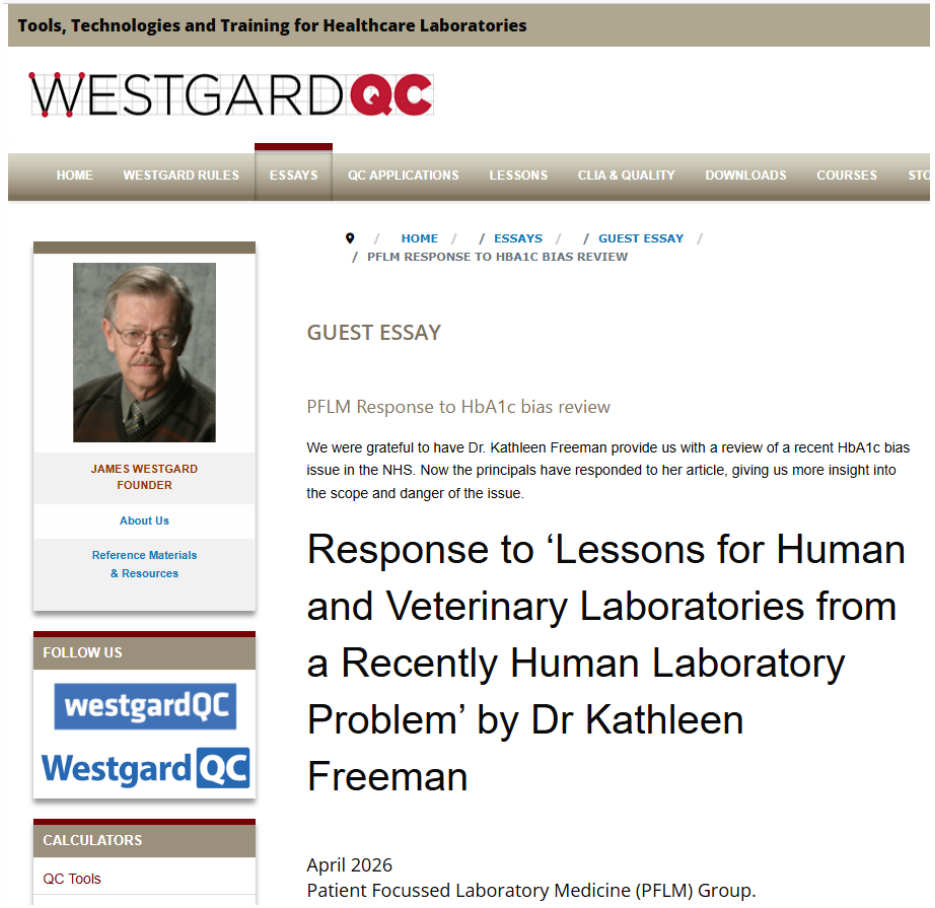
Bedfordshire Hospitals NHS Foundation Trust

Weqas

Patient Focused Laboratory Medicine





https://westgard.com/essays/guest-essay/diabetes-misdiagnoses-uk-lessonsl.html

https://westgard.com/essays/guest-essay/hba1c-pflm-response.html

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10 Recommendations

Patient Focused Laboratory Medicine Group

NHS

1. Each laboratory should understand the consequences to the patient on the performance
2. Fully implement Recommendation 13 of the GIRFT Pathology Report.
3. Analytical Performance Specifications (APSs) for clinical biochemistry analytes- Analytes of Concern
4. LabMed to lead a review of criteria for the diagnosis of Diabetes Mellitus and NDH
5. ISO 15189:2022 accreditation should be focused on risk management of the whole patient pathway
6. MHRA introduce formal process for post-market surveillance of IVDs. Laboratories need to increase usage of the MHRA yellow card system.
7. NHS Supplies to have a greater awareness of the quality infrastructure of IVDs
8. LabMed to provide guidance/toolkits on quality processes
9. LabMed to provide further training and education of consultants/laboratory directors
10. Corporate members group

