



NHSE GIRFT Pathology

Martin Myers



GIRFT is delivered in partnership with the Royal National Orthopaedic Hospital NHS Trust and NHS Improvement



Getting It Right First Time

- Started in orthopaedics, 2013
- Objective review of available evidence
- Seek out unwarranted variation
- Use evidence to improve quality
- Now > 40 specialties in England
- Led by senior clinicians
- Key Driver: Quality
- Savings from improved quality
- NHS England



Professor Tim Briggs CBE
NHS England National Director for Clinical
Improvement and Elective Recovery



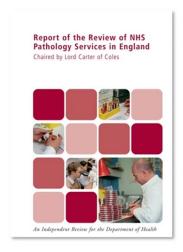
Moving Forward:

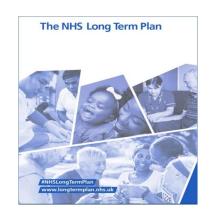
A balance of emphasis





Integrated





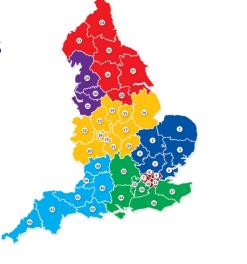








- 7 Regions
- 44 ICSs



- Right Test
- Right Place
- Right Time



"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)."

The need for Total Pathology Quality Management

Right tube, correct labelling

Transport to the lab

Sample integrity

Use of POCT



The Patient's perspective



The Laboratory's perspective

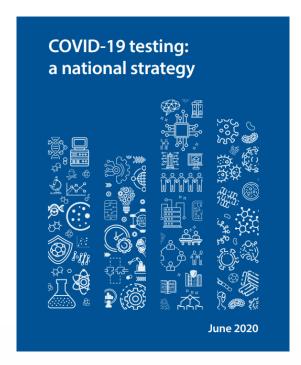
Pre-analytical Analytical Post analytical Process quality What test? Turnaround time Analytical quality appropriate requesting **Urgent results** Manpower quality intelligent requesting Reference intervals E-requesting IT quality Interpretation What tests are included NHS number IT What place? Harmonisation of language Phlebotomy quality Where does the result go?

- We found that the Laboratory, and Accreditors, had a "central focus" on Quality
- Who looks after the Total Pathology stuff?

Why do we need a Total Pathology Quality Management?



- "Testing is not something that is just done and counted. It is a process with clinical purposes for individual patients, for those who care for them and for the population at large.
- Professor Jo Martin President RCPath



Immensa lab errors may have led to 23 Covid-19 deaths





Testing at the Immensa Health Clinic, in Wolverhampton, was suspended after the errors were discovered



GIRFT Methodology

- 1. Collect relevant data
 - National, e.g.: HES, professional bodies, national audits
 - **Questionnaire**: issued to all Trusts *crucial for Pathology*
- 2. Report (data pack) issued to each trust, prior to Visit (deep dive) with Path clinical staff, senior Trust managers
 - 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















Deep Dives

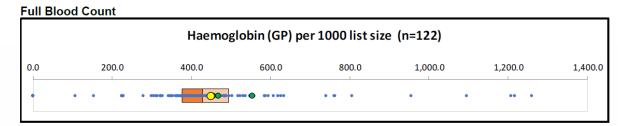




- Each Laboratory received a data-pack comparing their activity with all other English laboratories
- Every Lab in England had a Deep Dive (ish)
- At each Deep Dive we discuss the variation
- Made *local* recommendations on how to reduce unwarranted variation











Unwarranted Variation

We looked at variation in the Pathology process

- Pre-analytical
- Analytical
- Post-analytical
- Point of Care
- Model Hospital

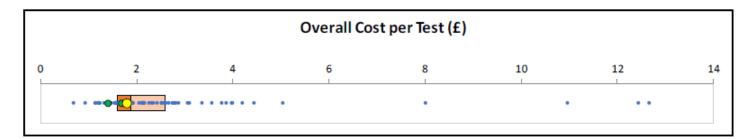


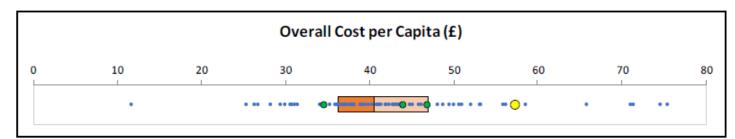
Model Hospital

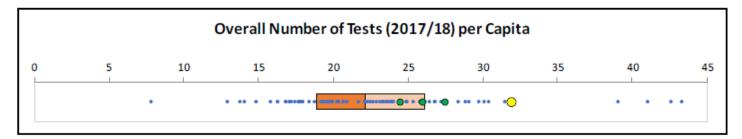


2. Model Hospital Indicators

NHSI/E Model Hospital - Pathology Compartment (April 2018 to March 2019)







Productivity versus inappropriate testing

- Post Carter, it was mostly about making the test cheaper (to save money)
- Post GIRFT it is about doing the right thing for the patient (and save money)
- We need a balance of them both



National Specialty Report



Main themes:

- Quality
- Data and Digital Delivery
- Service Delivery

Our 5 principals

- Focus on the patient
- Prioritise Quality
- Support best clinical practice
- Build Clinically Led integrated service
- Improve data interoperability