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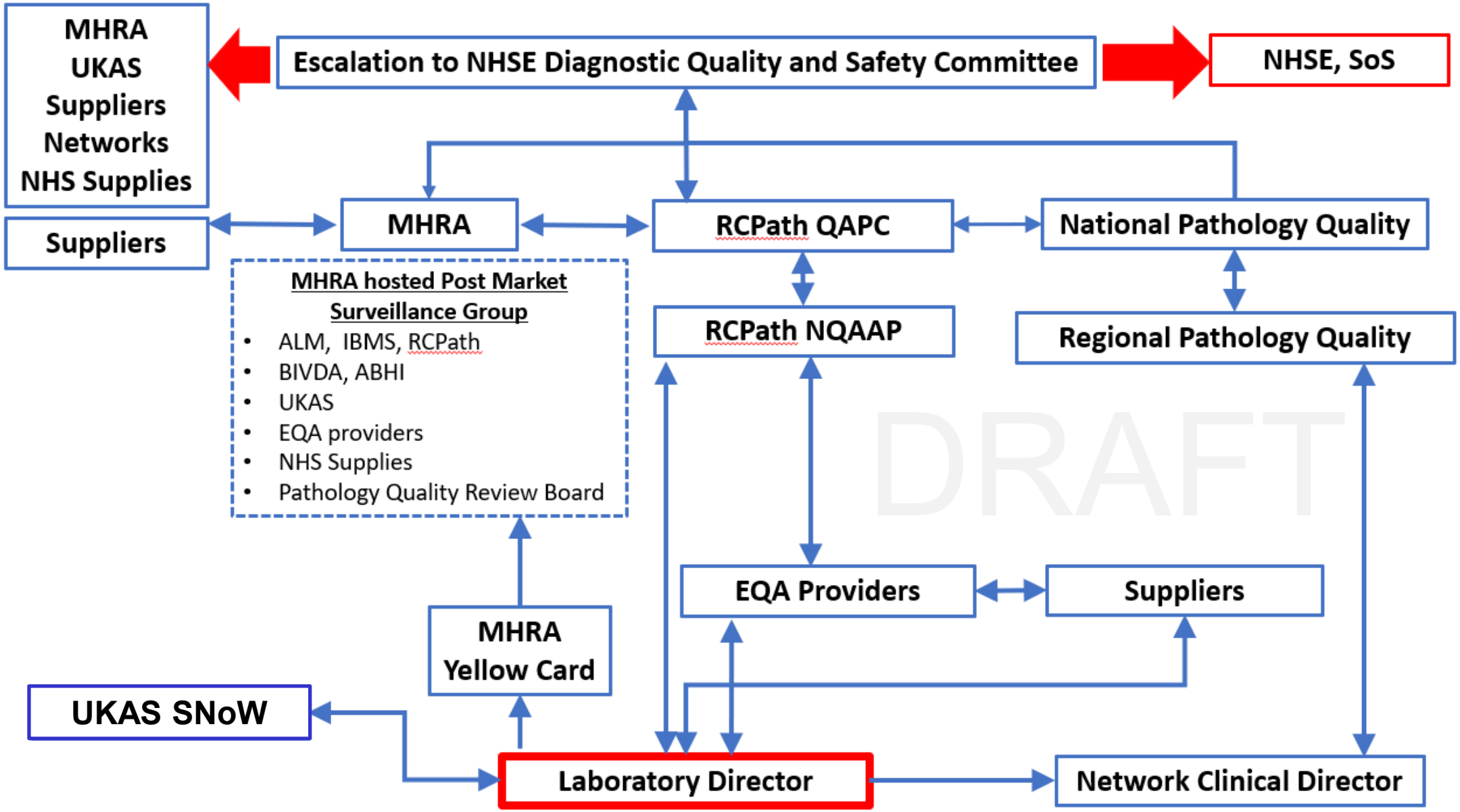
1. Each laboratory should understand the consequences to the patient of the Laboratory Performance