NHS

Unwarranted Variation

- We found significant unwarranted variation in all elements of the service
- Unwarranted variation in service delivery leads to a poorer service and confusion amongst users
- Removing unwarranted variation will:
 - lead to savings
 - improve patient care
 - contribute to green and sustainable laboratories
- In order to reduce the unwarranted variation, we have made 21 key recommendations
- The recommendations embed quality into the Pathology Service and to ensure that pathology is an integrated service and not an isolated service



Implementing our Recommendations:



Recommendations:	21
Clinical Quality:	6
Data Quality:	6
Process Quality:	7
Workforce Quality:	1
Financial Quality:	1

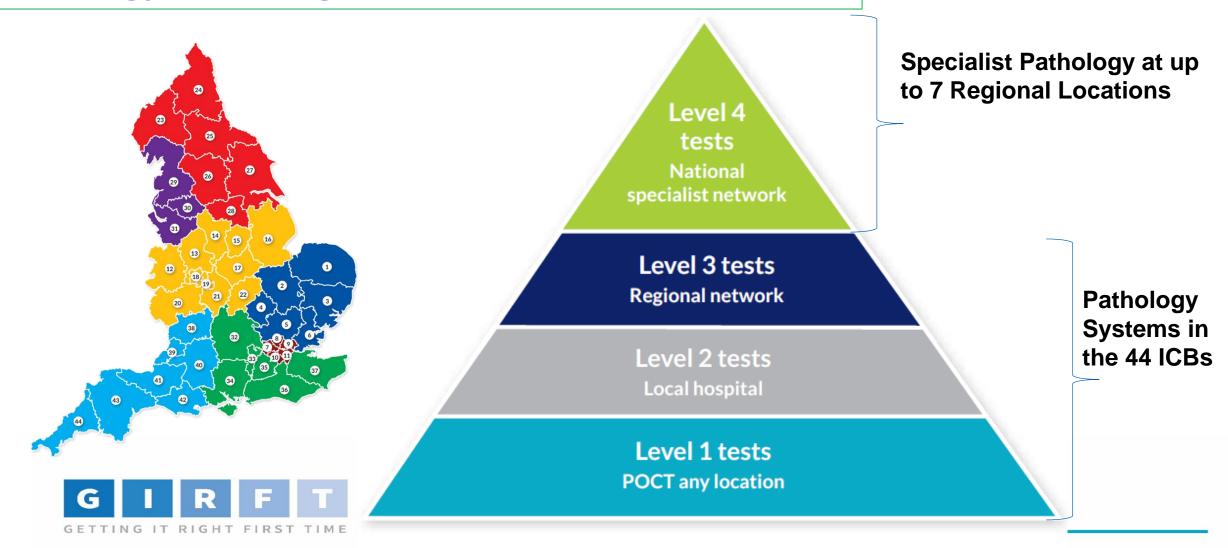
- Identify the "owners"
 - Individuals
 - Networks
 - National Pathology Board
 - Learned Societies
- Suggest timescale
- Work collaboratively to co-produce system change
- Report progress to NHS England
- This has already started
- Not enough time today for too much detail, but will highlight a few issues



Create flexible Pathology networks that reflect local needs



Pathology as an integrated national clinical service



Embed Clean Framework in Quality Governance







Clean Framework:

• Clean in: pre-analytical ISO 15189:2012 - **5.4**

• Clean through: analytical ISO 15189:2012 - many

Clean out: post-analytical ISO 15189:2012 - 5.7

- GIRFT has data on the variation of pre- and post-analytical processes and on the analytical process
- GIRFT support a risk-based, patient-focussed, accreditation process
- ISO 15189 allows us to look at a risk-based quality framework
- GIRFT has asked for an accreditation process that uses the ISO standards for all phases of the pathology process



Clean in



Are the tests appropriate?

- There is a valid clinical question.
- The tests are necessary, appropriate and sufficient to address that clinical question.

Are the samples collected, labelled and stabilised correctly?

- The samples are collected correctly.
- The samples are labelled appropriately.
- The samples are stabilised at the right time.

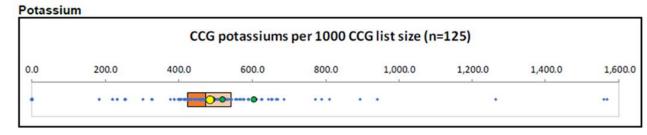
Are the samples delivered to the lab on time?

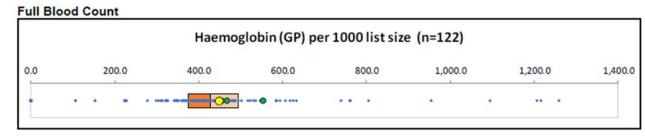
The samples are delivered to the point of testing on time.

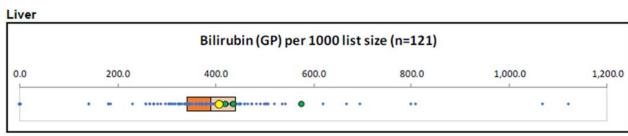


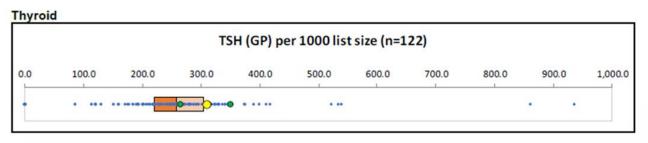
Demand Optimisation: are tests appropriate?