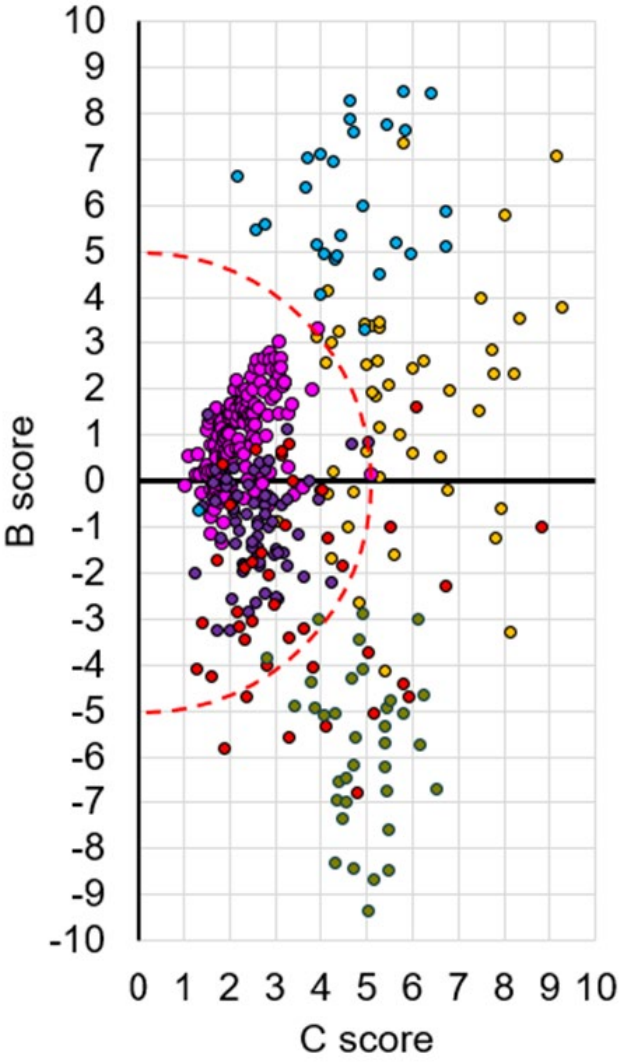
1. PFLM Webinars, Reports, Guidance, Publications, Presentations at Conferences
2. Impact on the patient
3. Accreditation: UKAS
4. Regulation: MHRA, Post Market surveillance, Yellow Card Rachel Marrington)
5. Quality Infrastructure and Toolkit
6. The use of Analytical Performance Specifications in choosing and monitoring a test
7. Laboratory Director Master Class
8. PFLM Debates (with representatives from the Learned Societies, UKAS and MHRA)

2. Fully implement Recommendation 13 of the GIRFT Pathology Report



3. Analytical Performance Specifications

- Workable APSs not agreed internationally
- Birmingham UKNEQAS now embed Analytical Performance Specification into their EQA reports. Using Total Error (analytical) = 5% - which encompasses bias and imprecision, for HbA1c
- First of its kind in the World. This has been live for several months
- WEQAS are doing the same
- Each Lab will now know whether their lab, or Method, meets the Analytical Performance Criteria for the use of HbA1c in the diagnosis of DM and NDH



3 (a) Analytes of Concern

- AOC
- Creatinine Jaffe and enzymatic?
  - Can eGFR and AKI Alerts be used with Jaffe? (spoiler alert- NO!) money v Patient Safety

Annals of Clinical Biochemistry
Volume 60, Issue 6, November 2023, Pages 406-416
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https://doi.org/10.1177/00045632231180403

Sage Journals

Research Article

National recommendations to standardise acute kidney injury detection and alerting

Rachel Marrington [1], Anna L Barton [2], Alexandra Yates [3], William McKane [4], Nicholas M Selby [5], Jonathan S Murray [6], James F Medcalf [7], Finlay MacKenzie [1], and Martin Myers [8]

Annals of Clinical Biochemistry
Volume 60, Issue 5, September 2023, Pages 328-338
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https://doi.org/10.1177/00045632231173233