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



Demand Optimisation: Patient-focussed requesting





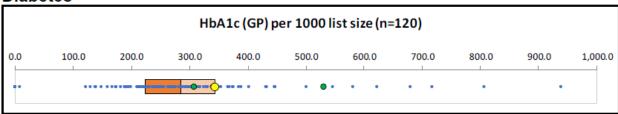
- Recommend the introduction of Care Set requesting and move away from "test" requesting
- We are working with the RCPath to set up National Care Sets which could be integrated into electronic requesting
- Co-produced with Pathology and GPs



Demand Optimisation: are tests appropriate?

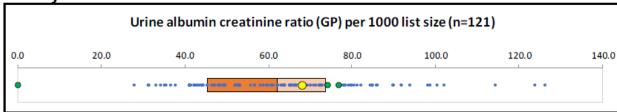


Diabetes

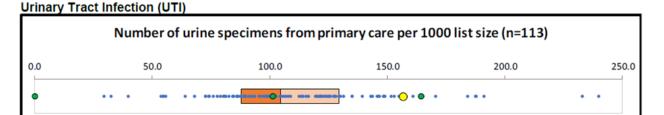


 Are we doing enough HbA1cs and ACRs (probably not)?

Kidney



 Are we doing too many urine testing for UTI (probably)?





Recommend that national guidelines to be taken up locally

Demand Optimisation: Diagnostic Pathways



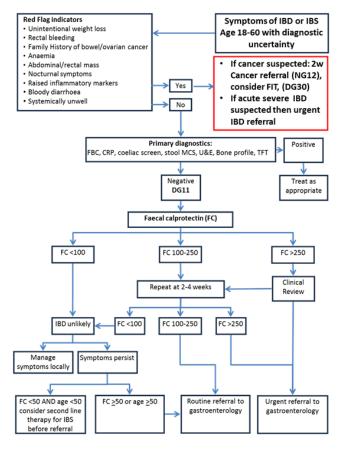


Figure 1. NICE algorithm summarising recommendations for the diagnosis of heart failure2 Take a detailed history and perform a clinical examination Previous MI No previous MI Within 2 weeks Measure NTproBNP High Raised Normal Within 2 weeks levels levels Specialist assessment and Within 6 weeks Doppler echocardiography Heart failure unlikely

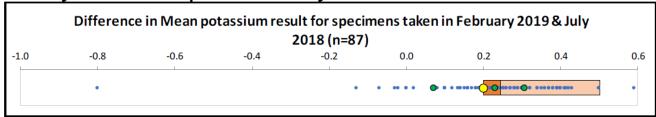
- FIT Testing to reduce colonoscopy
- Calprotectin to reduce colonoscopy
- NTProBNP to reduce echo (and diagnose earlier)
 - 80% of patients with HF diagnosed in ED
 - ?access to testing issue
- NAFLD pathway to diagnose earlier and reduce fibroscan
- Tumour Marker Pathways
- Vitamin B12 insufficiency
- Introduce more diagnostic pathways and ensure adoption
- We are working with the Diagnostic Demand Advisory Group to create National Diagnostics Pathways
- These have potential to reduce secondary care referrals for further diagnostics



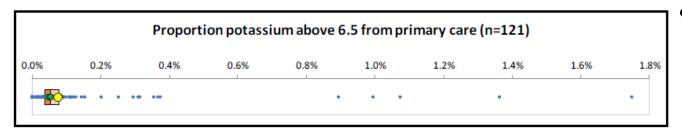
Are the samples collected, labelled and stabilised correctly?



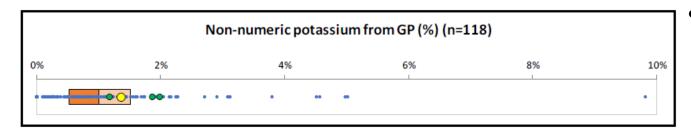
Primary Care Blood Specimen Quality



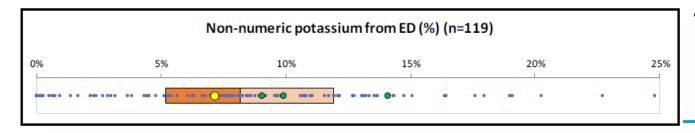
 Some labs have a mean potassium difference of 0.4 mmol/L between February and July



 The percentage of GP samples with a potassium >6.5 mmol/L varied between 0.01% and >1%



 The percentage of GP samples rejected varied from 0.01% to over 4%



 The percentage of ED samples rejected varied from 0.01% to over 20%

Are the samples collected, labelled and stabilised correctly?