SAGE journals

Research Article

Variation of eGFR reporting and CKD equations used in the United Kingdom

Rachel Marrington and Finlay MacKenzie

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Analytes of Concern: CA125

Suspected cancer: recognition and referral

NICE guideline | NG12 | Published: 23 June 2015 | Last updated: 15 April 2026

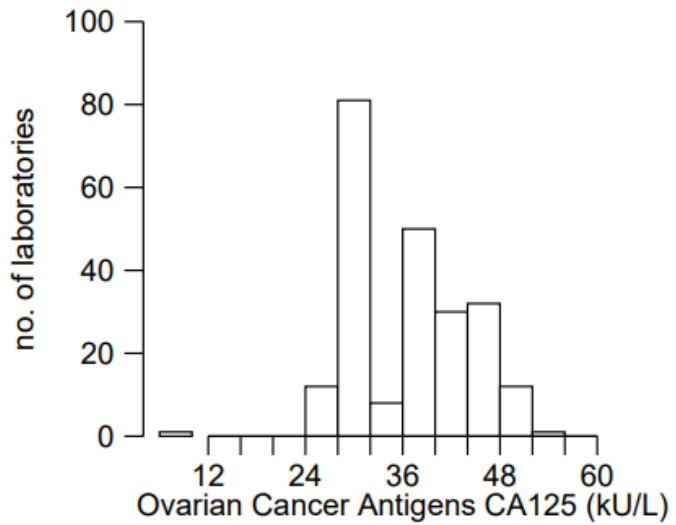
Table 1 Age and serum CA125 thresholds

Age group (years)	CA125 threshold (IU/ml)
40 to 49	35 IU/ml or greater
50 to 59	31 IU/ml or greater
60 to 69	24 IU/ml or greater
70 to 79	25 IU/ml or greater
80+	31 IU/ml or greater

- NICE have a decision levels
- Unwarranted variation between laboratories
- Unwarranted variation between methods
- How can the laboratory support the NICE Guideline?

n	Mean	SD	CV(%)
227	37	7	18.9
52	46	3	5.4
9	47	2	5.1
34	39	1	3.7
92	30	1	3.9
25	40	1	2.6

UK NEQAS
International Quality Expertise



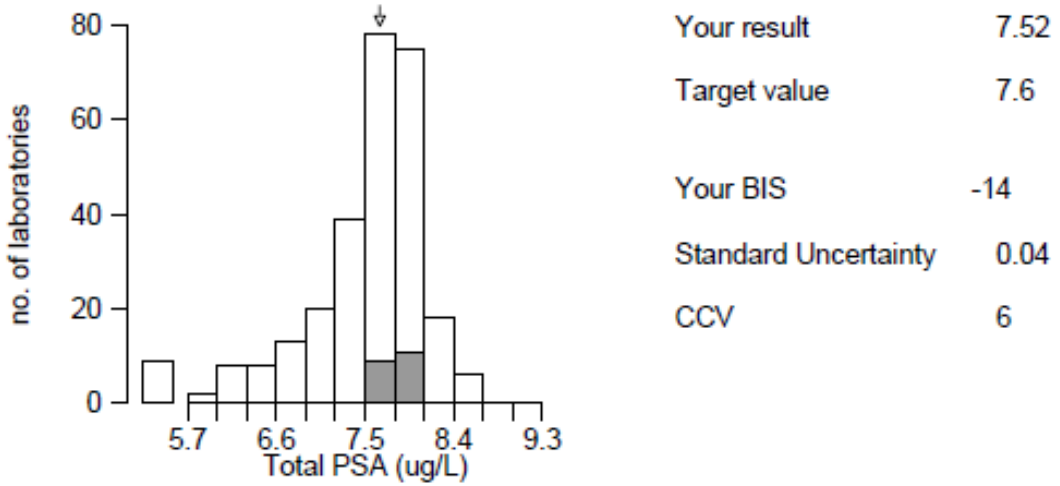
Analytes of Concern: PSA

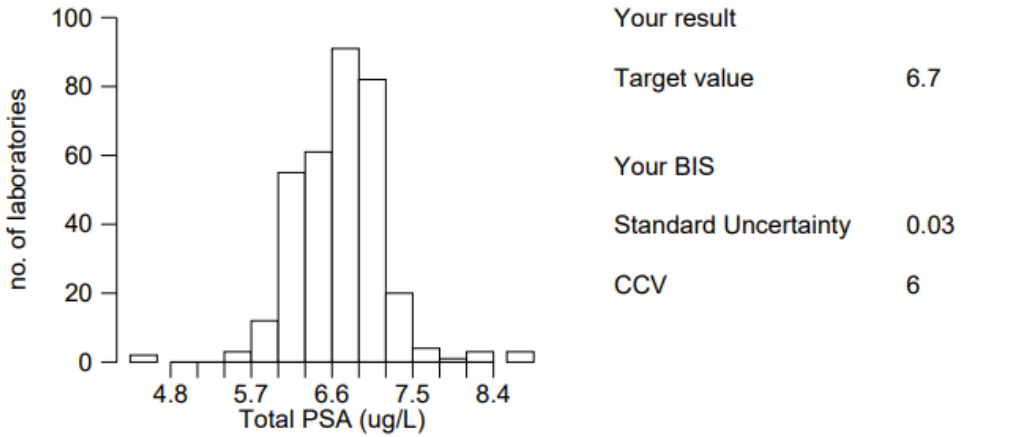
NICE National Institute for Health and Care Excellence