Significant variation in the quality of the pre-analytical phase

- Delays in transport
- No control of temperature of transport
- No real debate about sample stabilisation during transport
- Errors in phlebotomy

GIRFT have recommended that

- The pre-analytical process must be better designed, monitored and controlled
- KPIs are developed for the time from needle to centrifuge KPI
- KPIs are developed for transport temperature
- Systems are introduced to measure and audit against the KPIs, and to mitigate if KPIs are failed
- The pre-analytical process should be accredited under ISO15189:X
- Discussions between GIRFT, ACB and EFLM on pre-analytical phase



Clean through



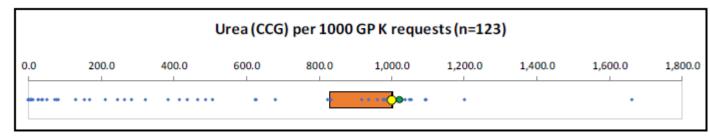
In this section, we have focused on:

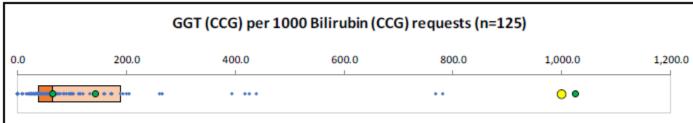
- understanding variation and minimising error;
- processing results in a clinically relevant timeframe;
- improving lab oversight of POCT.

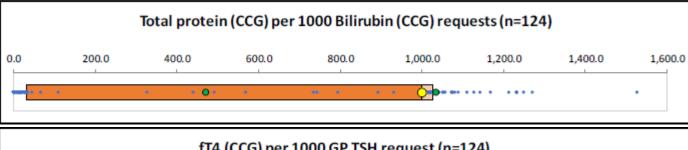


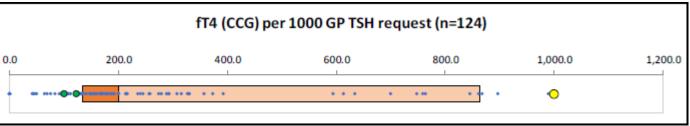
What's in a profile?











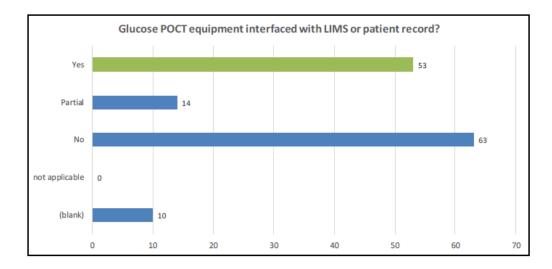
- Variation about what is in a profile
- Many labs do not have a Urea in Primary Care U&E!
- Intelligent requesting and Smart IT to guide appropriate testing e.g. TFT
- Why do we do what we do?
- Too much variation in name, test code, UoM. This needs to be harmonised to create a harmonised

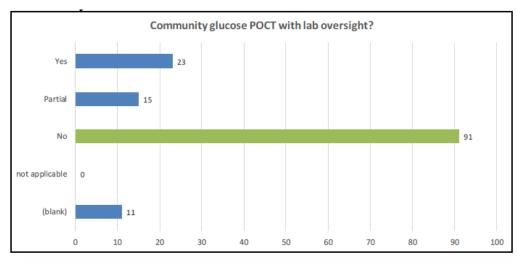
Data Lake



Increased use and better governance of Tier 1 POCT

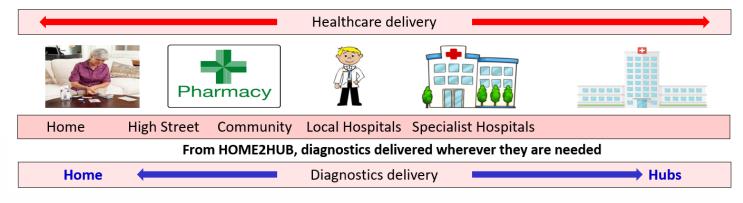






POCT needs to:

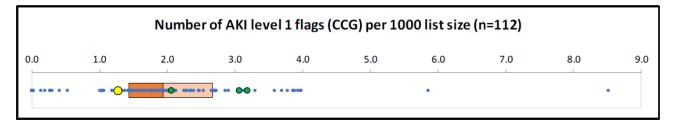
- operate under a Governance Framework
- include competence, training, analytical quality, result capture etc
- Involve laboratory for MHRA and ISO accreditation
- embed diagnostics in the patient journey
- patient-focussed diagnostics, not buildingfocussed diagnostics

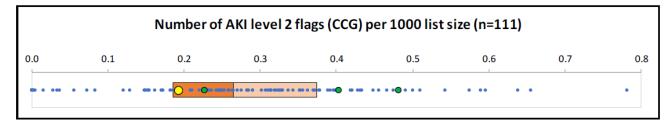


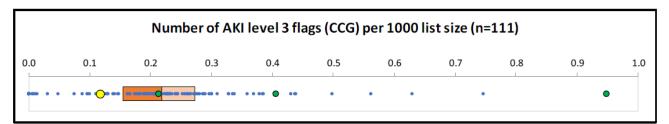


Urgently investigate AKI









Significant variation in AKI reporting

- 4-5 fold variation in AKI reporting
- We discussed this during our Deep Dives:
 - Methodology
 - LIMS
 - Equation
 - No post-market surveillance in place
- This was also noted by NHSE GIRFT Renal and the UKKA
- Something not quite right!