Table 1 Age-specific PSA thresholds for people with possible symptoms of prostate cancer

Age (years)	Prostate-specific antigen threshold (micrograms/litre)
Below 40	Use clinical judgement
40 to 49	More than 2.5
50 to 59	More than 3.5
60 to 69	More than 4.5
70 to 79	More than 6.5
Above 79	Use clinical judgement

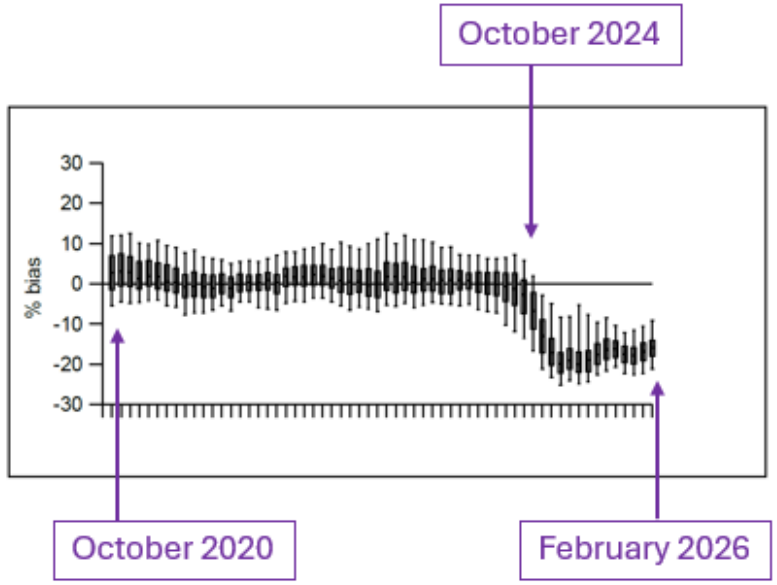
PSA





- NICE have age related thresholds
- Many labs do not use them
- Unwarranted variation: laboratories and methods
- How can the laboratory support the NICE Guideline?
- How can we use PSA as a screening test?

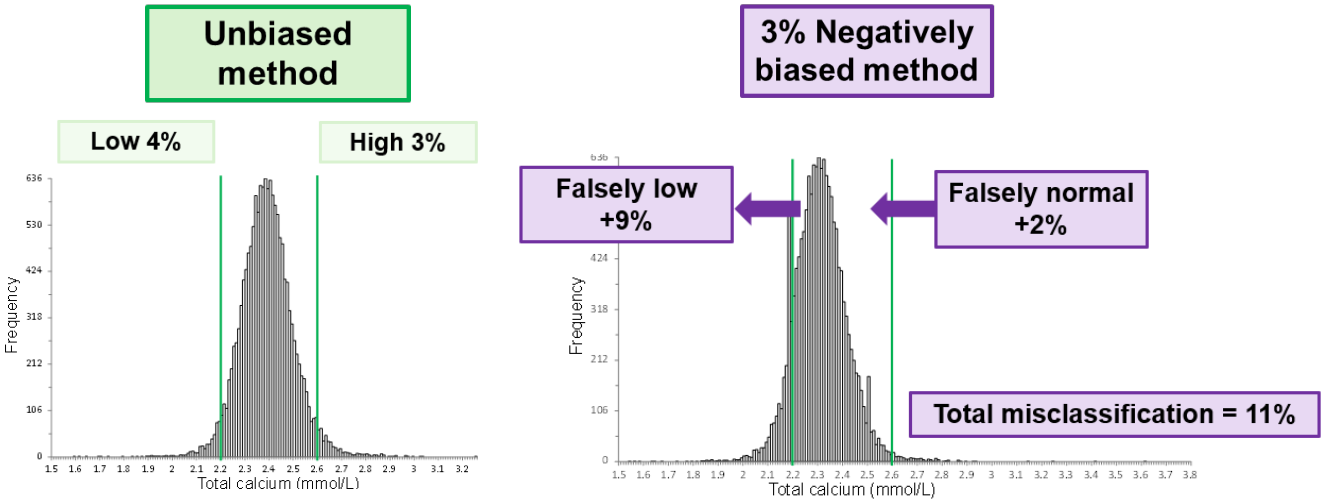
AoC: Folate (Folic Acid)