Urgently investigate AKI



- AKI Task Force:
 - NHSE GIRFT Pathology
 - NHSE GIRFT Renal
 - ACB
 - UKNEQAS
 - UKKA
 - NHSE









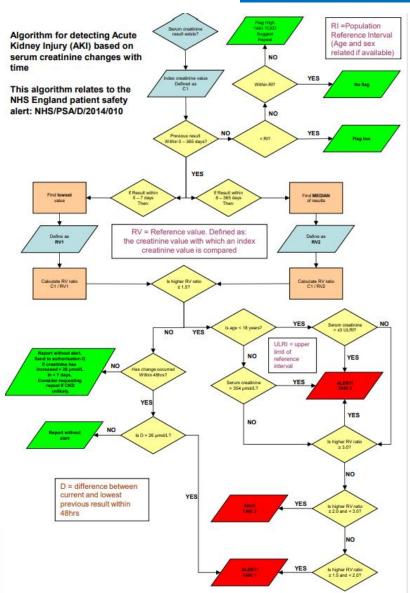




1. LIMS algorithm

- NHS/PSA/D/2014/010 Algorithm for detecting Acute Kidney Injury (AKI) based on serum creatinine with time
- 30% of AKI algorithms wrong in LIMS
- NHSE GIRFT (MAM and Will McKane) had discussions
- Resulted in a LIMS update
- But there are options
- Strongly advise that the NHS England algorithm is used



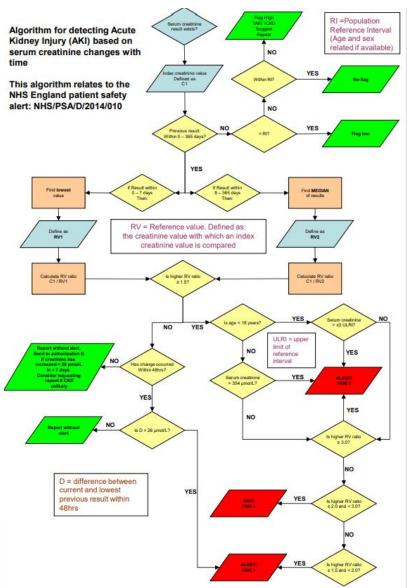


2. Aligned NICE and NHS Algorithm

- NICE focussed on only one arm (7 days) and did not include the right hand arm
- NHSE GIRFT (MAM and Will McKane) had discussions
- Resulted in a NICE update
- 1.3.1 Detect acute kidney injury, in line with the (p)RIFLE (paediatric Risk, Injury, Failure, Loss, End stage renal disease), AKIN (Acute Kidney Injury Network) or KDIGO (Kidney Disease: Improving Global Outcomes) definitions, by using any of the following criteria:
 - a rise in serum creatinine of 26 micromol/litre or greater within 48 hours
 - a 50% or greater rise in serum creatinine known or presumed to have occurred within the past 7 days (see also an <u>algorithm for early identification of acute</u> <u>kidney injury</u>, endorsed by NHS England)
 - a fall in urine output to less than 0.5 ml/kg/hour for more than 6 hours in adults and more than 8 hours in children and young people
 - a 25% or greater fall in eGFR in children and young people within the past 7 days. [2013]





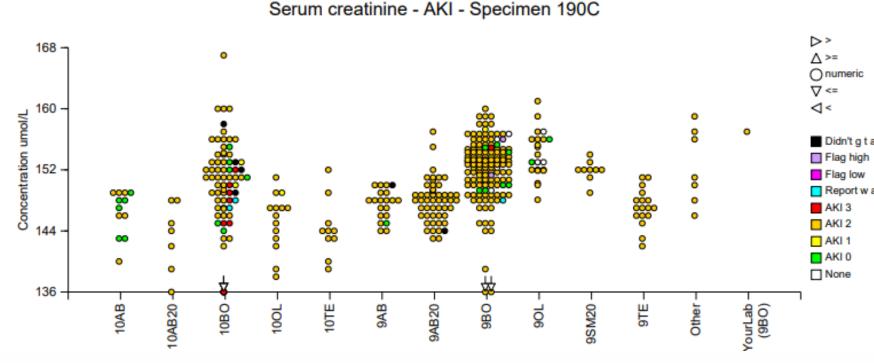




3. Post market surveillance on AKI service

- There were no mechanisms in place to monitor the quality and variation of the AKI alert
- NHSE GIRFT asked UKNEQAS to introduce an EQA scheme for AKI







4. National Audit on AKI



To understand the variation in AKI delivery, we undertook a National Audit on AKI and have made 10 recommendations

- 1. All Laboratories should use enzymatic creatinine assay
- 2. All Laboratories should participate in EQA for AKI
- 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





5. Embedding the recommendations into the NHSE Toolkit

- Our 10 recommendations are being added to the RSTP Template and will part of the NHSE Toolkit and Service specification
- This will encourage laboratories to follow our guidance
- Encourage clinicians to have discussions with the laboratory
- Enable audits on compliance with National Service Specification for embedding quality into service delivery and for accreditation of services