Clinical Impact of 20% negative bias

- 3 times more patients diagnosed with extremely low folate
- estimates of 100,000 patients annually in England could undergo additional investigations

AoC: Calcium



Clinical Impact of a negative bias of 3%

- 2 times more patients diagnosed with hypocalcaemia due to negative bias (based on Total Calcium)
- estimates annually 150,000 patients in England could undergo additional investigations and treatment)
- estimates annually 50,000 patients being classified as normo-calcaemic hypocalcaemia

Sarah Davies, David Housley

3(a) Analytes of Concern

- AOC: unwarranted variation in imprecision, bias –and what is it that we are measuring?
  - Creatinine Jaffe and enzymatic?
  - ALT and AST: IFCC (with Pyridoxal Phosphate) or not
  - Calcium, Adjusted Calcium
  - Albumin
  - Folate
  - fT4
  - PSA
  - CA125
  - B12
  - Bilirubin (***especially used in neonates for treatment decisions)
  - CA125
  - Trop T and I
  - Female Testosterone and Immunoassays (don't do it!!)

Analytical Performance Specifications

- We are focussing on **Analytes of Concern** and developing Analytical Performance Specifications to define what is, and what is not, acceptable performance in an assay
- Royal College of Pathologists has set up a group to define acceptable Analytical Performance Specifications for Decision Diagnostics, Chaired by Professor Eric Kilpatrick
  - But do we know what Truth is?
  - International Standards, Traceability etc Agreed Reference Points
  - Greater rigor in following the Known Truths
  - Can we work with Relative Truth, but relative to what?
  - Greater rigor in defining and following unknown truths

4. LabMed to lead a review of criteria for the diagnosis of Diabetes Mellitus and ND

- We have asked the ALM Clinical Group to provide advice on the diagnosis of DM and NDH, to include the analytical variation around decision limits
- This is Chaired by Dr Mayur Patel, Consultant in Chemical Pathology/Metabolic Medicine, ALM Director of Clinical Performance.
- NICE will be asked to review our evidence

DRAFT Discussions of the Diagnostic Pathway for T2DM and NDH

Risk Assessment for Type 2 Diabetes in selected patients

High Risk Score

Suspected Type 2 Diabetes

South Asian, Black and Chinese ≥25yr with BMI >23

Moderate or Low Risk Score:
- re-assess at least every 5 years

Collect Blood sample for HbA1c

HbA1c ≥ 48 mmol/mol
- Suggestive of DM
- Clinically Assess
- **Repeat within 2 weeks**

HbA1c 42-47 mmol/mol
- Suggestive of Non Diabetic Hyperglycaemia
- **Repeat to confirm within 2-4 weeks**

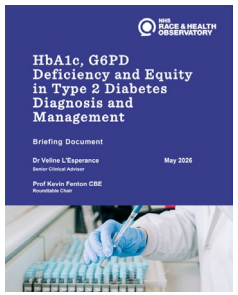
HbA1c <42 mmol/mol
- Not consistent with DM or NDH
- But may still be high risk.
- Give lifestyle advice and monitor as clinically indicated
- Re-assess at least every 3 years

Repeat HbA1c ≥ 48 mmol/mol
- Diagnose Type 2 DM

Repeat HbA1c 42-47mmol/mol

Repeat HbA1c 42-47 mmol/mol
- Consistent with NDH
- Intensive lifestyle change programme
  - Inform patients of the symptoms of T2 DM
- Annual HbA1c