6. Kidney Failure Risk Equation



- 1. It is essential to use the 2009 CKD-EPI equation for eGFR as the input to the KFRE, omitting the ethnicity correction factor as per NG203. The 2021 equation was not used in the original validation and subsequent recalibration studies for KFRE as it was published after the NG203⁵. The 2021 equation has also not been validated for use in the UK. UKNEQAS has demonstrated that use of CKD-EPI 2021 results in a clinically significant bias that might lead higher risk patients not being referred to nephrology services. Likewise, use of the older MDRD eGFR equation is inappropriate¹.
- 2. It is essential to use the UK validated version of the equation^{1,3,6} not the "North American" and not the "Non-North America" versions. The latter two are widely available and typically found by clinicians using web searches for KFRE in the UK, increasing the likelihood of this error. The appropriate equation to be used has been published in NG203 ("Terms used in this guideline" section).
- 3. It is essential that laboratories are aware of analytic errors associated with their serum creatinine and eGFR methods through internal QA and participation in an external QA scheme. Specifically, an enzymatic method should be used for eGFRs being used to calculate KFRE². UKNEQAS data demonstrates that Kinetic Jaffe method creatinine assays can underestimate risk when used in KFRE.
- 4. To reduce the risk of a non-standard implementation, we recommend that the LIMS is the primary site for KFRE implementation in the long term. We acknowledge that implementation within primary and secondary care EHRs is already in progress. Implementation within primary care EHRs has merit as an initial strategy because it may be delivered more quickly than in LIMS in some regions, and primary care is the most important place for early KFRE adoption.



Make better use of EQA information at national level



NICE National Institute for Health and Care Excellence

Ovarian cancer: recognition and initial management

Clinical guideline [CG122] Published: 27 April 2011

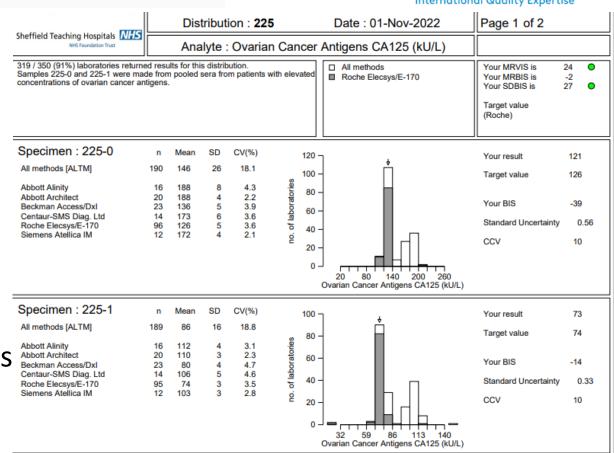
CA125

International Quality Expertise

1.1.2 Asking the right question – first tests

- 1.1.2.1 Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer (see <u>section on awareness of symptoms and</u> signs).
- 1.1.2.2 If serum CA125 is 35 IU/ml or greater, arrange an ultrasound scan of the abdomen and pelvis.

- NICE have a decision level of 35 IU/L
- Unwarranted variation between laboratories
- Unwarranted variation between methods
- How can the laboratory support the NICE Guideline?





CA125 Task Force and discussion with NICE on the value of a single cut-off

Make better use of EQA information at national level.



PSA

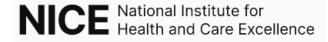
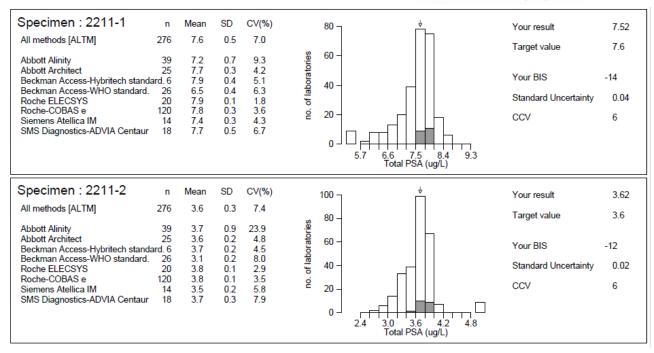


Table 1 Age-specific PSA thresholds for people with possible symptoms of prostate	cancer
---	--------

able I Age-speci	inc 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



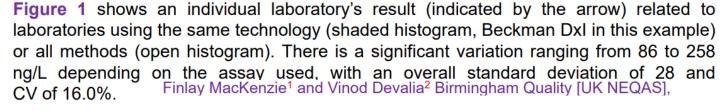
- NICE have a age related reference ranges
- Many labs do not use them
- Unwarranted variation between laboratories and methods
- How can the laboratory support the NICE Guideline?

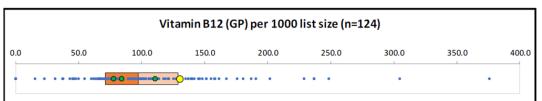


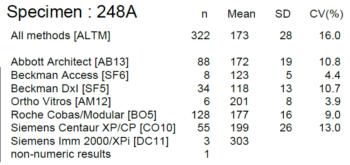
Make better use of EQA information at national level.

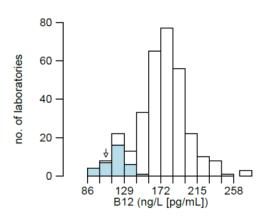


Vitamin B12









- Unwarranted variation between laboratories
- Unwarranted variation between methods
- Role of the laboratories and the manufacturers (link to Recommendation 2)



Vitamin B12 Clinical Group



Purpose of Group

- Receive data on assay performance
- Review multiple biomarkers (TB12, Holotranscobalamin, Methylmalonic acid, Homocysteine)
- Audit the reference intervals being used
- Undertake an interpretative exercise on B12 results
- Carry out a National Audit of the Vitamin B12 Service
- Produce a patient pathway Best Practice, through the GIRFT Academy
- Produce informative interpretative comments
- Ensure that the correct tests are used for the investigation of Nitrous Oxide abuse



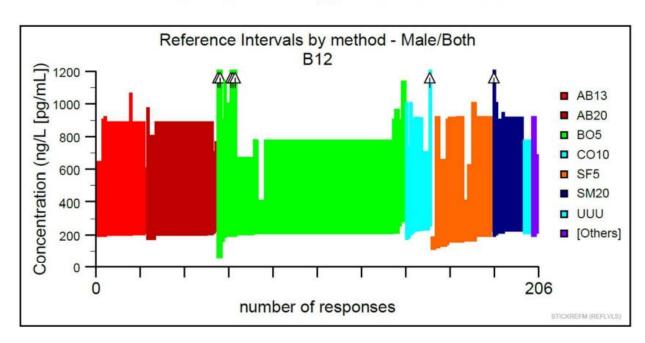
Reference intervals: Initial Findings

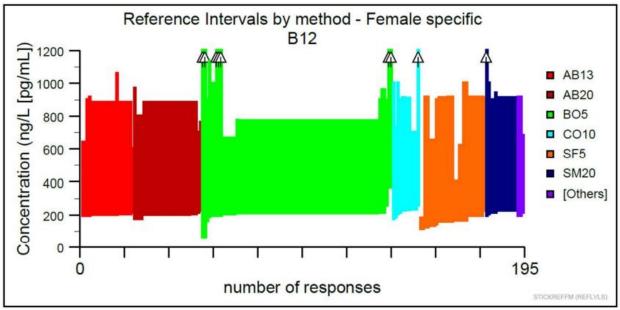


UK NEQAS for Haematinic Assays

B12 [Male] from August 2022, Dist 296

B12 [Female] from August 2022, Dist 296

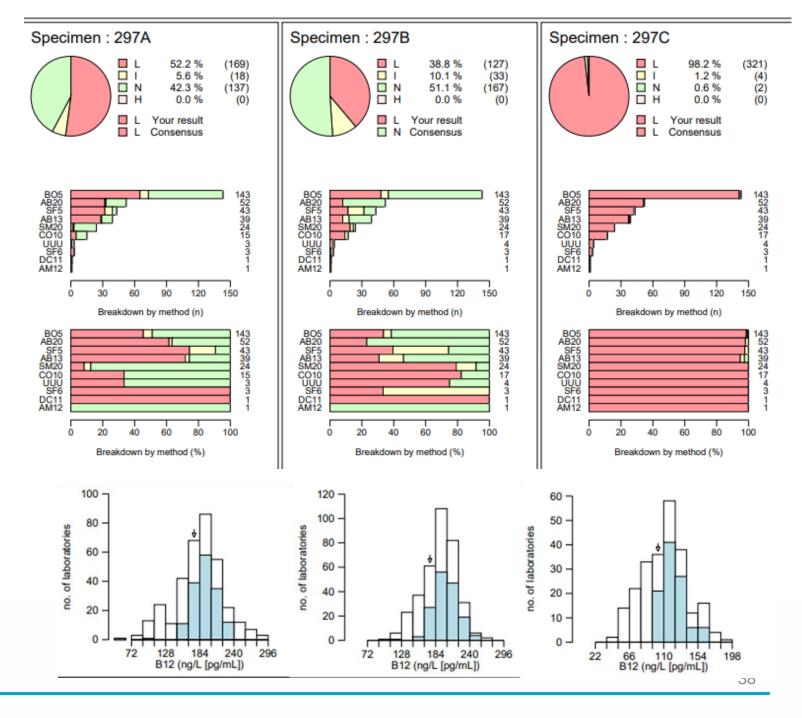




The method biases do not match the Reference Ranges. For example Both Abbott methods, [AB13] Architect and [AB20] Alinity, tend to have higher Hi-ends than Roche, yet it is Roche that is the slightly positively biased method in the Scheme. The Beckman systems [SF5] DXi and [SF6] Access, give low results but their ranges do not reflect this. There are issues of selectivity/specificity which we need to be aware of, but the example shown below in the Rainbow Trout Plot for 293A is just an un-manipulated serum, so there should be only a small possibility of commutability issues. For this reason, I would suggest this represents the true picture. (For completeness, [CO10] is the Siemens Centaur and [SM20] is the Siemens Atellica.)

UK NEQAS International Quality Expertise

- Significant variation in result
- Significant variation between platforms
- Significant variation within same platform
- Significant variation in reference intervals
- Significant variation in interpretation





Make better use of EQA information at national level



When is poor performance of a method unacceptable?

- GIRFT is working with the RCPath to ensure that existing EQA Oversight Board can make national recommendations
- GIRFT will liaise with Manufacturers to reduce unwarranted variation in results;
 reference material, reference intervals etc
- When is a test an acceptable test?