Repeat HbA1c <42 mmol/mol

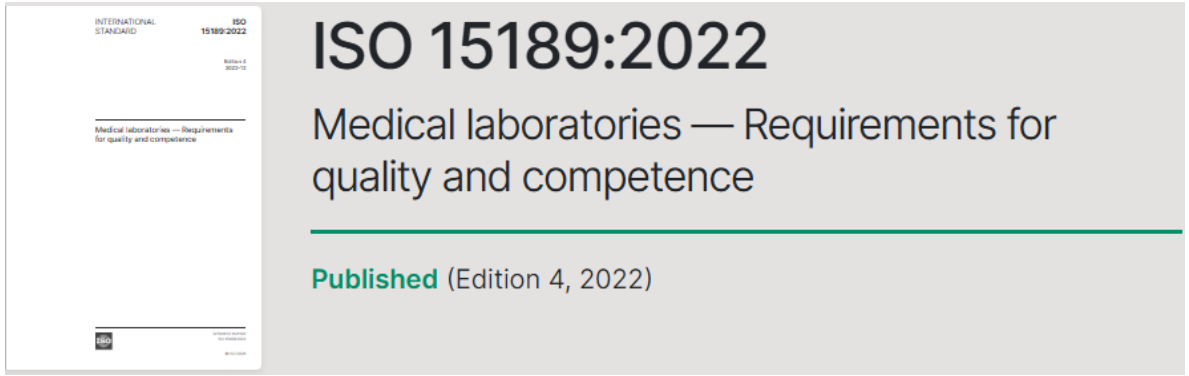


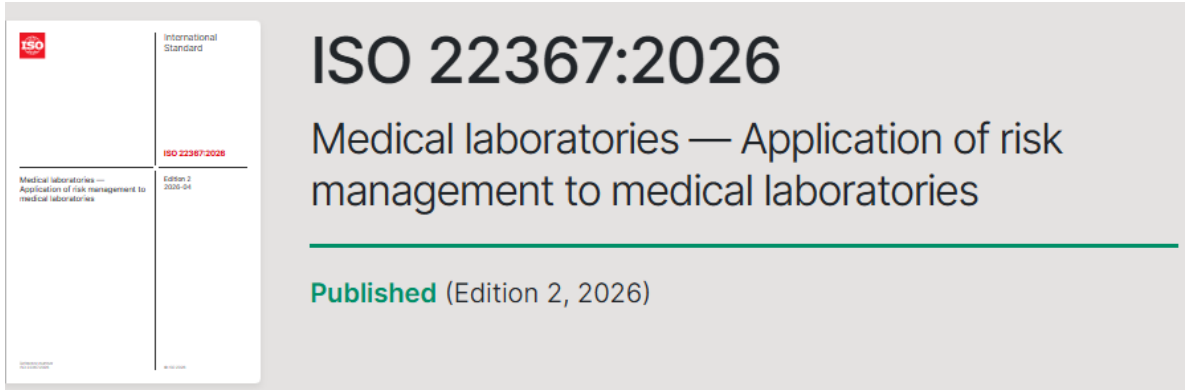
NICE and Magic Numbers

- NICE produce clinical guidelines that are evidence-based and respected throughout the world
- However, at times, there is too much reliance on “magic numbers”.
- Even when the Laboratory Medicine Profession meets the defined APSs, there will still be Measurement Uncertainty, resulting in Clinical Diagnostic Uncertainty.
- We have contacted NICE to ensure that the Learned Societies are included in ALL diagnostic algorithms that include proposed “magic numbers” so that the Clinician is aware of the potential Diagnostic Uncertainty around these numbers
- I have been contacted by the Pharmaceutical Industry with concern about unwarranted variation in the Pathology results in Clinical Trials

5. ISO 15189:2022 accreditation should be focused on Clinical risk management

- UKAS inspected just on ISO15189:2022, but Labs are expected to use ISO 22367:2026 in their **Clinical Audits** to assess the Patient Safety Risk of their service





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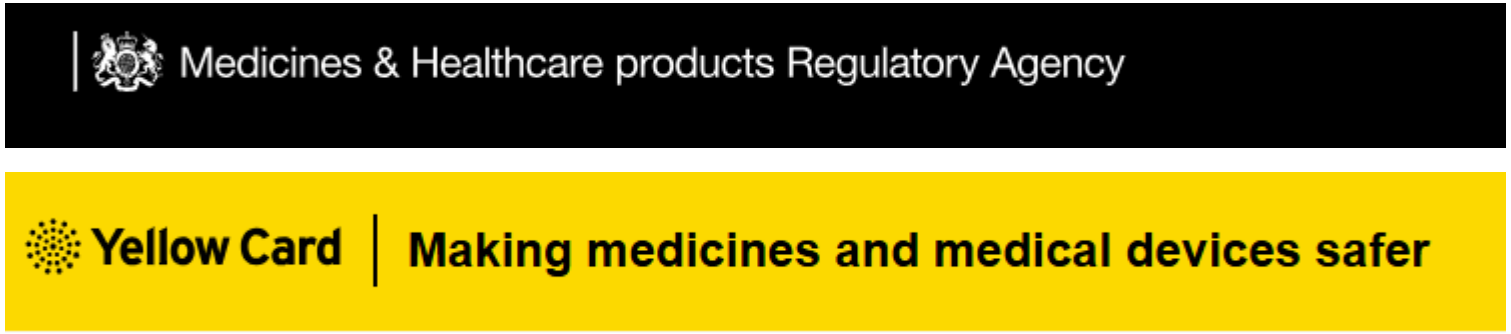
6. MHRA led post-market surveillance of IVDs