Clean out:



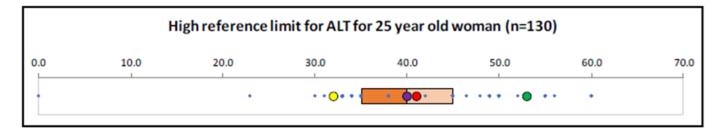
To deliver diagnostic tests in a way that aligns to what matters to patients, we need to focus on:

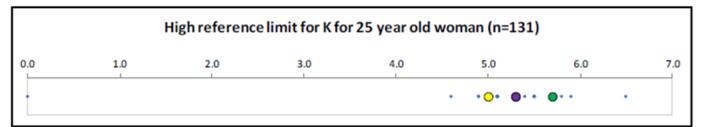
- results that describe normality for that patient;
- results that help to define next actions clearly;
- results that are visible to clinicians when they are needed.



What reference interval to use







Reference ranges:

- Unwarranted variation in reference ranges
- Impact on patient algorithms, NICE guidelines, patient focussed pathology
- Pathology Harmony has already undertaken a significant amount of work on this

Reporting units:

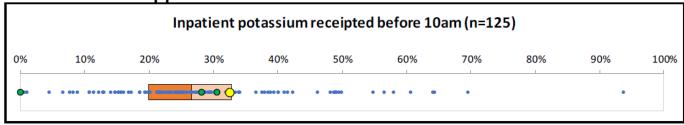
- GIRFT working with the British Heart Failure Society to harmonise units of measurement for NTproBNP
- We have produced a discussion document on units of measurement and decimal points

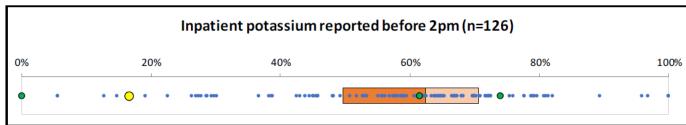


Turnaround time



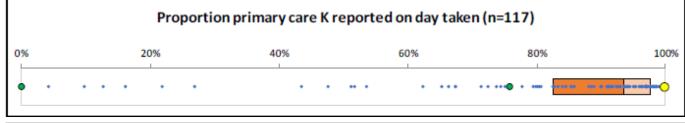
Timeliness of Support for IP flow

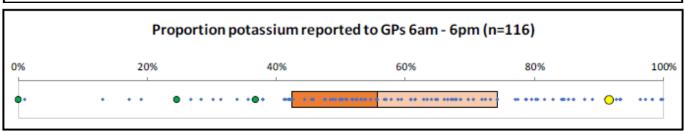






Align pre-analytics with analytics





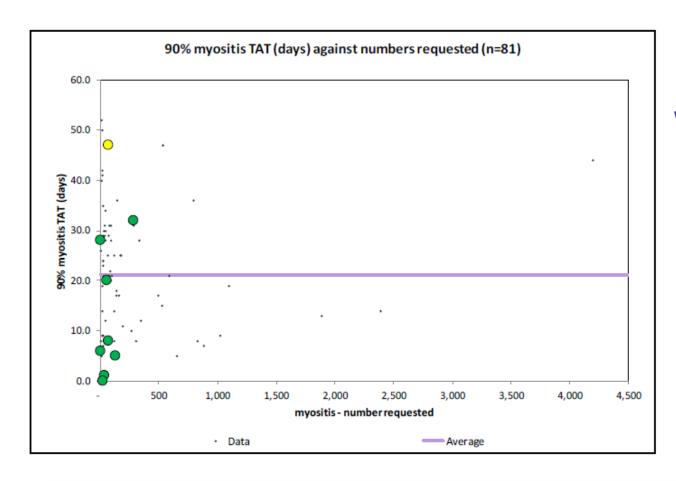
GP samples:

- Align reporting with the requirement to act
- Pressure on out of hours GP services



Turnaround time





What is an acceptable turnaround time?

- We showed significant variation
- In house/low numbers
- Referred not using electronic referral
- Referred, unacceptable TAT



Summary: Clinically led Quality Change Management



- NHSE GIRFT Pathology has provided evidence on unwarranted variation in the way that Pathology is delivered
- We have recommended ways to reduce this variation Locally and Nationally
- We have set up workstreams to ensure adoption of our recommendations
- Reduction in unwarranted variation and optimising process will
 - improve total pathology quality management
 - improve the service
 - save money
- GIRFT is about gathering the evidence, harmonising the service and improving the clinical and analytical quality of Pathology
- The GIRFT report has specific recommendations that will be addressed but the GIRFT Report should also be used as a framework for a paradigm shift in Pathology delivery, based on the patient



GIRFT Project team

- Tom Lewis: Microbiology
- Martin Myers: Clinical Biochemistry
- Marion Wood: Haematology
- Simon Knowles:Cellular Pathology
- Olu Akinremi / Caroline Ager-project managers
- Andrew Daniel, Abi Searle Jones
- Julie Renfrew data manager

Vitamin B12 Task Force

- Martin Myers
- Julian Owen
- Beverley Oakes
- Ian Davidson
- Geraint Fuller
- Adrian Hopper
- William McKane
- David Richmond
- Marion Wood
- Tom Lewis
- Dominic Harrington (G&ST)
- Rachel Mannington (UKNEQAS)
- Emma Stevenson (ACB)



- Martin Myers
- William McKane
- Alex Yates
- Rachel Marrington
- Finlay MacKenzie
- Nicolas Selby
- Jonathan Murray
- James Medcalf
- Rupert Major
- Nitin Kolhe