- MHRA are setting up a Post Market Surveillance for IVDs, working closely with the EQA providers, RCPath QAPC and Pathology Networks
- Manufacturers are required to undertake Post-Market Surveillance (PMS) under the EU MDR/IVDR
- PFLM have undertaken an Audit on the current use of Yellow Cards for IVDs and recommendations for future use. (Rachel Marrington)
- Requirement for improved use of the Yellow Card for IVD by the Pathology Community
- Use-case of IVDs



7. NHS Supplies to embed Quality of IVDs into Contracts

- Who agrees to whether an IVD, or test, is fit to be used in the NHS?
- Being on the NHS Supply Chain says nothing about the Quality of the IVD or Test.
- NHS Supply Chain have recruited a Head of Clinical Diagnostics and Capital Equipment, who is currently recruiting additional new team members who will clinically support NHS Supply Chain colleagues to embed Clinical Quality into NHE Contracts for IVDs and Managed Service Contracts
- Huge concerns about Diagnostics and Neighborhoods.
- NHSE have made it quite clear that IVD usage in Neighborhoods MUST be accredited to ISO 15189:2022 and work with the local ISO 15189:2022 Accredited Laboratory
- POCT Blue Books
- PFLM POCT Webinar

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8. LabMed to provide guidance/toolkits on quality processes

- Do Labs know how to use IQC and EQA?
- Are we all in agreement about how Measurement Uncertainty is defined, and what we do with it?
- If your Method Mean has a clinically significant positive or negative bias, but your lab is "doing OK" when scored against the Method Mean, does that mean everything really is OK? – Spoiler alert – would the patient agree that everything is OK when a diagnosis is missed, or a false diagnosis is made, or the patient undergoes expensive and unnecessary tests?
- Changes in positivity rate
- David Housely is heading this up

Incorrect Faecal Immunochemical Test (FIT) results issued between 27 December 2025 and 4 March 2026

9. LabMed to provide further training and education of consultants/laboratory directors

- We are in discussion with LabMed on developing a Master Class on the Roles and Responsibilities of a Laboratory Director

Corporate members

- PFLM encourages the link between the Learned Societies and Corporate Members to ensure that discussions on APSs and Post Market Surveillance occur in a “shoulder to shoulder” manner for the mutual benefit of Patient Safety

- PFLM are working very closely with BIVDA and would like to thank
  - Angela Douglas, President
  - Helen Dent, CEO
  - Mike Messenger, Head of regulatory Strategy
  - Beth Loudon, Director of Market Access and Operations

Patient Focused Laboratory Medicine Group

Association for Laboratory Medicine

IBMS Institute of Biomedical Science

The Royal College of Pathologists
Pathology: the science behind the cure

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Summary: Clinically-Led Quality Change Management

- There is too much unwarranted variation in the way that Pathology is delivered and in results between methods and labs
  - This has implications:
    - NICE clinical guidelines rely on “magic numbers”.
    - Unwarranted variation in results will impact patient care
    - Pharmaceutical Industry who have noticed variation between labs
- Reduction in unwarranted variation and optimising processes will:
  - improve the Pathology Clinical Quality Management System (CQMS)
  - save money for Pathology and the NHS
- We must never forget that the purpose of the Pathology Service is about the Clinical Quality of the service and the service to the patient
- Decision Hygiene, Digital Hygiene and Analytical Hygiene techniques will reduce unwarranted variation
- This must be Co-produced AND co-delivered by the Pathology Service, the Regulators, the Accreditors, the Manufacturers, the Commissioners and the Patients

- **Patient-Focussed Laboratory Medicine**

GIRFT Project team

- Martin Myers: Clinical Biochemistry
- Tom Lewis: Microbiology
- Asia Iqbal, Imran Ali: project managers
- Andrew Daniel: GIRFT Academy

PFLM

- Martin Myers
- Danielle Freeman
- Rachel Marrington
- Finlay MacKenzie
- David Housley
- Annette Thomas
- Gareth Davies

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